CROSSING THE GLOBAL QUALITY CHASM

Improving Health Care Worldwide

Committee on Improving the Quality of Health Care Globally

Board on Global Health

Board on Health Care Services

Health and Medicine Division

A Consensus Study Report of

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This Consensus Study Report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

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Preface

This report minces no words about the magnitude and costs of the "global quality chasm." Although evidence is scattered and incomplete, the conclusion is inescapable: For billions of people, universal health coverage—the important mainstay of the World Health Organization's (WHO's) Sustainable Development Goal (SDG) 3—will be an empty vessel unless and until quality improvement, for all nations, becomes as central an agenda as universal health coverage itself. In view of the immense dedication and effort of tens of millions of health care workers worldwide, often against massive obstacles of resource limitations, political and social fragmentation, corruption, collusion, and even threats to personal security, the central assertion that the current system too often fails to provide high-quality care is not to be made lightly or with disrespect. The study committee vehemently rejects the idea that the workforce is generally at fault, neglectful, or uncaring. On the contrary, without doubt, they deserve credit and the world's gratitude for a large proportion of the extraordinary progress in population health of the Millennium Development Goal (MDG) and early SDG eras.

What we do believe, informed by the guiding intellectual framework of this report—"systems thinking"—is that many of these workers, the would-be healers of the world, are ill served by being embedded in and dependent on systems of care that impede excellence rather than supporting it, and that drain their energy rather than nurturing it. Systemic conditions—such as fragmentation, malaligned payment, unclear goals, poor training, unreliable supply chains, burdensome rules, inadequate information flows, lack of useful data, corruption, and fear—prevent even the most willing workforce from carrying out its daily tasks successfully and contributing to the success of the whole system. As a result, patients suffer needlessly; communities squander scarce resources; and the workforce itself becomes frustrated and exhausted as a part of the ill-functioning system.

The good news in this report is that all these problems are remediable—indeed, preventable. Foundational, of course, are adequate social investments in health care supplies, personnel, equipment, and space; these are preconditions for excellence. But alone, they do not assure excellence. To mobilize change, system leaders must reassess values, principles, and systems designs. Even in wealthy settings, where resources are abundant, quality can and does fail because of improper care designs and poor systemic conditions, such as those listed above. Keys to success, given adequate resources, lie in modern, evidence-based methods of quality assurance and improvement. They also lie in full-hearted embrace of the new digital age of medical care, and in making sure that the well-being of patients and the integrity of their care journeys are the compass bearings for all that we do. It is leaders, above all, who have the opportunity and responsibility to nurture those methods and to continually reinforce those aims.

The committee is convinced, after 1 year of study and reflection, that these values—especially person-centered care—and these systems-based methods hold as much promise in low- and middle-income settings as in wealthy ones. This report sets out an agenda for action on policy, management, and clinical care that, we believe, can deliver far better outcomes for the people who depend on us and far more satisfying and respectful conditions of work for those who try to help.

This report joins two others from important organizations: one from a consortium of WHO, the World Bank, and the Organisation for Economic Co-operation and Development, and another from *The Lancet Global Health* Commission on High-Quality Health Systems in the SDG Era. Together, this report and these two sibling efforts offer the entire global health community evidence-based guidance and, we hope, further motivation to engage in comprehensive health care redesign in pursuit of continual quality improvement as a priority equal to what is now, happily, assigned to universal health coverage. The combination can save lives, financial resources, and pride and joy in the workforce, all at the same time.

If 2018 has been a year of study and reports on quality, let 2019 and beyond be an era of action on quality.

Donald M. Berwick, *Co-Chair*
Sania Nishtar, *Co-Chair*
Committee on Improving the Quality of Health Care Globally

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Contents

PART I: THE IDEAL VISION FOR FUTURE HEALTH CARE

PART II: THE CURRENT STATE OF QUALITY IN HEALTH CARE

PART III: THE PATH TO CONTINUAL GLOBAL IMPROVEMENT

APPENDIXES

Boxes, Figures, and Tables

BOXES

FIGURES

TABLES

Acronyms and Abbreviations

ACT	artemisinin-based combination therapy
ADDO	Accredited Drug Dispensing Outlet
AFRO	African Regional Office (WHO)
AGP	Abel Gilbert Pontón
AI	artificial intelligence
AMI	acute myocardial infarction
ANC	antenatal clinic
ASHA	accredited social health activist
BCG	Bacille Calmette-Guerin
BMAT	BioMedical Admissions Test
BMI	body mass index
BP	blood pressure
BPHS	Basic Package of Health Services
CBHI	Community-Based Health Insurance
CDS	clinical decision support
CHW	community health worker
CIN	Clinical Information Network
COPD	chronic obstructive pulmonary disease
CR	citizen representative
CRISPR	clustered regularly interspaced short palindromic repeats
CS	caesarean section

CVD	cardiovascular disease
DALY	disability-adjusted life year
DHS	Demographic and Health Surveys
DNA	deoxyribonucleic acid
DRC	Democratic Republic of the Congo
EHIS	electronic health information system
EHR	electronic health record
EMRO	Eastern Mediterranean Regional Office (WHO)
FDA	U.S. Food and Drug Administration
FHS	Family Health Strategy
FMOH	Federal Ministry of Health
FSI	Fragile States Index
GBD	Global Burden of Disease
GDP	gross domestic product
GPW	General Program of Work
HCAC	Health Care Accreditation Council
HCD	human-centered design
HDA	Health Development Army
HEW	Health Extension Worker
HFE	human factors and ergonomics
HIC	high-income country
HIV/AIDS	human immunodeficiency virus/acquired immunodeficiency syndrome
HMC	Hamad Medical Corporation
HPV	human papillomavirus
ICHOM	International Consortium for Health Outcomes Measurement
ICT	information and communication technology
IDB	International Development Bank
IOM	Institute of Medicine
IP	informal provider
ISIS	Islamic State in Iraq and Syria
ISO	International Organization for Standardization
ITU	International Telecommunication Union
JICA	Japan International Cooperation Agency

LHCS	learning health care system
LMIC	low- and middle-income country
MCH	maternal and child health
MDG	Millennium Development Goal
MESH MH	Mentoring and Enhanced Supervision at Health Centers for Mental Health
MOH	ministry of health
NAM	National Academy of Medicine
NCD	noncommunicable disease
NGO	nongovernmental organization
NICU	neonatal intensive care unit
NIH	National Institutes of Health
NPR	National Public Radio
NQPS	National Quality Policy and Strategy
NQS	National Quality Strategy
OECD	Organisation for Economic Co-operation and Development
OOP	out-of-pocket
ORS	oral rehydration salt
ORT	oral rehydration therapy
P4P	pay for performance
PCA	patient-controlled analgesia
PHA	Private Hospital Association
POC	point-of-care
PPH	postpartum hemorrhage
PREM	patient-reported experience measure
PRI	Panchayati Raj Institution
PROM	patient-reported outcome measure
PTSD	posttraumatic stress disorder
QEWS	Qatar Early Warning System
RCT	randomized controlled trial
RSBY	Rashtriya Swasthya Bima Yojana
SDG	Sustainable Development Goal
SEIPS	Systems Engineering Initiative for Patient Safety
SPO	Structure-Process-Outcome

TB	tuberculosis
TBA	traditional birth attendant
UHC	universal health coverage
UN	United Nations
VAS	Vajpayee Arogyashree Scheme
WHO	World Health Organization
YLD	years of life lived with disability
YLL	years of life lost

Summary[1]

> *Between the health care that we have and the health care that we could have lies not just a gap, but a chasm.*
>
> *Institute of Medicine*, Crossing the Quality Chasm, *2001*

In 2015, building on the advances of the Millennium Development Goals (MDGs), the United Nations declared a second global revolution based on the Sustainable Development Goals (SDGs), which were adopted by 193 countries. The SDGs include an explicit commitment to achieving universal health coverage (UHC) by 2030 "so that all people and communities receive the quality services they need, and are protected from health threats, without suffering financial hardship." Accordingly, UHC is the central theme of global health policy today. Yet, the evidence is clear: Even if the movement toward UHC succeeds, billions of people will have access to care of such low quality that it will not help them, and indeed often will harm them. While the tremendous gains made against the burden of illness, injury, and disability in recent years warrant celebration, these gains and the new commitment to UHC are not sufficient to close the enormous gaps that remain between what is achievable in human health and where global health stands today, and progress has been both incomplete and unevenly distributed. Thus, without a deliberate and comprehensive effort to improve

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[1] This summary does not include references. Citations to support the text and conclusions herein are provided in the body of the report.

the quality of health care services globally, UHC will too often prove to be an empty vessel.

This report focuses on one particular shortfall in health care affecting global populations: defects in the quality of care. The committee tasked with conducting this study set out to review the available evidence on the quality of care worldwide, with a special focus on low-resource areas. The evidence demonstrates that, even when care is available, quality problems are widespread and take many forms. For example, a study in China, India, and Kenya found that providers adhered to evidence-based treatment for such conditions as asthma, chest pain, diarrhea, and tuberculosis only 25 to 50 percent of the time. Thus, patients who visited a clinician for these common, simple conditions in those settings often had less than a one in two chance of being helped by that encounter. Even though the knowledge for proper treatment exists, providers are not reliably absorbing and using it for the right patients at the right time.

High levels of inappropriate care are also pervasive. For example, a World Health Organization (WHO) report on overuse of ineffective care states that more than 6 million excess caesarean sections are performed every year (50 percent of which occur in China and Brazil). Another example—the high rate of inappropriate use of antibiotics—not only is harmful and costly to patients but also is an important contributor to the global scourge of antimicrobial resistance. In the United States, 30 percent of estimated prescriptions for antibiotics are found to be unnecessary. Worldwide, moreover, the journeys of patients and their families through the health care system are fragmented and difficult to navigate, and in some cases can constitute such a negative experience that it deters them from interacting with the system in the future.

THE DIRE STATE OF HEALTH CARE QUALITY

Health care in all global settings today suffers from high levels of defects in quality across many domains, and this poor-quality care causes ongoing damage to human health. Hospitalizations in low- and middle-income countries (LMICs) lead to 134 million adverse events each year, and these adverse events contribute to more than 2.5 million deaths annually. More than 830 million people with a diagnosed noncommunicable disease (NCD) are not being treated, and more than 4 million avoidable quality-related deaths each year are attributable to ineffective care for NCDs. In total, between 5.7 and 8.4 million deaths occur annually from poor quality of care in LMICs for the selected set of conditions the committee analyzed (see Figure S-1), which represents between 10 and 15 percent of the total deaths in LMICs reported by WHO in 2015. For some conditions, deaths due to poor quality contribute to more than half of overall deaths.

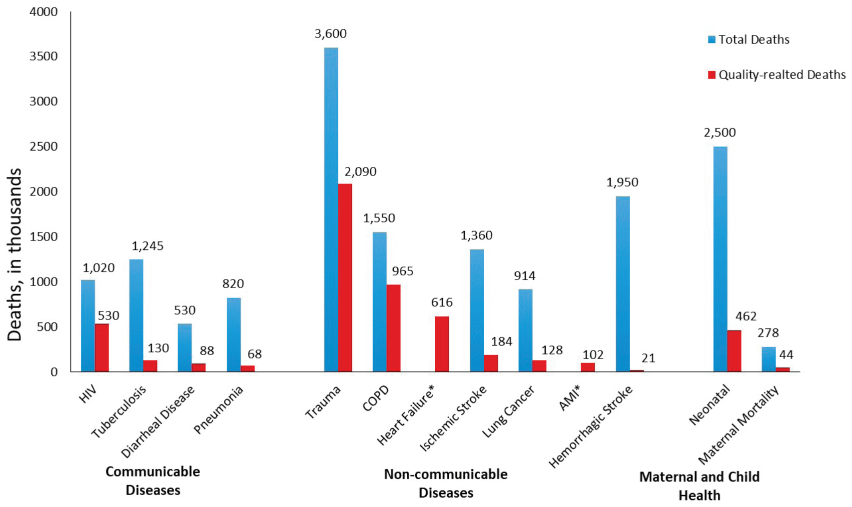

FIGURE S-1 Overall number of deaths from poor-quality care annually in low- and middle-income countries compared with total deaths, in thousands.
* Total deaths unavailable.
NOTE: AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disorder; HIV = human immunodeficiency virus.
SOURCE: Institute for Health Metrics and Evaluation, Appendix D.

Poor-quality care is not limited to LMICs. Studies from such countries as the United Kingdom and the United States reveal far too many preventable deaths due to poor-quality care. These defects have high economic costs as well. A recent Organisation for Economic Co-operation and Development (OECD) analysis found that 15 percent of all hospital costs in OECD nations are due to patient harms from adverse events. Care is also not reliably person-centered, and patients often report a negative experience with their health care interactions. Indeed, the reported experiences of care are sometimes even dismal, ranging from less than respectful care to abusive behavior on the part of providers. The world's poor are particularly vulnerable to this kind of disrespect, but the problems are global.

In sum, defects in the quality of health care deny patients and communities the potential benefits of effective care. The currently prevailing forms, habits, and models of care worldwide are incapable of bridging this global quality chasm. Beyond the consequences for people's health, costs rise when defects in care—such as errors; failure to use effective care; overuse of ineffective care; disregard of a person's values and resources; and waste of equipment, supplies, time, and spirit—are common. The committee has attempted to quantify roughly the cost of poor quality in at least some low- and middle-income settings, and found it to be enormous. Across LMICs, the costs of lost productivity alone due to poor-quality care amount to between $1.4 trillion and $1.6 trillion each year. And this figure does not include the immense costs incurred in health care systems as the result of wasted resources and of having to deal with the downstream consequences of errors and harms attributable to poor quality. Arguably, countries or regions with the fewest resources can least afford this economic toll. Given these costs, improving the quality of care may be one of the most powerful strategies available for achieving affordable c

The committee does not offer this dramatically worrisome picture of the quality of global health care lightly. We understand fully that millions of health care workers, managers, executives, and policy makers are struggling daily to offer patients better care and better health, often in the face of great obstacles. We also understand that, especially in the dire conditions of extreme poverty or adversity, our calls for redesign, bold improvement, and modernization may sound unrealistic. When there is no clean water or when the supply chain for essential medicines is broken, it may seem unrealistic for us to suggest imagining a perfect patient journey or fully integrated, seamless care. We intend nothing about this report or our recommendations to gainsay the basic, humanitarian agenda of ensuring essentials for the people who lack them or to undercut the vast, unmet social needs for justice, human rights, equity, and physical security. Nor do we wish in any way to slow the long-overdue momentum toward UHC. Instead, we hope to build on the lessons that have been learned worldwide, to call attention to the gaps that remain for every country seeking higher-quality health care, and to suggest how to bridge that chasm.

BUILDING ON HISTORY

In 2001, the Institute of Medicine (IOM) published a seminal report on the state of quality in health care in the United States. The report's title, *Crossing the Quality Chasm: A New Health System for the 21st Century*, heralds its conclusions. Speaking of Americans, it states: "Between the health care that we have and the health care that we could have lies not just a gap, but a chasm." The report parses the concept of "quality of care" into six basic dimensions. The committee charged with conducting the present study, initiated in 2017, examined these six dimensions in reviewing the evidence for the quality of health care globally and developing recommendations and a research agenda for its improvement. The committee concluded that these six dimensions remain germane to the current global context and that, with some modifications, they are thoroughly applicable to low-resource settings and modern times. The committee's modifications to the six dimensions of the 2001 IOM report include changing the wording for the "patient-centered" domain to "person-centered," reflecting sensibilities and knowledge not widespread when the IOM report was written nearly 20 years ago.[2] We believe that "person-centered care" better captures the goal of organizing care around the total (preventive and curative) needs and circumstances of each person, not merely around a disease category. We also added to the dimension of "timeliness" (i.e., services given in good time to avoid adverse events) the broader concepts of "accessibility" and "affordability," acknowledging the importance of financial protection for quality care. Finally, the 2001 report does not address a crucial contextual element of the global health care scene: integrity. It is now recognized that corruption takes far too great a toll on health care systems, and therefore integrity, accountability, and transparency are key in trying to improve health system performance in every dimension. With these changes, the committee applied the following definitions of the six dimensions of quality in analyzing the current state of quality and identifying future needs:

- **Safety:** Avoiding harm to patients from the care that is intended to help them.
- **Effectiveness:** Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit (that is, avoiding both overuse of inappropriate care and underuse of effective care).
- **Person-centeredness[3]:** Providing care that is respectful of and responsive to individual preferences, needs, and values and ensuring that people's values guide all clinical decisions. Care transitions and coordination should not be centered on health care providers, but on recipients.
- **Accessibility, Timeliness, Affordability:** Reducing unwanted waits and harmful delays for both those who receive and those who give care; reducing access barriers and financial risk for patients, families, and communities; and promoting care that is affordable for the system.
- **Efficiency:** Avoiding waste, including waste of equipment, supplies, ideas, and energy, and including waste resulting from poor management, fraud, corruption, and abusive practices. Existing resources should be leveraged to the greatest degree possible to finance services.

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[2] While the committee is endorsing this change in the language moving forward, there have been many reports published in the past two decades that measure and refer to "patient-centeredness." Where those are mentioned in this report, the language "patient-centeredness" will still be used for accuracy.

[3] Although this report uses the term *patient* when referring to the recipient of clinical medicine, the committee's position remains that quality improvement requires emphasis on the *person*, by way of reminding the reader that health is determined by circumstances far beyond the clinical setting.

- **Equity:** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, race, geographic location, and socioeconomic status.

This committee concludes that the global quality chasm is even larger than the quality chasm identified by the IOM in the United States in 2001, and that in human costs, it is much more disturbing. Ineffective treatment for human immunodeficiency virus (HIV), tuberculosis, diabetes, and diarrheal disease (for children under age 5) alone contributes to more than 1 million excess deaths annually. One in 10 drugs in LMICs are estimated to be substandard or outright falsified, resulting in ineffective treatment, contributing to the loss of nearly 8 million disability-adjusted life years (DALYs), and likely exacerbating the problem of antimicrobial resistance. Thus, a careful and open-minded review of the current state of global health care quality leads us to the conclusion that, absent a serious, massive commitment to transparency, accountability, and substantial improvement of care, billions of human beings will simply fail to benefit from the advances made in science and medicine, greatly diminishing the value of UHC. This is especially the case in LMICs, where, because of resource limitations and poverty-related threats to health, people and the care systems on which they rely are especially vulnerable to quality defects. In short, without major attention to quality improvement, UHC will be a grievous disappointment, delivering access to care that has far too little real value for health and well-being. For UHC to be effective, access and quality need to go hand in hand.

LEVERAGING UNIVERSAL HEALTH COVERAGE TO IMPROVE THE QUALITY OF CARE

The changes recommended in this report could not be more urgent. Political will and committed executive and operational leadership are essential to finance and suitably equip the health sector to deliver and continually improve high-quality care. To realize the benefits of UHC, all countries need to commit to achieving "universal quality care." Doing so will require investment, responsibility, and accountability on the part of health system leaders. This applies especially to ministries of health, but enabling this accountability requires that health system leadership not only have continuity, but also that leaders have the authority, responsibility, and autonomy to make appropriate decisions, regardless of their level. Countries need not tackle this challenge alone. Global resources are widely available, including technical and policy guidance on how to set national quality policies and strategies. Embracing principles of transparency, accountability, continual learning, and co-design, countries will need to work with the end users of their health systems—their citizens—to design their strategies, policies, and clinical care systems, as well as to create mechanisms for monitoring, evaluating, and reporting progress.

Beyond commitment and strategy development, implementation is key. Currently, there is a scarcity of strong, generalizable evidence and research on the quality outcomes of various financial and policy strategies employed in UHC. Nonetheless, several interventions have proven successful in specific settings, and these efforts provide some guidance for building quality assurance and improvement into health system structures. As countries move toward broader health coverage, governments can use the mechanisms inherent in UHC as levers to accelerate improvements in care, actively considering quality when making decisions on what services and products to commission or purchase, for whom to provide them, and how much to pay for them.

Recommendation 7-1[4]: Make Accountability for Quality a Top Priority
Ongoing improvement of the quality of care in all dimensions should be the daily work and constant responsibility of health care leaders, including, but not limited to, ministries of health. The committee endorses the recent Global Quality report and recommendations of the World Health Organization, World Bank, and Organisation for Economic Co-operation and Development, and further recommends the following steps:

- Every ministry of health should develop a national health care quality strategy, together with supporting policies, and should agree to be held accountable for progress.
- Every ministry of health should adopt goals for achieving high-quality care, adapted to their national context, but considering all the dimensions of quality highlighted in this report.
- The United Nations System or a respected global civil society organization should maintain an independent accountability mechanism with which to monitor and report on the progress of nations toward achieving high-quality care.
- Governments, international agencies, and private-sector partners should activate public demand for high quality care through education on patient rights and health literacy, provider choice, measurement, and transparency.

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[4] The committee's recommendations are numbered according to the chapter of the main text in which they appear.

Recommendation 7-2: Use Universal Health Coverage (UHC) as a Lever to Improve the Quality of Care
As ministries of health and health care leaders implement UHC they should work with payers and providers to improve quality by institutionalizing evidence-based policy levers and systematically assessing their effects on quality. Countries should gather and report on quality metrics in global frameworks and across a range of quality dimensions. Steps within nations should include:

- using financing and coverage mechanisms in UHC that support the provision of high-quality care, such as strategic commissioning and purchasing of services and products, selective contracting, and paying for the value of care;
- carrying out monitoring and evaluation, including clinical audits, community involvement and co-design, and customer satisfaction surveys, to generate data that can be used to ensure that UHC resources are fostering high-quality, continuously improving care; and
- conducting research and evaluation on the impact of policy levers on the quality of care received to improve the evidence base on what interventions lead to better care at a systems level.

EMBEDDING SYSTEMS THINKING AND MEASUREMENT

Insufficient resources are not the only threat to quality care. The mere supply of staff, space, and other resources, while essential, falls short of guaranteeing good quality. Indeed, numerous studies have shown little correlation between these health care inputs and quality. In any nation, poor or rich, quality defects derive largely from the same historical fragmentation that the IOM's *Crossing the Quality Chasm* report documents in the United States. In most nations, health care is more a collection of separate, siloed activities than a coherent, self-conscious, purposefully designed system. Hospitals lack strong connections to community-based care. Professional disciplines train and work separately, lacking the skills and ethos required for true teamwork and for thriving in interdependency. Patients often play a passive role, deferring to doctors and medical technology for instruction rather than fully utilizing what they can bring to their own care. Health care providers and payers often work against each other rather than in synergy. Staff continually must use workarounds in broken systems just to get through the day. Data systems are fragmented, mirroring the systems in which they are embedded, and offering no windows on the longer-term status, care coordination, and ultimate outcomes of patients. Furthermore, even as technology advances, information is often stored in forms inaccessible to reflection, inimical to smooth patient care, and useless for learning and comparison.

The vast majority of failures in health care result from how the system was designed or evolved. As the saying goes: "Every system is perfectly designed to achieve exactly the results it gets." By implication, if it were somehow possible to substitute a new workforce for an existing one, quality would not change meaningfully because the people themselves are not the cause of poor-quality performance. Rather, theory and evidence accumulated over the past half century or more make clear that the quality of care is determined far more by the design of the systems in which people work (such as culture, norms and expectations, the learning environment, the organization of care processes, and incentives) than by the people themselves. Without examining each level of a health care system—the environment, the organization, the health workers, and the patient at the center—and how they interact and either help or inhibit one another, it is difficult to discern how their incentives and activities align and contribute to positive or negative effects on quality. Figure S-2 illustrates this concept of nested, mutually interacting systems.

Principles of Health Care Redesign

If systems thinking and proper design are keys to high-quality, continually improving care, what basic guidelines for design are most promising? The committee considered many candidates for such redesign principles for

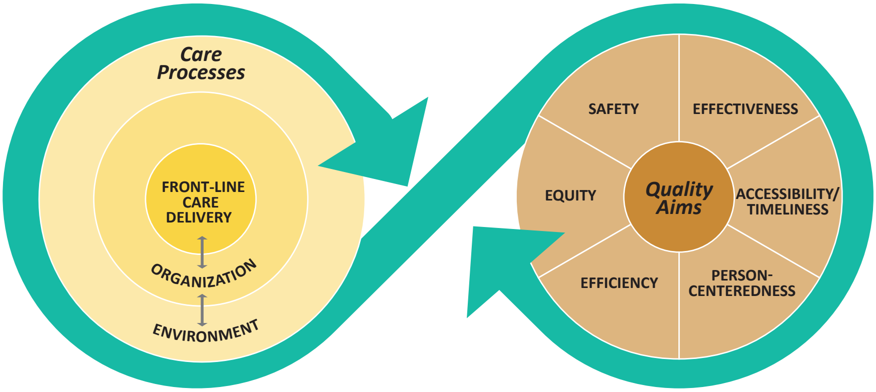

FIGURE S-2 Guiding framework for the transformation of care delivery.

low-resource settings, and reviewed the evidence and logic chains for the set of “Ten Simple Rules for Redesign” articulated in the *Crossing the Quality Chasm* report. Importantly, we chose to explore redesign and quality improvement as applied not to the legacy health care delivery systems of the past and present, but to what are likely to be the new and emerging health care systems of the 21st century. After comparing the legacy and emergent systems, we formulated our own new set of 13 principles as guidelines, which would need to be adapted to local contexts. These 13 principles are united by an overarching design principle: that a strong and constant focus in any setting should be on the needs of the person being cared for at the center, and organized around what we call the “patient’s journey” over time and space.

> **Recommendation 2-1: Fundamentally Redesign Health Care Using Systems Thinking**
> **Health care leaders should dramatically transform the design of health care systems. This transformation should reflect modern systems thinking, applying principles of human factors and human-centered design to focus the vision of the system on patients and their experiences and on the community and its health.**
>
> To guide that new care system, health care leaders should adopt, adapt, and apply the following design principles:
>
> 1. **Systems thinking** drives the transformation and continual improvement of care delivery.
> 2. Care delivery **prioritizes the needs** of patients, health care staff, and the larger community.
> 3. Decision making is **evidence based** and **context specific.**
> 4. Trade-offs in health care reflect **societal values and priorities.**
> 5. Care is **integrated and coordinated** across the patient journey.
> 6. Care makes optimal use of technologies to be **anticipatory and predictive** at all system levels.
> 7. Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote **integrity, stewardship, and accountability.**
> 8. Navigating the care delivery system is **transparent and easy.**
> 9. Problems are addressed at the source, and patients and health care staff are **empowered** to solve them.
> 10. Patients and health care staff **co-design** the transformation of care delivery and engage together in continual improvement.
> 11. The transformation of care delivery is driven by **continuous feedback, learning, and improvement.**

12. The transformation of care delivery is a **multidisciplinary** process with adequate resources and support.
13. The transformation of care delivery is supported by **invested leaders.**

The Proper Use of Metrics

In addition to design principles, appropriate and meaningful measurements are necessary to gain an understanding of the quality of care delivered, and eventually to support learning and to guide improvement. The vast majority of current indicators do not measure outcomes, focusing instead on structural inputs or processes of care. For many diseases and many types of care settings, however, the state of quality is unknown because it is not being measured adequately in an ongoing fashion, if at all. Although process measurements do have value and can provide actionable information, patient and population outcome metrics are fundamentally important and are too rare in current assessments, partly because they are often much more difficult to measure; require a longer-term view; or represent the joint effects of health care and non–health care interventions, which do not share common databases.

Many metrics for measuring quality of care already exist; after dedicated focus through international partnership, for example, more than 650 hospitals in OECD countries have adopted standard metrics for measuring quality. Therefore, time is better spent mainly on selecting from among existing indicators than on developing new ones, which warrant the effort only when they would be more valuable. In applying metrics, considering the context is, of course, vital. Even indicators with strong pedigrees must be vetted and adapted to low-resource settings so that they can provide contextually appropriate, helpful insights for patients, providers, and policy makers, taking into account the implications for culture and effectiveness at the front lines of care. It is essential as well for the use of measurement to be person-centered, health-oriented, intentional, selective, respectful of the many pressures on health care providers, and parsimonious, aligned with core goals of accountability to the public and learning and improvement for providers and with patients.

Recommendation 4-1: Embed and Refine Quality Measurement in Health Care
Nations, regions, and health care organizations should routinely and transparently measure and report on domains of quality, especially their relevant outcomes, to support learning, as well as foster accountability and trust in the health care system.

- Ministries of health and multilateral organizations should maintain ongoing, collective efforts to identify and implement a core set of quality metrics for lower-resource settings (such as those developed by OECD, as well as standards and outcome metrics from the International Consortium for Health Outcomes Measurement) to allow for benchmarking and learning.
- Health care leaders should prioritize patient-reported outcome measures and patient-reported experience measures as well as health outcome metrics for assessing quality whenever possible.
- Governments and organizations should track metrics frequently to assess performance and improvement over time. They should make performance transparent to all parties through such mechanisms as public reporting, and use metrics and co-design with three goals in mind: accountability to patients, building trust in the system, and learning.

THE FUTURE OF HEALTH CARE

The committee believes that the care systems of the future will differ radically from those of the past. Although a full review of the future health system was beyond the scope of this study, the clear implications for quality led the committee to suggest some concerns and safeguards to mitigate risks that the new forms of care may bring. Digital health technologies are key enablers to optimize health systems and improve the quality of care for individuals and populations, yet they are double-edged. If left unchecked, these technologies can deepen inequities among populations, with hidden biases being embedded in the new tools.

With the explosion of new digital tools over the coming years, new players will join the health care field. In particular, patients will become ever more active in consuming information about prevention and diagnosis; researching options for treatment; and communicating with care providers using a wide range of media, not just in-person visits. The new health care system will have a more authentic focus on prevention, risk factor management, and personalized care, using precision medicine and predictive models and with the patient at the center shaping the demand for and the design and delivery of care. These changes will be disruptive, even threatening, to legacy structures, jobs, and beliefs, but they are inevitable. The committee believes that health systems need to embrace new digital care technologies, guided by a vision of patient care that is anticipatory rather than reactive; thoroughly integrated across time and space; and wholly centered on continually improving the experiences—the "journeys"—of patients, families, and communities.

The committee envisions these new designs delivering care directly to people wherever they are—in schools, in homes, or in market stalls—and relying far more on community resources and far less on formal health care facilities. This shift will require new skills, attitudes, and culture among health care providers and new, more active roles for patients and families in shaping, evaluating, and delivering the care they need. Payers, academics, patient groups, health care networks, and medical product development and technology companies in the private sector will need to develop multisector governance mechanisms appropriate for these new models of health care delivery to maximize their benefits and minimize their risks. Co-design and co-production of health care between providers and patients, as well as consideration of human factors in the design and use of technology, will become the norm, with benefits to both.

These changes will necessitate attention at multiple levels. The question of whether technology will be, overall, a disruptor that improves or worsens quality remains unanswered. Currently, many countries exercise little regulatory oversight of care and little use of care guidelines to ensure quality. That will not suffice in the future health care world or in the era of UHC. Ministries of health will need to accept a dual role: identifying and applying policy, financing, and regulatory frameworks to accelerate the growth of new, digitally assisted health care, while also remaining mindful of quality and mitigating the risks of these new care models. They will need assistance in taking on these roles. Global partners, including private companies within both the health care and information communication sectors, have new opportunities to join ministers of health, health care leaders, and other stakeholders in pursuing a joint path forward that will benefit all parties as technology advances. Health systems within each country will need to embrace this transformation in partnership with one another, while anticipating and mitigating the risks that such changes will bring.

Recommendation 3-1: Build a Global Community for Digital Advances in Health and Health Care Delivery
The United Nations System should convene an international task force with multisectoral representation to provide guidance to the global community on advances in digital health technologies. This task force should develop:

- data standards, norms, ethical frameworks, and guidance for modernized regulation and human resource capacity to enable countries to better benefit from the transformative technologies in the health sector;
- engineering and design standards that emphasize interoperability, human factors, and human-centered design to align technologies

and innovation with the aspirations of global health care quality; and

- an international resource to guide countries in incorporating regulation of digital health technologies so as to protect users and their privacy while fostering innovation, with input from an external board of experts.

Recommendation 3-2: Adopt and Adapt the New Technological Realities of the Present and Future
Countries should prepare for and embrace the technological (especially digital) changes in health care by adopting and adapting standards; ethical frameworks; and governance, payment, regulation, and workforce designs that are anticipatory and that embrace, rather than impede, the potential of transformed care.

- Ministries of health should collaborate with ministries of communication and technology to build national health strategies that embed digital technology as an integral part of the health system and address their countries' priority health needs.
- Governments and organizations should develop and support multisectoral task forces to guide their digital health strategies to ensure that all deployed digital health technologies are evidence-based and coordinated, that patient safety is protected, and that risks are mitigated.
- Government and private-sector leaders should revise competency requirements and educational curricula to better meet the workforce needs created by digital health advances, including skills in data science and analytics, interpersonal skills for teamwork and person-centered care, and systems-based thinking.

HIGH QUALITY FOR EVERYONE: MAKING INFORMAL CARE VISIBLE AND ADDRESSING CARE UNDER EXTREME ADVERSITY

In many parts of the world, significant proportions of the population choose to seek care in the informal sector, either because they lack access to formal health care providers or, sometimes, because they do not trust the formal system. For millions of people—in some countries more than 75 percent of the nation's population—this means receiving care from providers who lack formal training but are often well known in the community.

In addition, millions more people are suffering in fragile states or humanitarian relief settings with haphazard access to health care, and without strong infrastructure for oversight or regulation of care. The majority of these sources of care in the informal sector and under conditions of extreme adversity operate outside of formalized health systems, meaning that people in these settings are receiving care that may not be regulated, measured, or coordinated with other providers. Taken together, these alternative care systems, their complexity, and the corresponding lack of scrutiny and transparency subject billions of people worldwide to care of largely unknown quality.

Informal Care Providers

Informal care providers have variable definitions and various scopes of practice among countries, and much remains unknown about their exact numbers and their utilization. The available research makes clear, however, that the quality of the care they provide is often poor (although in many cases comparable to the quality of care in the formal sector). This is a challenge, but also an opportunity. Many health care systems struggle with severe shortages of both health workers and general physical infrastructure for health care facilities. Governments and leaders in the formal health care system would benefit from acknowledging that informal care providers are the source for a significant proportion of health services in many countries, and from bringing these providers into mainstream care delivery and working to assess, streamline, and improve their quality.

> **Recommendation 5-1: Incorporate the Informal Care Sector in the Pursuit of Improved Care Delivery**
> **Country governments should integrate informal care providers into their national health strategies and quality monitoring and improvement efforts. To this end, they should acknowledge that these informal providers exist and undertake efforts to assess and improve the care they provide, such as through education, training, and incentives, to the full extent possible.**

Quality in Extreme Adversity

About 2 billion people live in fragile states and conflict settings worldwide. Their access to quality care is unreliable at best, and often, frankly, nonexistent. Research on health care in these contexts is scarce, leaving health care leaders and providers with an unclear picture of what interventions lead to best outcomes and what to prioritize with limited funds. The committee characterizes these chaotic and uncertain environments as “settings of extreme adversity” to shine a light on the dearth of quality health care affecting enormous numbers of people, a large proportion of whom are women and children. Addressing health care quality in these chaotic and often violent settings has often been relegated to “not now” status, with priority being given to simply providing access to care. Yet, this approach is misguided. In fact, given how vulnerable the people in these settings are, providing them with high-quality care is arguably more important than is the case anywhere else. There is an urgent need to understand what interventions work best in these settings so they can be implemented as soon as possible to avoid preventable mortality and harm and the waste of already insufficient resources.

Recommendation 5-2: Make Settings of Extreme Adversity a High Priority

National governments, multilateral institutions, nongovernmental organizations (NGOs), bilateral donors, humanitarian stakeholders, and philanthropic donors should make studying and improving the quality of care in settings of extreme adversity a high priority. More specifically:

- The international humanitarian system, multilateral organizations, and NGOs should identify priorities for assessing the quality of care in these settings and develop strategies for its improvement. Emphasis should be placed on addressing conditions that are particularly burdensome in these settings, such as treating conflict-related trauma and mental illness, optimizing the patient experience to ensure trust in providers, protecting providers from harm, and adequately managing chronic diseases.
- The National Institutes of Health (NIH) and other research funders should support primary and implementation research aimed at identifying what interventions work and in what contexts to improve health outcomes in fragile states and austere environments.
- Multilateral organizations and the United Nations System should create multistakeholder collaborations for purposes of reviewing and vetting the available evidence; developing consensus on promising interventions for improvement; and identifying issues of leadership and accountability for quality of care in particular circumstances, such as conflict zones, humanitarian crises, and fragile states.

THE ADVERSE IMPACTS OF CORRUPTION

Corruption, in all its forms, is an enormous contributor to poor quality of care worldwide. Its effects are felt in longer wait times, poorer treatment by health care workers, absenteeism of providers, unnecessary charges for services, and general misuse of funds, leading to decreased trust among governments, health care systems, and citizens. In essence, integrity, if not a dimension of quality, is itself an essential precondition for the pursuit of quality in health care. Thus, in the pursuit of universal quality care, it is critical for governments and societies to create better governance structures that are accountable and transparent and fund health systems so as to decrease instances of corruption and improve health outcomes for populations. Until this takes place on a national scale for many countries, UHC may be subverted to enrich the powerful and leave vulnerable populations without adequate care.

> **Recommendation 6-1: Address Corruption and Collusion**
> **Ministries of health should include in their national health care quality strategies, directly and clearly, safeguards against corruption and collusion and actions for improvements in integrity throughout their health care systems. The health sector should draw on expertise and resources from outside the health care system, including related core state institutions and dedicated anticorruption institutions, to combat corruption through prevention, detection, and enforcement.**

CREATING A CULTURE OF LEARNING

Health care systems worldwide still struggle with operationalizing a *systems approach*, despite its proven utility in other sectors, such as aviation and transportation. One of the important properties of sound systems is the capacity for improvement through learning over time. Quality, in any of its domains, is not a static property, and continual quality improvement, encompassing the processes of assessment, learning, and continual redesign, as well as the incorporation of data streams and feedback loops into current guidelines and practice, needs to be actively nurtured and intentionally maintained in organizations that seek always to do better.

The committee concludes that the vision of a learning organization applies to low- and middle-income settings just as it does to high-income settings, where there remains much room for growth and learning. In most nations and most organizations, achieving this vision will require a profound cultural shift from reliance on inspection to investments in learning and action. Countries and organizations committing to a strategy without this cultural shift are unlikely to be successful. And this shift is only the first of many steps toward successful transformation. Successfully and sustainably changing the culture of health care systems will require investment, leadership, and willingness to take risks and fail in the service of learning. But many businesses have already accomplished this, and successful private-sector examples can be found in almost any country. The committee believes that, unless and until nations and their leaders adopt this philosophy that improvement depends on learning, progress toward a future of high-quality health care will be slow indeed.

In part, the existing defects in quality reflect gaps in leadership and management. Without specific attention, quality of care almost inevitably deteriorates. The forces of entropy are rampant in any complex system, including health care. Self-conscious, planned investments of time, money, and leadership attention are required to ensure the processes of continual learning and change that lead to improvement. This need has become even more acute with the shift in the global burden of disease toward chronic illnesses and conditions associated with aging, which beg for attention to patient journeys over time and space.

A culture of continual improvement (adopting bold aims for improvement, guided by systems thinking, continual learning, and innovation and devoted to redesign and implementation guided by new design principles) is impossible without strong leadership at all levels, characterized by widespread cooperation. The committee identifies health care leaders as including, among others, ministers of health, other government officials, organizational executives, clinicians, financing organizations, and patient and community representatives. A high level of shared vision, cooperation, and shared intent is required among all stakeholders.

The alternatives to systems thinking and continual learning can appear seductive, but they are less likely to achieve the desired outcomes in the long run. Leaders lacking a systems perspective or impatient for instant success can turn to blame, exhortation, and mere goal setting, as if just asking for better results or simply trying harder were somehow enough. Such shortsighted approaches often are made even worse by blunt oversight—whether in the public or private sector—that entails demanding a better bottom line or immediate results to show donors. The effects of such pressures on a workforce can be toxic to morale, trust, cooperation, honesty, and quality itself. Leaders—at every level—who are truly intent on supporting improvement must take responsibility not just for creating accountability, but also for supporting the continual design and redesign of systems of care toward improvement, and for supporting the cultures and processes that can fully engage the workforce as participants in that learning process. Tracking of metrics over time can be used to identify small improvements that can fuel more successes.

When top leaders, such as executives and health ministers, act inconsistently with the systems-oriented approach to quality (see the design principles under recommendation 2-1 above), improvement stalls. Why should a workforce take a chance on testing changes, setting bold improvement goals, or being transparent about results—good and bad—if the consequences will be blame, criticism, table pounding, and budget cuts? A workforce treated as objects to be controlled will soon cease to learn; it will regress to pursuing timid aims, hiding defects, and ticking boxes. It will become less, not more, focused on the deeper needs of the patients and families it serves because understanding unmet needs will be a route only to further frustration. In contrast, when top leaders guide their own actions according to science-based principles of systems thinking and support continual learning as the mainstay of their organization, they can liberate enormous energies and aspirations in the workforce. With proper methods and leadership, improvement can soar.

> **Recommendation 8-1: Encourage a Culture of Learning to Fundamentally Redesign Health Care**
> **Health care leaders in all settings should master and adopt the vision and culture of a learning health care system, striving for continual learning and avoiding an approach that relies primarily on blame and shame. This learning system should extend beyond hospitals and providers to include patients, payers, administrators, community health workers, and others involved in health.**
>
> - Country governments should implement policies designed to effectively educate and supply health care professionals who are trained to provide high-quality care. These professionals should include a cadre of clinical and nonclinical leaders that are versed in creating a culture that rewards openness, transparency, and a commitment to improvement.
> - Governmental and organizational leaders should ensure that efforts to create accountability in the health care system, although fundamental, do not create a culture of fear and reaction, which is inimical to system improvement and change. Performance in all domains of quality should be measured and reported transparently, and the results should be widely available to patients to encourage feedback and improvement over time.
> - Governmental and organizational leaders should learn and use modern approaches to improving science, practice, and organizational culture.
> - Nations, regions, and health systems should establish and maintain programs to facilitate shared, collaborative learning about improvements and innovations in health care.
> - Leaders should ensure that health care systems harness new digital health technology to help reduce costs and improve care through real-time use of data.

THE CRUCIAL NEED FOR MORE EVIDENCE

The committee uncovered a vast number of unanswered questions related to quality and a dearth of evidence supporting interventions worldwide. Given these findings and the importance of people's health and well-being, the amount of funding directed toward the assurance and improvement of quality in health care, relative to other industries, is remarkably low. A much larger dedicated research agenda related to quality of care in various settings—including not only primary research and highly rigorous clinical trials where appropriate but also implementation research—would far better inform leaders about priorities and appropriate interventions. As discussed throughout this report, the widely diverse environments in low-resource settings, and indeed across countries of all income levels, demand contextual validation of interventions before they are deployed at a larger scale. The success of financial incentives or new checklists in a facility during a randomized trial does not guarantee the same results in the field or in a different social context. A collaborative research agenda geared toward continual learning would help. This agenda could have exponential effects on the quality of care, especially if a global community focused on quality mobilized to share lessons and to better understand what strategies and interventions to employ.

> **Recommendation 8-2: Define and Mobilize a Research and Development Agenda**
> **The U.S. National Institutes of Health, philanthropic organizations, and other bilateral donors, as well as low- and middle-income country (LMIC) governments and other stakeholders, should increase investments in research and development on interventions that would improve the quality of care at the system level, encompassing both primary and implementation research. The following questions should be priorities:**
>
> - What is the impact on population health outcomes of the digitization of health care?
> - What innovative or proven models exist for local use of measurement for improvement?
> - What are the roles of various actors in quality management across LMICs?
> - Which digital health technologies can best contribute to better quality of care in resource-constrained settings?
> - Do private markets reward higher quality?
> - To what degree does corruption have effects on the quality of health care delivered in various settings? How can these effects best be mitigated?
> - What 10 interventions are most likely to improve health care quality in settings of extreme adversity?

- What 10 interventions are most likely to improve the quality of care in the informal sector?
- What are the best strategies for addressing quality in fragmented settings where most patients pay out of pocket?
- What strategies can reduce overuse of health care services in low-resource settings, especially when regulatory capacity is limited or absent?
- How can strategic purchasing best help improve the quality of care delivery?
- What strategies are effective in engaging patients and people in general to demand high-quality (and especially safe) care for themselves and their families?
- How can leaders effectively and efficiently implement a systems approach for strengthening the quality of health care in LMICs?
- What skill sets for the workforce are linked to better health outcomes for patients, especially in the emerging digital age of health care?

A FINAL WORD

The committee realizes that, when presented with so many areas to work on and high-level approaches to operationalize, leaders may wonder where to begin. While prioritizing the recommendations and interventions proposed in this report would be an extremely valuable contribution, the committee believes that doing so is beyond the scope of this study. There is no silver bullet solution, and each country and health system will need to tailor its approaches according to needs of its populations. It is our hope that future projects can gather national and regional stakeholders to take on this crucial task of setting priorities for action.

In our year of hard work together, we have come to agree on at least three fundamental premises. First, a vast quality chasm plagues health care globally. It affects billions of people, and no nation and no population is exempt. The costs in lives, health, and society are enormous—far greater than most people know, including the committee when we began this inquiry. This burden will continue unless nations and leaders work actively to eliminate it. Second, it is possible to do better, even in low-resource settings, and even without substantial additional resources. There are approaches that work. Modern systems sciences and several decades of distributed experience in quality improvement offer a firm foundation for starting on the road to improvement. While there is no doubt about the need for more evidence, there is enough evidence of efficacy to start now. Third, leaders must act. Improvement depends on them, and it is their responsibility. The success of the MDGs shows what can be achieved, even in resource-poor settings, when a global consensus grows on the value of bold aims, scientific methods, and shared learning. The MDGs resonated even in the poorest nations on earth. The committee hopes for the same resonance around the quality imperative now. For the most disadvantaged people and in the most austere settings, the need is greatest. The longer-term promise of fully transformed care, technological modernization, and personalized care may as yet be far out of reach for some, but the first steps are not. As the momentum for UHC continues, so, too, is it time to seek quality care for all. Equity and quality of care need to arrive together, or they will arrive not at all.

1

Introduction

Since 2000, programs to improve health across the world have accelerated rapidly. The Millennium Development Goals (MDGs) in particular have intensified the focus on health, development, and poverty reduction and encouraged the scale-up of investments in interventions worldwide. Spurred by the MDGs, the proportion of undernourished people in developing regions fell from 23 percent to 13 percent; the burdens of human immunodeficiency virus (HIV), tuberculosis (TB), and malaria fell dramatically, meeting global targets; and child and maternal mortality decreased by 53 percent and 43 percent, respectively (WHO, 2015). Yet, despite the overall success of the MDGs, progress has been uneven. The MDGs largely overlooked inequalities within nations, and placed insufficient emphasis on improving conditions for the poorest populations in both low- and middle-income nations.

As a successor to the MDGs, in September 2015 the global community adopted a new development agenda—the Sustainable Development Goals (SDGs)—agreed on by 193 countries (UNDP, 2015). The SDGs represent an attempt to address the unfinished agenda of the MDG era, setting forth a comprehensive set of integrated targets through economic, social, and environmental lenses. Of particular relevance to this report, SDG 3 focuses on "ensuring healthy lives and promoting wellbeing for all at all ages" (UN, 2017). The pursuit of equity is at the heart of the SDGs, and Target 3.8 specifically addresses the achievement of universal health coverage (UHC), a central pillar of SDG 3 overall (UN, 2017):

> Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

THE SUSTAINABLE DEVELOPMENT GOALS AND THE UNIVERSAL HEALTH COVERAGE AGENDA

The current UHC movement represents the culmination of an ongoing emphasis by the World Health Organization (WHO) and the World Bank on ensuring access to quality health care for the poor. The intent of UHC is that "all people [receive] the health services they need … while at the same time ensuring that the use of these services does not expose the user to financial hardship" (WHO and World Bank, 2015, p. 7). However, UHC should be considered a continuous journey and not a panacea for achieving health improvements (Horton, 2018).

A first step to achieving UHC will be to address the inequitable distribution of health gains. Between 2005 and 2015, for example, only 17 percent of mothers and infants in households in the poorest quintile in low-income and lower-middle-income countries had access to at least six of seven basic interventions, versus 74 percent in the richest quintile (WHO and World Bank, 2017). This report, however, focuses on an often-overlooked issue that goes beyond access. Simply interpreted, access to care is only part of the goal of UHC; ensuring that this care is of high quality is also essential (Scott and Jha, 2014). Until recently, however, the quality of available health care has not been incorporated consistently into global and national discussions of UHC, nor has it been a consistent focus in practice. The UHC movement will succeed only if quality is placed squarely at the heart of the agenda. Recognition of this fact has given rise to the concept of "effective coverage." While "crude coverage" measures only access to services, "effective coverage" takes into account the need for, the use of, and the quality of the services (Ng et al., 2014).

Quality, Universal Health Coverage, and Global Health Security

While the quality of care is not always linked to UHC, some argue that both should be linked more closely with global health security, which WHO defines as the reduced vulnerability of populations to acute threats to health (WHO, 2007). All three are the subject of prominent conversations globally, but they sometimes are seen as disparate, even as competing for attention and resources. The West African Ebola outbreak of 2014–2015 in particular has led to growing recognition of the need for local health systems to contain outbreaks before they cause catastrophic loss of life and economic turmoil. The harmonization of efforts at the local level is needed at higher levels as well: health security, quality, and UHC implementation need not be promoted in opposition to one other, but instead can have synergistic effects when seen as complementary. The inputs for quality, such as reliable power, adequate medical equipment, and trained health care personnel, are also inputs for health security and resilience. If UHC can successfully stimulate demand for care in a country and increase utilization, ongoing case detection and surveillance can be incorporated into strong primary care systems and be used to detect early warnings of outbreaks (Jain and Alam, 2017).

The global community is coming to recognize the strong interrelation among these agendas. In the 13th draft General Program of Work (GPW) for 2019–2023, WHO has outlined a set of three interconnected priorities: healthier populations, protection from health emergencies, and more people benefiting from UHC to meet the SDGs (WHO, 2018a). As argued in the 13th GPW, the three agendas require implementation that is mutually reinforcing, meaning that future health systems should be characterized by strong integration of quality, resilience, and UHC efforts. According to Jain and Alam (2017), it would be hazardous to suggest that countries have achieved UHC without having developed a sustainable capacity for the key public health services that are integral to health security—infectious disease prevention, detection, and response. In short, health systems of the future, while becoming more predictive and holistic, also represent an important opportunity for a better merging of quality, UHC, and global health security to achieve positive, synergistic effects.

What Is Universal Health Coverage Without Quality?

As indicated above, a central premise of this report is that, while achieving UHC is important, its full potential to reduce the burden of ill health will not be realized without a commensurate effort to improve health care quality. In recent decades, several analytical frameworks have emerged to guide health care quality, which at its core is comprised of six dimensions as set forth in 2001 by the Institute of Medicine in *Crossing the Quality Chasm: A New Health System for the 21st Century*: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity (IOM, 2001) (see Box 1-1). This framework for assessing health care remains influential to this day.

These six dimensions are interrelated, and are, both individually and collectively, essential properties of high-quality health care. Indeed, high levels of inappropriate care are pervasive. For example, a WHO report finds that more than 6 million excess caesarean sections are performed each year, 50 percent of which occur in China and Brazil (Gibbons et al., 2010). If care were only equitable and efficient but neither safe nor effective, the very

BOX 1-1
Definition of Health Care Quality

The Institute of Medicine report *Crossing the Quality Chasm: A New Health System for the 21st Century* defines health care quality as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 2001, p. 44). The report further defines quality as having the following six dimensions:

- **Safety:** Avoiding injuries to patients from the care that is intended to help them.
- **Effectiveness:** Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding overuse and underuse, respectively).
- **Patient-centeredness:** Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- **Timeliness:** Reducing waits and sometimes harmful delays for both those who receive and those who give care.
- **Efficiency:** Avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equity:** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

SOURCES: IOM, 2001, pp. 5–6; NASEM, 2018, p. 36.

access to care could lead to adverse medical outcomes or even mortality due to hazards and defects in care. Poor-quality antimalarials, for example, were associated with the deaths of more than 122,000 children under the age of 5 in sub-Saharan Africa (Renschler et al., 2015). Similarly, immunizations are a vital medical intervention for children, but their effectiveness depends on timeliness and proper storage. If vaccines are not high quality, "stored appropriately, dispensed at the requisite time, and properly administered," they cannot provide the expected benefits (Rasanathan et al., 2016, p. 4). Finally, if care delivery does not treat patients with respect and dignity, trust in the system and providers can erode, and people therefore may not seek care that could help them in the future.

The challenge of assuring and improving quality is not limited to low- and middle-income countries (LMICs). High-income countries have fallen short on the quality scale as well. A recent news series in the United States reveals excess and preventable deaths due to poor-quality care in surgery centers in multiple states (Jewett and Alesia, 2018), and in 2013 researchers estimated medical error to be the third leading cause of death in the United States, behind only heart disease and cancer (Makary and Daniel, 2016). These defects have high economic costs as well, with 15 percent of all hospital costs in Organisation for Economic Co-operation and Development (OECD) countries being due to patient harms resulting from adverse events. The lack of coordination within and among health care providers and networks appears to be the greatest concern, as failures in coordination can significantly delay treatment and deter people from seeking care (Picard, 2010). For example, when a person visits a specialist but is given a paper summary and instructions to follow-up with a general provider at another location, the general provider may not know the outcome of the visit before seeing the patient again in person, and must hope that the patient brings the necessary paperwork. While improving access and quality may appear to be two different aims, achieving one without the other is futile. Without quality at the center, UHC is an empty vessel.

CHALLENGES FOR HEALTH CARE QUALITY

Improving quality of care in low-resource settings is a vexing challenge. The quality of care can vary dramatically both within (Das, 2011) and across nations (Barber et al., 2017). For example, the Dartmouth Atlas Project in the United States analyzed variations in how medical resources are distributed and used (The Dartmouth Atlas of Health Care, 2015). These researchers found that more resources and more services delivered do not lead to better or more effective care. In fact, higher resource intensity is sometimes associated with worse care. Other studies analyzing health care in both government-run and private-sector health facilities have found poor quality across multiple dimensions (Berendes et al., 2011), with little difference between the public and private facilities (Basu et al., 2012). Some countries, such as Costa Rica (Pesec et al., 2017) and Rwanda (Sayinzoga and Bijlmakers, 2016), have invested heavily in health system–wide reforms, leading to improved health outcomes and increases in life expectancy (Pesec et al., 2017). However, translating these successes to scale globally is difficult given the variations in context among nations. This section outlines some of the challenges faced by low-resource settings in the areas of fragmentation of care delivery and poor health system building blocks. These challenges can result in a fragmented and complex patient journey (described later in the chapter) within and among health facilities, often resulting in poor experiences for those who depend on care. The committee emphasizes that improving the patient journey across the life course is an essential lens through which to view improving health care quality.

Fragmented Health Care Delivery

Fragmented health care is a problem shared by all countries, whether high-, middle-, or low-income. Health care delivery often requires a patient to transition from unit to unit, from one care setting to another, or from a care setting to home, receiving care from a range of providers (Ben-Tovim et al., 2008). Too often these interactions are siloed. Providers and facilities fail to communicate with each other or coordinate their work, causing important health information to fall through the cracks and impairing patient experiences. While users in high-income countries may have an electronic health record (EHR), they often lack easy access to it, or it is distributed across multiple providers. Users' information thus is carved into pieces. One study evaluating fragmentation of hospital care for patients with chronic conditions in New York City found that Medicaid enrollees were 24.4 percent more likely to experience highly fragmented care relative to commercially insured patients, even after adjusting for demographic characteristics (Schrag et al., 2006). Likewise, fragmented health insurance has caused suffering among interstate migrant workers in India. The migrant workers are excluded from any form of employee state insurance because they work in the informal economy. Even those registered under state-specific health insurance schemes are not eligible to access health care services outside of the originally registered states. Because they lack interstate insurance coverage, migrant workers avoid using health services until their conditions become advanced. They then often seek care from an expensive private facility, thereby incurring severe financial debt. A fragmented health insurance scheme allows an already vulnerable population to slip through the cracks (Mohan, 2017).

This failure of health care systems to take into account the entire journey across clinical encounters and instead treat each encounter in isolation leads to care that is reactive, episodic, treatment focused, provider focused, duplicative, and wasteful. Because records and histories are difficult for patients to access, duplicate tests are often ordered when people migrate across care providers and hospitals (Kripalani et al., 2007). Failing to consider the user's perspective can also raise costs and injure patients. Clinical encounters that are geographically inaccessible, unacceptable, and disrespectful for patients can be especially harmful, as they deter patients from returning for needed care.

Poor Health System Building Blocks

Fragmented care is exacerbated by factors both at the clinical encounter and at more upstream organizational and policy levels. WHO developed a framework that organizes these various factors, or health system building blocks: service delivery, health workforce, health information systems, access to medicines, financing, and leadership and governance. If these building blocks fail to function optimally both separately and in conjunction with one another, they cannot support high-quality health care (WHO, 2010).

Service Delivery

In a health care facility, good service delivery has at least two components: availability and readiness. In low-resource settings, both are at risk. Service availability depends on the distribution of facilities and a trained health workforce (discussed below). Service readiness depends on the presence of basic amenities, such as reliable power, improved water, and sanitation; standard infection precautions; and medical equipment (WHO, 2010). Unfortunately, many health facilities in LMICs lack improved water[1] and sanitation[2] and standard infection precautions. In a global survey of 54 countries, for example, WHO found that 39 percent of health facilities lacked an improved water source, 19 percent lacked improved sanitation access, and 35 percent lacked water and soap for handwashing (WHO and UNICEF, 2015). Another study of 78 LMICs found that 73 percent of health facilities lacked sterilization equipment (Cronk and Bartram, 2018).

Health facilities require adequate quantity and quality of water sources to maintain a hygienic environment and deliver health care optimally. But a systematic review of hospital-acquired infections in LMICs found that inadequate environmental hygiene can be a determinant of poor outcomes (Allegranzi et al., 2011). Similarly, a lack of reliable power disrupts health care delivery. It can prevent the use of sterilization equipment, limit the use of electrically powered tools (Adair-Rohani et al., 2013), impede the use of information and communication technology (Cronk and Bartram, 2018), cause vaccine spoilage (WHO, 2018b), and impede the capacity to provide both surgical care (Meara et al., 2015) and service at night (Adair-Rohani et al., 2013). Disruptions of power at health care facilities are prevalent in LMICs, occurring by one estimate at 59 percent of facilities (Cronk and Bartram, 2018).

High-quality health care also depends on functional medical equipment, such as laboratory testing and imaging tools. Many hospitals and clinics in

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[1] An improved water source, by the nature of its construction, protects the water from outside contamination. Common examples include piped water, a public standpipe, a borehole, a protected dug well, a protected spring, and rainwater collection (WHO and UNICEF, 2012).

[2] Improved sanitation facilities hygienically separate human excreta from human contact. Types of facilities include flush or pour flush toilets to piped sewer systems, a septic tank or pit, a ventilated improved pit latrine, a pit latrine with slab, and a composting toilet (WHO and UNICEF, 2012).

LMICs rely on donations, which account for approximately 80 percent of medical equipment in these countries (Bhadelia, 2016). Often, such equipment can be impossible to use as its voltage requirements are incompatible with those that exist in the hospitals (Jones, 2013). Even if the equipment is technically compatible, health care personnel may not have the capacity to use it (Howie et al., 2008). Reports of medical donations lacking manuals at all or in the correct languages, as well as contact details for the manufacturer needed for repairs and proper utilization, render the equipment useless (Healy, 2015). If the roles of human factors and ergonomics in the transfer of these technologies are not considered, safety and proper utilization cannot be guaranteed (Meshkati, 1989). Furthermore, a lack of spare parts and personnel often makes it impossible for health care facilities to maintain or repair medical equipment when it falls out of service. As a result, equipment can sit unused in hospital hallways or in "equipment graveyards." An analysis of inventories in 16 low-income countries found that an average of about 40 percent of pieces of medical equipment in hospitals were nonfunctional (Perry and Malkin, 2011), compared with less than 1 percent in high-income countries (Howitt et al., 2012). In fact, this gap may be even larger because many hospitals in low-resource settings do not maintain up-to-date inventories.

Health Workforce

High-quality health care requires skilled health care workers (Speybroeck et al., 2006). Unfortunately, however, there is an estimated shortfall of 2.5 million doctors, 9 million nurses and midwives, and 6 million allied health professionals globally (WHO et al., 2018). With few lucrative opportunities to work in home countries and few incentives to work in rural areas and even in the public sector, many health professionals leave the countries in which they train for other, more profitable markets. WHO emphasizes the importance of health worker density,[3] but that concept may implicitly assume that these workers are adequately trained and consistently deliver care that meets clinical standards. Yet, even when health workers are present, several studies indicate a lack of adherence to clinical guidelines and implementation of evidence-based practice (Puchalski Ritchie et al., 2016). In a study in China, India, and Kenya for example, adherence to evidence-based treatment for such conditions as asthma, chest pain, diarrhea, and

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[3] Health worker density refers to the numbers of physicians, nurses, midwives, dentists, community health workers, and other related health care workers in a given area. It is usually given as a ratio—number of workers: 1,000 population. The SDGs set a threshold of 4.45 physicians, nurses, and midwives per 1,000 population as the minimum density needed for an adequate health workforce (WHO, 2016).

TB occurred little more than 50 percent of the time, and often less than 25 percent of the time (Daniels et al., 2017).

This failure to adhere to evidence-based practices may be due to a "know" gap—a lack of knowledge or awareness of guidelines. Without institutional support, health care workers may not have access to the latest published guidelines. The problem can also be due to a "know-do" gap, such as a lack of understanding of how guidelines were developed. Or it can be due to competing priorities, a lack of technology and medicines to support the application of guidelines, a lack of supervision and mentorship, and even organizational barriers—all of which are systemic challenges faced by health systems globally (Puchalski Ritchie et al., 2016). During his testimony to the committee, Pierre Barker from the Institute for Healthcare Improvement underscored the gap between knowledge and optimal outcomes. He stressed that the integration of quality into the health care system needs to merge command and control, quality assurance, and quality improvement (Barker, 2017).

Another explanation for the "know-do" gap is a lack of accountability. Accountability in health care rarely strikes the right balance between promoting quality of care and preventing a culture of blame. In an environment of too much accountability, a culture of blame and a litigious environment can develop. As a result, health workers may underreport errors out of fear (Keepnews and Mitchell, 2003). Conversely, too little accountability entails little to no oversight of health workers, allowing them to shirk responsibility and engage in perverse behaviors, such as absenteeism (Nishtar, 2010). In low-resource settings, accountability can be lacking because of weak regulations and the limited capacity of organizations to hold health workers to professional, discipline-based standards, which may explain why the performance of health workers, even those who are trained, is low and highly variable in LMICs (Das, 2011). Indeed, this was the case in high-income countries before medicine became professionalized, standardized, and regulated (Starr, 1982). The Indian government has attempted to increase accountability within the health sector by creating Panchayati Raj Institutions (PRIs), locally elected bodies of governments in rural areas, meant to decentralize political, administrative, and fiscal responsibilities. Yet, while decentralization has progressed, problems of accountability remain because PRIs make irrelevant and unproductive decisions as the result of having neither the resources to undertake development nor the power to influence existing programs (World Bank, 2000). Importantly, as low-resource settings start to develop standards and accountability structures, they will need to ensure that they are given the necessary authority and resources to do so, while also promoting a culture of learning and improvement.

The "know-do" gap can also be blamed on the misalignment of incentives. Closely related to accountability, incentives on "what to do" or "what not to do" can guide health workers' behavior. Incentives are driven mainly by measurements. These measurements can be linked to payments or provider ratings. Thus, in a way, incentives and measurements act as a form of economic and clinical accountability (Goeschel, 2011). However, often "what gets measured gets done," and so identifying the right measurements to highlight the right outcomes is critical.

Health Information Systems

Clinical decision making depends on sound and reliable information. A health information system (HIS) can support decision making with data generation, compilation, analysis, synthesis, communication, and use (WHO, 2010). However, HISs globally do not always synthesize data effectively to inform sound clinical decisions—a problem shared by countries of differing income levels.

A reliable and efficient HIS goes beyond improving monitoring and evaluation to influence alert and warning systems, patient health data and trends analysis, and global reporting. An HIS should be comprehensive at four levels: individual, health facility, population, and public health surveillance (WHO, 2008). To achieve equal success across all levels, a system must operate interdependently. Increasing capacity to undertake effective health information exchange is essential, but many LMICs face structural, political, and financial barriers to making the transition from paper-based to electronic documentation (Akhlaq et al., 2016). A BMC Health Services Research study explored the sustainability of electronic health information systems (EHISs) in Malawi, Zambia, and Zimbabwe. The study revealed high levels of optimism for EHISs coupled with hesitation about successful transition. The key challenges could be addressed through the technical design of systems, stakeholder coordination, and increasing organizational capacity to sustain and improve such systems (Moucheraud et al., 2017). Regardless of which system is used, the elements of interoperability and the generation of feedback to inform providers and administrators are critical to establishing a learning system (see Chapter 8) and being able to measure quality.

Access to Medicines

A leading cause of poor health outcomes in low-resource settings is poor access to medicines, often due to inadequate capacity of in-country supply chains to forecast, procure, and deliver essential commodities (Dowling, 2011). In Kenya, for example, a 2013 service availability and readiness assessment mapping study found that "[non]availability of medicines is commonly cited as the most important element of quality by health care consumers, and the absence of medicines is a key factor in the underuse of public health services" (Ministry of Health, 2013). If they cannot procure the right medicines or if patients instead find substandard medications at a nearby pharmacy, it is extremely difficult for providers to deliver effective care. Patient dispensing sites frequently experience stockouts even when adequate stocks of medical commodities exist at the central or provincial level (PwC, 2017). The challenge of distributing goods in this "last mile" is pervasive in low-resource settings. Even when medicines do make it to sales points, moreover, there is a danger that substandard and counterfeit medicines will enter the supply chain. These products often contain no active ingredient, leading health systems to waste resources. Other falsified products may have weakened active ingredients and, even more dangerous, toxic compounds, posing a potential danger to patients (WHO, 2018c). Whether the illness is infectious and acute or longer term and chronic, treatments with weakened or inappropriate ingredients can have serious adverse effects.

On the opposite end of the spectrum of access, the overuse of medications and services has increasingly become a problem in many countries. Overuse of unnecessary services can harm patients physically and psychologically, and can harm health systems by wasting resources, some of which are in short supply (Brownlee et al., 2017). In the United States, at least 30 percent of antibiotic prescriptions in an outpatient setting are unnecessary (Incze et al., 2018). One study found urgent care centers and retail clinics—both on track for high growth—to be underrecognized sources of antibiotic prescribing (Palms et al., 2018). In Europe, researchers found that one-half of patients were prescribed unnecessary antibiotics (Brownlee et al., 2017). Providing the right medication, in the right dosage, and at the right time are all critical factors for health care quality.

Financing

Despite the high priority accorded to UHC on political agendas, health care financing models in many countries fail to extend high quality health care to their populations while also protecting them from impoverishment. With few financial resources available and with patchwork health care coverage, a majority of people living in low-resource settings are forced to forego or delay treatment, which exacerbates the fragmentation of the care they do receive and impairs their health outcomes. Furthermore, without a sustainable source of revenue, health care facilities can experience stockouts; fail to deliver care that meets clinical guidelines; or engage in aberrant behavior, such as patient detention, in an effort to garner revenue. These problems related to the financing of UHC are discussed in more detail in Chapter 7.

Leadership and Governance

Leadership at all levels is vital for a health care organization, both to optimize operations and to shape culture. Further challenging many countries is the rapid turnover of leaders within ministries of health, as many decisions affecting the health care of the country come from a centralized level. High staff turnover within ministries of health results in excessive costs, a decline in efficiency, and compromised quality. Demirkiran and colleagues (2016) found that a decrease in organizational performance can result from delays in filing vacated positions and difficulties in finding qualified candidates. Reducing staff turnover within health ministries would allow for more focus on long-term health programs that will yield improvement in health care quality.

Because of this challenge and other issues, there is a dearth of managerial and executive expertise in LMICs. Unlike high-income countries, however, LMICs can have difficulty relying on a cycle of searches and appointments. Rather, leaders must evolve into their roles, growing through their experiences. Under these circumstances, the culture of an institution can become extremely important for developing leaders. If an organization does not allow for learning and growth to take place, emerging leaders will be more reactive and less strategic. Furthermore, without checks and a culture of professionalism in place, resource capture and other aberrant behaviors, such as absenteeism and misuse of resources, can occur. In fact, leadership and governance of a country too often are tainted by corruption and collusion, as discussed further in Chapter 6.

A POOR PATIENT JOURNEY

Given the fragmented nature of health care delivery in LMICs and the weaknesses in health system building blocks discussed above, it is crucial to view health care quality not just as a point estimate that applies during one clinical encounter. Rather, health care quality is appropriately considered essentially as a longitudinal concept, a collection of properties of care that patients experience over an extended period of time. This observation is reminiscent of Vincent and Amalberti's (2016) expanded view of the concept of one specific quality domain—patient safety. Unfortunately, many health care professionals are trained to practice with a focus on individual clinical encounters—a myopic perspective reinforced by dichotomous metrics, fragmented payment systems, and simplistic targets. Instead, this report emphasizes the importance of the patient journey, defined as follows:

> The patient journey consists of the myriad interactions that patients have with the health care system, health care providers (formal and informal),

> and families and friends and among themselves. These interactions occur over time and across multiple health care settings, such as clinics and hospitals, and within communities. The spatio-temporal interactions and transitions in care experienced by a person constitute the essence of the patient journey.

Given that fragmented care harms the quality of health care, improving quality will require improving the patient journey. Doing so will in turn require understanding the challenges that occur when patients transition among care settings and in between clinical visits. One crucial challenge is the issue of "health literacy," or "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (IOM, 1990, p. 4). Health literacy influences not only communication at a health facility but also how a person understands health and health care, such as the value of treatment adherence, after leaving a facility (Foubister, n.d.). Experts believe that health literacy is dynamic and can change as a person continually interacts with a health care system (Malik et al., 2017). This perspective is especially important given that people's needs, motivations, and health literacy levels can evolve throughout their lives. Thus, the committee sees the patient's journey, depicted in Figure 1-1, as an important aspect of health care quality. People's interactions can occur in person or virtually, but will also be impacted by surrounding socioeconomic factors or political and geographical factors, which may influence their decision making (see Figure 1-1).

The Structure-Process-Outcome (SPO) model articulated by Avedis Donabedian (1988), a physician and the founder of the study of quality in health care and medical outcomes research, lends a process perspective that is useful for understanding these challenges. By introducing three areas of assessment for quality, the SPO model offers windows through which to understand the interaction of patients and care delivery. Also important in this equation, however, is the notion of context. Although many process-oriented frameworks have arisen in response to the SPO model, most of them ignore the perspective of the patient, and the fact that a patient's experiences can influence both care-seeking behavior and adherence to care. The concept of the patient journey is intended to fill this gap.

Improving the patient journey requires in turn that patients be empowered and brought to the center of health care decision making. To achieve this, governments and health systems need to make a concerted effort to educate people about what high-quality care looks like and how their decisions can affect their own health. Emerging health care technologies can facilitate this endeavor (as discussed further in Chapter 3), but to fully realize the potential of optimizing the patient journey, policy makers

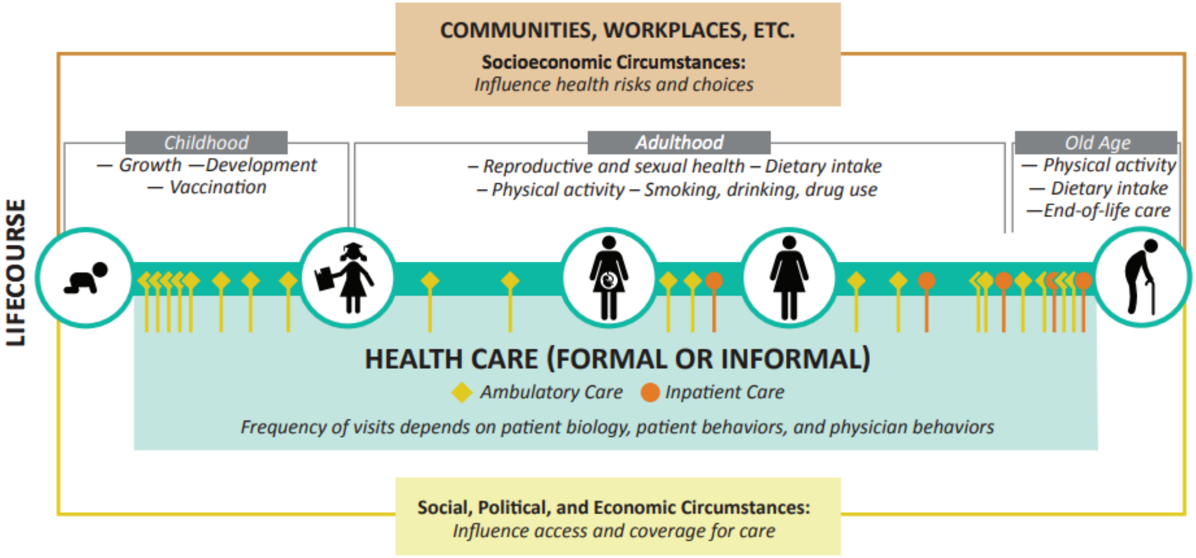


FIGURE 1-1 The patient journey from a life-course perspective.

and health care leaders need to consider key influencing factors, including health system levels, the well-being of health care providers, and the private sector's role in the delivery of care.

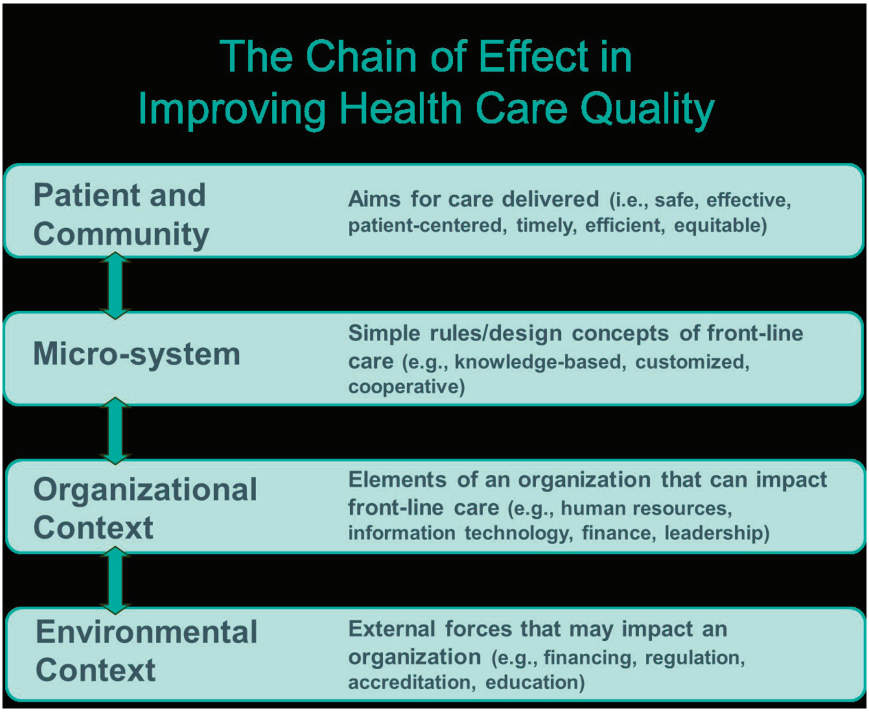
Influence of Health System Levels

Though not explicitly diagrammed in the 2001 *Crossing the Quality Chasm* report (IOM, 2001), an underlying framework guided the committee that produced that report, as documented by Berwick (2002) following the report's release. Driven by a systems-thinking perspective and an acknowledgment that health care outcomes depend on upstream organizational processes and the policy and regulatory environment, this framework has four levels, depicted in Figure 1-2.

Figure 1-2 shows that the patient experience is influenced by the "microsystem" or the setting in which health care is delivered. This could be represented as a health care team. The "microsystem" is further influenced by the "organization," such as the hospital in which the health care team works. Lastly, all three are influenced by upstream factors from the surrounding policy and regulatory "environment." Given the committee's emphasis on the patient journey and people's experience with the health care system, the influence of the more distal organizational and environmental levels is important to consider. It is widely known that upstream inefficiencies can cascade down to the clinical encounter and result in a degradation of quality (Cook and Woods, 1994). Too often, blame for medical errors is assigned to the health care worker, and incident analysis and root-cause analysis frequently fail to consider broader system failures (Leistikow et al., 2017; Peerally et al., 2017). Berwick's (2002) framework offers a valuable perspective that poor-quality care is often a consequence of upstream factors.

Influence of the Well-Being of Providers

The committee unequivocally embraces the centrality of the patient experience in defining and pursuing quality, but it also recognizes that the experience of health care providers is equally important to high-quality health care. Reports of burnout among physicians and nurses are common in high-income countries and are the topic of many discussions (Dyrbye et al., 2017). The issue is emerging in LMICs as well, with a systematic review finding levels of burnout similar to those among family doctors in Canada and Europe, as well as general internists in the United States (Dugani et al., 2018). Another study, in Kenya, found a burnout rate of more than 95 percent of medical workers at Kenyatta National Hospital in 2014, with the work environment being identified as the major contributor (Kokonya et al., 2014). In turn, health care providers' burnout, stress, and defective



The Chain of Effect in Improving Health Care Quality

Patient and Community — Aims for care delivered (i.e., safe, effective, patient-centered, timely, efficient, equitable)

Micro-system — Simple rules/design concepts of front-line care (e.g., knowledge-based, customized, cooperative)

Organizational Context — Elements of an organization that can impact front-line care (e.g., human resources, information technology, finance, leadership)

Environmental Context — External forces that may impact an organization (e.g., financing, regulation, accreditation, education)

FIGURE 1-2 Health system levels that can impact one another bidirectionally.
SOURCE: Adapted from Berwick, 2002.

work environments are linked to poor patient experiences and health outcomes (Bodenheimer and Sinsky, 2014). Therefore, improving care requires improving the well-being of the health care workforce, as failing to do so can lead to increased clinician burnout (Babbott et al., 2013). To better balance the agenda, many organizations have adopted the aim of improving the “work-life” of health care providers (Bodenheimer and Sinsky, 2014). The constraints and barriers faced by health care providers often fall within the “organizational” and “environmental” levels of the framework in Figure 1-2. These encompass ways in which organizations treat providers and the effects of new work processes and technologies, which can either ease or add to the workload constraints providers face. The committee believes that improving the “work-life” of health care providers is a goal germane to quality improvement in all health care systems, societies, and countries, regardless of income level or existing infrastructure.

Influence of the Private Sector's Role in the Delivery of Care

In considering the patient journey, health care leaders would be remiss to ignore the role of the private sector in health care. Discussions of global health and quality of care sometimes stress the importance of the private sector in expanding access, with the assumption that market forces will drive quality improvements. However, no pervasive difference in quality has been found between government-run and privately run facilities (Berendes et al., 2011). In one systematic review, the private sector did rank higher in offering timely service and hospitality, but strong evidence showed as well that it violated medical standards and had low efficiency. Furthermore, the authors note that private-sector facilities had higher risks of low-quality care and lower transparency. These findings may partly be explained by the large and diverse nature of private-sector health care, which ranges globally from informal-sector traditional healers (discussed in Chapter 5); to unique health care innovators, such as Narayana Health Care and PurpleSource (discussed in Chapter 7); to high-tech health facilities serving as hubs for medical tourism (*Medical Tourism Magazine*, 2018).

Given the size and diversity of the private sector involved in health care and the predominance of informal providers, the private sector's impact on health care quality—especially in light of the dearth of reliable data—cannot be ignored. A single patient's journey can easily encompass both government-run and private-sector facilities or multiple types of private-sector facilities. Thus, the committee believes it is especially important to shed light on private providers and to include them in quality improvement efforts. Even though some private innovators, as mentioned above, are delivering high-quality care, their models are not always generalizable. Thus, they cannot serve as strong evidence for a blanket assertion that the private sector provides a simple route to improved quality (Sauerborn, 2001), no more than public-sector provision of services is a magic bullet solution to improving quality.

One challenge to better leveraging the strengths of the private sector is the lack of available information in this area. In part this is due to the private sector's failure to publish data by which its performance could be evaluated (Basu et al., 2012). This finding is extremely salient for quality improvement efforts, since without data on quality problems, policy makers and other stakeholders cannot devise effective solutions. Another barrier to more streamlined, high-quality care is the fragmentation, discussed earlier, that plagues all sectors in health care. Recognizing these challenges, however, the private sector still represents a large portion of the health care sector in LMICs, serving more than half of the population in some countries. Public–private partnerships offer an opportunity for health care improvement, as they have done in the service of broader global health efforts, but leveraging them will require changes at the organizational and environmental levels. Without affecting the system upstream and tailoring incentives at the right level, it will be difficult to help the lower levels of the microsystem and the patient experience achieve high-quality care.

CHARGE, APPROACH, AND SCOPE OF THIS STUDY

With the global momentum of the SDGs and UHC as a backdrop, combined with the previous decades of work on health care quality worldwide, the time is ripe for a deeper examination of the quality of care and its determinants globally. Several federal agencies, foundations, and private-sector partners came together to request that the National Academies of Sciences, Engineering, and Medicine (the National Academies) convene an ad hoc committee to conduct a study that would build on the wealth of quality work undertaken domestically and abroad and apply it to the global context (see Box 1-2 for the study's full Statement of Task).

In the context of the signing of the SDGs in 2015 and the majority of countries now striving to cover entire populations with health care services, it is imperative that the continual improvement of quality be inextricably linked with the provision of care. Unless proper measures, oversight mechanisms, patient awareness, and health literacy are built into systems, it is possible that UHC efforts will provide access to poor-quality, even harmful care, accomplishing the opposite of what the SDGs were designed to achieve.

Approach

A 14-member committee was appointed in July 2017 to conduct this study, meeting four times over the course of the study. Three of these meetings included open sessions, soliciting input from expert speakers and members of the public. At the first meeting in October 2017, the study sponsors were invited to state their priorities and clarify their views of the charge to the committee, and additional expert testimony on quality improvement theory, methods, and experience was solicited. In the public session of the second committee meeting, held in Nairobi, Kenya, in December 2017, the focus was on the current state of health care quality, with invited testimony from regional health experts from the WHO Regional Offices for the Eastern Mediterranean (EMRO) and Africa (AFRO), as well as from innovators from East and West Africa. At the third meeting, hosted by the Institute of Global Health Innovation at Imperial College London, United Kingdom, in March 2018, the public session explored the future of health care quality. Subject-matter experts in the areas of ethics and regulatory issues for digital health were also consulted by telephone to obtain input to supplement the limited published research in these areas. (A list of those interviewed can be found in the acknowledgments section in the front of this report.) In March

BOX 1-2
Statement of Task

In light of the call in the Sustainable Development Goals (SDGs) for achieving Universal Health Coverage (UHC), the National Academies of Sciences, Engineering, and Medicine will convene an ad hoc committee to study particular prospects for improving health care quality globally while expanding access to preventive and therapeutic services, with a focus in low-resource areas.

This study will put the emphasis on the organization and delivery of safe and effective care at the patient/provider interface. Dimensions of care to be considered by this committee should include access (to services and commodities), effectiveness, safety, efficiency, and equity. The focus will be on front line service delivery that can directly impact health outcomes for individuals and populations. Recommendations would be targeted to key stakeholders, governments, donors, health systems, professions, and others.

The report will specifically address the following tasks:

- Describe the context—Illuminate the consequences of poor quality care in low-resource areas and the challenges regarding both acute and chronic care for diseases that relate to avoidable morbidity and mortality, as well as lost productivity. The degree of financial waste and increased cost from ineffective or poor quality care should also be covered.
- The committee should also consider nonhealth features of low-quality care, e.g., the question of financial protection, particularly as it relates to the implementation of universal health coverage elements.
- Define the opportunity—The committee should review the evidence on the potential to systematically improve quality of effective and safe care and offer recommendations about when and where quality improvement methods (defined broadly to include policies, processes, behavior change, and system modifications) most reliably benefit health outcomes. Issues of financial protections, especially in the setting of out-of-pocket payment for services, are germane.
- Analyze gaps—Giving attention to the constraints on health systems in many countries, the committee should suggest promising models (including short, intermediate, and long-term time frames) that, if employed, might facilitate improvements in quality, give countries a descriptive pathway to consider, and build capacity for widespread progress.
- Define a research agenda for the application of implementation science to the improvement of quality—The committee should offer an agenda of high-priority implementation science research topics that would enable translation and broad implementation of scalable quality interventions, including issues of enrollment and financing UHC expansion.
- Offer approaches to setting priorities for advancing quality improvement—The committee will offer recommendations on systematic approaches to setting priorities for implementing interventions and more institutionalized processes. Issues of process quality, continuity of care, and retention of patients in programs are germane.

2018, the committee also held a webinar with staff from the World Bank to learn more about their efforts in health care quality worldwide.

In developing its approach to this study, the committee recognized that the six quality dimensions described in the 2001 *Crossing the Quality Chasm* report (IOM, 2001) and listed earlier in Box 1-1 have continuing relevance despite being drafted nearly 20 years ago. Yet, while evidence has supported their continued importance, the vast majority of that evidence originates from high-income countries rather than from low-resource settings. The 2001 report also does not address issues of accountability and transparency and their fundamental relationship to achieving high-quality care delivery. Furthermore, understanding of the nature of "patient-centered care" has evolved in the intervening years. As a result, the committee decided to introduce a few modifications of the original six dimensions of quality to make them even more germane to low-resource settings and modern times:

- **Expanding "patient-centeredness" to "person-centeredness"[4]:** In all settings, modern sensibilities suggest that care should be organized to the extent possible around the needs and goals of each individual person rather than around disease categories or homogeneous groups (sometimes summarized as "What matters to you?" medicine rather than "What is the matter with you?" medicine) (Barry and Edgman-Levitan, 2012). Such a focus, in addition to an emphasis on improving health literacy, allows services to be more responsive, more effective, and more acceptable. Accordingly, interest has recently grown in "co-designed" and "co-produced" health care, with the aim of ensuring that people can be full partners in service delivery design and governance and in improving their own health (WHO, 2010).
- **Broadening "timeliness" to include "accessibility and affordability":** This important distinction incorporates financial risk protection firmly into the definition of quality. While financial protection has been subsumed by some in the past within the dimension of "access," the committee believes that, especially in low-resource settings, financial risk protection warrants being specified, because without it the quality of care is in severe jeopardy. For example, if there is no health care facility nearby that is financially accessible, people may either forego care they need or seek some kind of treatment from an informal provider with unknown education or train-

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[4] While the committee is endorsing this change in the language moving forward, many studies published in the past two decades measure and refer to "patient-centeredness." Where those studies are mentioned in this report, the term "patient-centeredness" is preserved.

ing. In the worst scenarios, people may even be denied emergency care unless they can pay for services up front, or suffer abuses in exchange for their inability to pay (Fagan, 2017) (see Chapter 7).

- **Accounting for corruption and integrity as determinants of quality:** The committee believes that acknowledging the importance of accountability and transparency for quality of care brings needed attention to the pervasive corruption and collusion that adversely affect health care around the world (see Chapter 6). Corrupt behaviors in health care occupy a spectrum. On one end are administrative and operational practices that are, in fact, aimed at redirecting and pilfering resources for private gain. On the other end, corruption entails state capture, which stems from weak capacity of state institutions and diminished accountability. This can cause health care resources to be depleted by vested economic interests of the powerful elite.

Thus, this report uses the updated six dimensions to guide quality measurements:

- **Safety:** Avoiding harm to patients from the care that is intended to help them.
- **Effectiveness:** Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit (that is, avoiding both overuse of inappropriate care and underuse of effective care).
- **Person-centeredness:** Providing care that is respectful of and responsive to individual preferences, needs, and values and ensuring that people's values guide all clinical decisions. Care transitions and coordination should not be centered on health care providers, but on recipients.[5]
- **Accessibility, Timeliness, Affordability:** Reducing unwanted waits and harmful delays for both those who receive and those who give care; reducing access barriers and financial risk for patients, families, and communities; and promoting care that is affordable for the system.
- **Efficiency:** Avoiding waste, including waste of equipment, supplies, ideas, and energy, and including waste resulting from poor management, fraud, corruption, and abusive practices. Existing

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[5] Note on the language used throughout this report: Although this report uses the term *patient* when referring to the recipient of clinical medicine services, the committee's position remains that quality improvement requires emphasis on the *person*, to remind the reader that health is determined by circumstances far beyond the clinical setting.

resources should be leveraged to the greatest degree possible to finance services.

- **Equity:** Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, race, geographic location, and socioeconomic status.

Scope

In conducting this study, the committee focused on the interface between the health system user and the care provider and on how quality at that interface can best be assured and improved. Other important components of the health system, especially public health protections and social determinants of health, can of course contribute greatly to the overall health of a population and also can benefit from attention to quality improvement, but they are not a primary focus of this report. The committee acknowledges this gap, and hopes that additional reports will soon address those crucial components. Other areas and issues that will require additional study and more focused examination are numerous, and include, among others, settings of extreme adversity; supply chains; pharmaceutical integrity; surgery and cancer; mental health and substance abuse; and dental care.

Another important choice the committee made was to focus not only on low-income nations but on low-resource settings within all nations. While many reports are segmented by country wealth or income level, the committee recognizes that poor populations are found across the world, including within middle-income and wealthy nations. As health care continues to advance, and patients receive care transnationally or from multinational companies, the committee believes that purely national lines will fail to capture quality of care adequately. For instance, just as deleterious effects from poor quality can occur in high-income countries, such as the United States (Jewett and Alesia, 2018), so too can examples of quality improvement be found in low-income settings.

Innovations from low-income settings can be adopted and adapted widely. In fact, Lord Nigel Crisp, author of *Turning the World Upside Down*, argues that bringing developing countries to the same playing field as developed nations creates an open exchange of ideas, informed by the realization that between low- and high-income settings, learning is not one-way (Crisp, 2018). In Mozambique and Pakistan, for example, midlevel workers are successfully trained to complete procedures that require a full professional education, such as caesarean sections or cataract operations. No clinically significant difference in outcomes has been proven between the surgeries performed by midlevel health workers and physicians. Thus, this workforce innovation has increased the access of communities to services and treatments without compromising quality of care (Crisp, 2010). Crisp notes that the North American system is designed for an age of acute care, which, given epidemiological trends, is becoming an increasingly inappropriate and unaffordable focus (Smith, 2010). Some organizations are already beginning to recognize the need for this global information exchange, especially in terms of research where certain low-income populations may share more similarities with cohorts in other countries than with their own fellow citizens (Evangelista, 2018). The committee expects great benefit from bidirectional information flows and learning networks, recognizing that ongoing attention to and improvement of quality is a global challenge that requires all hands on deck to address.

A Note on the Committee's Recommendations

The committee recognizes that the recommendations offered in Chapters 2 through 8 of this report are aspirational, requiring in many cases transformative efforts that will necessitate combined and sustained action on the part of the full range of governments, leaders, and organizations worldwide involved at every level of the health care enterprise. However, the committee believes that the evidence reviewed in this report clearly demonstrates the need to think big while also identifying specific actions that, collectively, can advance global health care toward a quality system that meets the needs of all the world's citizens, including those in the most resource-poor regions. To this end, the committee offers a set of overarching principles for the transformation of health care worldwide (see Chapter 2), along with specific actions that can be taken by all stakeholders to achieve a transformed system that reflects these principles. Some of these actions can be taken in the near term, while others will require efforts that extend over the mid- to long term. Overall, the committee wishes to stress that the somewhat overwhelming scope of the transformation needed to achieve quality health care for all globally should not deter efforts to take the steps that can lead, over time and with focused dedication, to realizing improvements. We also realize that when presented with so many areas to work on and high level approaches to operationalize, leaders may wonder where to begin. While prioritizing the recommendations and interventions proposed in this report would be an extremely valuable contribution, the committee believes that doing so is beyond the scope of this study. There is no silver bullet solution, and each country and health system will need to tailor its approaches according to needs of its populations. It is our hope that future projects can gather national and regional stakeholders to take on the crucial task of setting priorities for action.

ORGANIZATION OF THE REPORT

Part I of this report presents the committee's view of "The Ideal Vision for Future Health Care." It begins in Chapter 2 by describing changes that will be necessary to improve quality at the systems level—mainly mastering and using systems thinking and system-level designs, as well as shifting the focus and ownership of health matters to empowered and educated users and communities. Chapter 3 then explores what the world can expect from future health systems. Many innovations are already in use and will become more widespread, and others, though nascent today, have the potential to fundamentally transform how people seek and receive care. Thus, it is essential for the pursuit of quality to attend not only to current care delivery systems but also to those that will soon emerge, and even become dominant.

Part II, "The Current State of Quality in Health Care," includes Chapters 4 through 6. Chapter 4 explores the current state of data on global health care quality and the lack of the evidence and metrics needed to ensure that quality is being adequately measured to drive improvement in the defective processes of care that are currently widespread. Chapter 5 calls attention to the billions across the world who fall outside of formal health care systems, including those whose care comes from informal providers and those in settings of extreme adversity where health care is scarce and infrastructures absent. Chapter 6 highlights the negative health impacts of corruption in the health sector and how tools outside the health sector can be used to address this important problem.

Finally, Part III, "The Path to Continual Global Improvement," includes Chapters 7 and 8, presenting strategies and recommendations for achieving the ideal vision laid out in Part I. Chapter 7 outlines the commitment that will be necessary for countries to enable both current and future systems of care to meet their potential and ensure that quality is being built into UHC frameworks and systems. This chapter also describes what is known about the policy levers that can help induce better quality, especially through effective financing and incentives. Developing accountability for this commitment will require creating public demand for better quality, since the will for such change from within the current care system alone will be insufficient. Finally, Chapter 8 issues a call for creating an environment that supports a culture of learning, including in particular the leadership necessary for this culture to succeed. This chapter also outlines the research agenda identified by the committee as necessary to inform many of these quality initiatives.

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2

The Path to a High-Quality Future: The Need for a Systems Approach and a Person-Centered System

Do we fix the way the system works, or do we change the way we think about health care?

Key Findings

- Using a sociotechnical system approach to analyze health care systems can elucidate drivers of health care quality, recognizing that people have behaviors and limitations that need to be accounted for and that their work environment will affect them. The end goal for this approach is joint optimization for both the people and the organization.
- The role of human factors must be considered at all system levels if the patient journey and health care quality are to be optimized at the patient–provider interface. Misalignment of organizational structures and levels can have severe health consequences for patients and providers. With the application of human-centered design, solutions can be tailored to people's needs while accounting for their implicit cognitive biases.
- Trusted and accurate communication between health care staff and patients (and their family members) is a central clinical function and a key component of quality health care delivery. Effective communication has been linked not only to higher patient satisfaction, amenability to follow-up, and adherence to care but also to improved health outcomes.

Achieving high-quality health care is a complex pursuit in any setting, even one with rich resources. However, it is particularly difficult, and arguably more important, for low-resource settings. As demonstrated in Chapter 1, many challenges to achieving high levels of quality care still exist worldwide, leading to fragmented and undesirable patient journeys. Improving the patient journey requires an integrated system of care and productive interactions among many system levels—both public and private.

Given the complexity of the interactions involved, the pursuit of excellence in health care depends deeply on systems thinking—a perspective that draws on the sciences of sociotechnical systems and human factors, among others. This chapter first outlines the committee's commitment to systems thinking as foundational for high-quality care, and calls for a health system that is consciously designed and continually improved to optimize the interactions between people (patients and providers) and the tasks, technologies, equipment, and organization of health care that are essential to the pursuit of quality. Given that the results achieved by any system depend on its design, the committee then presents 13 general principles to help guide the design of a person-centered health system in any setting. This section also presents real-world examples of these principles in action, and how they can influence a more person-centered health care system. The final section presents a summary and the committee's first recommendation.

THE NEED TO REDOUBLE EFFORTS FOR A SYSTEMS APPROACH

In response to the fragmentation of care described in Chapter 1, models of integrated care have been proposed with the promise of providing safer (Vincent and Amalberti, 2016), more effective and efficient (Armitage et al., 2009), and more person-centered care without sacrificing health outcomes (Mason et al., 2014). However, such integration efforts have had mixed results, possibly because of how they have been structured. Instead of seeking to improve outcomes and the patient experience, integration in low- and middle-income countries (LMICs) often focuses on structural and process issues, such as increasing access, increasing uptake of services, clustering services for specific populations, and improving resource efficiency (Mounier-Jack et al., 2017).

LMICs would benefit from a greater focus on the pursuit of services that are integrated and that emphasize the patient experience, as stressed by the World Health Assembly in its call for strengthening integrated, people-centered health services (WHO, 2015). Success in this pursuit requires that support systems, such as information, finance, contracting, and training, work in harmony. This means that LMICs need to integrate not only services but also these support systems, which can be a more difficult undertaking. However, if LMICs take full advantage of ongoing trends of interprofessional education, collaborative practice, task shifting, and community health care, they are in a strong position to succeed with this type of integration (Mounier-Jack et al., 2017).

To integrate care, optimize the patient journey through the health care system, and thereby improve health care quality, all countries will need to apply a systems-thinking perspective. Systems thinking has long been embedded in other sectors, such as manufacturing, transportation, construction, and engineering. This approach has been discussed and sometimes attempted in high-income countries, but few health systems have been able to execute it at full scale as designed to realize its full potential. The U.S. Institute of Medicine (IOM) defined a systems-thinking perspective for health care as follows:

> A systems approach to health is one that applies scientific insights to understand the elements that influence health outcomes; models the relationships between those elements; and alters design, processes, or policies based on the resultant knowledge in order to produce better health at lower cost. (Kaplan et al., 2013, p. 4)

This definition acknowledges that systems outside of health care also strongly affect the health of a population, and that each system component needs to be optimized not only in isolation but also in conjunction with others lest "suboptimization" of individual elements degrade the care provided by the system as a whole. Although the call for a systems approach to health care made in *Crossing the Quality Chasm* (IOM, 2001) did influence various efforts to mesh systems engineering and health care—such as the World Health Organization's (WHO's) analytical guide to the use of systems thinking to strengthen health systems (WHO, 2009)—the execution of this approach remains a work in progress for all countries. Thus, there is a need to renew systems thinking to better integrate care worldwide and optimize the patient journey for high-quality care.

Systems Thinking for Health Care

While much conceptual work has applied systems thinking and systems principles to the health care field, most interventions to date have focused on increasing access, improving training, instituting financial incentives, and a few other targeted efforts. By neglecting to take a holistic perspective, such interventions fail to address the underlying issue behind poor quality: poorly structured organizational contexts and process inefficiencies that interact with each other and at multiple levels (e.g., country, region, community, hospital). If ignored, these interdependent upstream factors degrade the provider–patient interface, leading to poor outcomes.

The importance of systems thinking is reflected in Figure 2-1, which integrates the prior conceptual frameworks on which the committee drew: Donabedian's (1988) Structure-Process-Outcome (SPO) model; WHO's (2010) health system building blocks; Berwick's (2002) health system levels; WHO's (2010) health system goals; and the (adapted) six dimensions of quality care from *Crossing the Quality Chasm* (IOM, 2001). Chapter 1 describes these frameworks in greater detail. Donabedian's SPO model is placed at the top of the figure to provide an overarching structure for all of the frameworks. The WHO health system building blocks measure structural inputs, Berwick's health system levels address issues of process, and the WHO health system goals on the right side of the equation can be used to measure outcomes for both the system and the user. In accordance with a systems-thinking perspective, the adapted IOM quality dimensions are characterized in the figure as cross-cutting, suited for use in measuring the structure, process, and outcomes of health care quality. The committee encourages nations and leaders seeking to improve the patient journey to adopt the systems thinking approach, viewing health care as a sociotechnical system and accounting for the emerging field of human factors and ergonomics (HFE), which is discussed below.

Applying Sociotechnical Systems Theory to Improve Quality of Care

Health care delivery relies on people (patients and providers) interacting with technologies in diverse settings and in physical, organizational, and social environments that are influenced by a myriad of policies. Furthermore, health care is not only dynamic in nature but also highly technical. Given the multiple interactions that occur and the highly complex environment in which they occur, a health care system can be characterized formally as a sociotechnical system (Carayon et al., 2011).

Sociotechnical systems theory is an approach used to analyze a complex system or work environment and the interactions among people and organizational structure and processes in this environment. Using a sociotechnical system approach to analyze health care systems can elucidate drivers of health care quality (Chisholm and Ziegenfuss, 1986). First, the approach recognizes that the people involved in health care—patients and all providers—have particular behaviors and limitations, such as competing interests and cognitive loads and nonoptimal health literacy. Second, it recognizes that the technical aspects of a work environment, such as medical knowledge, medical procedures, and electronic health records (EHRs), have a very real impact on people and how they work (Carayon

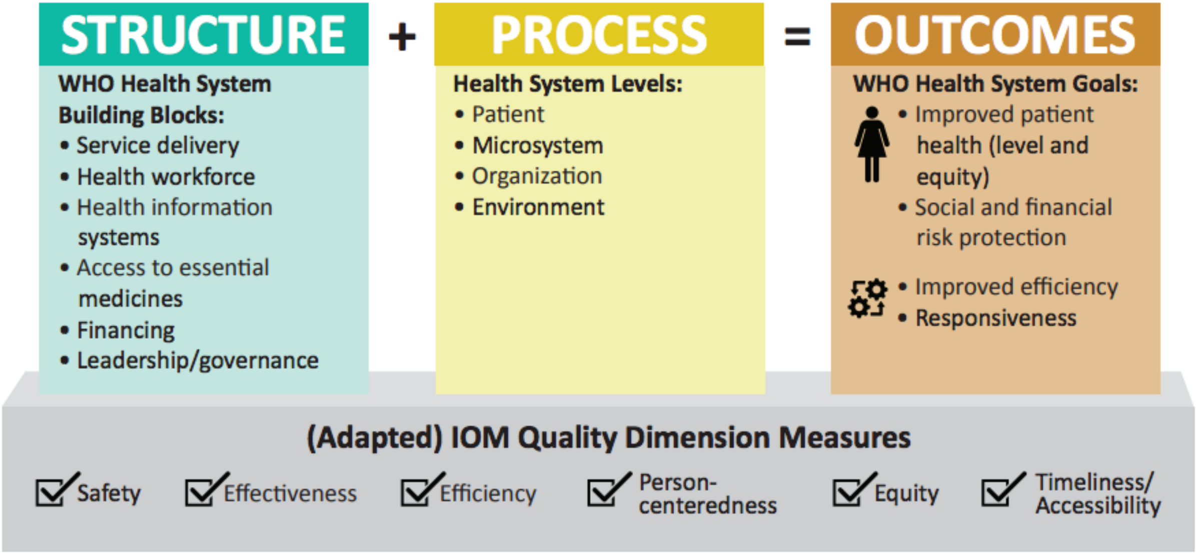

FIGURE 2-1 Integration of conceptual frameworks guiding health systems and quality of care.
NOTE: IOM = Institute of Medicine; WHO = World Health Organization.

et al., 2011; Lawler et al., 2011). The end goal of using a sociotechnical system approach is joint optimization for both the people and the organization (Braithwaite et al., 2009). For a health care system, this means that a clinic should

- deliver high-quality health care for patients;
- improve the patient experience;
- provide a high-quality work environment for health care workers; and
- reduce waste for all involved—that is, achieve the "Quadruple Aim" (Bodenheimer and Sinsky, 2014).

The application of a sociotechnical system approach for health care systems can have positive effects on the quality of care. Traditionally, but incorrectly, poor health care outcomes have been attributed to the individual health care worker or health care team. It is for this reason that many quality reform efforts have consisted of positive and negative incentives targeted at the individual provider, such as sanctioning, blame, and training. Such an approach ignores the upstream impacts of organizational deficiencies. Often referred to as the "blunt end" of a complex system, the sociotechnical context can create inefficiencies that cascade down to the "sharp end" of the clinical encounter, manifesting in low-quality outcomes (Cook and Woods, 1994). For example, a design team based at St. Mary's hospital in London found that doctors were specifying units of a drug incorrectly when writing prescriptions (i.e., micrograms instead of milligrams). To rectify this problem, the design team redrew the form so doctors just had to circle the unit (*The Economist*, 2018), demonstrating that this "blunt end" change affected the "sharp end" of care. If quality is indeed a systems property affected by decisions occurring at all levels of a health care system, optimizing the system design at all levels should be a priority. This means making a complex system work well for the people within it, which is the object of the discipline of HFE, discussed below. In many low-resource settings, however, the organization or design of the health care sociotechnical system is lacking, leaving front-line health care workers with little support and often trapped in failures not of their making, for which they are unfairly blamed.

It is important to note, moreover, that while understanding and applying sociotechnical system theory as an approach to quality improvement in health care includes identifying what interfaces are weak or when and where processes break down and errors occur, this is only part of the picture. Recently, health care quality experts have been providing additional support for understanding what makes care delivery go well in so many of these complex systems—the majority of the time. Also known as "Safety II," this new approach is defined as "the ability to succeed under varying conditions, so that the number of intended and acceptable outcomes is as high as possible" (Hollnagel et al., 2015). In other words, care is delivered in a variety of real-world settings that look nothing like the careful environment of many randomized clinical trials. Many interactions and instances of health care that occur in these environments produce good outcomes, and understanding why these successes happen and how to replicate them regardless of the circumstances can be just as illuminating for quality improvement as understanding why things go wrong. Doing so can assist in achieving "resilient health care," whereby the system can adjust in response to disturbances to maintain continual and optimal performance. At the same time, however, it must be emphasized that for either approach, understanding human behaviors and incorporating them into systems design and interventions will play a significant role in the quality that results.

Considering Human Factors in Design

To optimize an organization for those within it, considering the strengths and constraints they face is important. A health care system should be designed and structured in a way that makes it easy for patients to access quality health care and easy for providers to deliver such care. Such an approach draws on the field of HFE, which is defined:

> the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance. (IEA, 2018)

At its core, HFE entails applying knowledge of human behavior, capabilities, and limitations to design systems, tasks, work environments, technologies, and equipment. Its focus, thus, is "on how people interact with tasks … technologies, and … the environment," with the goal of optimizing human and system efficiency, effectiveness, and safety (NRC, 2011, p. 61). Unfortunately, many health care systems are not designed with these concerns in mind (if, indeed, they are designed at all). They may favor patients at the expense of providers or vice versa, or even show favor to external parties at the expense of both patients and providers. For example, the advent of patient-centered care has led to many interventions that, while ideally beneficial for the patient at the center, fail to respect the limitations of or constraints on providers, often requiring of them additional work and tasks. Similarly, hospitals and clinics can be, and often are, designed and structured in a way that makes care delivery easy for the provider at the expense of the patient. An example is labor and delivery units that fail to meet the real needs of patients and families by imposing restrictions on who can be in which room at which times, regardless of the mother's wishes. Likewise, administrative tasks, such as those supported by EHRs, while beneficial in terms of record keeping, can be established for billing purposes and impose an undue burden on both providers and patients.

The Impact of Failing to Account for Human Factors at Multiple System Levels

Although health care journals increasingly appreciate and report on HFE approaches, it often remains difficult to convince funders, clinical decision makers, and managers that HFE assessments should be systematically embedded in clinical practice, clinical trials, and product development (Buckle et al., 2018). Buckle and colleagues argue that the limited application of HFE in health care indicates that the discipline—along with its multidisciplinary methods of evaluation—has yet to be addressed consistently within the national and international health care communities. Incorporation of HFE in health care has positive impacts on patient safety

BOX 2-1
Case Study: Misalignment of Incentives Across Organizational Levels

Complex sociotechnical systems such as health care can be seen as a hierarchy of organizations, teams, and individuals. Properties of these systems—for example, the safety of care—are therefore affected by the decisions of those at all levels, including customers, staff, companies, regulators, associations, and government. Adverse events, then, can be caused by inconsistencies between the policies and practices set by actors at different levels of the system (see Figure 1-2).

These levels in the real world are demonstrated by the case of the patient-controlled analgesia (PCA) pump, a medical device developed in 1988 in the United States to assist patients with pain management and reduce workload for nurses. However, a programming error in the device led to multiple cases of delivery of the wrong dose of medication, proving fatal for a handful of patients. Despite multiple patient deaths throughout the 1990s, the response initially was limited to providing additional nurse training, thus overlooking the design of the PCA as the source of error. This is reflective of a broader trend in relation to how faulty medical devices were evaluated. Though nearly 50 percent of all recalls in the 1980s were due to poor product design, it took almost a decade for human factors to influence design requirements issued by the U.S. Food and Drug Administration (FDA).

The PCA pump case illustrates the importance of incorporating human factors into all system levels, as well as aligning staff trends and capabilities with organizational changes such as the introduction of technology. In fact, a retrospective study found that trends in nursing practice, such as a growing use of part-time workers, increased the and the well-being of health workers (Bagian, 2012; Mao et al., 2015). The role of human factors must be considered at all system levels if the patient journey and health care quality are to be optimized at the patient–provider interface. Misalignment of organizational structures and levels can have severe consequences for both patients and providers. Consider, for example, the case study on patient-controlled analgesia pumps in Box 2-1.

The case described in Box 2-1 clearly depicts the dangers of failing to validate medical products with HFE data. Perhaps as a result of safety issues, the U.S. Food and Drug Administration (FDA) has issued guidance on the application of HFE studies to medical devices (FDA, 2016a), on the use of HFE data in the design of combination products (FDA, 2016b),[1] and on which types of devices should include HFE data in pre-market submissions (Hodsden, 2016). Although these are nonbinding recommendations, the issuance of this guidance is a clear indication that regulatory bodies are

potential of errors occurring with the use of computer-based devices: the lack of standardization of medical devices across the United States caused temporary nurses to lack familiarity with technology they encountered. This issue, coupled with poor product design, likely contributed to the rising numbers of PCA pump–related patient deaths.

In response, the PCA pump manufacturer injected human factors expertise into management levels and product design processes—a strategy that can be used to improve health care quality in other settings. Hospitals could use this approach by incorporating human factors expertise throughout their enterprise—for example, conducting appropriate evaluations before purchasing medical devices to ensure their success. Also, it is important to form relationships among and create joint efforts with the different system levels of the external environment to make meaningful and lasting changes. Hospitals and media, for example, can work together to promote the importance of a human factors approach to patient safety and human-centered design of technologies to avoid future adverse events and deaths.

The key conclusion of this case study is that the policies and practices of different actors should be consistent to improve patient safety. Thus, it is important to understand how seemingly isolated decisions can impact multiple actors and feed upstream within the system levels of Figure 1-2, thereby affecting the patient. For example, the following key questions should have been asked in the above case: How will budget decisions influence nursing staging? and How well will temporary nurses work with the medical devices in use at this hospital? Answering these questions is complicated, and requires aligning system levels and enabling information to move freely upward and downward across the various levels.

SOURCES: Vicente, 2003; Vicente et al., 2003.

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[1] A combination product is a product that combines two or all three of a medical device, a drug, and a biologic. An example of a combination product is a drug-eluting stent (Drues, 2014).

recognizing the importance of HFE for medical products. Given the high financial stakes of approval, manufacturers are likely to utilize HFE methods in study designs to verify and validate medical products.

Human-Centered Design and Health Care

Human-centered design is increasingly being recognized in both high- and low-income countries for its benefits to health outcomes and provider satisfaction (Bazzano et al., 2017). The importance of human factors for optimal health outcomes lends credence to the impact of human-centered design on health care. With the application of human-centered design, solutions are tailored to people's needs while accounting for their implicit cognitive biases (Searl et al., 2010). Maintaining a patient- and staff-focused mindset at the heart of clinical redesign will benefit all relevant parties in a clinical encounter. Human-centered design is discussed in more depth in Chapter 3.

Expanding the Donabedian Model

Although Donabedian's SPO model (introduced in Chapter 1) highlights the importance of processes for health care outcomes, it does not allow for in-depth analysis of the interactions that occur within a system, nor does it account for the experiences of patients and providers. In response to this gap, the literature on sociotechnical systems has proposed an expanded SPO model—the Systems Engineering Initiative for Patient Safety (SEIPS) model—that captures the interactions that occur in a health system's structure (termed the sociotechnical "work system" here) and the feedback on the health system's structure from processes and outcomes (Carayon et al., 2006).

According to the SEIPS model, the elements of the work system are the *people* (i.e., patients, caregivers, providers), their *tasks*, the *technologies* used to perform those tasks, the *physical environment* in which the tasks are performed, and the context of the *organization* in which people perform the tasks individually or collectively as members of teams (Carayon et al., 2006). The individual elements of the system need to be designed appropriately—for instance, technologies should follow usability heuristics, or simple rules used to help make decisions (Zhang et al., 2003). However, this is not sufficient. All of the system elements should support, in synergy, the goals of health care quality. This brief example shows how all work system elements need to be considered, especially when implementing any change such as new technology. For instance, *technologies* that follow these usability principles should be designed to support *tasks* performed by *people* who have received adequate training (*organization*) and receive help in case the technology breaks down (*organization*) or malfunctions in a specific *physical environment*. Interactions among work system elements and feedback from processes and outcomes need to be considered and purposefully designed. For example, health care leaders and policy makers need to consider the following questions when designing the work system to optimize the patient journey and achieve high-quality care (Carayon et al., 2006):

- What are the characteristics of the individual performing the work? Does the individual have the physical, sensory, and cognitive abilities to do the required tasks? If not, can accommodations be made to account for the individual's abilities so that high-quality work and outcomes are achieved?
- What tasks are being performed, and what are characteristics of those tasks that may contribute to low-quality patient care? What in the rest of the work system allows the individual to perform tasks safely and at a high level of quality?
- What in the physical environment can be sources of error or promote safety and other quality dimensions? What in the physical environment ensures high-quality performance? How does the physical environment (e.g., layout of workspace) support high-quality interactions between people in performing care tasks?
- What tools and technologies are used to perform the tasks, and do they increase or decrease the likelihood of quality care?
- What in the organization prevents or allows exposure to hazards? What in the organization promotes or hinders patient safety and other quality domains?

Following a root-cause analysis of unexpected deaths in the Hamad Medical Corporation (HMC), the largest health care system in Qatar, investigators found clear evidence that there had been worsening vital signs, even just hours before cardiac arrest, but that no action had been taken. This is, in part, because the significance of these signs had not been recognized, but also because those that did notice them—often nurses—did not feel empowered to notify physicians. In response, HMC developed the Qatar Early Warning System (QEWS) using evidence-based vital sign charts and a response trigger. Resistance was encountered initially, but because the QEWS prioritized good governance, credibility, and defining training requirements and standard indicators, the program became highly successful and was credited with a 40 percent reduction in cardiac arrest rates (Vaughan et al., 2018).

The crucial roles of sociotechnical systems, human factors, and the interactions within the work system make it clear that to improve the patient journey and health care quality, health care leaders need to build a truly person-centered health system. The people on whom the system is centered need to include not only patients but also providers at all levels of the system.

REDESIGN FOR A PERSON-CENTERED HEALTH SYSTEM

In drafting the design principles presented below, the committee maintained the lens of sociotechnical systems and human factors. The sociotechnical systems literature emphasizes the importance of a methodical approach to designing any system (Cherns, 1987). One such approach is organized into three categories: meta, content, and process (Clegg, 2000). The meta category is focused on defining the "values" that drive design, the content category on identifying "what" needs to change or be accomplished, and the process category on determining "how" the first two categories can be realized (Carayon, 2006). To complement this top-down approach, the committee applied a bottom-up approach, in which committee members discussed current research to determine whether the "simple rules" presented in *Crossing the Quality Chasm* (IOM, 2001) would be applicable to this new, 21st-century system and for health care settings globally, and agreed that this was indeed the case. By applying this methodical approach, the committee was able to formulate the following principles for designing health care delivery (see Table 2-1). These principles are intended to serve as guidelines for detailed designs, which need to emerge from and be adapted to local contexts.

At the core of the committee's proposed design principles is a framework that considers the various health system levels (as laid out in Chapter 1), the role of human factors, and the structure of the work system (see Figure 2-2). This framework emphasizes that health care occurs within a system in which organizational processes and environmental policies influence front-line health care delivery. Thus, an aim of implementing the above principles will be to ensure that the intersections among front-line care delivery, the organization, and the environment are self-conscious and seamless, and that system elements and care processes work well together. Only by achieving this harmonization can the quality aims of *Crossing the Quality Chasm* (IOM, 2001) be achieved.

TABLE 2-1 Proposed New Design Principles to Guide Health Care

Number	Principle
1	Systems thinking drives the transformation and continual improvement of care delivery.
2	Care delivery prioritizes the needs of patients, health care staff, and the larger community.
3	Decision making is evidence based and context specific.
4	Trade-offs in health care reflect societal values and priorities.
5	Care is integrated and coordinated across the patient journey.
6	Care makes optimal use of technologies to be anticipatory and predictive at all system levels.
7	Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote integrity, stewardship, and accountability.
8	Navigating the care delivery system is transparent and easy.
9	Problems are addressed at the source, and patients and health care staff are empowered to solve them.
10	Patients and health care staff co-design the transformation of care delivery and engage together in continual improvement.
11	The transformation of care delivery is driven by continuous feedback, learning, and improvement.
12	The transformation of care delivery is a multidisciplinary process with adequate resources and support.
13	The transformation of care delivery is supported by invested leaders.

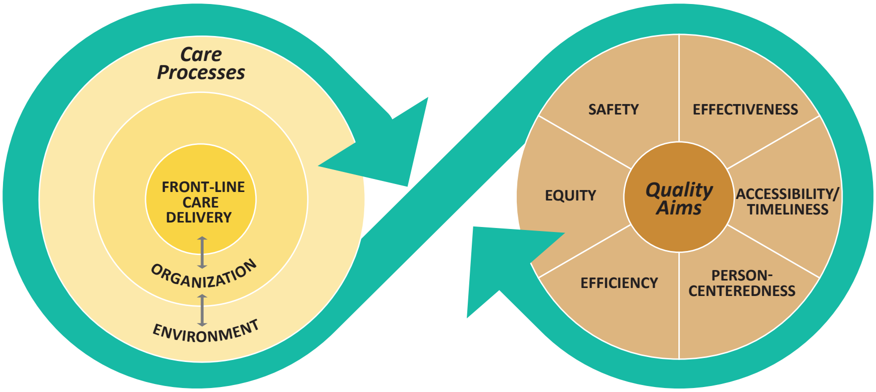

FIGURE 2-2 Guiding framework for the transformation of care delivery.
NOTE: This framework integrates Berwick's (2002) system levels and the adapted quality dimensions of *Crossing the Quality Chasm* (IOM, 2001) (see Chapter 1).

New Design Principles for Health Care Delivery

Meta Principles: Core Beliefs and Values

1. **Systems thinking drives the transformation and continual improvement of care delivery.**
   Health care delivery does not always seek to achieve all six of the quality dimensions identified in *Crossing the Quality Chasm* (IOM, 2001), often delivering on only a few of them. This gap can easily occur if a systems-thinking approach is not used to design a health system purposefully with the six quality dimensions in mind. A systems-thinking process that especially takes into consideration the interactions that take place within the work system can help address this gap.
2. **Care delivery prioritizes the needs of patients, health care staff, and the larger community.**
   Depending on the setting, care delivery often prioritizes the needs of the health care facility over those of the patient, staff, or the community. Joint optimization among all parties is possible and should be made a continuing goal. An important component of this principle is improving health literacy among members of a community so they know what high-quality care looks like and can hold caregivers accountable. Doing so will incline patients to return to facilities, establish good relationships between facilities and the community, and give care providers a comfortable and minimally stressful work environment, thereby helping to achieve good health outcomes, continual improvement, and financial sustainability for facilities.
3. **Decision making is evidence based and context specific.**
   As discussed in Chapter 1, the quality of care delivery in LMICs varies significantly, in part because of both a "know" gap and a "know-do" gap. Given the inconsistent use of evidence-based practices across health care facilities, there is a clear need to increase efforts to disseminate guidelines more widely and invest in supportive structures that allow for their consistent implementation and their context-specific application.
4. **Trade-offs in health care reflect societal values and priorities.**
   Designing care delivery systems entails trade-offs—for example, between resources and outcomes or equity and efficiency. For years, however, the trade-offs made have been determined by donors, investors, or politicians or the lending requirements of development banks. As a result, trade-offs have frequently been forced on health care systems instead of being based on societal values. As countries increasingly invest their own resources in the develop-

ment of health systems, leaders should base the trade-offs made on the values of their own communities and health facilities, taking national cultural factors into account.

Content Principles: Core Characteristics of High-Performing Care Delivery

5. **Care is integrated and coordinated across the patient journey.** As discussed in Chapter 1, health care currently is fragmented and siloed, often involving multiple providers at multiple facilities who may even be in different networks and often do not share information with one another. Given this lack of communication, a patient's vital information may be missing in subsequent encounters, and the burden is on system users as patients to update each provider with what they know. Quality outcomes are then attributed to each encounter alone rather than being recognized as the result of a continuum. Instead, the system should track the patient journey—not just over multiple encounters but ideally over a person's life course. This would enable more seamless coordination among multiple organizations and open up a channel for dialogue between the health system and the person to capture the patient's experience.
6. **Care makes optimal use of technologies to be anticipatory and predictive at all system levels.** For a health care system to truly track information across the patient journey, it needs to be backed by robust technologies, which offer the added benefit of allowing health care to be anticipatory. Currently, health care delivery is far too episodic, reactive, and treatment-based. Using technology and leveraging the promise of algorithms, artificial intelligence, and data sciences more broadly, health care systems can provide care that is anticipatory and predictive. The increasing usage of digital health technologies globally makes this vision even more feasible. The role that technology can play in transforming health care delivery is discussed further in Chapter 3.
7. **Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote integrity, stewardship, and accountability.** To achieve organizational goals—including, in health care facilities, the goal of high-quality care—leadership, culture, and incentives must work in concert. However, many health care facilities in low-resource settings do not align these three supportive structures as necessary. If a facility sought to achieve iterative improvements

in quality but used punitive incentives, for example, the end goal might not be achieved because of misalignment of leadership and incentives. Aligning leadership, culture, and incentives will be essential for creating a learning health care system (discussed in Chapter 8).

8. **Navigating the care delivery system is transparent and easy.**
   As emphasized throughout this report, the patient experience is a vital aspect of health care. Should patients have difficulty navigating the system, feel disrespected, or be unaware of their health care options, outcomes will suffer, and patients likely will not return to a facility. Thus, improving the patient experience and reducing the barriers to navigating the care delivery system will help achieve high-quality care.
9. **Problems are addressed at the source, and patients and health care staff are empowered to solve them.**
   Health care is often viewed as simply a provider–patient encounter. However, this is a reductionist perspective. It ignores upstream inefficiencies in a hospital, and it can easily ignore the profound effects of social determinants of health. For example, the causes of a patient's failure to adhere to a treatment may have little to do with the patient's decisions or will, but instead may result from a stockout at a pharmacy, the need to travel long distances, or stigma. Thus, by attempting to identify the upstream causes of poor outcomes, a health care system can achieve better health outcomes. The capacity for such analysis has been realized in various existing learning health care systems and has benefited from innovative team-based health care models that include ancillary health care workers, such as those in social work and community health workers.

Process Principles: Core Processes for Transforming Care Delivery

10. **Patients and health care staff co-design the transformation of care delivery and engage together in continual improvement.**
    The transformation of health care delivery is frequently driven by a top-down approach that fails to account adequately for the actual, felt needs of patients and providers. Given the essential role of human factors and the work system in health care outcomes, as discussed earlier, this is a misguided approach. For optimal outcomes, it is necessary for the transformation process to start and end with input and involvement from end users (both patients and providers). Such a human-centered approach is emerging in global health, being used most frequently with digital health technologies

to maximize their impact when introduced in the field. However, before such patient input can be provided, it will be important for health systems to build health literacy among their populations. The potential for co-design, especially in the context of digital health, to contribute to the future transformation of health care is discussed in greater depth in Chapter 3.

11. **The transformation of care delivery is driven by continuous feedback, learning, and improvement.**
    Often, the transformation of care is driven by command and control. However, this approach leaves little room for understanding the right balance among staffing, commodities, and technology, or even what care delivery models and protocols yield the best outcomes. Instead of issuing decrees, health care leaders should seek to implement a system that generates data, provides continual feedback, and creates opportunities for learning and improvement at all levels. Such a system is a first step toward creating the culture of a learning health care system. While most documented examples of the development of learning health care systems come from the United States (Finney Rutten et al., 2017; Psek et al., 2015), the emergence of this approach in Kenya (Irimu et al., 2018) indicates that this goal is feasible for low-resource settings.
12. **The transformation of care delivery is a multidisciplinary process with adequate resources and support.**
    The transformation of care delivery usually falls under the purview of health care managers or physicians. Their skills and ability to produce valuable change notwithstanding, other important skills are necessary for care transformation as well. This is especially true as an increasing number of health care facilities turn to digital technologies to deliver care and to shift the locus of care delivery from hospitals to communities. The transformation of care thus requires a multidisciplinary process that encompasses people with backgrounds in human factors and ergonomics, anthropology, human-centered design, information and communication technology, and other sectors. While ambitious, such a model has already been launched at Hospital Italiano in Buenos Aires.[2]

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[2] Hospital Italiano in Buenos Aires, Argentina, has a portfolio of health informatics, housed in a stand-alone department that was established in 1999 within the health care network. Department personnel are from backgrounds such as sociology, anthropology, research, technology development, and engineering and include medical students to inform how digital health technologies are being used and how they can improve. The department's operations are heavily influenced by invested leadership and governance (personal communication, C. Murga, Chief Resident, Health Informatics, Hospital Italiano de Buenos Aires, February 20, 2018).

13. **The transformation of care delivery is supported by invested leaders.**
    Given the multiple different perspectives involved when a multidisciplinary process is implemented, conflicts will inevitably arise. This is especially true if health care workers who previously had traditional forms of professional autonomy must relinquish control of portions of their scope of practice. Thus, the transformation of care will also require an investment from leadership that entails not only resources but also the time and commitment needed to build organizational support, keep a focus on overall aims, and negotiate conflicts.

The committee acknowledges that these proposed design principles are ambitious and disruptive to many prevailing habits and beliefs, but firmly believes they are realistic and should be used as a guide and vision for health care systems in all settings. Furthermore, the committee believes that setting future-oriented goals will be useful for health systems as they undergo transformation as a result of the emergence of digital health technologies. Applying these principles will also help health care facilities in low-resource settings avoid the some of the inefficiencies that plague their counterparts in high-income settings.

Using a Systems Approach and Applying the Committee's Design Principles for a More Person-Centered Health System

The committee believes that by applying the above design principles, it is possible to achieve a health system that is more person-centered. The approach embodied in these principles represents a shift not only from organizing care delivery around providers and facilities, but also from the conventional notion of person-centered care to care that aims to improve the experiences of family members and providers as well.

First, by specifying a systems-thinking approach for the transformation of care delivery and calling for consideration of the needs of patients and health care staff, the design principles envision care that acknowledges a person's self-determination and personal preferences and reflects respect for choices while also supporting health workers and providing employment conditions that are safe and promote their well-being. An indicator of whether these characteristics are being achieved is increased health literacy and effective communication among all parties. Trusted and accurate communication between health care staff and patients (and their family members) is a central clinical function and a key component of quality health care delivery (Ha and Longnecker, 2010). Effective communication has been linked not only to higher patient satisfaction, amenability to follow-up, and adherence to care but also to improved health outcomes (Ha and Longnecker, 2010). To achieve such communication, it is essential to minimize information asymmetry between providers and patients (and their family members) so that everyone comes to the table feeling like an equal participant.

Second, care delivery can be further characterized as person-centered if it takes societal values into account. Health care by its very nature is a social endeavor as it consists of interactions among people. As care delivery becomes transformed, however, it goes beyond these interactions to reflect the values that exist locally. Only by doing so is it possible to ensure that changes made can truly support person-centered care (Sheikh et al., 2014). To this end, it is necessary to engage multiple stakeholders in decision making on how to structure service delivery and direct resources (Sheikh et al., 2014), creating a foundation on which patients and health care staff can co-design changes (Gilson, 2003) to make health care more person-centered.

Third, by seeking to make health care more integrated and coordinated and to make navigation of the care delivery system more transparent, it becomes possible to structure care in a way that optimizes interaction for those the system serves: the patients. Integration of care allows patients and their families to access multiple, related services at the same facility instead of traveling to multiple sites, while coordination of care assists patients with multiple health needs. Taken together, integration and coordination of care help organize services around the patient such that quality will be improved, while more transparent navigation of the care delivery system can reduce the burden patients experience when they access care. It is important to note that integration and coordination of services will likely be of little value unless health care facilities are open at times convenient for patients. For those without sick days or paid time off, missing work to travel to a health care facility can impose an enormous opportunity cost, making patients less likely to access care.

Finally, the committee wishes to emphasize that, although ambitious, its design principles are within reach of many health care systems in LMIC settings, and are often already being used. The examples in Box 2-2 illustrate this point.

SUMMARY AND RECOMMENDATION

Progress in the transformation of health care will require an unprecedented commitment to quality improvement, but it will not be possible to continue using the methods and approaches of the past. The future, person-centered health system, recognized as a complex system with multiple interactions and human behaviors, will require the development and adoption of new models of care; embracement of the new forms of care

BOX 2-2
The Committee's Design Principles in Action

PurpleSource Healthcare

Based in Lagos, Nigeria, PurpleSource Healthcare seeks to solve the issue of health care fragmentation. In Lagos, private health care is highly fragmented, with 90 percent of facilities being sole proprietorships. Poor management capacity, lack of quality assurance, and lack of access to finance lead to unsustainable business performance and poor patient outcomes. These problems are especially pronounced for primary health care in Lagos. PurpleSource aggregates such facilities and deploys financial management, SafeCare quality certification, and technology solutions to integrate care across facilities. It also works with patients to understand what matters to them, using a deep customer development focus to build services around their priorities. This alignment of patient and organizational needs places PurpleSource on the path to becoming one of the largest networks of health care providers in Nigeria (Center for Health Market Innovations, 2018; Innovations in Healthcare, 2018; PharmAccess Foundation, 2016).

Partners in Health (Mentoring and Enhanced Supervision at Health Centers [MESH])

The prevalence of mental health disorders in Rwanda is relatively high, with the national prevalence rate in 2009 being estimated at 26.1 percent. Although a mental health policy was developed in 1995, only 16 percent of health centers provided mental health services for many years (Rusangwa, 2017). Since 2012, Partners In Health (PIH) has collaborated with the Rwandan Ministry of Health (MoH) to integrate mental health services into primary care through the Mentoring and Enhanced Supervision at Health Centers for Mental Health (MESH MH) program. Through "mentorship and supervision by MoH psychiatric nurses and [a] systems-level quality improvement initiative," primary care nurses' capacity in mental health care is increased (Nyirandagijimana et al., 2017, p. 31). Initially launched in the Buera district, the MESH MH program has been scaled out to the Southern Kayonza and Kirehe districts. This expansion incorporates 3 district hospitals and 42 health centers into the program, with a catchment area of 860,000. Community health workers, trained in case finding, referral, and adherence follow-up, supplement this program. The integration of mental health services into Rwanda's extensive primary care network has reduced the distance that patients need to travel, thereby increasing the number of mental health–related clinic visits (Rusangwa, 2017).

Citizen Representative Strategy

In 2000, the government of Mexico launched a sector-wide health reform initiative to improve the quality of care, decrease variations, and improve confidence in health care institutions. Termed the National Crusade for Quality Health Services, this reform was guided by three strategies: new paradigms for work environments, continuous learning, and sustainability (Ruelas, 2002). A significant component was the implementation of a social guarantor of good health care service—the "aval ciudadano" or "citizen representative" (CR) strategy (Nigenda-Lopez et al., 2013). The general goal of this strategy was to promote citizen participation on the evaluation and improvement of health services (HFG Project, 2017). Furthermore, the strategy sought to inform patients of their rights—especially in terms of what medical care they should expect—and incorporation of a CR was required for a health unit to receive resources from social insurance (Nigenda-Lopez et al., 2013). Although CRs could be academic institutions or civil society organizations, the vast majority were individual citizens with prestige and credibility among the population (HFG Project, 2017). Given how the CRs took patients' preferences into account when evaluating health services, the CR strategy can be thought of as a collaboration between patients and the health system (Nigenda-Lopez et al., 2013). By 2002, progress could already be measured in terms of improved clinical indicators, such as wait times and patient satisfaction (Ruelas, 2002).

Improved Hospital Management: Abel Gilbert Pontón (AGP) Hospital

In response to economic pressure and decreasing levels of health care quality, the government of Ecuador initiated reforms in 2012 with the goals of consolidating the public health network, improving the quality of care, and expanding health coverage. As a result of prolonged government neglect, AGP Hospital experienced frequent instances of contracted services, being overcrowded with patients, and other forms of reduced capacity to provide quality health care. The initiation of reform efforts, coupled with change in management, turned the tide for AGP Hospital. Three milestones mark its pathway to a flourishing hospital: (1) using information technology and data to guide process management, building transparency, and providing dignity in the provision of health care; (2) taking into account the needs and culture of the community to redefine the portfolio of services, with an emphasis on patient empowerment and engagement; and (3) sharing responsibility between health care workers and patients, instituting a culture of broad empowerment in which all staff are involved in decision making, and building health literacy among the community. As a result of these efforts, AGP Hospital has greatly expanded its portfolio of services, from only 12 specialties to 28. AGP has also implemented a system of triaging that has greatly reduced overcrowding of its emergency room. Lastly, AGP has vastly increased its staff of qualified health care workers, in addition to creating departments for quality management and planning, follow-up, and evaluation to sustain its gains in health care quality (Gonseth and Acuna, 2018).

Community-Based Geriatric Care

To address mobility and accessibility challenges faced by the elderly, Guyana launched its Care for the Elderly program in the East Berbice-Corentyne Region during 2013. This program was designed to provide low-cost, holistic geriatric care at mega-clinics within the community. To develop functioning clinics, health care workers and social workers were trained to offer an integrated set of services. Existing health centers within the catchment area of the Berbice Regional Health Authority were initially targeted as sites to be designated as mega-clinics. Launching the program required heavy involvement by the community and partnerships with faith-based organizations and nongovernmental organizations for financial and in-kind support. A key form of support was the transportation of patients, which lowered this potential barrier to accessing services and enabled clients to socialize with one another. During their clinic visit, the elderly were tended to by a health care team that provided basic primary care, health education, mental health screening, and specialized care as needed. Because the clinics were located within the community, they could leverage a spirit of volunteerism from local organizations that aimed to improve the experience of receiving care. The impact of the mega-clinics was notable: 40 percent of clients reported feeling they had improved health knowledge, previously undiagnosed conditions were detected in clients, subjective assessments of clients' quality of life improved, and self-reported self-esteem grew among clients. These benefits came at little cost to the health system as it could leverage strong community partnerships, which were targeted early in the program design (Adu-Krow et al., 2018).

delivery; the application of the design principles set forth in this chapter; and much greater participation of patients, families, and communities in the assessment and design of care systems. The key will be an unwavering focus on what matters to patients, their families, and communities and the application of systems thinking as the scientific foundation for change, centered on an individual's journey through the health care system. Many countries have already undertaken efforts to improve the quality of their country's health care, using systems approaches and principles similar to those the committee is endorsing. Such efforts are possible at many levels of the health care enterprise, and should continue across a variety of settings.

Conclusion: Current health care systems cannot reliably achieve the levels of quality that patients need and have a right to expect. Their designs are inadequate to that task, and their fundamental redesign—built on what currently exists and functions—is required. Many countries have already integrated elements of person-centered care into their health care systems and can provide lessons to help guide future efforts. In the systems of the future, the needs of citizens and the patients will need to come first, shaping the demand for and the design and delivery of care. Health systems need to embrace a vision of the patient journey that is anticipatory, not reactive, and wholly centered on continually improving the experience of patients, families, and communities.

Recommendation 2-1: Fundamentally Redesign Health Care Using Systems Thinking

Health care leaders should dramatically transform the design of health care systems. This transformation should reflect modern systems thinking, applying principles of human factors and human-centered design to focus the vision of the system on patients and their experiences and on the community and its health.

To guide that new care system, health care leaders should adopt, adapt, and apply the following design principles:

1. **Systems thinking** drives the transformation and continual improvement of care delivery.
2. Care delivery **prioritizes the needs** of patients, health care staff, and the larger community.
3. Decision making is **evidence based** and **context specific.**
4. Trade-offs in health care reflect **societal values and priorities.**
5. Care is **integrated and coordinated** across the patient journey.

6. Care makes optimal use of technology to be **anticipatory and predictive** at all system levels.
7. Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote **integrity, stewardship, and accountability.**
8. Navigating the care delivery system is **transparent and easy.**
9. Problems are addressed at the source, and patients and health care staff are **empowered** to solve them.
10. Patients and health care staff **co-design** the transformation of care delivery and engage together in continual improvement.
11. The transformation of care delivery is driven by **continuous feedback, learning, and improvement.**
12. The transformation of care delivery is a **multidisciplinary** process with adequate resources and support.
13. The transformation of care delivery is supported by **invested leaders.**

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3

Optimizing the Patient Journey by Leveraging Advances in Health Care

Key Findings

- Toward the end of 2015, 83 developing countries had achieved the United Nations Broadband Commission's affordability target for broadband Internet access (services costing less than 5 percent of monthly gross national income per capita). By 2016, it was estimated that Internet connectivity had reached almost 70 percent of the world's population. Mobile phone usage is similarly prevalent, reaching an estimated 62.9 percent of the global population in 2016.
- The explosion of connectivity and the concomitant increasing availability of digital health tools present an opportunity for people to take greater ownership of their health. Accordingly, the balance of power in health care will need to shift to include patients as part of the decision-making team.
- A global survey found that 77 percent of respondents want more control when it comes to their health care decisions. Also desired are person-centered care and respect for personal attitudes. Women in Nigeria, for example, believe their negative birth experiences could have been alleviated or avoided had their traditional birth attendants been allowed to accompany them.
- Strong primary care systems can produce better health outcomes cost-efficiently and can offset the impacts of poor socioeconomic conditions on health. The first level of contact for primary care is the community, and health systems can use community health workers to deliver lifesaving interventions and preventive care where people live.
- Human-centered design approaches can shed light on the needs and perspectives of people using health technologies, thereby removing unnecessary barriers to high-quality care for patients and making workload more manageable for health care workers.
- Although digital health technologies offer great promise, caution is needed in the areas of ethics and regulation, including data protection, bias, and equity.

Fatima is a 37-year-old in 2025 living in a large African city, pregnant with her third child, and also diagnosed with hypertension. She manages the majority of her health care from her smartphone. At the beginning of her pregnancy, she contacted her primary care center via text message. She received a link to complete her prenatal survey online. An algorithm determined her risk profile, which flagged her for an early midwife appointment because she has hypertension.

Most of Fatima's appointments, however, take place at her house or down the street at her children's school, where community health workers and midwives meet community residents for checkups and to answer questions about their health conditions. She also belongs to a WhatsApp counseling group facilitated by a health worker for pregnant women in her community so they can share their experiences and learn from one another. Through this group, she receives personalized weekly updates on her pregnancy, including how her baby is developing, changes she can expect in her body, and dietary recommendations. Receiving care during her pregnancy is much easier than when she was a child, and her parents had to save up for taxi fare or spend an entire day taking buses to the hospital and waiting for a doctor. She also has a wearable device on her wrist that tracks her exercise and heart rate. Recently, blood pressure devices have become available for rent at the market near her house, so she goes there every Monday, plugs the device into her phone, and takes her blood pressure measurements. Results are automatically uploaded to her electronic health record (EHR), and she receives direct communication from the midwife should her blood pressure increase.

Her EHR is stored in the Cloud but is at her fingertips when needed during appointments with different health care providers. For her last appointment, she hired an Uber driver from her phone and paid for her portion of the visit using the health savings section in her m-Pesa account, with the rest of the cost being covered by her insurance, which was sold through Google because she does not have access to employer insurance. After her appointment, she reordered her medication through Amazon, and stopped at one of its delivery centers near her house the next day to pick it up.

Health care systems across the world have been experiencing changes due to emerging digital technologies and tools, and many more exciting technological advances are on the horizon. They offer the potential for a new health care paradigm designed to support a coordinated patient journey throughout the life span, with high levels of communication and collaboration among health care teams. These digital health technologies can be amplified even further by using the systems approach described in Chapter 2 and focusing on the priorities of patients across their journeys—revamping primary care to be more easily navigable and delivered where the patient is instead of limiting care delivery to brick-and-mortar health care facilities. Such a proactive approach can yield benefits in the face of changing epidemiologic burdens and demographic shifts. Costa Rica, for example, began reforming its primary care system in the 1990s, and between 2000 and 2012, deaths due to noncommunicable diseases (NCDs) decreased by 3 percent even as they rose globally (PHCPI, 2015). Along with these technological and systems changes, attention to the notion of patient involvement and patient ownership has been growing worldwide. The health care system of the future will need to account for more a

While it was beyond the scope of this study to provide a full review of the future of health care, the committee remained cognizant of these changes, which entail both opportunities and risks for the health care sector and have important implications for the quality of care. For some countries, these scenarios and technologies will not be a reality for many years. Nonetheless, technology is advancing rapidly, and health care in every setting can work to tap into the potential it provides.

This chapter begins by exploring global trends in health care and the growing number of digital health technologies that are coming into play across various countries and settings. Next, it examines the implications of these changes for quality, especially in terms of person-centered care, accessibility, and equity. It then describes the benefits of moving from a reactive to a predictive system. Subsequent sections address the organizational and care delivery changes that need to be made to leverage these advances and the challenges that need to be kept in mind throughout this process to maintain and assure high quality. The chapter ends with a summary and recommendations.

GLOBAL TRENDS IN HEALTH CARE

Historically, health care has been paternalistic: power has rested with providers and health care staff. However, this situation is shifting, as patients are beginning to play a more active role in their health. The potential for low-resource settings is possibly the most exciting, as digital technologies and the shift to consumer ownership of health care can allow populations in low- and middle-income countries (LMICs) to leapfrog high-income country systems and avoid mistakes that have been made elsewhere. Consumer expectations in LMICs appear to match this trend. When respondents to a 2017 survey on global trends in health care were asked whether they expected their quality of care to improve or worsen in the coming years, the most frequent predictions for improvement came from mainly middle-income countries, while the most frequent responses for worsening came mainly from high-income countries (see Figure 3-1).

Health care leaders are also beginning to view health care more through a wellness lens than the traditional perspectives of disease intervention and provision of care once a patient becomes sick. Moreover, health care organizations are also extending their reach, working to deliver care through more innovative methods in the community instead of just in hospitals, and understanding that the journeys of their patients take place in many locations over time, not just at one point. Implementing such an approach may require more complex interactions and understanding on the part of health care organizations, but with the wealth of community, government, and civil society partners and increases in connectivity and virtual tools, now is the time for systems to use these shifts as opportunities to meet the principles outlined in Chapter 2. At the same time, however, as discussed later in this chapter, these advances are not without risks, so while they present many opportunities, careful design and oversight are needed to ensure that they assure and improve the quality of care.

Use of Systems Thinking and Digital Health Technologies

Smart devices are creating revolutionary changes in health care by allowing people to accurately monitor their health remotely. These developments often occur outside of traditional settings to enable individual monitoring of health and empower people to take more responsibility for their own health (JASON, 2017). Much of this progress is attributable to increases in connectivity. While more than 45 percent of the world's population does not utilize the Internet (World Economic Forum, 2016), the current goal of the International Telecommunication Union (ITU) is to increase this proportion to 55 percent of the population by 2020, up from 29 percent in 2010 (ITU, 2014; World Economic Forum, 2016). Given this increase, the wireless infrastructure has enabled a leapfrogging of the process typically required to connect rural areas, leading to plummeting costs and a lower bar of entry for those with limited income. In fact, toward the end of 2015, 83 developing countries had achieved the United Nations (UN) Broadband Commission's affordability target for broadband Internet access of services costing less than 5 percent of monthly gross national income per capita (Broadband Commission for Sustainable Development, 2016). Even though fast connections, broadband, 3G, or better mobile connections reach only 30 percent of the world's rural population, they are available to almost 70 percent of the world's overall population (World Economic Forum, 2016). Similarly, mobile phone usage is prevalent and is projected to grow from an estimated 62.9 percent of the population worldwide in 2016 to 67 percent by 2019 (Statista, 2018a). This digital

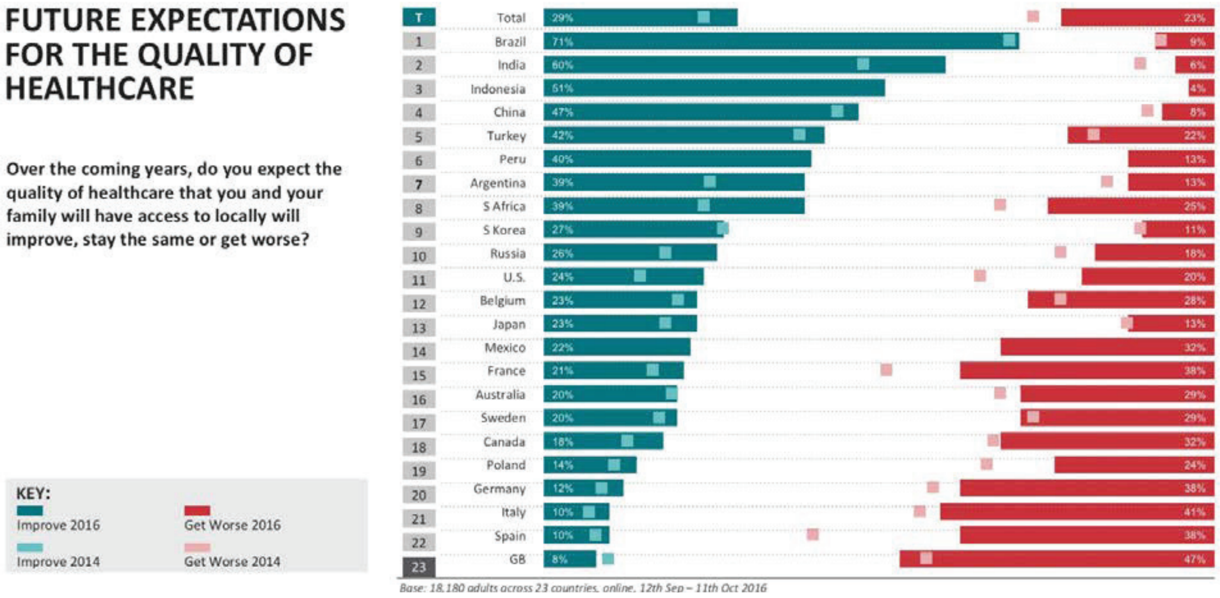

FIGURE 3-1 Future expectations for the quality of health care globally.
SOURCE: Ipsos, 2016.

revolution has the potential to provide individuals with increased access to care and empower them to take more responsibility for their own health (JASON, 2017).

Digital Health Technologies and Tools

With the explosion of new digital technologies in the past decade and new opportunities emerging each year, it is becoming possible to change and advance medicine and health care delivery systems in unprecedented ways. While some changes may initially be limited to high-income countries and to people with the resources to afford them, others have already become available to communities in low-income settings worldwide. Innovation is routinely of prime interest to companies in the information and communication technology (ICT) sector, and accordingly, many partnerships have been forming to improve health systems. For example, although initially for military applications, the use of aerial unmanned drones has increased commercially, and organizations are currently testing them to deliver blood supplies to remote areas of Rwanda. In just the past year, the drones have made more than 950 deliveries of essential blood supplies to Rwandan communities in need. Additional uses can include delivery of emergency defibrillators or drug overdose antidotes where needed (Nuki, 2018). Figure 3-2 shows the progression of technologies within the health sector.

Digital: A Paradigm Shift to the Medical Model?

The current thinking about health systems is fundamentally a top-down medical model, driven by doctors and nurses as the purveyors of knowledge and the arbiters of care. The goal is to give people the information they need and to access care delivered primarily in facilities by medical personnel. There are strict licensing rules to make sure that the system remains controlled by those who do the licensing. Lip service is given to “client-centered care,” but the reality is that this model is primarily doctor and facility centered.

However, as with other industries, access to digital technology is changing this model rapidly, with the balance of power moving from the medical establishment to the individual and with a redefinition of access and care. In high-income countries these changes are being driven by the need to lower cost, while in low-income countries the driver is the poor access and quality of the care that is delivered.

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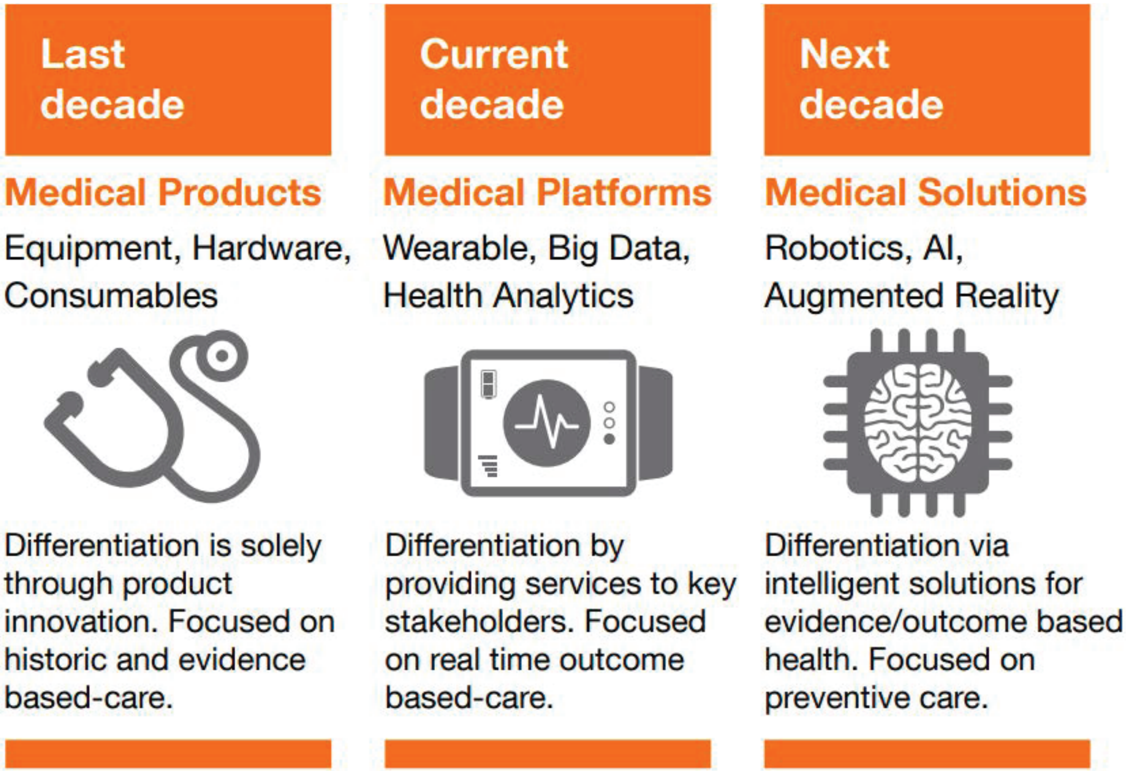

Last decade	Current decade	Next decade
Medical Products	Medical Platforms	Medical Solutions
Equipment, Hardware, Consumables	Wearable, Big Data, Health Analytics	Robotics, AI, Augmented Reality
Differentiation is solely through product innovation. Focused on historic and evidence based-care.	Differentiation by providing services to key stakeholders. Focused on real time outcome based-care.	Differentiation via intelligent solutions for evidence/outcome based health. Focused on preventive care.

FIGURE 3-2 Trends in health care technology throughout the decades.
NOTE: AI = artificial intelligence.
SOURCE: PwC, 2017.

The committee sees these tools as an avenue to strengthening health care delivery and improving quality, with exciting prospects. Corresponding to this explosion of tools, myriad terms for describing these types of technology have emerged. The committee has chosen to use the term "digital health technologies," which include mobile health, health information technology, wearable devices, telehealth and telemedicine, big data, and personalized medicine (Iyawa et al., 2016). As discussed below, for these technology advances to assure high-quality, ethically sound services, a dedicated effort will be required on behalf of manufacturers, regulators, health care providers, and patients.

It is also important to recognize that the successful uptake and wider adoption of efficient and effective digital health systems will be determined by the integration of bottom-up and top-down approaches (see Table 3-1). The bottom-up approach focuses on how distributed tools are developed to gather and share data with the users of a digital health ecosystem, while the top-down approach considers how the ecosystems as a whole are developed to enable proficient use of the data among a network of agents.

Effects on the Patient Journey

The increasing use of wearable health devices, such as Apple Watch and Fitbit, is making it possible for people to take greater ownership of their health. Furthermore, such devices are allowing people to become more aware of their risk behaviors and lifestyle choices, thereby creating a bridge to the formal health care system. For example, patients with chronic conditions can use their smartphones and paired Bluetooth devices to take vital measurements and transmit them digitally to a general provider or special-

TABLE 3-1 Comparison of Bottom-Up and Top-Down Approaches to the Development of Digital Health Systems

Digital Health	Bottom-Up Approach	Top-Down Approach
Rationale	Enable ubiquitous gathering of personalized data	Enable data aggregation, access, and manipulation for health care system service purposes
Methods	Innovation in materials, engineering, and computing	Ecosystem design by innovation in information technology and computer science
Implementation	New devices and sensors to ensure portability	Ecosystem models of hardware and software to manage data

SOURCE: Buckle et al., 2018.

ist to evaluate.[1] Such devices have been found to be useful in emergency settings as well. For example, in April 2018 in the United States, a healthy 18-year-old woman, although sitting still, was alerted by her Apple Watch of an alarmingly high heart rate. After repeated alerts, her family sought care at the emergency room, where they discovered she had an underlying condition in which her kidneys were failing (Capatides, 2018).

As people continue to manage their health in these ways, the balance of power in health care will need to shift accordingly to include them as part of the decision-making team. Technology companies are laying the groundwork for this shift. In early 2018, Apple rolled out a feature that allows people to access their EHRs on their phones. This capability makes it possible for Apple's underlying health app, Apple Health, and the data it stores to be connected with other digital tools, allowing people increasingly to make health decisions independently (Chopra and Rab, 2018). Additionally, consider the launch of MyHealthBank, a Web-based service in Taiwan that gives patients access to their entire medical record. Because Taiwan is a single-payer system, this service can be scaled nationwide, thereby enabling the country's entire citizenry to become engaged more actively in health care decisions (Li et al., 2018). As such innovations continue to be introduced, people's interactions with the health care system may become more self-directed and frequent, thereby resulting in better health management.

Even payment for health care services is being revolutionized, with the process becoming much more streamlined and easier for patients. In Kenya, for example, in the wake of the popularity of its mobile payment system through the M-Pesa platform, a new infrastructure with similar usability called M-Tiba was established for health care. It provides health care financing for patients, such as vouchers, managed funds, and low-cost insurance, and allows both insurers and patients to see where the money is being spent. This digital technology reduces transaction costs and improves data collection, while also creating opportunities for links to safety. M-Tiba is linked to the maintenance of quality standards through such programs as SafeCare,[2] which establishes a national system for quality assessments and provides LMICs with stepwise quality improvement plans that are often linked to loans. If treatments and procedures are approved via the SafeCare quality standards, the money in a person's M-Tiba account is transferred

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[1] See https://www.getqardio.com/qardiomd-ccm (accessed July 17, 2018).

[2] SafeCare was developed to provide standards and a grading system for health care quality; an incremental quality improvement process that is divided into achievable, measurable steps; and a health financing model supported by the private sector. SafeCare standards have been implemented in more than 800 primary and secondary facilities in six sub-Saharan African countries (Ghana, Kenya, Namibia, Nigeria, Tanzania, and Zambia) (Johnson et al., 2016).

to the health care facility, creating a much more seamless process for the individual, with quality safeguards built in.

How people interact with the system is changing worldwide as well. Today, patients have often consulted with "Dr. Google" before even having their first professional medical consultation.[3] This shift has created challenges for physicians in light of the volume of fake and irresponsible information on the Internet and in social media. A survey showing the levels of social media penetration among Latin American countries found the highest level in Uruguay (72 percent) and the lowest in Venezuela (44 percent) (Statista, 2018b). National health authorities thus have an opportunity to increase their contributions of quality health information to the Internet and social media. Patients also engage with their physicians today through other nontraditional modes of communication, such as text messages, telemedicine video chat, online portals, and even social media. In Chile, for example, the National Health Insurance program reimburses public health care providers for 100 percent of the cost of telemedicine services, including tele-radiology, tele-dermatology, tele-ophthalmology, and general tele-consultations. For communications occurring via social media, new ethical standards will be needed to balance this opportunity for access with the right of patients to quality medical advice, with professionalism, and with issues of litigation risk. See Box 3-1 for a description of China's experience with the explosion of the WeChat platform for health care and the opportunities it provides for quality care, especially in terms of person-centeredness, effectiveness, and efficiency.

Artificial Intelligence

Artificial intelligence (AI) can take a variety of forms in health care, including machine learning, predictive algorithms, speech recognition, computer vision, and digital medical consults, ideally tailored to a particular region or community. AI can use large databases to recognize trends in disease manifestations and treatment outcomes, and when combined with the EHR, can be used to predict an individual's risk for disease and to create a precise, personalized treatment plan (Krisberg, 2017). Truly taking AI and virtual care to the next level, the Center for Body Computing at the University of Southern California opened a Virtual Care Clinic in 2016. Through this operation, patients drive their care experience through an app that connects them with avatars of their real-life doctors. Mercy Hospital in Saint Louis, Missouri, has also created a "hospital without beds" through virtual care that monitors 2,431 patient beds (Frenk, 2006; Frenk and Gómez-Dantés,

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[3] Personal communication, T. Herbosa, paper read at Improving the Quality of Health Care Globally, Meeting 3, 2018.

BOX 3-1
Case Study: China's WeChat

Previously, payment within China's hospitals was a fragmented, lengthy process that was difficult to navigate for the user. One would first go to a public hospital to make an appointment, sometimes waiting in line for several hours. One would then wait in another line to pay a fee. Following consultation with a doctor and diagnosis, one would wait in another line to pay for a prescription, and then another line to pick it up. The need for improvement here in terms of the patient journey is clear. Enter Tencent's WeChat application communication service, with more than 900 million monthly active users. It has become so ubiquitous that one can use this app to do everything from paying a parking fine to finding a date to ordering food (Parker, 2017).

In 2014, the WeChat Intelligent Healthcare app, which "allows users to book appointments, make payments, and more at hospitals and [health clinics] through WeChat public accounts" (Lew, 2018), was launched. As of 2017, these public accounts had been instituted in more than 38,000 medical facilities in China. Approximately 60 percent of these facilities provided web-based consultation, and more than one-third supported payment of medical bills via WeChat Pay (Lew, 2018). Patients are also able to read and receive their medical reports on the app. With all of these functions being consolidated in a familiar location, patients are able to enjoy tremendous increases in efficiency (Lam, 2017).

As might be expected, there is more to come. A new medical insurance pilot through WeChat (called WeSure) began in November 2017 for nearly 10 million platform users. For those who clock more than 8,000 steps each day, money is deposited into their WeChat wallet. Also being launched is an artificial intelligence (AI) medical imaging service working with labs across the country. Currently, the accuracy rates of this program are 95 percent for lung sarcoidosis and 95 percent for diabetic retinopathy. This service not only saves time and money for the user but also saves time for doctors, who are overworked and often cannot see as many patients as is necessary.

SOURCE: Lew, 2018.

2017). These virtual doctors are created with AI so they are able to answer thousands of questions on a variety of diagnoses. Patients have even been found to be more forthcoming and to share more information with the avatar version of their doctor than with its real-life counterpart.[4]

AI can also be used to analyze radiographic images (Jha and Topol, 2016) and dermatologic findings (Beam and Kohane, 2016). In the United Kingdom, AI is being used to interpret mammograms and evaluate patient data to produce highly accurate diagnostic information 30 times faster than is possible for a human. This capability allows clinicians to determine

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[4] Personal communication, L. Saxon, University of Southern California, February 28, 2018.

breast cancer risk efficiently and reduces the need for unnecessary biopsies (Griffiths, 2016). This advance has the potential to improve the quality of diagnoses and follow-up care in settings where the availability of radiologists, dermatologists, and other specialists is limited.

For any system to perform effectively, the role of the human in designing, interacting with, or completing the system must be recognized. All systems, even autonomous ones, involve human contributions (Buckle et al., 2018). Therefore, understanding the capabilities and limitations of humans within complex systems will be essential. A key misunderstanding is the implicit assumption that the capabilities of AI will automatically overcome the problems of large amounts of complex and imperfect health data. But these AI systems will be created, operated, and informed by humans. Thus, the potential exists for erroneous information to guide AI decision making and feedback, thereby causing harm or breeding distrust of AI applications for health (Crider, 2018). Facial recognition, for example, which is being tested by police in London, has been wrong as much as 98 percent of the time (Crider, 2018). Websites, apps, and companies have already emerged that, based on the available information, appear questionable (JASON, 2017). Guidelines and policies are needed to hold users of AI systems, as well as those who build them, accountable (Crider, 2018).

Medical Advances in Other Areas

In addition to the increasingly familiar digital health technologies of today, other medical advances offer exciting potential for health care and quality as well. Point-of-care (POC) testing, gene editing, precision medicine, robotics, blockchain technology, and regenerative medicine are a few examples of the innovations of the future. POC testing can aid clinicians in the rapid diagnosis and treatment of diseases at the time of patient contact in a variety of settings (NIBIB, 2013). It is currently being used to improve health care through the use of noninvasive, rapid, and accurate tests for diagnosing malaria (Abbott, 2018b), filariasis (Abbott, 2018a), and sexually transmitted diseases (WHO, 2018d), among other applications. A portable, cell phone–based transmission polarized light microscope system has been developed for imaging malaria pigment that is normally difficult for technicians to identify without polarized light. This design is low cost and easy to use, allowing for higher detection rates of malaria in LMICs (Pirnstill and Coté, 2015). Another example of POC testing is the use of a pocket ophthalmoscope (Blaikie et al., 2016) for patients who may not have access to ophthalmologists or diagnostic imaging tools. The Arclight, a pocket-sized ophthalmoscope, otoscope, and loupe powered by a solar-charged lithium battery (Arclight Medical, 2018), has been used to screen infants for retinoblastoma in Kenya and Uganda, trachoma in Ethiopia, and middle-ear disease in Malawi. During discussions at a public meeting held in Nairobi for this study, the committee was briefed on an innovation called Mama Ope, a biomedical smart jacket engineered in Uganda that can aid in rapid diagnosis of pneumonia in young children without the use of imaging and is much more accurate than a doctor's physical exam (MamaOpe, 2018). To diagnose pneumonia, the jacket monitors the patient's chest and lung sounds, breathing rate, and temperature, and can sense the severity and point of infection, avoiding misdiagnosis as malaria and the waste of irrelevant drugs. Given the shortage of doctors in Uganda, many patients are unlikely to see a doctor and instead must see a less-skilled health worker for a physical examination, which often results in the disease being misdiagnosed as malaria (Koburongo, 2018).

Another recent advance, gene editing, entails using biochemical tools to edit DNA sequences in living organisms (NASEM, 2015; NLM, 2018). Several approaches to gene editing, including clustered regularly interspaced short palindromic repeats (CRISPR) (Broad Institute, 2018), are being developed, with the goal of making it possible to correct mutations at precise locations in the human genome, thereby preventing and treating genetically linked diseases (Hsu et al., 2014). CRISPR systems are being used to treat genetic disorders in animals, and may in the future become a promising method for preventing and treating such genetically linked conditions as sickle cell disease (King, 2018) and using mosquito knockouts to control malaria (Dong et al., 2018).

Precision and regenerative medicine are other new areas of clinical care that hold promise for improving future health. As a future technology, regenerative medicine has the potential to improve care in LMICs through the creation of biocompatible substitutes for transfusion requirements, treatments for inherited blood disorders, hepatocyte transplants for liver disease, and autologous cell treatment for regeneration of heart muscle (Greenwood et al., 2006). The infrastructure for these applications is already being established in LMICs, including the development of a framework of guidelines and best practices for "genomic research and biobanking in Africa" in 2017 (H3Africa Working Group on Ethics, 2017). Importantly, this framework, led by the Human Heredity and Health in Africa Initiative, embraces the committee's design principles in Chapter 2 of co-design with end users, transparency, and feedback to and sharing of benefits with all parties.

Although not typically associated with health care, blockchain technology is increasingly appearing in health-related discussions. According to Zambrano (2017), a blockchain "can be defined as a public spreadsheet that sequentially records transactions among users operating within a decentralized peer-to-peer network." The use of blockchains in health care could create common databases of health information that clinicians could use regardless of the type of EHR they have (Marr, 2017), potentially improving patient care. Blockchain technology may improve transparency by decentralizing the system and using a fully auditable and valid ledger of transactions that cannot be forged (Myler, 2017). Additionally, once a transaction has been recorded, it cannot be edited retroactively because doing so would require that all subsequent blocks be altered, making it impossible to delete a transaction or add a fraudulent one. This transparency eliminates the need for many typical checks and balances currently in use, which could in turn reduce financial reporting costs by up to 70 percent. The built-in transparency of the blockchain system may also allow its use as a method for countering corruption (Aldaz-Carroll and Aldaz-Carroll, 2018).

While these are all exciting advances illustrating what is possible on the horizon, advocates cannot forget that some countries will not have the legal, technological, and regulatory landscape to accommodate these advances for many years. Thus, regardless of the starting point today, it is important for countries to begin putting these important legal mechanisms into place and thinking about designing capabilities from a high level. The widespread introduction of digital tools and sensors can lead to disjointed and disorganized data generation in the clinical setting, especially if the technologies are not supported by a framework to guide the integration of health data streams. Leadership and involvement at the national level and alignment of the technology with the priorities of the country are paramount for successful implementation. Otherwise, health professionals could be faced with extra work, and patients would see no improvement in their patient journey or experience. Buckle and colleagues (2018) argue that without a top-down component that sees the big picture of where and when the data can be integrated in a flexible ecosystem, the full benefit of these technological advances will not be realized. Yet, if the implementation of these technologies is done well, they offer enormous potential to reach previously underserved populations, to improve the quality of care through cost-effective solutions, and to augment scarce workforces to reach more patients and serve them better.

IMPLICATIONS FOR QUALITY: PERSON-CENTEREDNESS, ACCESSIBILITY, AND EQUITY

The digital tools and changing systems described above clearly have implications for quality—both good and bad. Using these tools, and embracing the design principles for system change outlined in Chapter 2, the committee envisions three positive changes in particular within the quality dimensions of person-centeredness, accessibility, and equity, through patient ownership and empowerment, improved communication, and better measurement.

Increased Patient Ownership and Empowerment

By all accounts, health care systems of the future will, and should, dramatically shift to become more person-centered—centered around not only patients' physical health needs but also their mental and social health needs, their caregivers, and the broader community. For this change to truly take place and be sustainable, however, the responsibility for high-quality health care will need to be shared among patients, providers, families, and the community. To be empowered, patients need to take ownership of decision making, have a better understanding of their health conditions, and demand high quality. A recent survey across 12 countries gauging the public's willingness to use an AI-type "health care assistant" via smartphone or tablet revealed some striking results for those living in middle-income countries. Compared with high-income countries, participants in middle-income countries were much more willing to use a type of AI tool through a computer or smartphone (see Figure 3-3).

The need for co-design and cooperation with patients and the health care team also becomes clear when hospitals and clinics look at incident analysis. Often the investigation of patient injuries and errors in care focuses on singular events, narrowing the aperture even further to include only health care personnel. However, a limited focus on root-cause analysis may neglect systems thinking; it may ignore the reality of health care today (and that of the future): that care takes place in multiple places and over time. In most cases, an organization as a whole, complexly interacting systems, and multiple causes contribute to error, rather than a single clinical interaction. Instead of focusing on specific events, the emphasis of analysis needs to shift to care processes over time, or what this report refers to as the lifetime "patient journey." Patients and their families traverse the health care system over time and through multiple places. Thus, they often have a greater understanding than clinicians of the care received longitudinally, and they have the ability to provide key information needed to identify causes contributing to an adverse event. Patients and families are essential aides in the investigation of a quality failure (Vincent et al., 2017).

Advances in digital health technologies can afford new opportunities for moving care into the community and out of potentially hazardous clinical settings. But this shift will require moving away from the paternalistic relationships that have characterized health care, demanding instead partnership and collaboration between patient and provider. Patients are certainly eager for more knowledge and want to be informed decision makers. A global survey found that 77 percent of respondents want more control when it comes to their health care decisions (Volpe, 2017). When asked if they seek out more information beyond what their doctor tells them, nearly 80 percent of respondents in China, India, Indonesia, and South Africa said,

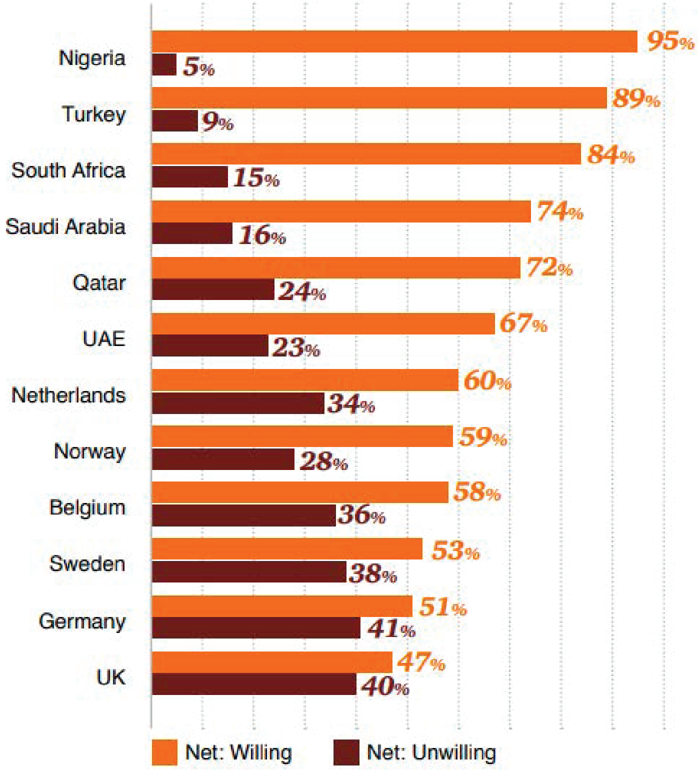

FIGURE 3-3 Percentage of respondents willing or unwilling to use an "intelligent health care assistant" via phone or computer.
NOTE: UAE = United Arab Emirates; UK = United Kingdom.
SOURCE: PwC, 2017.

"Yes." Involving users in the design of health care systems and the incorporation of digital health tools can ensure that the systems are well adapted for people and minimize the need for people to adapt to accommodate the system. Early user involvement can also facilitate early identification of design problems, reduce development costs, and ultimately lead to higher levels of user acceptance and fewer usability problems (Buckle et al., 2018). This involvement will also require patient and community education, but can lead to a shared burden of illness and ideally result in better health outcomes and more productive societies.

Improved Communication

An ideal future system delivering high-quality care will need to feature improved communication among all stakeholders. Means of communication have already changed dramatically over the past decade with the spread of mobile phones and Internet connectivity. In 2012, a survey of more than 150,000 women in a rural, low-resource district in Bangladesh revealed that 71 percent owned phones, compared with only 23 percent of those same homes that reported access to electricity (Labrique, 2018). In today's digital world, with the pervasiveness of digital connectivity, people's involvement in their own health is common.

Women in Tanzania receiving treatment for prevention of mother to child transmission reported three specific factors that decreased the quality of their health care experience, two of which were arguably related to communication issues: a visit time exceeding 2 hours, perception of poor communication skills by health care workers, and a lack of understanding of patient concerns (Naburi et al., 2016). Significant maltreatment in maternal care was also reported in Ghana and Nigeria (Izugbara and Wekesah, 2018; Moyer et al., 2014). Interpersonal relationships with health care staff and patients was cited as a priority by all patients, with exit interviews sometimes attributing provider friendliness and time spent with the patient as a main factor in the quality of the care experience. None of these findings should come as a surprise, yet there are numerous places around the world where, for a variety of reasons, patients are not treated well, and the communication skills of health care providers are not addressed.

Rather than just interacting with patients, moreover, health care providers also need to interact with the communities in which patients live. Following a multisector workshop in 2017, the World Health Organization (WHO) developed a "community engagement framework for quality, [person]-centered, and resilient health services." As part of this framework, WHO defined community engagement as a "process of developing relationships that enable stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes" (WHO, 2017). Similarly, effective communication between a health facility or health system and its surrounding community can increase trust overall, which can in turn lead to a healthier population and a more resilient system.

More Holistic Measurement

Determining how to measure aspects of quality within a new health care system that focuses on person-centeredness, communication, and human-centered design is difficult. Indicators describing the infrastructure of buildings, whether a correct medicine was given or whether an accurate diagnosis was made in a timely manner, will not be sufficient. These are all critical elements of high-quality care, but in addition, indicators are needed that can be used to assess whether patients and family members feel engaged as members of the health care team, whether they feel respected and listened to, and whether the health care system has an understanding of and meets their fundamental needs. One such advance is a tool designed to assess person-centered maternity care across multiple low-income contexts, which demonstrated validity and reliability when tested in rural and urban settings in Kenya (Afulani et al., 2017). While additional testing will be necessary, this tool shows the potential for enabling assessments that can adequately gauge the quality of care a patient is receiving and target ways to improve it, beyond inputs and processes (Berwick et al., 2017).

Examination of global health care practices reveals wide variance in experiences and perceptions. Patient satisfaction and experience studies conducted in contexts ranging from resource-plentiful settings in the United States to resource-constrained facilities in Burkina Faso demonstrate that the effectiveness of communication is poor, leading to patient dissatisfaction. While current patient satisfaction research may shed light on how providers and insurance companies are performing, it does not always illustrate the actual priorities of patients and what matters to them. Careful measurement and understanding of patient experiences and outcomes will be needed to track progress, as discussed in more detail in Chapter 4.

Education and Communication as Indicators

Education, or health literacy, and treatment through a culturally appropriate lens are imperative for improving the patient experience in countries around the world. In one study, members of an indigenous community in Australia were interviewed for their opinions on hepatitis B–related knowledge, perceptions, and experiences. The respondents expressed a strong desire for learning more about the disease and for having more culturally appropriate discussions in their first language about education and treatment (Davies et al., 2014). These findings accord with attitudes toward maternal care in Nigeria and the need for integration between methods and practices of traditional and modern medicine. Traditional birth attendants (TBAs) often offer support and low-cost treatment throughout Nigerian women's pregnancies, but modern health facilities often refuse to let TBAs accompany the women in labor. Numerous women interviewed believe many of their negative birth experiences could have been alleviated or avoided had their TBA been allowed to accompany them (Izugbara and Wekesah, 2018). Delivering education and treatment through a culturally sensitive and appropriate lens can improve patients' experiences and enable health care systems to create greater trust between patients and providers.

Digital health literacy is also becoming increasingly important as the health care delivery system shifts toward digital tools and consumer ownership, as described in this chapter. The Shanghai Declaration for Improving

Health in 2016 highlights this need for a commitment to health literacy—for citizens to be engaged both as patients and drivers of their own health and as leaders in decision making about care. The participants in the declaration committed to increasing citizens' control of their own health by harnessing the power of technology, as called for by the committee to improve both quality and person-centeredness (WHO, 2016).

Common themes are seen among countries even when their policies, infrastructure, and resources are vastly different. The above findings from more resource-limited settings, for example, reveal the importance of considering such concerns as the availability of appointments at physicians' offices in designing quality-improving interventions that are medically pluralistic. Improving health education to allow patients to have more self-efficacy in their health care decisions also aligns with the priorities of health care consumers (Boivin et al., 2014). Thus, creating interventions that can translate cross-culturally is crucial to improving the quality of care globally.

MOVING FROM REACTIVE TO PREDICTIVE CARE

The increase in digital health technologies and the transition to more person- and community-centered care are not the only changes to expect as health care systems adapt to societal and technological changes. In part because of these increasingly available technologies, future health care systems will also focus much more on risk management and prediction relative to the traditional model of episodic disease management. This shift will also be driven by the enormous increase in NCDs worldwide, a change in the global epidemiologic burden that will make prevention much more cost-effective. Overall, health care delivery will need to shift from acute and episodic care to organized monitoring and evaluation of patient outcomes, preventive care, standardized quality, and systematic follow-up, especially for chronic diseases.

Successfully Delivering Primary Care Where People Are

Primary health care is a foundation for "equitable, efficient, and resilient" health care and enables care to meet the needs of people wherever they live (Bitton et al., 2017). The 13th WHO General Program of Work recognizes primary care as key for realizing universal health coverage (UHC) (WHO, 2018a). The strong evidence for the importance of investing in primary care (Starfield et al., 2005) provides an opportunity to emphasize people- and community-centered care and a new focus on the patient journey. If designed with the needs of users in mind and with contextual nuances of the community incorporated, primary care can be a critical tool in the quest for higher-quality care and better health outcomes. And leveraging the digital health technologies discussed throughout this chapter, with the consumer at the center, can amplify the positive effects of primary care. With telemedicine and virtual appointment options, patients will no longer be constrained by where health care facilities are located and have to worry about scheduling follow-up appointments at the hospital every few months for chronic diseases, wondering how their family will be able to find money for the trip. Investing in an evidence-based system using human-centered design can lead to lower costs, higher quality of life for patients, and a better overall patient experience. The recent joint global quality report from WHO, the World Bank, and the Organisation for Economic Co-operation and Development (OECD) highlights the exciting concept of using primary care as a coordination hub (see Figure 3-4).

The Alma-Ata Declaration of 1978, signed by 134 countries, was one of the first global consensus statements to identify the importance of primary health care (Rao and Pilot, 2014). It defined primary care as

> the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constituting the first element of a continuing health care process. (WHO, 1978)

Yet, 40 years later, unfortunately, this vision remains unfulfilled in many places around the world, despite the establishment of several milestones in its support. As a result, integrated primary health care is lacking in LMICs, and the quality of primary care varies widely among and within regions (Das and Hammer, 2014; Das et al., 2008).

Low primary health care capacity is "exposed and exacerbated by the increasing burden of [NCDs], increases in care complexity," and acute threats (such as infectious disease outbreaks) (Bitton et al., 2017). The problem is truly global: Primary care typically is highly undervalued in many countries by everyone from patients to providers to politicians, and insurance schemes tend to incentivize the use of hospital-based complex care and procedures over preventive services, making it difficult to realize the benefits of high-quality care (Rao and Pilot, 2014). Yet, given such converging forces as demands for quality, the rising costs of health care, and the increase in NCDs, the importance of a strong primary health care system is increasingly being recognized (PHCPI, 2017b).

Strong primary care systems can produce better health outcomes cost-efficiently (Starfield, 1998; Starfield et al., 2005) and offset the health impacts of poor socioeconomic conditions (Shi, 2012). These systems can be augmented even further when they are supported by the vast array of digital tools discussed above. Understanding this potential and implementing reforms that reflect the value of primary care can be key in establishing

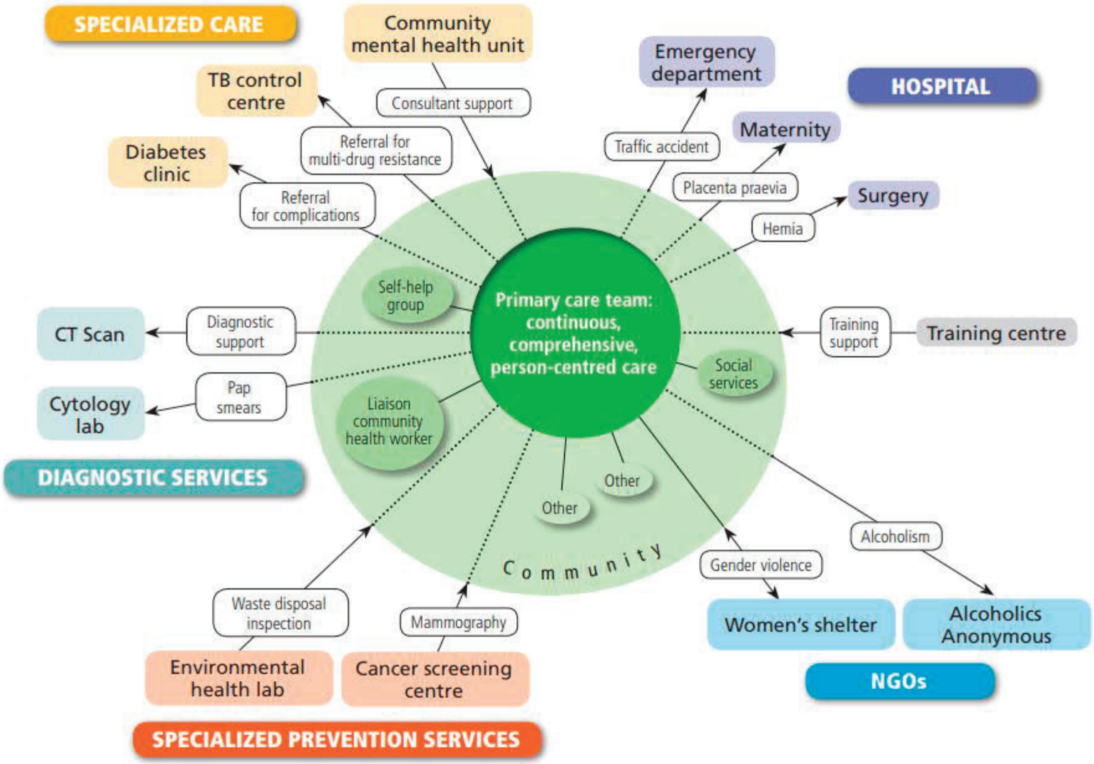

FIGURE 3-4 Primary care acting as a hub of coordination to provide person-centered care.
NOTE: CT = computed tomography; NGO = nongovernmental organization; TB = tuberculosis.
SOURCE: WHO et al., 2018a.

high-quality systems. One case in point is Costa Rica, which undertook vast reforms to its primary care system over the past 20 years and has reaped the benefits. Before Costa Rica took on the challenge of nationwide reform of primary health care in the 1990s, only 25 percent of the population had access to primary care (Cercone and Jiminez, 2008); by 2006, this figure had increased to 95 percent (Cercone and Jiminez, 2008). Simultaneously, in addition to access to care, life expectancies rose, and Costa Rica currently ranks second-highest in life expectancy in the Western Hemisphere, behind only Canada and Chile (Pesec et al., 2017). An important feature of the country's reform process was its iterative nature, with strong measurement and monitoring allowing for such properties of a learning system as adaptation and continuous refinement (Pesec et al., 2017).

Another important resource for improved primary care is the utilization of community health workers (CHWs), a role that has been used with great success around the world in various contexts. Evidence shows that CHWs can deliver "safe and effective care for childhood illnesses, reducing the spread of communicable diseases and [NCDs], promoting nutrition, and providing family planning services, at low cost" (WHO et al., 2018b, p. 42). In low-resource settings, CHWs play a vital role among mothers and young children, reducing maternal, neonatal, and child mortality (Gilmore and McAuliffe, 2013). They also are able to optimize risk factor management and early diagnosis in communities through screening and referral programs. Chou and colleagues (2017) ran a model to test the impact of expanding CHW programs for lifesaving interventions in 73 countries and found it to be a useful strategy for achieving UHC and ending preventable maternal and child deaths by 2030. Financial benefits can accrue as well. A high-level panel in 2016 found that investing in CHWs in sub-Saharan Africa could produce "an economic return of up to 10:1—due to increased productivity from a healthier population, potentially reducing the risk of epidemics such as Ebola" (Dahn et al., 2015, p. 2).

While more than 45 countries have committed to CHWs as their frontline providers of health care, it is important to stress that each CHW system needs to be adapted locally to optimize these workers' skills and potential regardless of where they are being deployed, and to nurture productive relationships between them and their patients. Integration of these workers into the community can make all the difference. Systematic reviews have found that community embeddedness—when community members have oversight of "the selection, monitoring, activities, and priority setting of CHWs" (Campbell and Scott, 2011)—can improve CHWs' motivation and performance and, conversely, that a lack of community support can increase their attrition (Campbell and Scott, 2011; Kok et al., 2015).

The Brazilian Family Health Strategy (FHS) has been especially successful in utilizing a community-based approach. The core of each FHS team consists of "a physician, a nurse, a nurse assistant, and four to six full-time community health agents" (Macinko and Harris, 2015). Each community health agent "is assigned to approximately 150 households … usually within the same micro-area where the agents live," which the agents visit each at least once per month (Macinko and Harris, 2015). With the FHS program, Brazil has achieved improvements in breastfeeding rates, near-complete immunization coverage among children, a decrease in inequality and inequity in health care utilization, and a patient satisfaction rate of 85 percent approval for CHWs (Domingues et al., 2012; Wadge et al., 2016). Note that consideration of local context and the skills and perspectives of CHWs is especially significant when digital tools are being introduced in this type of decentralized environment (Daelmans et al., 2016; Hall and Taylor, 2003) (see Box 3-2).

As with other aspects of the transformation of health care, a "one-size-fits-all" approach to the utilization of CHWs will not suffice, and contextual adaptations of the basic design will be essential to success. According to Ballard and colleagues (2017, p. 3), "CHWs can contribute to advancing [UHC], but only if they are set up for success [by being integrated] into well-designed and adequately funded health care systems." To help countries accomplish this at scale, six organizations with considerable experience on the ground developed a report outlining eight design elements that illustrate the minimum standards necessary for CHWs to succeed (see Box 3-3).

As an example of the implementation of these elements, following the Ebola outbreak in West Africa, Liberia's Ministry of Health revised its policies for community health services and launched a multipartner program to increase the reach and quality of CHWs (Raghavan and Kelley, 2018). As a result, the number of people accessing care has increased, with multiple counties reporting increases in children receiving treatment for such conditions as malaria and pneumonia (Luckow et al., 2017; White et al., 2018, in press). At the same time, Liberia implemented a special focus on quality through a nationwide performance management system, which utilizes such metrics as timely payments to CHWs, supply restocking, quality of clinical supervision, and competency of CHWs (Raghavan and Kelley, 2018). The goal is to improve the accountability and adaptability of CHWs. Employing such design principles as co-design, continuous feedback, and solving problems at the source, the initiative regularly reviews data and identifies changes and adaptations that can improve quality in various areas.

CHW models are applied successfully not only in LMICs but also among low-income populations in higher-income countries such as the United States, where these models have helped achieve a more holistic patient journey and better health outcomes. For example, a Massachusetts program integrating health, behavioral, and social services for low-income

BOX 3-2
Case Study of Optimizing Community Health Workers

Although Nepal had seen overall reductions in maternal and child mortality rates, glaring disparities remained as the result of such factors as rural versus urban setting, education level, and wealth. To address these disparities, Medic Mobile launched a pilot in 2013 that implemented a mobile phone monitoring solution using community health workers (CHWs) with low levels of literacy and technical skills. The CHWs conducted home visits and registered maternal health information directly to their mobile devices to increase coverage of antenatal visits among women with low income or little formal education.

To develop the pilot, Medic Mobile first targeted stakeholder feedback from communities with low digital or traditional literacy, given that more than 40 percent of registered CHWs have no formal schooling. They then mapped Nepal's existing health care system activities to the CHWs and supervisors to identify constraints and opportunities before developing a prototype model.

Major insights gained included the following:

- **Health worker motivation:** Because of a perceived sense of isolation and lack of support from supervisors, CHWs had low levels of motivation and sought links to a higher system and purpose. Consequently, the tool was designed to acknowledge the CHWs each time data were submitted, using their name and a warm greeting.
- **Continuous adaptation:** While the early design included only a flagging option for high-risk pregnancies, the pilot revealed that calling was preferred during emergencies. In the second iteration of the design, therefore, the workflow was redesigned to allow for submission of reports following an initial phone call. This adjustment demonstrates the importance of sustained user input and the opportunity for iteration in the design.
- **Manageable workload:** Although some groups pushed for more comprehensive reporting protocols initially, analysis of the feasibility for CHWs on the ground showed otherwise. Eventually, agreement was reached on a more limited set of essential data that reflected the priorities of the initiative's primary objectives.

Project outcomes included

- increased frequency of contact with mothers and newborns;
- increased routine home visits to provide health services;
- timely management of complex cases; and
- a sense of achievement provided by immediate acknowledgment.

SOURCES: Castillo and Vosloo, 2013; Sharma and Holeman, 2017.

BOX 3-3
Optimizing Community Health Systems

- **Accredited:** The health knowledge and competencies of community health workers (CHWs) are assessed prior to their practicing; CHWs must meet minimum standards before carrying out their work.
- **Accessible:** To improve the accessibility, timeliness, and equity of care, point-of-care user fees should be avoided when possible.
- **Proactive:** For active disease surveillance, CHWs go door to door looking for sick patients and provide training on how to identify danger signs and quickly contact a CHW.
- **Continuously trained:** CHWs are trained using modular approaches or other types of in-service learning. Continuing medical education is not only available to but required of CHWs.
- **Supported by a dedicated supervisor:** On a frequent and regular basis, CHWs benefit from a dedicated supervisor who assesses patient experience and provides one-on-one coaching (potentially through digital communication).
- **Paid:** CHWs are compensated financially at a competitive rate relative to the respective market.
- **Part of a strong health system:** Deployment of CHWs is accompanied by investments to increase the capacity, accessibility, and quality of the primary care facilities and providers to which the CHWs link, including pharmacy management.
- **Part of data feedback loops:** CHWs report all data to public-sector monitoring and evaluation systems, and the data are used by those who collected them to improve programs and CHW performance.

SOURCE: Ballard et al., 2017.

clients reduced hospitalization rates by more than 7 percent relative to the previous year; visits to the emergency room declined by about 6 percent (Klein et al., 2016). This type of model has inspired new programs such as CityBlock Health,[5] which seeks to make care more personalized, accessible (i.e., through digital platforms, mobile access, or delivery of care outside of health facilities), and contextual by recruiting a team of residents in urban communities to co-design care pathways that make sense for themselves and their neighbors. Health care delivered in the community by people who understand the detailed circumstances of the patients with whom they are working may become be a fundamental element of high-quality primary care in the future.

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[5] See https://www.cityblock.com (accessed June 2, 2018).

A Critical Shift for the Growing Burden of Noncommunicable Diseases

Mortality from NCDs has been projected to grow by 15 percent globally from 2010 to 2020 (WHO, 2011). In 2015, more than 70 percent of global deaths were due to NCDs, primarily cardiovascular disease, cancers, diabetes, and chronic lung diseases. More than 75 percent of this highly preventable mortality is borne by populations in LMICs, with nearly half of these deaths occurring before the age of 70 (WHO, 2018c). Research has found that chronic disease can be treated effectively through primary care models (Harries et al., 2008; Nigatu, 2012) , but in practice, primary care facilities in most resource-limited settings often refer NCD chronic care cases to secondary or tertiary centers because they lack the capacity to treat them, thus overwhelming higher-level facilities (Walley et al., 2012). In low-resource settings, moreover, secondary and tertiary health care facilities are typically much scarcer than primary care and concentrated in larger cities. As a result, patients and their families in smaller towns or rural areas face a travel and financial burden.

To address the growing burden of chronic disease, it is essential to innovate in the delivery of care for these conditions and think differently about how and where to treat these patients. Some examples of such innovations even outside of the primary health care system are beginning to emerge. In Ghana, for example, where the estimated prevalence of hypertension exceeds one-third of the population, community-based hypertension management is being implemented (Ofori-Asenso and Garcia, 2016). The Community-based Hypertension Improvement Project, supported by several partners, began in 2015 to shift these patients' interface with the health care system from the hospital to the community. Local businesses, CHWs, and nurses are trained to screen, diagnose, and initiate first-line treatment for people with hypertension (Novartis Foundation, 2018). This approach removes the barrier of transport to and wait times for hospitals, and through digital health technology allows seamless connectivity between screening sites and physicians at referral sites for supported decision making. Such models share elements that include empowering patients to take more responsibility in the management of their own health; using nontraditional health care providers to optimize screening and diagnosis opportunities; linking them to the health care system through digital tools; and offering first-line treatment through community health care providers, thereby reducing the burden on the health care system.

Digital technology and tools described previously can facilitate and accelerate many types of interventions necessary to address NCDs. One example already reaching scale is that of CaSalud in Mexico, supported by the Carlos Slim Foundation. It includes screening and risk assessment for cardiovascular disease and diabetes, both in clinics and in patients' homes, as well as clinical decision support, online stock monitoring, and patient education platforms to reengineer the prevention and management of NCDs (Carlos Slim Health Institute, 2018). Another example is telemedicine, in increasingly common use. Novartis Foundation and the Ghana Health Service are integrating and scaling up telemedicine services across the country following a successful multisector partnership pilot. As of early 2018, six 24-hour tele-consultation centers had been established and staffed to connect CHWs and medical specialists, with full national coverage expected by 2019. Doctors, nurses, and midwives in the centers coach CHWs through their patient care (including care for acute and chronic conditions). This approach allows for improved quality of care through the centralization of (often scarce) expertise, and also empowers CHWs, who feel more confident and motivated to remain in their jobs. Perhaps most important, especially in rural areas where access to specialists is limited, this infrastructure improves the quality of care by avoiding unnecessary referrals and reducing transport times and costs for patients. The initiative's developers found in 2016 that more than half of all tele-consultations could be resolved by phone, and that 31 percent avoided the need for referrals (Pennic, 2018).

Costa Rica is also struggling with the increasing burden of NCDs, but its strong primary health care system, described earlier, should help in adapting to the challenge. In fact, despite a rising burden of NCDs, deaths due to these conditions actually fell in Costa Rica between 2000 and 2012, from 15 to 12 percent of all deaths (PHCPI, 2017a). Ariadne Labs' 2017 report (Pesec et al., 2017) outlines several factors that can account for this decline, which the committee sees as representing elements of a quality future health system with clear implications for an optimal patient journey:

- **Continuity—**Patients see the same provider for many years, enabling a shared understanding of goals, effective treatment, and motivating factors.
- **Team-based care—**This represents an effective approach to managing chronic illness because teams are better able than clinicians operating independently to provide coordinated, patient-centered, and effective care.
- **Focus on prevention—**Because Costa Rica's system was designed around infectious disease, it can translate that emphasis and its lessons learned on prevention to NCDs.
- **Community orientation—**These programs have been shown to be cost-effective and could increase knowledge in the community of risk factors for and management of NCDs.
- **Health data management structure—**A countrywide, standardized measurement and monitoring system designed to ensure good health outcomes provides fundamental tools that can be applied to the NCD burden.

NEEDED ORGANIZATIONAL AND CARE DELIVERY CHANGES

Given the excitement about and promise of these new system approaches, technologies, and ideas, it is important to step back and consider the barriers that could prevent them from realizing their potential. Many of these new developments are taking place in silos within countries and sectors. To help countries and health systems take advantage of the growing number of tools available, policy makers need to play an active role in shaping the markets and economies affecting the health system and ensuring that their citizens' needs are well represented (Bloom et al., 2017). Yet, given the costs associated with the rising NCD burden, sufficient funding will be needed for many countries to undertake significant reforms, such as those instituted by Costa Rica, to strengthen their primary care systems to prepare for the future needs. Additionally, the systems thinking and design principles underpinning quality care discussed in Chapter 2 will be necessary to overcome the current fragmentation and paternalistic dynamic still present in many places. To better understand what will be needed for health care to complement the rapid development of digital health technologies, the committee identified and interviewed 12 subject-matter experts in the area of digital health ethics and regulation. These experts provided insight into what changes and policies could help protect patients and improve quality as health systems change, as well as some concerns due to the involvement of a larger number of stakeholders and the lack of regulatory oversight in many LMICs. They offered varying perspectives and some concrete, straightforward steps toward action, which are summarized in the section below, as well as the subsequent section on cautions for quality in the future system.

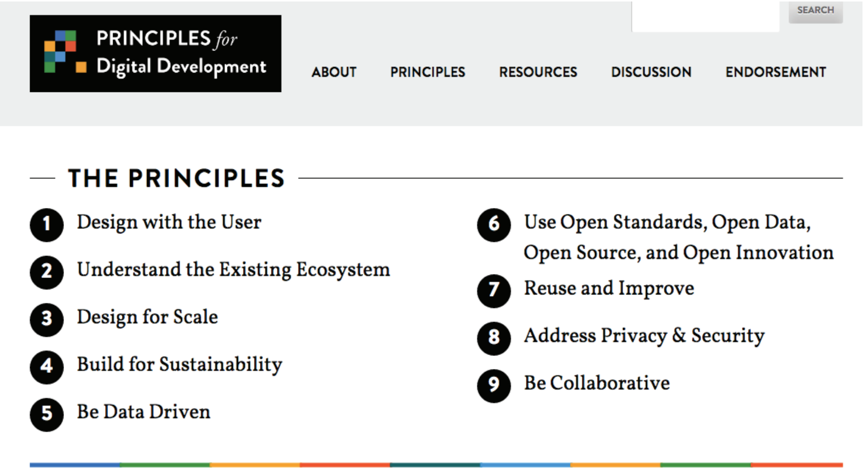
Human Factors and Human-Centered Design

As discussed in Chapter 2, the discipline of human factors and ergonomics (HFE) recognizes the importance of the interactions among multiple components of a system, including the variability introduced to those interactions by humans. Currently, the elements of human factors science are not widely understood or used to inform the design of health care systems, but they are deeply embedded in other industries. Lessons from those other industries can be gathered and applied to health care, offering the opportunity, for example, to integrate a variety of innovations and design changes into a broader health care system.

Considering the role of human factors can often demonstrate to health leaders the reasons why some health care reforms work and others do not.

The development of digital health within a health care ecosystem requires increased participation from potential stakeholders (using principles of co-design) to define how the data should be collected and used (Lupton, 2017; Pagoto and Bennett, 2013). To this end and to leverage the opportunities offered by digital tools, a community of global health nongovernmental organizations (NGOs) and donors launched the Principles for Digital Development in 2016 to build the rationale for a paradigm shift (Principles for Digital Development, 2018a) (see Figure 3-5). These principles reflect a set of best practices developed over the past decade that programs and governments can use to build their systems.

HFE methodologies can support the design and evaluation of safe and usable medical and information technologies. Buckle and colleagues (2018) argue that human factors science "should be the engine to rigorously support the digital transformation of healthcare." Similar to HFE, human-centered design (HCD) is an approach to designing a system or tool so as to make it as effective as possible while prioritizing people's needs, desires, and ordinary activities (Sharma and Holeman, 2017). While there is a technical definition of HCD according to the International Organization for Standardization (ISO), there is no universally agreed-on view of it in health care. Nonetheless, thanks to constantly evolving new research, technology, and innovation, this practice continues to evolve as well. Sharma and Holeman (2017) highlight three key elements MedicMobile employs when deploying digital health tools throughout its CHW network (Bazzano et al., 2017):



THE PRINCIPLES

1. Design with the User
2. Understand the Existing Ecosystem
3. Design for Scale
4. Build for Sustainability
5. Be Data Driven
6. Use Open Standards, Open Data, Open Source, and Open Innovation
7. Reuse and Improve
8. Address Privacy & Security
9. Be Collaborative

FIGURE 3-5 Principles for digital development.
SOURCE: Principles for Digital Development, 2018b.

- **Participatory design—**Engaging people as partners instead of viewing designers as experts and potential users as informants. This approach is especially salient in the area of "configurable tools" that are often finalized through local tailoring.
- **Supporting human skills—**A commitment to augmenting people's skills instead of making workers obsolete through automation and technology. This element discourages design that dehumanizes the workplace experience.
- **Human values—**Examining moral stances within a project and pairing stakeholder values with the priorities behind the system being designed. There should be a focus on methods for reflecting the values of people likely to be influenced by the intervention.

The way people participate in their own health is changing, but no one approach will work everywhere. Instead, to ensure that interventions, tools, and systems are designed for the users for whom they are intended, decision makers need to encourage these types of HCD approaches, beyond just the involvement of end users. For example, "function allocation" is a key concept in any system design. It entails identifying which tasks the technology is capable of performing and aligning those tasks to the extent possible—i.e., not assigning humans tasks that a computer could do better, and vice versa. Consideration of human factors in the transfer of technologies has also been found to be a major determinant of the success of a technology, and thus is important for health care and policy leaders when introducing new devices (Cunningham and Sarayrah, 1994; Meshkati, 1989). HCD approaches can shed light on the needs and perspectives of people using health technologies, thereby removing unnecessary barriers to high-quality health care for patients and making the workload more manageable for health care workers.

Integration Across the Health Care Continuum to Promote Primary Care

Health systems often grapple with the question of whether vertical or horizontal approaches are more effective at delivering high-quality care. Vertical programs dedicated to a singular disease, for example, can be effective because of their narrow focus and alignment of funding and goals, but advances are limited to the area of focus. Horizontal approaches, often referred to as "health system strengthening," can address a broader range of health issues or disease areas, but successes are difficult to measure and attribute. Yet, depending on the country, the health infrastructure, the political environment, and many more factors, success will often require both, or a "diagonal" approach. Frenk (2006) defines a diagonal approach as a "strategy in which we use explicit intervention priorities to drive the required improvements into the health system, dealing with such generic issues as human resource development, financing, facility planning, drug supply, rational prescription and quality assurance." More recently, Frenk and Gomes-Dantes (2017) have argued that, to meet the complex health challenges of the interdependent 21st-century world successfully, it will be necessary to move away from the currently pervasive dichotomies and embrace integration. Several researchers have suggested that achieving a sustainable version of quality UHC will require moving toward integrated health systems, which will be accomplished in large part by prioritizing primary care (Kringos et al., 2013; Kruk et al., 2010; Macinko et al., 2009). This relationship will be bidirectional and symbiotic, as WHO (2018a) emphasizes that "effective and efficient primary health care requires integrated health care services." Finally, given the ICT advances, HCD approaches, and community care delivery elements discussed throughout this chapter, successful integration of systems will depend on intersectoral collaboration. For example,

> evidence emerging from Bangladesh, Pakistan, and Nepal suggests that integrated packages of community- and facility-based services provided across the continuum of maternal care, from pre-pregnancy through the postpartum period, could reduce neonatal mortality by 11 to 34 percent. (Labrique, 2018)

Meeting the demands of the Sustainable Development Goals (SDGs) will require this type of action and cooperation. Otherwise, many passionate and hard-working people will continue working in silos, often harder but less effectively, to achieve their stated goals.

Understanding and Partnering with the Private Sector

The private sector is making enormous investments in digital health across all countries, driven by long-term goals and aspirations. But without parallel investments and capacity building in the public health sector and new business models to encourage partnerships and data sharing, opportunities for improved care through digital health will not be fully realized. Given that the ICT sector is rarely publicly owned, most types of digital health investments or tools will be created through a public–private partnership model. Accordingly, countries need to consider how to build these partnerships and attract investment while still protecting patient data and privacy. Some of the largest global companies are making big bets on health care. Amazon, Apple, Google, and Uber all have announced their interest in disrupting a health care industry that has been slow to change and maintained high costs to patients and facilities while being riddled with inefficiencies and room for growth. For example, Amazon is entering a partnership with JPMorgan Chase and Warren Buffet; Apple is establishing a line of medical clinics; Verily, Google's sibling company under Alphabet, is assessing market potential under Medicaid; and Uber is seeking to disrupt services for ambulance care (Scott, 2018). These are all multinational companies, with massive potential to effect change in health systems globally and improve the quality of services being delivered.

Workforce Competencies

The need for education in the rapidly growing and changing digital health sector is absolute. Given that health care quality will depend on the quality of the health care workforce and its pipeline, crucial changes in education are needed now. The use of digital content, for example, has been estimated to decrease the cost of training 1 million new CHWs in sub-Saharan Africa from $65 per person to $15 per person (Hausman, 2012). In addition, health care workers of the future will need a new set of skills, including the ability to manage complex cases; better bedside manner; and higher literacy to understand, use, and inform data analytical tools. According to Labrique (2018), "decision makers at every level of government, especially program implementers, will need to be retrained as consumers of information," acquiring the ability to read and interpret data visualizations and a continuing thirst for data on program performance. Currently, few LMICs maintain trained informaticists and analysts to study data patterns and recommend course corrections within programs. Going in this direction could help the health systems in these countries achieve higher quality and understand more rapidly where mistakes are being made, helping them close the gap with many high-income countries, which are also just beginning this process.

A straightforward first step would be to implement changes at the college and university level, as these institutions are currently vertically oriented, making it difficult to work across sectors outside of one's specialization. However, the health care workforce will also need to acquire knowledge and skills in such areas as connectivity, data validation, and algorithm engineering, which are not routinely taught in any premedical or nursing programs. Universities have an opportunity to act proactively to meet this need by creating more multidisciplinary programs not only in medical and nursing programs, but also scaled for health care administrator and corporate training, thus providing a baseline of knowledge across all pipelines feeding into the health care sector. Taking this idea a step further, international organizations and academic associations could create a full digital health curriculum to increase the capacity for using real-time data in health systems management and planning. With many analysts and futurists predicting that the future of health care is heading in this direction, building these curricula and making changes in the education system now would be a prudent and efficient move.

Similarly, it will be important to keep in mind that the new technicians and engineers developing many of these health tools are not trained as traditional clinicians. This means they likely did not receive training in bioethics and do not necessarily operate under the same "do no harm" ethos that governs health care providers. Thus, there is a need for cross-fertilization among different sectors to ensure that all stakeholders working in the health care system of the future have the right knowledge base for assuring and improving quality. Education and training will also be needed on the regulatory side, as regulatory bodies will require expertise to examine the validity of data and the algorithmic processes of new devices and tools to ensure that they are supportive of patient safety and clinical efficiency.

CAUTIONS FOR QUALITY IN THE FUTURE SYSTEM

The explosion of digital innovation and its potential to transform the health care sector invites a focus on the positive implications of these new tools, but they bring risks as well. Recognition of this potential demands strong leadership and multisector participation for the co-development of these tools and technologies to better achieve high-quality, equitable care for all the populations for which they are intended. Optimists may believe that digital health technologies will alleviate the current fragmentation and geographic limitations of health care systems. Yet, ethical considerations arise. For example, what are the negative consequences when people with low levels of health literacy take advice from an unregulated health app? If they follow the guidelines of the app and experience an adverse event, who will be held accountable? Multiple interviews with digital health subject-matter experts identified five major themes surrounding these important issues, which are explored below: the "digital divide," regulatory issues, patient safety issues, the need to avoid institutionalizing bias, and the need for data governance standards.

The Digital Divide

Compounding some of the ethical concerns mentioned previously is the digital divide in many countries. Although mobile phones are becoming ubiquitous around the world, many people (most often women and girls) still lack access to this technology, and the poorest populations will not benefit from the new digital innovations and tools. A study in India, for example, found that among poor households without mobile phones, access to private doctors decreased by 10 percent, while among those with phones, access grew by 4 percent (Haenssgen, 2018). This divide also exists between genders, with Internet penetration rates being “higher for men and boys than women and girls in all regions of the world today” (Broadband Commission for Sustainable Development, 2017). This disparity has significant consequences for women’s empowerment and entrepreneurship, impacting communities and economies. Fortunately, this problem is receiving attention from such groups as the Broadband Commission, which is developing recommendations for overcoming this gap, as well as from the UN High Commissioner for Human Rights (OHCHR, 2018). However, if the rapid growth among those possessing the right technology continues, these divides—whether geographically or gender based—will deepen, creating more inequity and impeding the ability of some nations to meet their UHC goal. As Internet and cellular coverage increases, governments need to ensure that the digital divide is addressed.

Regulatory Issues

What will the right level of oversight be in countries without strong regulatory bodies to protect populations and ensure that safety and quality-of-care standards are met while still encouraging innovation and involvement from the private sector? A 2014 study addresses the vast number of digital health tools and the benefits of more granular patient data and customized diagnoses. It also points out the challenges these advances pose for such regulatory bodies as the U.S. Food and Drug Administration (FDA). As of that article’s release, only 100 of about 100,000 health care apps had been FDA approved (Cortez et al., 2014). Apps and tools often encounter additional challenges during the post-marketing period, as the usual requirements do not align neatly with digital health tools. The software industry typically releases beta versions, followed by continual updates and improvements, and getting everything perfect prior to FDA approval is unlikely. Issues also arise with respect to determining who is responsible for dealing with adverse events and data privacy for unregulated digital health solutions (Cortez et al., 2014). The lack of regulation of these types of tools in many countries makes these issues all the more concerning. Countries need to build their capacity to think through the guidelines and frameworks necessary to protect the users of these tools. Ghana (Data Protection Commission, 2018), Kenya, and Tanzania (Domasa, 2017) are in the process of passing laws on protection of personal data, but “more than half of Africa’s 54 countries have no data protection and privacy laws, and of the 14 that do, 9 have no regulators to enforce them” (Fick and Akwagyiram, 2018).

The paucity of regulations and the inconsistency among the regulations that do exist present significant barriers and risks to international organizations that frequently deal with sensitive and critical data. The lack of data protection laws in Uganda, for example, resulted in three NGOs in that country being raided. The frequent occurrence of such events in many African countries led to the creation of the African Union Convention on Cyber Security and Personal Data Protection, also known as the Malabo Convention, in 2014. Its goal is to provide guidance on how to establish effective domestic data protection and information on how privacy demands could affect national security. While only 10 of 55 member states have signed on to the convention, 3 more have ratified it, and 18 have used it as guidance for drafting their own cyber legislation. The establishment and implementation of data protection laws will improve relationships with international organizations, and the committee endorses these moves to help assure high-quality care in the future (Green, 2018).

Another example of this concern is emerging in China, where patients and providers are very familiar with digital health technologies. Yet, while the WeChat platform, described earlier in Box 3-1, certainly increases convenience and decreases fragmentation, regulatory and ethical concerns have been raised. The widespread usage of WeChat has allowed unrestricted access to users' medical data, and China has not yet established regulations or laws to protect personal information. The access to medical data is used to profile users and create marketing tools for big pharmaceutical and insurance companies (ITU, 2014). With the growing number of stakeholders including providers, facility administrators, developers, data engineers, and others becoming involved in health care, ethics need to be considered. Without co-creation mechanisms and HCD approaches embracing human factors, will all of these players understand the cultures they are serving well enough so that their populations will actually use the tools that are being developed? Together with donors, NGOs, the private sector, and other invested stakeholders, governments need to develop a strategy for building a common vision that enables innovation while incorporating mechanisms to prevent and mitigate threats to safety and other dimensions of quality. This strategy needs to encourage the alignment of country and regional improvement priorities with the tools developed for increased efficiency and effectiveness.

Patient Safety Issues

If algorithms are kept proprietary by a company and developed without the input of the intended end users, they or the decision support mechanisms for which they are employed can be flawed without users' knowledge. If patients or providers rely on such flawed tools to diagnose or treat a condition, the result can be incorrect practice, wrong treatment, or errors in clinical decision making. Recent evidence from the United Kingdom, for example, shows that because of an error in a National Health Service algorithm since 2009, many women who should have received an invitation for breast cancer screening did not. At least 450,000 women were affected, and thousands of them did not come in for a screening. A computer model suggests that 135–270 women may have died as a result (Erickson, 2018).

A recent report commissioned by the U.S. Department of Health and Human Services and the Robert Wood Johnson Foundation similarly identifies the need for reliable data to inform accurate, consistent, and discriminate diagnosis (JASON, 2017). It additionally highlights the dangers of misinformation and ambiguous algorithms infiltrating the emerging field of AI for health (JASON, 2017). For example, consider Skinvision, an app from the Netherlands that offers to provide skin cancer diagnosis using an uploaded picture. Very little information exists about the methods used to inform diagnoses, and the developers make the disclaimer (stealthily) that the app is not a diagnostic device, thereby calling into question its reliability (JASON, 2017). Such nefarious examples notwithstanding, the use of accurate data is vital; however, many health care organizations have not invested in data validity capabilities (Accenture Consulting, 2018). While the opportunities offered by AI and other similar tools are exciting for health care, leaders are increasingly realizing the need to be cautious. In fact, 81 percent of health care executives interviewed for one study expressed the view that health care organizations are not prepared to explain AI-based actions should societal or liability issues arise (Accenture Consulting, 2018). To realize the full potential of these technologies and prevent adverse events, ethical concerns need to be addressed, beginning in the design stage. Furthermore, guidance and endorsement by learned bodies (or an organization that guides and governs a discipline) may be needed to identify best practices for deployment of AI tools (JASON, 2017).

Avoiding Institutionalizing Bias

Absent an HCD approach, the development of devices and tools that yield incorrect information and wrong diagnoses poses a continuing ethical and clinical danger. A particular problem is that, either intentionally or unwittingly, algorithm creators will build in their own perspectives and values (Rainie and Anderson, 2017). In a 2017 Pew Research report, these authors highlight this as an area of deep concern, backed by similar views expressed by numerous experts. According to one expert,

> Unless the algorithms are essentially open source and as such can be modified by user feedback in some fair fashion, the power that likely algorithm-producers (corporations and governments) have to make choices favorable to themselves, whether in internet terms of service or adhesion contracts

> or political biases, will inject both conscious and unconscious bias into algorithms. (Rainie and Anderson, 2017)

Biases can also affect a tool as a result of sampling design, because the use of design ethicists in this area is extremely rare. In the United States, human bias in public assistance systems has created deep inequalities for decades (Edes and Bowman, 2018). If not accounted for, these biases can seep into technology tools and algorithms and simply automate the bias and inequity.

Data Governance Standards

While innovation is exciting and encouraged by many national governments, this dynamic field requires balance. In many countries, data governance standards are old and in need of an upgrade. While some countries or regions within countries are still operating via a paper system for health records, many have begun migrating to digital health information systems. As the use of such systems grows, countries at all stages need to take note of important considerations related to data governance and management. To ensure quality in these systems, organizations need to implement robust data life-cycle management, including data pipelines that can be trusted over time. These pipelines need to have built-in feedback loops to ensure that ongoing monitoring and updating are occurring, as the data are likely leading to important decisions about people's health, and these systems should not be operating with outdated information and algorithms. Correctly designed, these feedback loops can support a "fail-fast" mentality, which encourages stopping a system to report issues instead of continuing with a flawed process. This approach can allow for faster redirection and pivoting while also ensuring that quality and safety are being measured, supporting an environment for continual improvement. Figure 3-6 illustrates the support that an "enabling ecosystem" can provide for the cycle of data production and information use.

Many health systems are also in need of improved data management. This function could be improved in part through advocacy among the donor community for good data management practices by governments and other project implementers, including incorporating data management requirements in requests for proposals and following through at the end of the award period to ensure that these requirements have been met. Over time, imposing these requirements can entrench best practices in data management and make them more commonplace as the default approach. Currently, it is also very difficult to track and validate which individuals are skilled in which disciplines, so it is challenging for countries to identify the right expertise to help develop national policies on digital health and informatics. A regional certification body could assist in addressing this issue and give governments access to the right professionals who have already been vetted and also have an understanding of their regional or national culture and its nuances. Countries further along in this process, moreover, can share lessons in creating policies and standard operating procedures that embody data quality assessments, including data ethics.

Sustainability also needs to be considered for data governance, especially in LMICs, as donors or outside companies implement countless digital health pilots. Without sufficient thought regarding the uptake of the program or device being tested, such projects can and do easily fail. Even projects that show great promise at the outset, such as the acclaimed telemedicine program implemented in Bihar, India, may not improve quality (Mohanan et al., 2017). This observation underscores the importance of rigorous evaluations and robust (and human-centered) program design for new innovations. Multiple studies have found that poor reproducibility or scalability with numerous pilots can impede digital health efforts in lower-income settings (Shuchman, 2014; Tomlinson et al., 2013; Waugaman, 2016) by eroding trust and community buy-in and by causing confusion that can compromise the quality of care.

Looking Ahead

Many of these issues have been raised by various stakeholders, and several countries have already seen much success when investing in technology and leveraging the tools already in use. WHO has made it a priority to leverage digital health technology for improvements in health care quality and patient safety. In an address to delegates at a conference on health care on digital technology,[6] WHO Director-General Dr. Tedros Adhanom Gebreyesus highlighted the impact of digital technologies on training health care workers, empowering patients and families, and improving patient safety and quality. For effective and sustainable improvements to occur, however, strong leadership at the national and local levels, clear policies and governance mechanisms, and data-driven improvements will be necessary (WHO, 2018b).

Global health care today is at a crossroads. Leaders have an opportunity now to make intentional and important changes to the way digital tools are designed and how they are implemented in the health care sector. If they fail to act on this opportunity, these technologies could actually be harmful, and those who are most vulnerable may be the ones most likely to suffer.

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[6] Dr. Tedros Adhanom Gebreyesus made this address at the 2nd International Conference of Ministers of Health and Ministers for Digital Technical Technology on Health Security in Africa (CIMSA) in June 2018.

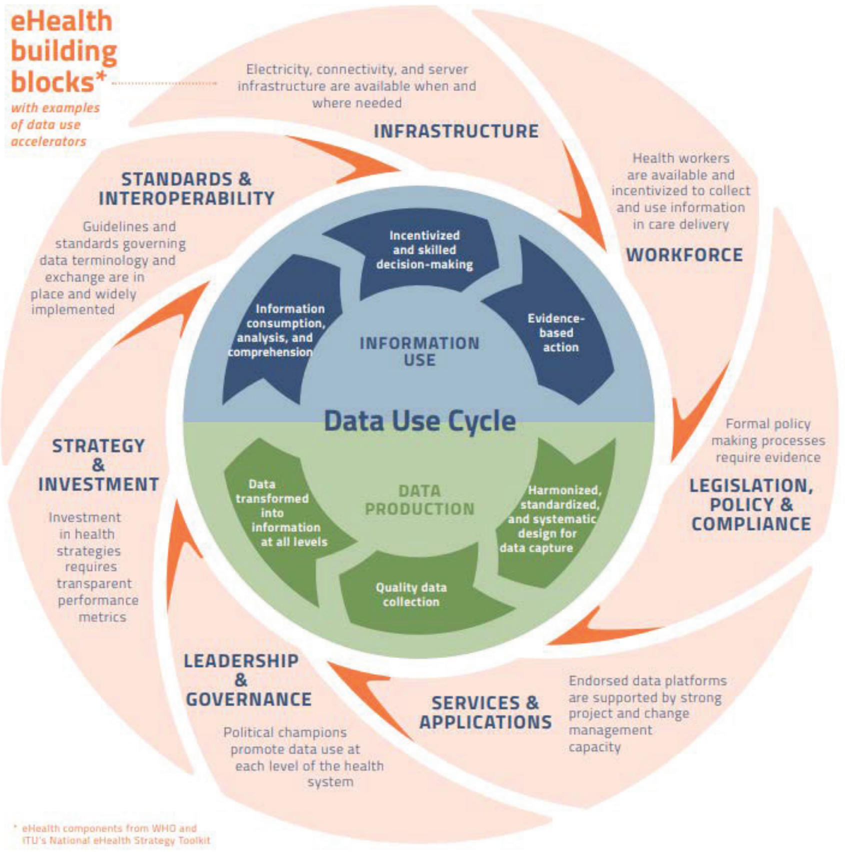

FIGURE 3-6 The PATH-Vital Wave data use cycle.
SOURCE: Image reprinted from "Theory of Change for the Data Use Partnership, Copyright © 2016, PATH, Vital Wave" courtesy of PATH, Vital Wave.

SUMMARY AND RECOMMENDATIONS

The health care system of the future will differ fundamentally from those of the present and past. Digital technologies are a key enabler to optimize health systems and improve the quality of care for individuals and populations. Fully tapping the potential of digital systems and tools will require new skills, attitudes, and culture in the workforce and new, more active roles for patients, families, and communities in shaping, evaluating, and delivering the care they need. New health-related human resource competencies will be necessary to understand and take advantage of the new health technologies and tools. Given the potential of big data and AI to transform systems, education programs need to be designed to better train health professionals in quantitative skills, statistics, and data analysis and use and to help leaders connect health policy with data and new evidence. Successful programs highlighted in this chapter have already begun this transition, shifting the focus to utilization of digital health technology as well as predictive rather than reactive care models. While the programs' successes are specific to the context in which they were implemented, they offer insight into methods and strategies that have the potential to be scaled and altered to be successful in a variety of contexts:

- The Brazilian Family Health Strategy, which focuses on the utilization of CHWs, has resulted in increased breastfeeding rates, near-complete immunization coverage among children, decreased inequality and inequity in health care utilization, and a patient satisfaction rate of 85 percent approval for CHWs.
- A Massachusetts program integrating health, behavioral, and social services for low-income clients led to a decline in hospitalization rates of more than 7 percent relative to the previous year; visits to the emergency room fell by about 6 percent.
- Novartis and Ghana Health Service implemented a pilot program aimed at integrating and scaling telemedicine services in Ghana. The result was that more than half of all tele-consultations were resolved by phone, and 31 percent avoided the need for referrals.
- Transitioning current training content to digital form to enable broad dissemination could lower the marginal cost of 1 million new CHWs in sub-Saharan Africa from an estimated $65 per person to $15 per person.

The health care system of the future will have a focus on prevention, risk factor management, and personalized care using precision medicine and predictive analytics. In this scenario, care will be delivered as close to the patient as possible, and will rely more on community resources and less on hospitals. Already with the introduction of digital technologies, the balance of power is shifting from providers to shared power and responsibility between providers and empowered patients.

This shift is being driven by public demand, and in the process may be shaped in ways not experienced before. Technology is a disruptor and has proven so in many other sectors. What remains to be seen is whether technology will close gaps and disparities in health care or widen them, such that those who can afford new technology and the options it provides will benefit, and those without resources will not. Health systems need to take a proactive approach to this shift, or they may be left behind in the process.

Conclusion: The use of personal digital devices and information technologies is bringing health care closer to patients and empowering patients to be more engaged in and proactive about their own health. Governments need to recognize that digital and other technologies will be an integral part of health care delivery in the future, even in developing-country settings; indeed, many countries are making quantum leaps in building digital infrastructure and are leapfrogging to 4G and 5G. Health systems within each country will need to embrace this transformation through multisectoral partnerships outside of the health sector while anticipating and mitigating the risks that such changes will bring. This change will demand new workforce skills. Educators, governments, clinical leaders, and executives will need to reshape and adapt workforce pipelines to take full advantage of this transformation. Payers, academia, patient groups, the private sector, and governments will have to learn to operate through multisector governance mechanisms fit for these new models of health care delivery to maximize their benefits; minimize their risks; and craft and maintain proper, modernized ethical guardrails.

Recommendation 3-1: Build a Global Community for Digital Advances in Health and Health Care Delivery
The United Nations System should convene an international task force with multisectoral representation to provide guidance to the global community on advances in digital health technologies. This task force should develop:

- data standards, norms, ethical frameworks, and guidance for modernized regulation and human resource capacity to enable countries to better benefit from the transformative technologies in the health sector;
- engineering and design standards that emphasize interoperability, human factors, and human-centered design to align technologies and innovation with the aspirations of global health care quality; and
- an international resource to guide countries in incorporating regulation of digital health technologies so as to protect users and their privacy while fostering innovation, with input from an external board of experts.

Recommendation 3-2: Adopt and Adapt the New Technological Realities of the Present and Future
Countries should prepare for and embrace the technological (especially digital) changes in health care by adopting and adapting standards; eth-

ical frameworks; and governance, payment, regulation, and workforce designs that are anticipatory and that embrace, rather than impede, the potential of transformed care.

- Ministries of health should collaborate with ministries of communication and technology to build national health strategies that embed digital technology as an integral part of the health system and address their countries' priority health needs.
- Governments and organizations should develop and support multisectoral task forces to guide their digital health strategies so as to ensure that all deployed digital health technologies are evidence-based and coordinated, that patient safety is protected, and that risks are mitigated.
- Government and private-sector leaders should revise competency requirements and educational curricula to better meet the workforce needs created by digital health advances, including skills in data science and analytics, interpersonal skills for teamwork and person-centered care, and systems-based thinking.

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4

The Current State of Global Health Care Quality[1]

Key Findings

- Overall, between 5.7 and 8.4 million deaths are attributed to poor-quality care each year in low- and middle-income countries (LMICs), and years of life lived with disability amount up to 107 million annually, primarily among those living with mental illness and untreated diabetes.
- Poor-quality care is responsible for up to 15 percent of overall deaths in LMICs.
- Poor-quality care imposes costs of $1.4 to $1.6 trillion each year in lost productivity in LMICs.
- Many metrics for measuring quality already exist and are established in Organisation for Economic Co-operation and Development (OECD) countries, and are ready and fit for use in learning health care systems in all settings.
- Choosing existing indicators rather than investing heavily in developing new ones can allow health systems in low-resource settings to close the gap with high-resource settings in transparency and knowledge of performance.

To improve the quality of health care globally, it is imperative first to be able to characterize and quantify the burden of low-quality care. To gain a comprehensive understanding of this burden in low-resource settings,

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[1] Details on the methods used to derive the information presented in this chapter are given in Appendix D.

the committee commissioned a team of analysts at the Harvard Initiative on Global Health Quality to analyze available data on the quality of care across low- and middle-income countries (LMICs), with emphasis on the six dimensions of quality care introduced in Chapter 1: safety, effectiveness, person-centeredness, timeliness, efficiency, and equity. While the results of this review reveal that the quality of care globally is poor, what is also clear is the paucity of data on quality for many places. Proper metrics for tracking quality—not just inputs, but also processes and outcomes—are necessary to assure and improve levels of quality. Several global efforts are under way to develop such metrics, but their effectiveness will depend on partnering with LMICs to adapt them to various settings.

This chapter focuses on estimating the burden of low-quality care among those who have been able to access the health care system. We quantify the burden of low-quality care as an estimate of the deaths and disability resulting from *unsafe* and *ineffective* care for the proportion of the population that has attained *actual coverage*. In addition, we demonstrate the variability of *person-centeredness* across countries by documenting variations in patients' assessment of their health care interactions. We discuss waiting times for treatment separately to demonstrate the variability in *timeliness* of care. Next, the chapter provides more detail on *equity*, or the variability in the burden of poor-quality care, particularly by geographic location. Since access to care is critically important in its own right, separate estimates are presented of the deaths and disability resulting from failure to obtain care among a subset of conditions. The total burden of low-quality care in terms of death and disability as measured across domains and conditions is also presented, along with some measures of *efficiency*. (Detailed methods relating to each domain are outlined in Appendix D.) Finally, this chapter reviews data availability and limitations, as well as potential reasons for variability. It closes with a call to action for countries to commit to developing National Quality Policy Strategies, and to provide the leadership and environmental conditions needed for this to become a reality.

Mansah's Story: The Consequences of Poor Quality

Mansah was a brilliant young woman. She was vivacious, fun-loving, and intelligent. She met her husband Kwame during her studies at the university in Ghana, and happily discovered she was pregnant a few months after their wedding. Kwame, an only child himself, was looking forward to starting a family. The two went to a nearby hospital, a large facility with 350+ beds offering specialist services. The obstetric unit had a maternity unit, several rooms for delivery, and two obstetric theaters. The maternity unit was run by four specialist teams (Teams A–D), each comprising a consultant (the leader), two or three specialists, and four house officers. Mansah visited the antenatal clinic (ANC) for a 6-week appointment and *was assigned to Team B, led by a consultant. She was given a maternal health record book with her expected date of delivery and was told when to return for her next visit. She continued with her ANC visits regularly and continued to be healthy with no known medical conditions.*

At each ANC visit with Team B, Mansah was attended to by the same resident doctor, who always declared her healthy and well, to her husband's great relief. She was apprehensive about having a vaginal delivery and expressed this to the resident doctor, who assured her that she would be fine as all her tests and scans had come in normal. But on her last visit (4 days before her expected date of delivery), her blood pressure (BP) was high (170/110). She was asked to go home and rest and return the next day for a recheck. Mansah complied, and upon returning the next morning had multiple BP measurements of 170/110. The resident doctor informed her and her husband that as her BP was still high, the plan was to control the BP and later induce labor. She was admitted to the maternity unit, and Kwame was given a prescription to fill for her for an antihypertensive and a prostaglandin to induce labor. He filled the prescription at the hospital pharmacy, and treatment was started immediately. Upon reviewing the case later that evening, the resident doctor stated that the priority was to control Mansah's BP while she awaited Team B's clinical rounds the next morning for a final decision. Initially her BP dropped from 170/110 to 160/110 and to 140/95, but it began to rise again to 150/110 and eventually, by 6:30 a.m. the next day, it had risen to 170/100.

After considering their options, Kwame and Mansah decided a caesarean section (CS) was the best way to deliver the baby. Kwame relayed this request to the resident doctor, who agreed to perform the CS at 2:00 p.m. that afternoon. Shortly thereafter, the consultant leader of Team B was briefed on Mansah's condition, and she also informed him of their choice of CS rather than vaginal delivery. The consultant, however, stated that labor should be induced, and he explained the risks associated with a delivery by CS, especially as it was her first delivery. In his opinion, her condition did not necessitate a delivery by CS. His plan was to proceed with the induction of labor, assuming that her BP would settle with the antihypertensives she was taking. He instructed that she receive the medicine to induce labor every 4 hours for up to three doses, after which if labor had not begun, he would proceed to deliver the baby by CS. The first dose of Cytotec was administered at about 10:00 a.m. and the second dose at about 3:00 p.m., but after both doses, no cervical dilation or contractions were recorded by the attending staff—a midwife and a house officer. Concerned, Kwame tried to reach the resident doctor, but with no success until about 7:30 p.m. Frustrated, he again requested CS for the delivery as the induction did not appear to be working. He was informed by the resident doctor that the consultant leader of Team B had called off the CS completely. At about 8:00 p.m., the third dose of Cytotec was administered, and about an hour and *a half later there were still no contractions or cervical dilatation, and Mansah's BP was still high (160/110). Kwame called the consultant, requesting yet again that the team proceed with the delivery by CS. The consultant insisted that Mansah would be fine and would continue to be monitored by the team, with the resident doctor updating him on Mansah's progress.*

Eventually, at about 10:45 p.m., Mansah begun to experience painful contractions, and her BP was still 160/100. Kwame informed the midwives, who examined her and confirmed that her cervix was just 2 cm dilated, and she would thus need more time to progress fully into labor. At about 3:00 a.m. the next day, Mansah's water broke, and at 4:30 a.m. she was taken to the stage 1 labor room with her BP at 170/107 and her cervix 5 cm dilated. At 7:45 a.m., she was reexamined by the midwives, who found that her cervix was 9 cm dilated, but the baby's head was still very high. Concerned about this and the fact that there was no doctor nearby, Kwame relayed this information to the resident doctor by phone. The night shift was coming to an end, and patients were being introduced and transitioned to the morning shift staff. One of them examined Mansah and confirmed that her cervix was 9 cm dilated, but added that part of the cervix was still tight and too firm. One of the midwives then suggested that Mansah be moved to the second-stage labor room and be forced to push. Coaxed by the midwives, Mansah began to bear down, and after about 30 minutes gave a very hard push to deliver her baby at 9:00 a.m. The baby, however, did not cry at birth, and the midwives started immediate resuscitation on the baby, later joined by the resident doctor, who had been informed of the situation by Kwame. After about 30 minutes, the resident doctor and one of the midwives rushed the baby to the neonatal intensive care unit (NICU), with Kwame following. He called the consultant at about 9:45 a.m. to inform him of the situation. The consultant had just arrived at the hospital and proceeded to the NICU to observe the baby's progress.

After about an hour of waiting and assurances that the baby was responding to treatment, Kwame returned to the labor ward to find Mansah in a wheelchair looking very pale and weak. She could not speak, and when he inquired of the consultant what the problem was, the consultant indicated that he suspected she had a severe tear, and he was going to repair it in theater. The midwife explained to Kwame that Mansah had not stopped bleeding since delivery. Shortly thereafter, the consultant emerged from the theater and reassured the family that he had fixed the bleeding, and Mansah was in the recovery room, after which he left the ward. Almost immediately, Kwame was asked to find a house officer to accompany him to the blood bank for four units of cross-matched blood, which they obtained after about 20 minutes and sent to the theater. He was told Mansah was well and in the recovery ward, but in less than 10 minutes, Kwame's and Mansah's family members were called into the corridor of the theater and informed that Mansah had died. Kwame was devastated.

Mansah lay on a stretcher in the corridor. None of the staff were familiar to Kwame, and there was no one of whom to ask questions. Kwame requested an immediate postmortem, which he said indicated that Mansah had died from primary postpartum hemorrhage secondary to a third-degree vaginal tear. (An endorsed report was sent to him later with the cause of death stated as hypovolaemic shock, primary postpartum hemorrhage, and hypertensive heart disease.) Shocked, Kwame and the family went to the NICU to inquire about the condition of the baby, where they were met by more heartache. The baby was convulsing and had to be admitted. Though in intense grief, Kwame had to visit his son twice per day while making arrangements for Mansah's funeral. The baby was finally discharged after 3 weeks with a diagnosis of severe asphyxia and right Erbs palsy, typically caused by excessive pulling or stretching of an infant's head and shoulders during birth.

THE STATE OF QUALITY ACROSS DOMAINS

For each domain of quality outlined in Chapter 1, the team of commissioned analysts defined a set of indicators corresponding to poor-quality care (detailed methods relating to each indicator are outlined in Appendix D). Two main sources of data were used to estimate the burden of poor quality for each domain: where available, data were obtained from national or international databases, including but not limited to the Global Burden of Disease (GBD), the Demographic and Health Surveys (DHS), and the World Health Organization (WHO) STEPwise approach to surveillance (STEPS) data. Where no data were available for indicators of interest, the team obtained estimates by carrying out systematic reviews of the peer-reviewed published English-language literature over the past decade. Details on the data sources used for all variables are outlined in Appendix D, which also includes details on the literature review results and methods. Across the estimates discussed in this section, issues that might impact the relationship among care delivery, receipt of intended services, and ultimately health outcomes are addressed.

The focus of this analysis is on estimating the burden of low-quality care among members of the population who have successfully interacted with the health care system. *Coverage* normally refers to the proportion of the population that can receive or has received a health care service. The Tanahashi (1978) framework (see Figure 4-1) expresses coverage in terms of potential coverage (the proportion of the population for whom service is available) and actual coverage (the proportion of the population who actually receives the service). This dyad can be further broken down into five important stages that lead successively from potential to actual coverage. The focus here is on estimating the burden of low-quality care among the

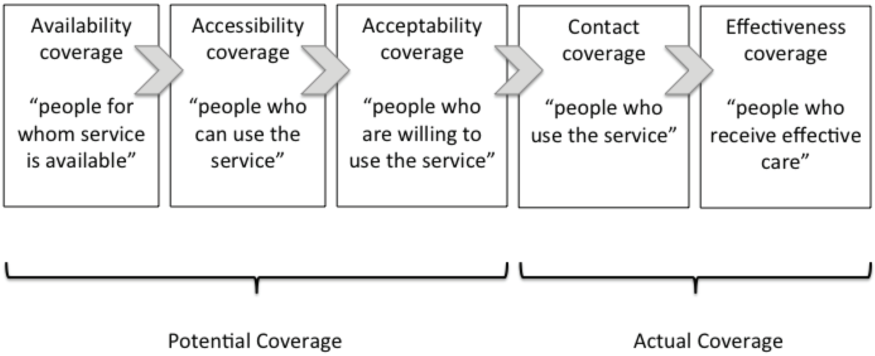


FIGURE 4-1 Stages of health care service coverage.
SOURCE: Tanahashi, 1978.

portion of population that has interacted successfully with the health care system, using the Tanahashi stages of health care service coverage.

Potential coverage is reflected in the first three stages shown in Figure 4-1. First is *availability coverage*, or the availability of the resources necessary to ensure that the service can be provided. Next, the service must be within the reach of its target population, as reflected in *accessibility coverage*. Once available, the service should be acceptable to people in terms of cost, respect for religion/norms, and quality, among other things, as reflected in *acceptability coverage*. For *actual coverage* to be attained, people must come into contact with service providers through *contact coverage*. However, contact does not guarantee that they will receive a satisfactory level of service. The receipt of high-quality, effective service occurs in the final stage, *effectiveness coverage*. It is crucial to recognize that the gap between contact coverage and effectiveness coverage is not just an academic concept, but impacts the lives and livelihoods of people around the world, as demonstrated in the narrative at the beginning of this chapter.

Safety

To measure the global burden of unsafe care, an existing list of indicators commissioned by the World Alliance for Patient Safety in 2007 was used. This review, which was conducted with the input of the WHO Committee on Research for Patient Safety, identified 23 topics pertaining to patient safety, including adverse events. From those 23 topics, six indicators composed of types of adverse events and hospital-acquired conditions were selected for measurement, in line with a previous review on the global burden of patient safety and taking into account the availability of data (Jha et al., 2013). Data were obtained from a systematic review of these indicators in LMICs to produce estimates on the incidence of unsafe care; the number of such events; and, where possible, deaths arising directly from unsafe care (see Appendix D). Where data were not available through the review, estimates were taken from an existing study (see Appendix D).

Table 4-1 presents the incidence rates, number of events, and number of deaths for the six selected indicators. Nine percent of hospitalized patients experienced a decubitus ulcer, 7.4 percent of patients on a ventilator in the intensive care unit (ICU) acquired ventilator-associated pneumonia, and more than 5 percent of hospitalized patients experienced an in-hospital fall. Based on these estimates, nearly 134 million adverse events and 2,620,412 deaths are estimated to occur annually as a result of unsafe medical care in LMICs.

These estimates of incidence, number of events, and deaths related to the selected indicators are likely an underestimate of the true burden of unsafe care in LMICs. The numbers presented reflect estimates obtained from the literature for the six selected safety indicators, representing a subset of all adverse events. This subset excludes other important adverse events such as injuries due to medical devices, unsafe injections, and surgical errors. In addition, the lack of availability of high-quality data in these settings may result in an undercount of adverse events, limit the ability to estimate mortality rates directly associated with unsafe care, and contribute to uncertainty in the number of hospitalizations in LMICs. Another relevant consideration when examining patient safety is rates of counterfeit and substandard medicines. Box 4-1 highlights a case study in this area with a

TABLE 4-1 Safety Events Occurring in Low- and Middle-Income Countries (LMICs)

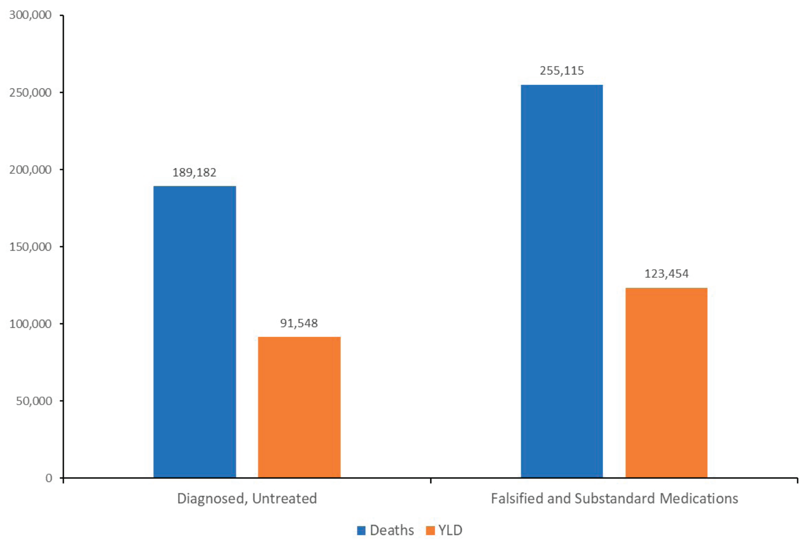
Indicator	Incidence Rates (% of those hospitalized)	No. of Events	No. of Deaths
Adverse drug events	3.2	17,152,226	222,979
Falls	5.1	27,198,059	40,797
Ventilator-associated pneumonia	7.4	316,279	63,256
Decubitus ulcers	9.0	47,931,418	239,657
Catheter-associated urinary tract infections	0.9	27,187,770	1,631,266
Venous thromboembolisms	2.6	14,081,893	422,457
Overall		133,867,645	2,620,412

NOTES: Ventilator-associated pneumonia is applied to the intensive care unit (ICU) population on ventilators only; the rates for all other measures are applied to an estimate of total global hospitalizations, including ICUs (studies that are limited to the ICU population are excluded). The estimated total number of hospitalizations for LMICs is 531 million. Incidence rates are not additive because of the difference in denominators among indicators.

BOX 4-1
Safety Case Study: Substandard and Falsified Medications

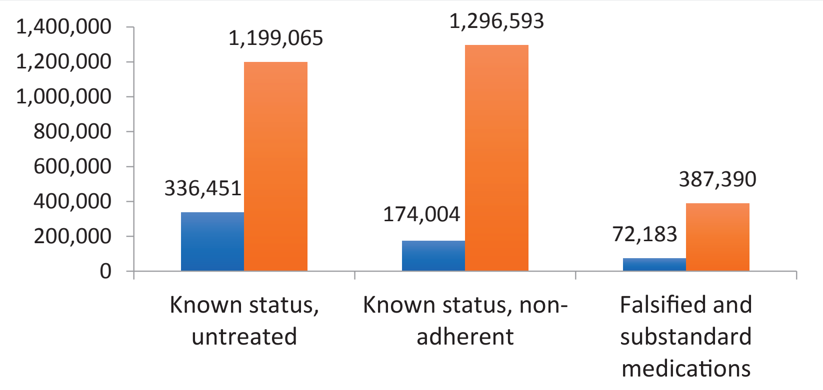
Each day around the world, patients make journeys seeking care. Whether an elderly person on a bus to the city or a mother accompanying her sick child on foot, people make significant investments to get the care that they need. Once patients have made this journey and received a diagnosis and a prescription, they face another potential barrier that often receives insufficient attention: ensuring that the medicines they receive actually do what they are meant to do. People may receive antibiotics made of cornstarch or antiretroviral medications for HIV that do not have adequate active ingredients. The cases that are known to result—a 6-year-old who misses months of school because of an unnecessarily long recovery from malaria or a man who inadvertently spreads drug-resistant HIV to his partner—are the proverbial tip of the iceberg.

Poor-quality pharmaceuticals, defined by the World Health Organization (WHO) as any products that are substandard and falsified, are responsible for a large number of preventable, poor health outcomes, including substantial suffering and death. Millions are exposed to and thousands are killed each year by these drugs, yet countries around the world have struggled to make this issue a priority. Building on the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (WHO, 2017b), which estimates that one in ten medicines in low- and middle-income countries (LMICs) are fake, the figures below quantify the human burden of those fake medicines for tuberculosis (TB) and HIV.



Deaths and years of life lived with disability (YLD) as a result of falsified and substandard-quality tuberculosis (TB) medicines.

SOURCE: See Appendix D.



Lost disability-adjusted life years (DALYs) due to falsified and substandard-quality HIV medicines.

SOURCE: See Appendix D.

These numbers clearly show the need to address substandard and falsified medicines on the global agenda. For TB in particular, more deaths and a greater burden of illness are attributable to the use of substandard and falsified medicines than to the failure to receive treatment among diagnosed patients. Work conducted to date by a selected few provides a strong foundation on which to call for improved tracking systems, technical innovation, and policy solutions. Investing in these solutions would be both timely and of significant importance for improving the health of the world's population.

specific focus on quality of tuberculosis (TB) and human immunodeficiency virus (HIV) medications.

Effectiveness

The burden of ineffective care was estimated for a range of conditions that represent leading causes of mortality and morbidity in LMICs (see Table 4-2). To quantify the mortality and morbidity burden of these conditions, outcome indicators (see Table 4-3) were restricted to populations with actual coverage (as defined above), where actual coverage served as a proxy for diagnosis and care-seeking behavior. For some conditions, the receipt of effective care prevents mortality, and thus *any* death associated with these indicators (for example, death from untreated diarrheal diseases under age 5 among those who accessed care) was measured as a quality-related death. Other deaths (for example, deaths from acute myocardial infarction) are not entirely preventable by but amenable to effective care, such that the number of deaths and the incidence of disability can be reduced. For these conditions, quality-related deaths were defined as deaths above what is seen in high-income settings for the same conditions.

It is important to note that while these estimates include conditions that represent leading causes of mortality and morbidity, the lack of data availability prevented a more exhaustive estimate for all conditions for which poor-quality care can result in a high burden of death and disability. In addition, this estimate does not always consider instances in which condi-

TABLE 4-2 Conditions Represented in the Effectiveness Domain

Communicable diseases	• HIV/AIDS • Tuberculosis • Pneumonia • Diarrheal diseases
Noncommunicable diseases	• Cancer: lung cancer • Cardiovascular disease: acute myocardial infarction (AMI), heart failure, and hypertension • Cerebrovascular disease: ischemic stroke and hemorrhagic stroke • Chronic obstructive pulmonary disease (COPD) • Type 2 diabetes • Injury and trauma • Mental health: depression, anxiety, bipolar disorder, schizophrenia, and substance abuse
Maternal and child health	• Maternal mortality • Neonatal mortality

TABLE 4-3 Definition of Ineffectiveness Indicators

Indicator	Definition
Communicable Diseases	
HIV/AIDS	Untreated HIV/AIDS among diagnosed and nonadherent patients
Tuberculosis	TB patients lost to follow-up among diagnosed patients
Pneumonia	Untreated pneumonia among those seeking care, with symptoms, under age 5
Diarrheal diseases	Untreated diarrhea among those seeking care under age 5
Noncommunicable Diseases	
Lung cancer mortality	Excess lung cancer mortality
Acute myocardial infarction (AMI) mortality	Excess inpatient AMI mortality
Heart failure mortality	Excess inpatient heart failure mortality
Ischemic stroke	Excess inpatient ischemic stroke mortality
Hemorrhagic stroke	Excess inpatient hemorrhagic stroke mortality
Chronic obstructive pulmonary disease (COPD) mortality	Excess inpatient COPD mortality
Diabetes	Untreated diabetes among diagnosed patients
Injury and trauma	Excess mortality from trauma and injury
Depression	Untreated depression among those seeking care
Anxiety	Untreated anxiety among those seeking care
Bipolar disorder	Untreated bipolar disorder among those seeking care
Schizophrenia	Untreated schizophrenia among those seeking care
Substance abuse	Untreated substance abuse among those seeking care
Maternal Mortality and Child Health	
Maternal mortality	Mortality among women during birth who had a skilled birth attendant at delivery
Neonatal mortality	Mortality among neonates in the first month of life who had a skilled birth attendant at delivery

tions were not appropriately diagnosed; accounting for misdiagnosis would increase the estimate of the burden. In certain cases, however, such as for pneumonia and diarrheal disease, the data represent care-seeking behavior among people with symptoms and were not limited to cases in which a diagnosis had already been made. Therefore, diagnosis as an element of ineffective care would be captured, to an extent, in these estimates.

Communicable Diseases

To estimate the burden of ineffective care, it was first necessary to quantify the rates of ineffective treatment. Table 4-4 presents estimates of ineffective treatment for communicable diseases measured as the percentage of the population diagnosed and not treated, by condition, while Table 4-5 presents the estimated annual deaths and disability resulting from ineffective care.

Across the communicable conditions studied, each year approximately 8.4 million people had a diagnosis yet were not being treated. People with HIV had the highest proportion of ineffective treatment (66 percent), representing people with known HIV status that were not on antiretrovirals or were nonadherent. This ineffective treatment is estimated to result in

TABLE 4-4 Number of People Impacted by Ineffective Treatment for Communicable Diseases in Low- and Middle-Income Countries, Annually (millions)

Condition	No. Diagnosed	No. Untreated (% untreated among diagnosed)
HIV/AIDS	19.5	3.8 (66)
Diarrheal disease (under 5 years)	11.2	3.9 (35.3)
Tuberculosis*	5.7	0.27 (4.7)
Total	36.4	7.97 (21.9)

*High estimate from two different data sources.

TABLE 4-5 Deaths and Disability Resulting from Ineffective Care for Communicable Diseases in Low- and Middle-Income Countries, Annually (millions)

Treatment Indicator	Quality-Related Deaths	Years of Life Lived with Disability
HIV/AIDS	0.46	2.5
Diarrheal disease (under 5 years)	0.14	—
Tuberculosis*	0.13	0.09
Pneumonia (under 5 years)	0.07	—
Total	0.8	2.59

*High estimate from two different data sources.

460,000 quality-related deaths and 2.5 million years of life lived with disability (YLD) in LMICs annually. In addition, 35 percent of children under 5 years taken to a medical facility for the treatment of diarrhea were not prescribed oral rehydration therapy, resulting in 140,000 quality-related deaths each year. Finally, 4.7 percent of TB patients were diagnosed but lost to follow-up, resulting in 130,000 quality-related deaths and 90,000 YLD annually. Overall, ineffective treatment for communicable diseases leads to 800,000 deaths and 2.6 million YLD annually.

Noncommunicable Diseases

Estimates of ineffective treatment for noncommunicable diseases (NCDs), measured as the percentage of the population diagnosed and not treated annually, are presented in Table 4-6. Estimated annual deaths and disability resulting from ineffective care for NCDs are presented in Table 4-7.

Overall, 831 million people had a diagnosis and were not receiving treatment for NCDs annually. Mental health conditions, both common (depression and anxiety) and serious (bipolar disorder and anxiety), represent a leading cause of human suffering. For depression, anxiety, and alcohol use disorder, we focus on moderate and severe disease states because of variations in the recommended standard of care for cases that are diagnosed as

TABLE 4-6 Number of People Impacted by Ineffective Treatment for Noncommunicable Diseases in Low- and Middle-Income Countries, Annually (millions)

Condition	No. of Diagnoses	No. Untreated (% untreated among diagnosed)[a]
Hypertension[b]	471.7	326.2 (49.7)
Diabetes mellitus	164.1	55.3 (33.7)
Depression	234.9	90.9 (38.7)
Anxiety	163.9	58.2 (35.5)
Bipolar disorder	19.9	8.1 (40.7)
Schizophrenia	13.2	7.6 (57.9)
Alcohol use disorder	45.2	8.1 (18.0)

[a] For mental health conditions, this figure is among those aged 15 and up, diagnosed, and seeking care. Depression, anxiety, and alcohol use disorder are limited to moderate or severe cases; mild cases are excluded because of variations in the standard of care. We are not able to account for comorbidity of mental health conditions and therefore present number of diagnoses as opposed to number of people diagnosed.

[b] Population over age 15.

TABLE 4-7 Deaths and Disability Resulting from Ineffective Care for Noncommunicable Diseases in Low- and Middle-Income Countries, Annually (millions)

Treatment Indicator	Quality-Related Deaths	Years of Life Lived with Disability
Lung cancer	0.13	—
Acute myocardial infarction (AMI)	0.10	—
Heart failure	0.62	—
Ischemic stroke	0.18	—
Hemorrhagic stroke	0.02	—
Chronic obstructive pulmonary disease (COPD)	1.0	—
Injury and trauma	2.1	—
Diabetes mellitus	—	13.1
Depression	—	44.6
Anxiety	—	17.9
Bipolar disorder	—	3.3
Schizophrenia	—	5.0
Alcohol use disorder	—	4.2
Total	4.15	88.1

NOTE: See Table 4-6.

mild. Across the mental health conditions examined, there were a projected 477 million diagnoses among adults, 206 million of whom sought care, and 173 million of whom were not retained in treatment. Nearly 150 million people with a diagnosis of depression or anxiety were untreated, resulting annually in 44.6 million YLD and 17.9 million YLD, respectively. Ineffective treatment for bipolar disorder and schizophrenia resulted in 3.3 and 5.0 million YLD, respectively. In addition, 8.1 million people who sought care for moderate or severe alcohol use disorder were not retained in treatment, leading to 4.2 million YLD annually.

Annually, of the 164.1 million people diagnosed with diabetes in LMICs, 33.7 percent were not being treated with insulin or oral medication, and 50 percent of people with a diagnosis of hypertension were not on any medication. Injury and trauma contributed the greatest number of quality-related deaths, at 2.1 million annually, followed by chronic obstructive pulmonary disease (COPD) (1 million), heart failure (620,000), ischemic stroke (180,000), lung cancer (130,000), and hemorrhagic stroke (20,000). In total, 831 million people were untreated for diagnosed conditions, resulting in 111.2 million YLD annually. More than 4 million quality-related deaths from NCDs were attributable to ineffective care each year.

Maternal and Child Health

In LMICs, 71 percent of births are attended, compared with 99.4 percent of births in high-income countries. Estimated annual maternal and neonatal deaths among women with a birth attended by a skilled health professional are presented in Table 4-8. There are an estimated 462,131 quality-related neonatal deaths and 43,602 quality-related maternal deaths in LMICs annually.

NCDs That Are Also Risk Factors for Other NCDs

While the conditions discussed above are representative of the leading causes of human suffering, one area that is more challenging to quantify with this methodology is the burden of disease for NCDs that are disease states themselves but also risk factors for other NCDs. Such NCDs are often chronic and may serve as an effect modifier for other conditions. One example is hypertension (see Box 4-2).

Person-Centeredness

Delivering person-centered care requires "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that [these] values guide all clinical decisions" (IOM, 2001, p. 6). Aside from being a cross-cutting component of quality in its own right, person-centeredness also impacts other aspects of quality. For example, poor experience with the health system is believed to have a significant impact on patients' care-seeking behavior, loss to follow-up, and unnecessary spread of disease. To address person-centeredness, this section examines both how it is currently measured and what the state of person-centered care across health systems is. However, while there is growing consensus globally that person (or patient)-centeredness should be measured and improved, there is much less clarity on what this actually means or how best to measure it, let alone achieve it. However, many international partners, including the Organisation for Economic

TABLE 4-8 Quality-Related Deaths Resulting from Ineffective Care for Maternal and Child Health in Low- and Middle-Income Countries, Annually

Indicator	Quality-Related Deaths
Neonatal mortality (attended)	462,131
Maternal mortality (attended)	43,602

BOX 4-2
Effectiveness Case Study: Hypertension

Low- and middle-income countries (LMICs) are undergoing an unprecedented epidemiologic transition marked by the rise of noncommunicable diseases. Indeed, the top 10 causes of mortality in LMICs in 2015 are strikingly similar to those in high-income countries (HICs) in 2000 (WHO, 2018d). Yet, while cardiovascular disease is the number one cause of death in both LMICs and HICs, 80 percent of cardiovascular disease deaths occur in LMICs (WHO, 2013a).

Hypertension is a leading preventable risk factor for cardiovascular disease. It is responsible for at least 45 percent of deaths due to heart disease, accounting for 9.4 million deaths worldwide annually (WHO, 2013a). Hypertension disproportionately affects populations in LMICs, where public awareness about risk factors is low, and integrated primary health care programs for early detection and treatment are lacking (WHO, 2017a). As a result, hypertension often goes undiagnosed. Even among those diagnosed, obtaining appropriate treatment continues to be a barrier to hypertension management.

Based on the World Health Organization (WHO) STEPwise approach to surveillance (STEPS) reports (WHO, 2018c), among the 10.7 percent of people diagnosed with hypertension or high blood pressure in LMICs, only 49.7 percent were on medication. Given that the burden of hypertension is projected to increase by 60 percent by 2025 (Kearney et al., 2005), the need to diagnose and appropriately treat those affected in LMICs is more urgent than ever.

Co-operation and Development (OECD), are working to advance and standardize these types of measures (Berwick et al., 2017). This lack of clarity on measures is reflected in the variability of strategies used to collect data on person-centeredness.

To measure the state of person-centered care, we reviewed existing national and international databases that include data on people's experience with the health system, measured over the past decade (such as the DHS Service Provision Assessment). This review was supplemented by a systematic review of the published literature to identify any publications on additional survey tools or data sources (often with smaller sample sizes, limited to one geographic area, etc.). This review included instruments recording experience as reported by the general population, system experts, providers, and patients (detailed methods are outlined in Appendix D). While the reviews were focused on people who have interacted with the health system, content collected through survey tools and other data collection strategies spans topics relevant to the whole person, the person's family, and aspects of person-centered care beyond the clinical interaction.

The published literature includes research across 30 LMICs over the past decade. Of these studies, 11.3 percent assess person-centeredness in private facilities, 45.1 percent in inpatient or hospital-based settings, 12.7 percent in rural facilities, and 14.1 percent for HIV services specifically. Primary clinical areas of focus include TB, cancer care, gynecology, emergency care, and diabetes. Only one study (in Pakistan) looks at person-centeredness in mental health care, as assessed by patients themselves. For these studies, a range of tools were used, 24 percent of which had previously been validated and more than 75 percent of which were newly developed, or had components that were newly developed, for the context in which they were employed. There were 12 countries for which no database data were available but that were represented in the literature.

Included studies look at "overall experience," a global rating of patients' (or in cases of pediatric care, caregivers') assessment of their care. With regard to actual ratings of care, there was significant variation across countries (see Figure 4-2). Levels of dissatisfaction ranged from 2.2 percent (United Kingdom) to 54.3 percent (Vietnam). Additional questions, such as assessment of disrespect, abuse, communication, engagement in decision making, and other aspects of person-centeredness, are represented throughout the published literature and often analyzed through factor analysis to assess the extent to which each question related to patients' overall rating of their care experience. However, the variability across countries should be interpreted with caution, as questions and sampling of respondents differ across tools.

The databases and included studies encompass many aspects of person-centeredness in addition to overall ratings. For example, similar to surveys in high-income countries, 23.9 percent of studies included in this review look at issues of communication, and 25 percent analyze respect or disrespect. Other items include privacy, perceived engagement of providers, and abuse, among others.

Timeliness

Lack of timely care can negatively affect patients emotionally and physically, in addition to increasing treatment costs. Timely care refers to care that is provided promptly, and minimizes waiting times and potentially harmful delays for both patients and providers (IOM, 2001). In this report, timeliness is considered in terms of the prevalence of patients reporting a lack of timely, prompt care in terms of either

- excessive waiting times; or
- lack of receipt of processes of timely care, which is associated with improved outcomes (see Box 4-3).

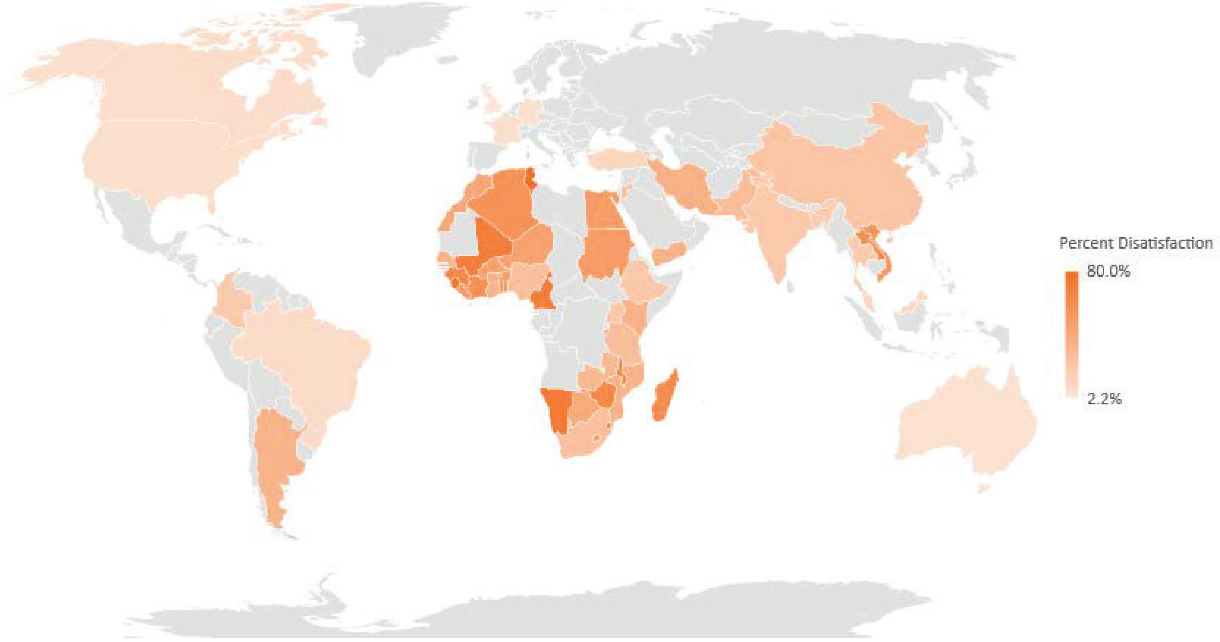


FIGURE 4-2 National levels of dissatisfaction with care.
NOTE: Grey color in the map indicates regions where data were not available for analysis.
SOURCES: Systematic review of the literature in low- and middle-income countries, Service Provision Assessment & Commonwealth Fund International Health Policy Survey (see the discussion of methodology in Appendix D).

BOX 4-3
Timeliness Case Study: Time to Antenatal/Postnatal Care

The health disparities between low- and middle-income countries (LMICs) and high-income countries cannot be demonstrated any more clearly than in the case of maternal mortality. Of the more than 300,000 deaths among women during pregnancy in 2015, 99 percent occurred in low-income countries (Alkema et al., 2016). Many of these deaths could have been prevented through regular antenatal and postnatal care and the presence of a skilled health care provider during childbirth.

The World Health Organization (WHO) recommends that women meet with their health care providers eight times during the antenatal period, noting that increasing the number of antenatal visits from four to eight can reduce perinatal deaths by up to 8 per 1,000 births (WHO, 2016). In the postnatal period, WHO recommends that women seek care four times, the first of which should be 48 to 72 hours after birth (WHO, 2013b).

Based on the most recent country-level data available from the Demographic and Health Surveys (DHS), only 57 percent of women in LMICs had four or more antenatal visits, and 14 percent had none. In the postnatal period, 59 percent of women had a checkup within 48 hours of delivery, and 35 percent had no checkup.

These findings suggest that there is a substantial gap between the practices recommended by WHO and uptake by LMICs. To meet the Sustainable Development Goals' 2030 goal of reducing the global maternal mortality ratio to fewer than 70 maternal deaths per 100,000 live births (UN, 2017), it will be necessary to increase number of contacts between women during the perinatal and postnatal periods.

There are existing efforts to collect comparable data on patient perceptions of timeliness. Examples include the International Development Bank's (IDB's) Public Opinion Health Policy Survey; the OECD Health Care Quality Indicator Project; and the Service Provision Assessment component of the DHS, which collects data on problems with health facility wait time for 10 countries, with an average satisfaction rate of 67 percent.

To augment this work, and assess whether and how timeliness is being captured in the literature, the same methods were applied as for patient-centeredness (see Appendix D). Table 4-9 presents selected information on satisfaction with wait times presented in the academic literature over the past decades. Again, comparability is limited across countries, since questions are posed differently based on the tool used and since the definitions of waiting time or satisfaction vary.

The burden of preventable death as measured for a selection of vaccine-preventable conditions is presented in Table 4-10. These deaths are accrued among people who receive poor-quality care because they are not able to

TABLE 4-9 Patient-Reported Data on Satisfaction with Wait Time by Country, Published Literature

Country	Framing Within Survey Tool	% of Patients
Trinidad and Tobago	• A poor to fair rating for the length of the wait time	58
Ethiopia	• Fair or poor perceived wait time	26
	• Fair or poor general satisfaction with wait time at the clinic	43
Kenya	• Felt that the wait time was "a bit long" or "much too long"	40
South Africa	• Fair or poor satisfaction wait time before consultation with nurses	38
Tanzania	• Promptness rated as not very good	54
Uganda	• Dissatisfaction with wait time before getting an appointment	63
	• Spent more than 2 hours waiting for care in clinic	72
Iran	• Wait time for receiving medical services not suitable	26
	• Time the patient waited to be referred to a specialist not appropriate	24
	• Did not have prompt provision of medical and nonmedical services in a medical context	19

TABLE 4-10 Deaths and Years of Life Lost to Vaccine-Preventable Conditions (Low- and Middle-Income Countries [LMICs])

Vaccine-Preventable Condition	Quality-Related Deaths*
Hepatitis B	427,026[a]
Whooping cough	80,449
Haemophilus influenzae	29,948
Rotavirus (under 5 years)	212,836
Tetanus	42,168
Measles	87,133
Human papillomavirus (HPV) (cervical cancer)	57,362
Total	936,922[a]

*Difference between deaths in LMICs and high-income countries.

[a] This number was revised after the prepublication release.

realize actual coverage in a timely manner that would minimize the risk of dying. Deaths from hepatitis B accounted for the greatest burden of life lost to these conditions (427,026[2] deaths annually), followed by rotavirus (212,836[2]) and measles (87,133[2]). Hepatitis B, rotavirus, and measles accounted for the most years of life lost (46.8 million), as they affect primarily young children. Vaccine-preventable conditions accounted for 936,922[2] deaths annually in total.

Efficiency

Undertreatment may result in greater costs to health systems and individuals down the line if they develop complications that are costly to treat, while overuse, representing the delivery of a service that was unnecessary, will always result in greater cost. Box 4-4 presents a case study focused on one area of overuse that has been documented in the LMIC setting: inappropriate antibiotic prescribing.

Equity

Equity is a cross-cutting concern. Ideally, quality of care should vary little among subgroups according to race, ethnicity, wealth, religion, and so forth. Therefore, variation among subgroups can be used to characterize the extent to which quality care is equitably distributed. In particular, the dimension of equity captures the extent to which patients' sociodemographic characteristics (such as gender, ethnicity, geographic location, and socioeconomic status) influence the quality of care they receive. In this report, the main variations of interest are those in the burden of poor-quality care borne by populations living in LMICs compared with those in high-income countries. (Chapter 5 includes a breakdown of differences in the burden of ineffective care and patient experience for a subset of fragile states.)

Figure 4-3 illustrates the differences in mortality rates between low- and middle-income and high-income settings for a subset of the effectiveness conditions discussed previously. Across all conditions, the mortality rate attributable to ineffective care in high-income countries is lower than that in LMICs. The greatest difference in mortality rates across the two groups of countries is for heart failure, for which inpatient mortality differs by 9 percentage points. Inpatient mortality for COPD follows closely, with a difference of almost 7 percentage points.

Large differences in mortality for conditions affecting the under 5 years population also are seen. Mortality rates differ by 5.8 percentage points, for example, for diagnosed pneumonia in children under 5 years that remain untreated, with the rate in high-income countries being almost zero (0.2 percent). This differential is followed closely by neonatal mortality among

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[2] This number was revised after the prepublication release.

BOX 4-4
Efficiency Case Study: Overuse in Antibiotic Prescribing

The World Health Organization's program to promote "rational drug use" suggests methods for evaluating the appropriateness of drug prescription practices. Polypharmacy, or the total number of medicines prescribed, is a simple and commonly used indicator in these studies (Duerden and Payne, 2014); another straightforward strategy is quantifying the unnecessary use of antibiotics. Challenges to this kind of comparison include accounting for complexity at the patient level, which drives clinically relevant variation, as well as clinical contexts in which the standard of care for prescribing antibiotics is not clear. The table below summarizes results from studies using standardized patients, actors who present to the clinic with the same symptoms across providers. This approach addresses both of the above concerns by using clinical cases in which antibiotics should never be prescribed and ensuring the same symptom presentation to all providers.

As the table shows, inappropriate antibiotic prescribing is a significant problem across multiple continents. In India, for example, antibiotics are inappropriately prescribed for 54 percent of all patients presenting with tuberculosis. In China, that number is 51 percent.

Key Findings of Studies on Unnecessary Antibiotics Using Standardized Patients

Location of Study		Condition	Correct Diagnosis and No. of Unnecessary Antibiotics Given	Rate of Unnecessary Antibiotics Given
India	Delhi, India (urban)	Tuberculosis (TB)	8%	54%
	Madhya Pradesh, India (rural)	Angina, asthma, and diarrhea	8%	35%
China	Sichuan, Shaanxi, and Anhui Provinces (rural)	TB	25%	51%
Kenya	Nairobi (urban)	Angina, asthma, diarrhea, and TB	22%	55%

SOURCES: Daniels et al., 2017; Das et al., 2012, 2015; Mohanan et al., 2015; Sylvia et al., 2015.

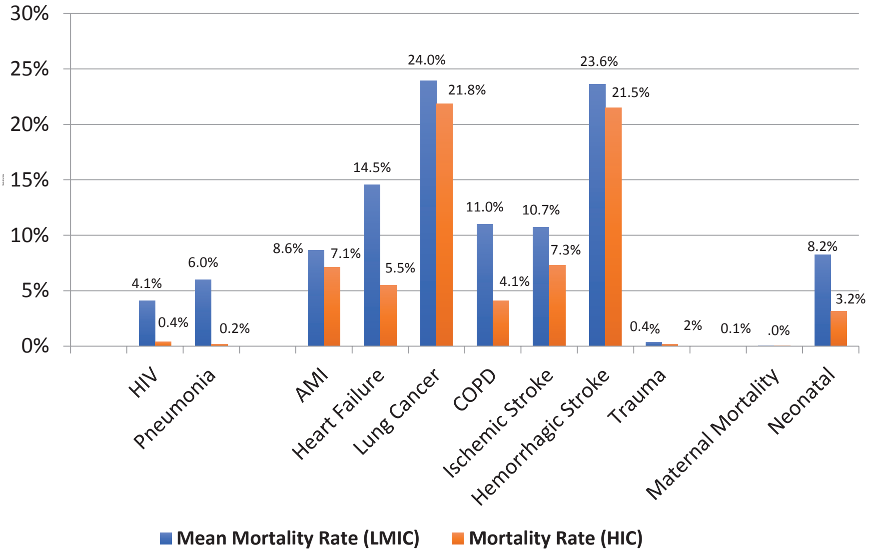

FIGURE 4-3 Variation in mortality rates for ineffective care, low- and middle-income versus high-income countries.
NOTE: AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disease; HIC = high-income country; HIV = human immunodeficiency virus; LMIC = low- and middle-income country.

children born in the presence of a skilled birth attendant, for which the difference between LMICs and high-income countries is 5.1 percentage points.

The difference in mortality rates among untreated, adherent HIV patients in LMICs and high-income countries is almost 4 percentage points, while the difference in mortality rates for inpatient ischemic stroke and hemorrhagic stroke is about 3.5 and 2.2 percentage points, respectively. The smallest differences are found for lung cancer (2.1 percentage points), acute myocardial infarction (AMI) (1.5 percentage points), trauma (0.2 percentage points), and maternal mortality (0.05 percentage points).

In addition to the gaps in mortality rates across conditions due to poor-quality care, LMICs and high-income countries have very different rates of diagnosis and treatment. Boxes 4-5 and 4-6 illustrate this point by highlighting differences in cervical and breast cancer screening rates across the two groups of countries.

THE BURDEN OF LOW-QUALITY CARE

The focus of this chapter has been on quantifying the burden of poor-quality care for that portion of the LMIC population that has *actual cover-*

BOX 4-5
Equity Case Study: Cervical Cancer

Screening is a well-proven method for preventing cervical cancer, dating back almost 70 years (Willoughby et al., 2006). With screening in combination with human papillomavirus (HPV) immunization and appropriate treatment for precancerous lesions, nearly all cervical cancer deaths are preventable. Yet, in 2015 nearly 270,000 women died from cervical cancer (WHO, 2018b), and 90 percent of those deaths occurred in low- and middle-income countries (LMICs) (WHO, 2018b). This striking geographic disparity highlights that a women's risk of dying from cervical cancer is driven largely by where she is born (Ginsburg et al., 2017). Limited patient education, poverty, and a lack of health care infrastructure and trained practitioners continue to be barriers to coverage of cervical cancer screening in LMICs (Catarino et al., 2015). As a result, the disease is often not identified until it is late-stage, at which point treatment is either ineffective or inaccessible (WHO, 2018b).

The World Health Organization (WHO) currently recommends that cervical screening be performed for all women aged 30 or older. Yet, despite this recommendation, the committee's calculation is that only 12.4 percent of women aged 16–69 had ever undergone cervical cancer screening in LMICs, compared with 72 percent of women in high-income countries (WHO, 2018c). The rates were 5.7 percent in Africa and 13.7 percent in Asia.

Although death from cervical cancer is preventable, WHO estimates a 67 percent increase in cervical cancer deaths by 2030, the vast majority occurring in LMICs. It is imperative that the international community support LMICs in developing national cervical cancer strategies, integrated with a national cancer control plan, to reduce the burden of unnecessary deaths from cervical cancer (CCA, 2015).

age. In total, the committee estimates that poor-quality care accounts for between 5.74 and 8.47 million deaths per annum and 106,928,005 YLD, or up to 15 percent of the 56.4 million annual deaths in LMICs reported by WHO in 2015 (WHO, 2015b). The bulk of these quality-related deaths are due to ineffective medical care (5.4 million). Unsafe care accounts for 2.6 million deaths, driven mainly by catheter-associated urinary tract infections, which are responsible for 1.6 million of those deaths. The burden of ineffective care is concentrated primarily in NCDs (4.11 million deaths) and trauma (2.1 million deaths), whereas ineffective care for communicable diseases included in this study accounts for 0.8 million deaths.

The majority of YLD due to poor-quality care were incurred by the population living with mental illnesses (79.1 million years), followed by untreated diabetes (13.1 million years), untreated HIV/AIDS (2.5 million years), and untreated TB (0.09 million years). These numbers are likely the lower bounds of the true burden of poor-quality care, as the underlying

BOX 4-6
Equity Case Study: Breast Cancer

Survival rates for breast cancer, the most common cancer affecting women worldwide, vary greatly by geographic region (Ginsburg et al., 2017). While 80 percent of women in high-income countries will survive breast cancer, this is the case for only 60 percent of women in middle-income countries and 40 percent of women in low-income countries (Coleman et al., 2008). This disparity is driven largely by a combination of low expenditures on breast cancer screening in low- and middle-income countries (LMICs) and the high financial and human resource demands of mammography (da Costa Vieira et al., 2017). As a result, women present with late-stage breast disease for which the chance of survival is low (WHO, 2018a).

According to the World Health Organization (WHO), only 50 percent of low-income countries have breast cancer screening programs or guidelines at the primary health care level, compared with 95 percent of high-income countries (WHO, 2015a). Even fewer have clearly defined referral systems (WHO, 2015a). Using WHO STEPwise approach to surveillance (STEPS) reports and the literature, we calculated that only 19.5 percent of women aged 40–59 in LMICs had ever had a mammogram, compared with 69.3 percent in high-income countries.

The incidence of breast cancer is expected to rise in LMICs (Ginsburg et al., 2017), which means more women will die unnecessarily simply because of where they were born. Thus, it is important to expand access to mammography and continue to build evidence for alternative screening modalities, such as clinical breast examination, for settings in which mammography is not feasible.

data used to construct these estimates are missing for many conditions and the estimates presented here are based on particular conditions and often restricted to a subset of countries.

Figure 4-4 illustrates the burden of ineffective care relative to total deaths for a subset of conditions. Ineffective care is responsible for a burden of death similar to that due to other factors, accounting for an average of approximately 25 percent of deaths caused by each condition overall. However, the proportion varies by individual condition, as does its relation to the overall prevalence of the condition. Whereas poor-quality care accounts for the majority of deaths from COPD (62 percent) and trauma (58 percent), the proportion is smaller for other conditions, such as diarrheal disease (17 percent), maternal mortality (16 percent), lung cancer (14 percent), and hemorrhagic stroke (1 percent), demonstrating how important access to care can be for these conditions.

Based on the variables presented throughout this chapter, the committee estimates the total economic burden of poor-quality care, measured as the cost of lost productivity to society, to be \$1.4 to \$1.6 trillion annually

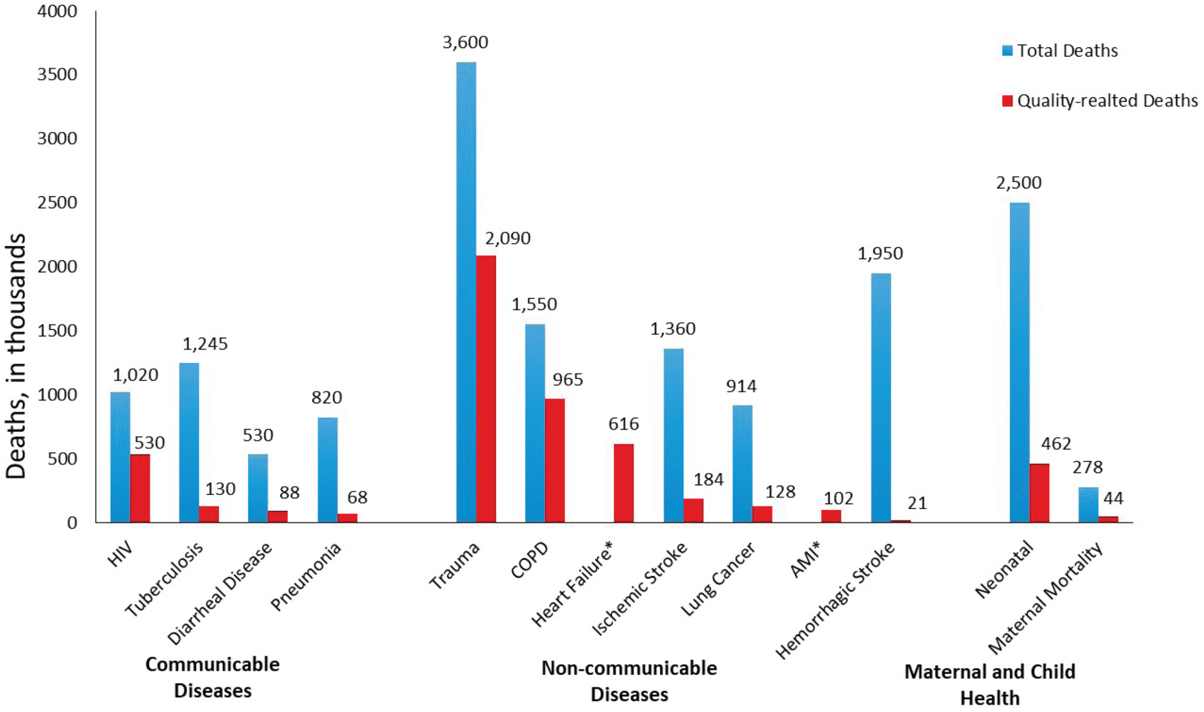

FIGURE 4-4 Total overall deaths and quality-related deaths by condition.
* Total deaths unavailable.

NOTE: AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disorder; HIV = human immunodeficiency virus.

SOURCE: Institute for Health Metrics and Evaluation, Appendix D (see Annex Tables 4-1 to 4-3 at the end of this chapter). This estimate is conservative, valuing the contribution of a life at 1 times gross national income (GNI) per capita in LMICs and includes years lost to both death (years of life lost, or YLL) and disability (YLD). The lower-cost estimate reflects the low estimates for each underlying variable throughout the chapter (variation in YLL and YLDs for each variable is informed by different estimates of incidence, mortality, and age, among other factors), whereas the high-cost estimate is in turn informed by the high estimates of the underlying variables. The high and low YLL and YLD estimates for each indicator are multiplied by one times GNI per capita to produce the calculated range of $1.4 to $1.6 trillion lost annually as a result of poor-quality care.

Note that this crude estimate of total cost is likely to be limited in many ways. As this range focuses only on the conditions identified above, it will underestimate the cost of poor-quality care more broadly. While these conditions represent the greatest mortality and morbidity burden in LMICs, they do not represent all of the conditions for which high-quality care can save lives or improve the quality of life. In addition, these estimates are based on the assumption that each life year saved would cost society one times GNI per capita. However, this will not be the case for all life years saved—there will be variations across the population.

Also note that this estimate reflects only the costs to countries in terms of the life years lost due to poor-quality care. However, poor-quality care will have other, more direct costs to countries and their health care systems. As noted earlier, for example, an adverse event (in most cases) and overuse (in all cases) will result in additional direct treatment costs to health systems and individuals.

Recently it was estimated that deaths from conditions amenable to high-quality care globally cost LMICs $6 trillion in 2015 (Alkire et al., 2018). This number includes deaths resulting from both poor quality and lack of access to health services for all amenable conditions. Our number builds on this work by examining a more specific component: the cost of poor-quality care, once people have access, for a subset of conditions. According to our estimates, poor quality accounts for approximately 23 to 27 percent of the total value of lost output estimated by Alkire and colleagues (2018).

DATA SOURCES AND LIMITATIONS

For this study, two main data sources were used to estimate the burden of poor-quality health care as defined by the variables outlined above. Where available, data were obtained from national or international databases. Where there was no available database for indicators of interest, estimates were obtained by carrying out systematic reviews of the peer-reviewed published literature over the past decade.

A total of 126 studies were used across the six safety indicators listed earlier in Table 4-1. Of these, 69 included incidence rates of ventilator-associated pneumonia; 14 decubitus ulcers; 23 venous thromboembolisms; 8 adverse drug events; 8 catheter-associated urinary tract infections; and 4 falls. Figure 4-5 illustrates the geographic representation of the published literature from which safety estimates for five of the six indicators (excluding catheter-associated urinary tract infections) were obtained, while Table 4-11 details this distribution by condition for selected countries.

Both Figure 4-5 and Table 4-11 illustrate the lack of available data on quality of care for the vast majority of LMICs, and entire geographical regions, in the peer-reviewed published literature. In some cases, however, such as adverse events and inpatient mortality, the literature was the only source of readily accessible data. Table 4-12 shows data sources for which quality indicators were available to inform the estimates in this chapter. For certain conditions, these databases represent a rich source of information on quality. However, these sources are few. Overall, there is a pressing need for the collection of data on quality of care globally.

VARIABILITY IN QUALITY: WHERE ARE THE GAPS?

Although the lack of quality data for many settings points to the need for more research, the data that are available reveal many variations in the quality of care. One theory advanced to explain this variation, at least in part, is the "know-do" gap introduced in Chapter 2, or the gap between the knowledge providers may have and their ability to apply that knowledge in practice. Evidence-based clinical guidelines provide standards for the provision of health care and are often known by and readily available to clinicians. However, the availability of these guidelines does not guarantee clinicians' adherence to them, and numerous disparities have been found in their application, leading to patients receiving care that is not evidence-based (Zhao et al., 2017). An observational study in rural India, for example, used vignettes and standardized patients, that is, "trained actors," to measure the performance of health care practitioners, finding stark differences in the treatments provided. For diarrhea, treatment with oral rehydration salts (ORSs) is commonly available. However, while 72.4 percent of practitioners reported that they would prescribe ORS in a vignette, only 17.4 percent actually offered the treatment to standardized patients presenting with symptoms of diarrhea (Mohanan et al., 2015). In many cases, moreover, whether ORS was being used correctly to actually have an effect on quality was unclear. In another study, measuring the use of clinical audits to monitor quality of care and management of cardiovascular disease (CVD), the authors found a lack of rigorous clinical trials measuring clinical outcomes for CVD, making it difficult to determine the true impact of

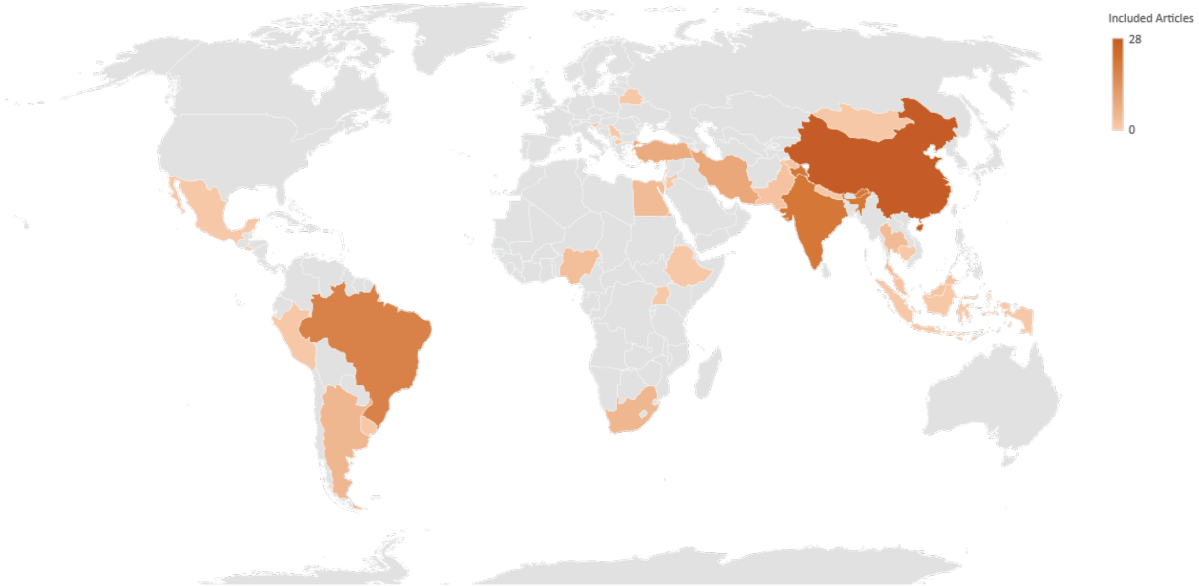

FIGURE 4-5 Availability of published literature in low- and middle-income countries (LMICs) on five safety indicators (2007–2017).
NOTES: See Appendix D for methods. Grey color in the map indicates regions where data were not available for analysis.

TABLE 4-11 Number of Studies by Country for Selected Safety Indicators

Country	Ventilator-Associated Pneumonia	Decubitus Ulcers	Adverse Drug Events	Falls	Venus Thromboembolism
China	9	2	1	1	15
India	17	0	4	0	0
Brazil	10	4	1	1	1
Nigeria	0	2	0	0	1
Ethiopia	0	0	1	0	0
Thailand	2	0	0	0	0
Other	31	6	1	3	6
Total	69	14	8	5	23

TABLE 4-12 Primary Data Sources and Number of Low- and Middle-Income Countries Represented for Selected Conditions

Condition	No. of Low- and Middle-Income Countries (LMICs) Included	Primary Data Source
HIV	114	Joint United Nations (UN) Programme on HIV/AIDS (UNAIDS) AIDSInfo, Institute for Health Metrics and Evaluation (IHME)
Tuberculosis (TB)	138	World Health Organization (WHO) Global Tuberculosis Report Database, IHME
Diarrheal disease	103	United Nations Children's Fund (UNICEF), U.S. Department of Homeland Security (DHS)
Diabetes	55	International Diabetes Federation, WHO STEPwise approach to surveillance (STEPS)
Neonatal mortality	134	World Bank DataBank, WHO Global Health Observatory (GHO)
Maternal mortality	134	UN World Population Prospects (WPP), WHO GHO, WHO BioMedical Admissions Test (BMAT) Model
Lung cancer mortality	139	World Bank DataBank, WHO GHO, IHME

care on quality. For LMIC settings, the authors could find no data on clinical audits for evaluation of CVD management (Zhao et al., 2017). Better understanding this know-do gap—especially for such high-burden diseases as diarrhea and CVD—is critical for improving quality. More studies are needed to ascertain which types of interventions are most successful in reducing this gap to increase the availability of high-quality care.

TRACKING PROGRESS IN QUALITY: WHERE ARE THE METRICS?

Health care quality is multifaceted and difficult to measure, but its measurement is essential nonetheless. Structural indicators, such as the numbers of clinics, providers, supplies, and equipment available, are helpful to know but are not true reflections of the quality of care. As health ministers said at a recent meeting, "We need to invest in measures that will help us assess whether our health systems deliver what matters most to people" (OECD, 2017b). Metrics used to measure quality as part of universal health care efforts, especially in LMICs, are stronger if they assess processes, and even better if they measure outcomes. Without good indicators and metrics with which to measure their baseline and progress, health systems will find it extremely difficult to know what is working in what context and where benchmarks should be set. Additionally, embracing the committee's recommended set of design principles (see Chapter 2) will require metrics that can track rates of improvement over time and progress toward achieving continual quality improvement instead of documenting scores at a point in time. Some successes can be highlighted, and lessons learned from high-income countries with strong quality improvement efforts can inform lower-resource settings so they can more quickly establish the measures needed and their feedback loops.

Patient-Reported Measures

With a growing shift toward increased patient-centeredness in health care and technology advances that make multiple data streams easier to integrate, measures of quality and satisfaction based on patient reports have become more common in health care. Patient-reported outcome measures (PROMs) are tools such as standardized, validated questionnaires used during the perioperative period to measure the efficacy of a clinical intervention from the perspective of the patient, rather than that of the provider (Kingsley and Patel, 2017). Various types of PROMs exist. Generic tools, for example, can measure a broad range of medical conditions to provide a holistic picture of quality of life and the cost-effectiveness of interventions. Disease-specific PROMs, on the other hand, examine individual aspects of a condition and their impact on a health outcome (Kingsley and Patel, 2017). Sometimes, combinations of patient-reported experience measures (PREMs) and PROMs can be helpful. For many large health systems in high-income countries, PROMs are being lauded as critical assets in real-time clinical care and as essential to measuring and improving the overall care system. Similarly, PREMs collect information on patients' views on their care experience, illuminating the quality of the dimensions of patient-centeredness and timeliness, as well as social support.

PROMs and PREMs will not be easy to implement globally, either within or across countries. They will require mechanisms for electronic surveys and ways to make the data actionable in real time, even when the workforce is facing increased productivity demands (Wagle, 2017). While PREMs can be useful, a recent systematic review calls for further validation work, especially for their use in emergency departments (Male et al., 2017). Other challenges entail reaching agreement on which indicators to measure (and which methods to use), determining how to ask the right questions, controlling the quality of data collection, avoiding response bias, and reducing survey fatigue (Coulter, 2017).

In an effort to better understand patient experiences globally, OECD commissioned a review of the use of national and international surveys. Based on this and other information-gathering efforts, the OECD Health Care Quality Indicator (HCQI) project developed a population-based survey to identify and share methods for measuring and reporting patient experiences (including PROMs) to improve the quality of indicators (OECD, 2018). The most recent Health at a Glance report, for 2017, includes the following indicators for quality and outcomes of care (for OECD countries) (OECD, 2017a):

- patient experiences with ambulatory care,
- prescribing in primary care,
- avoidable hospital admissions,
- diabetes care,
- mortality following ischemic stroke,
- mortality following acute myocardial infarction,
- hospital mortality rates,
- waiting times for hip fracture surgery,
- surgical complications,
- obstetric trauma,
- care for people with mental health disorders,
- screening, survival, and mortality for breast cancer,
- survival and mortality for colorectal cancer,
- survival and mortality for leukemia in children, and
- vaccinations.

While these indicators would not all be directly applicable to LMIC settings, the committee believes they can help LMICs better understand the varying levels of quality. Identifying the priority indicators for LMICs related to preventive, primary, chronic, and acute care and allowing countries with similar resources or infrastructures to learn from one another would be a valuable step forward.

International Consortium for Health Outcomes Measurement

The International Consortium for Health Outcomes Measurement (ICHOM) was founded in 2012 to address the challenges of variability in measurement and definitions of what matters most to patients across different countries. Global comparisons and learning are difficult without a common language and understanding of measurement. And while process and structure are important components of the Donabedian equation (see Chapter 2), outcomes are the ultimate measure of success in health care. Going beyond purely clinical outcomes in the quest for patient-centered care to understand what life will be like after treatment, surgery, or an illness will be important decision-making information for patients. As of 2018, ICHOM has published standardized metrics and risk-adjusted variables for 23 major conditions covering 50 percent of the global disease burden in developed countries. These metrics are being adopted by more than 650 hospitals and provider organizations around the world (WEF, 2018).

Taking the vision a step further, in 2017 ICHOM began a collaboration with OECD to make patient-centered care the "new normal" in health care systems (ICHOM, 2017). It will begin working toward globally standardized PROMs collected in key disease areas, which can then be aggregated and analyzed to support all levels of health system decision making, increase learning, and move toward value-based care. This large amount of data can allow for a massive increase in the exchange and accessibility of information for learning among countries.

These examples and the number of facilities and organizations already using the standardized measures are evidence that health care leaders are increasingly attempting to tackle the transformation of health care in a systematic way. Thus far, however, these efforts have been limited to OECD countries, and a gap remains in appropriate standards and measures that would apply to LMIC settings. As mentioned previously, leadership will be paramount for filling this gap, not only at the health system level but also at the regional and national levels (WEF, 2018). Such collective action will be necessary to realize the benefits that new care models can deliver.

Testing Indicators in Low-Resource Settings

In his remarks to the committee, Mondher Letaief of WHO's Eastern Mediterranean Regional Office advocated for the development of appropriate tools for a more comprehensive review of quality at the primary care level, and noted that these tools should be meaningful and foster continuity of care. To advance the development of a tool for assessment of quality, he presented the findings of desk and literature reviews resulting in a multistep validation and expert meeting to pilot a core list of 34 primary care indicators in five countries in the Eastern Mediterranean. The pilots and subsequent consultation revealed great variation in performance among the five countries, demonstrating the need for tailoring of interventions based on the country's context, a call echoed throughout this report for adapting to local context and culture. During the expert meeting, participants highlighted the importance of communicating the value of these types of indicators to those working on the front lines (EMRO, 2015). Buy-in from health services leadership can help establish a broader quality management strategy and support wider deployment of the indicators and quality assessment tools.

SUMMARY AND RECOMMENDATION

Health care today in all settings and all nations suffers from high levels of poor quality in many dimensions. This global quality chasm prevents patients and communities from reaping the potential benefits of effective care. The current forms, habits, and models of care are incapable of bridging this chasm. Many metrics for measuring quality already exist. These metrics are established, for example, in OECD countries, and are ready and fit for use to support learning and improvement in health care systems in all settings. Although process measurements are valuable, patient and population outcome metrics are much more important. Choosing existing indicators from publicly available resources rather than investing heavily in developing new, local ones can allow health systems in low-resource settings to match or surpass high-resource settings in transparency and knowledge of performance. Excessive measurement, where metrics are chosen because of their ease of calculation as opposed to their utility for assuring and improving quality of care, can be harmful, as demonstrated in many high-income countries. LMICs need not repeat these mistakes. Metrics used for exhortation or reprisal are counterproductive and usually lead to gaming and other behaviors that worsen the quality of care.

> *Conclusion: While defining and achieving minimum standards, or "quality assurance," is often appropriate, it is rarely sufficient. Instead,*

efforts aimed at improving care over time are more valuable. Proper quality measurement can help assure both a basic standard of care and improvement in that care over time. Maximally useful measurement, whether by health care leaders and policy makers or providers, is intentional, selective, and parsimonious; aligned with core quality improvement goals; and implemented with respect for the implications for culture and effectiveness at the front lines of care.

Recommendation 4-1: Embed and Refine Quality Measurement in Health Care
Nations, regions, and health care organizations should routinely and transparently measure and report on domains of quality, especially their relevant outcomes, to support learning, as well as foster accountability and trust in the health care system.

- Ministries of health and multilateral organizations should maintain ongoing, collective efforts to identify and implement a core set of quality metrics for lower-resource settings (such as those developed by OECD, as well as standards and outcome metrics from the International Consortium for Health Outcomes Measurement) to allow for benchmarking and learning.
- Health care leaders should prioritize patient-reported outcome measures and patient-reported experience measures as well as health outcome metrics for assessing quality whenever possible.
- Governments and organizations should track metrics frequently to assess performance and improvement over time. They should make performance transparent to all parties through such mechanisms as public reporting, and use metrics and co-design with three goals in mind: accountability to patients, building trust in the system, and learning.

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ANNEX TABLE 4-1 Excess Costs Resulting from Safety Events Occurring in Low- and Middle-Income Countries Annually, Low Estimates (1 × gross national income per capita in millions)

Safety Event	Deaths (low and high range estimates)	Years of Life Lost (YLL) (low and high range estimates)	Years of Life Lived with Disability (YLD) (low and high range estimates)
Adverse drug events	$1,041 (828–1,241)	$33,580 (30,879–45,719)	$800 (637–955)
Falls	$190 (183–199)	$5,844 (5,549–6,117)	$1,304 (1,253–1,362)
Catheter-associated urinary tract infection	$7,613 (7,268–7,955)	$140,843 (134,452–147,164)	$634 (606–663)
Ventilator-associated pneumonia	$295 (259–338)	$13,103 (11,463–15,286)	$79 (70–91)
Ulcers	$1,118 (1,028–1,211)	$28,651 (26,255–31,541)	$8,032 (7,381–8,693)
Venous thromboembolisms	$1,972 (1,775–2,188)	$60,618 (54,025–67,529)	$5,258 (4,733–14,003)
Total	**$12,229** **(11,341–13,132)**	**$282,639** **(262,623–313,356)**	**$16,107** **(14,680–25,767)**

NOTE: Variance, or high and low estimates, is informed by variation in estimated incidence, mortality, and age for the underlying indicators (which are presented throughout this chapter).

ANNEX TABLE 4-2 Excess Costs Resulting from Ineffective Care for Communicable Diseases in Low- and Middle-Income Countries Annually, Low Estimates (1 × gross national income per capita in millions)

Communicable Disease	Deaths (low and high range estimates)	Years of Life Lost (YLL) (low and high range estimates)	Years of Life Lived with Disability (YLD)
HIV	\$2,474	\$122,539	\$1,881
Diarrheal disease (under 5 years)	\$413	\$33,490	—
Tuberculosis (TB)*	\$526 (463–588)	\$38,328 (33,784–42,871)	\$1,002
Pneumonia (under 5 years)	\$315 (306–324)	\$25,526 (24,828–26,306)	—
Total	**\$3,728** **(3,656–3,799)**	**\$219,883** **(214,641–225,206)**	**\$2,883**

NOTES: In addition to sources of variation described above, for certain indicators (such as TB), variation is informed by estimates from different sources of mortality (e.g., range of estimates in how comorbidity with HIV might impact TB survival).

*TB is an estimate of absolute cost as opposed to excess cost (compared with high-income countries) because of the low prevalence of TB in high-income contexts; all costs can be roughly assumed to be "excess" for LMICs.

ANNEX TABLE 4-3 Excess Costs of Deaths and Disability Resulting from Ineffective Care for Noncommunicable Diseases in Low- and Middle-Income Countries Annually (millions)

Noncommunicable Disease	Deaths (low and high range estimates)	Years of Life Lost (YLL) (low and high range estimates)	Years of Life Lived with Disability (YLD)
Lung cancer	$607	—	—
Acute myocardial infarction	$474 (66–593)	$10,443 (1,462–13,061)	—
Heart failure	$2,875 (565–3,084)	$63,280 (12,446–67,888)	—
Ischemic stroke	$856 (208–1,193)	$12,487 (3,045–17,402)	—
Hemorrhagic stroke	$96 (23–134)	$1,850 (451–2,578)	—
Chronic obstructive pulmonary disease	$4,503 (572–7,212)	$37,440 (4,758–59,956)	—
Injury and trauma	$9,776	$451,145	—
Diabetes mellitus	—	—	$120,394
Depression	—	—	$208,918
Anxiety	—	—	$83,504
Bipolar disorder	—	—	$15,602
Schizophrenia	—	—	$23,359
Substance abuse	—	—	$19,502
Total	**$19,187 (11,817–22,480)**	**$576,645 (473,307–612,030)**	**$470,383**

NOTE: As in Annex Tables 4-1 and 4-2, variance, or high and low estimates, is informed by variation in the underlying indicators presented throughout this chapter.

5

High-Quality Care for Everyone: Making Informal Care Visible and Addressing Care Under Extreme Adversity

Key Findings

- Vast numbers of people receive care from informal providers worldwide, with utilization rates in some countries exceeding 75 percent. When comparing trained and untrained practitioners, studies have found small differences in performance with regard to adherence to approved checklists and accuracy of diagnosis. Often the breakdown in quality is translating knowledge to practice.
- Interventions should not rely on individual-level behavior changes alone, as they are extremely difficult to influence. Rather, a combination of training with market-based and regulatory approaches (e.g., incentives and accountability), along with rigorous evaluations, is most successful.
- An estimated 22.7 percent of quality-related neonatal mortality deaths occur in fragile states annually, despite those states representing only 8.5 percent of the population of low- and middle-income countries.
- In 2016, 1.8 billion people, or 24 percent of the world's population, lived in fragile contexts, a figure predicted to grow to 3.3 billion by 2050. Little is known about the health care received by people in these settings.

Much of this report addresses the quality of care provided by formal health care systems in more or less well-organized settings. In many parts of the world, however, significant portions of the population lack access to high-quality, formal providers—either public or private—so they must seek care elsewhere. For millions, this means receiving care from informal providers (IPs) who lack formal training but are well known in the community.

In the Indian state of Madhya Pradesh, for example, 77 percent of rural primary care is provided by IPs (Das and Mohpal, 2016). Millions more people are suffering in fragile or failed states, or in humanitarian relief settings without strong oversight or regulation of care. The majority of these sources of care operate outside of formal health care systems, meaning that their patients are receiving care that may not be regulated, measured, or coordinated with other providers. In such settings, follow-up over time may also be extremely difficult. Taken together, these alternative care systems and the corresponding lack of scrutiny and transparency subject millions of people worldwide to care of completely unknown quality.

This chapter begins with an overview of what is known about the demographics and profiles of IPs, the types of work they do, the patients they treat, and the quality of care they deliver. The chapter then explores settings of extreme adversity, estimates the number of people requiring health care in such settings, attempts to shed light on their specific needs, and briefly reviews relevant research and best practices. The chapter ends with a summary and recommendations.

INFORMAL HEALTH CARE PROVIDERS: OVERVIEW

The size of the informal health care sector varies substantially by region—for example, it accounts for 55 percent of all providers in India (Prasada Rao et al., 2017), 77 percent in Uganda (Konde-Lule et al., 2010), and 87 percent in Bangladesh (Ahmed et al., 2009). But it is, by all accounts, enormous—far too large to be ignored in a global agenda for improving the quality of care. Understanding how this sector functions is critical to improving health in low-resource settings (George and Iyer, 2013).

Who Are Informal Providers and Who Is Seeking Their Care?

In light of an inconsistent definition of IPs, Sudhinaraset and colleagues (2013) developed a helpful working definition, of which the committee selected three components:

> Caregivers lacking formal training with a defined curriculum who also meet at least two of the following three criteria:
>
> - receive payments (usually undocumented) from patients rather than institutions;
> - operate outside the purview of regulations, registration, or any official oversight; and
> - may be part of professional associations that do not have certification or regulatory authority.

Using this definition, Sudhinaraset and colleagues (2013) found that IPs had very high patient loads and sometimes represented more than half of all providers in Asia and Africa. They also found that the health sector globally has a significant number of IPs who operate in a variety of health areas. They may include community health workers (CHWs), allopathic providers, traditional healers, faith healers, homeopaths (Ahmed et al., 2009), or often people who are trained in one area but practicing in another—for example, trained pharmacists acting informally as doctors in their neighborhoods. The committee agrees with this working definition but would remove the part regarding training, as that becomes very difficult to define and categorize with CHWs. Instead, the committee highlights the importance of these IPs operating beyond the purview of regulatory oversight, being unlicensed, or providing a service beyond the scope of their license.

While IPs can fall into several categories, a study in Bangladesh, India, and Nigeria found that the majority are fairly well educated, having completed levels of secondary school and even beyond (Center for Health Market Innovations, 2010). While most lack formal medical training, most have some type of training, such as courses offered commercially, public training for CHWs, or some type of apprenticeship. Cases do exist of fraudulent IPs who are trying to deceive patients and who are driven more by a profit motive than by any strong desire to offer care of high quality (Bloom et al., 2011; Cross and MacGregor, 2010). But several studies demonstrate that the motivations of many IPs go well beyond only making money and include, for example, pursuit of social standing, knowledge acquisition, and community solidarity (Sieverding and Beyeler, 2016). For instance, volunteer CHWs in South Asia and sub-Saharan Africa have espoused social recognition and personal empowerment as reasons for becoming an IP, not linked directly to financial gain (Glenton et al., 2010; Gopalan et al., 2012; Kasteng et al., 2016). Likewise, medicine vendors in northwest Cameroon see themselves as gatekeepers for access to strong medications and take that responsibility seriously (Hughes et al., 2013).

Many people use IPs because they are available, while formally trained nurses and physicians are in very short supply. For example, the ratio of traditional healers to population in Africa is 1:500, while the ratio of medical doctors to population is 1:40,000 (Abdullahi, 2011). This imbalance is more pronounced in rural than in urban areas; urban populations in African countries typically have greater access to formal providers. Yet, even urban residents sometimes use traditional medicine more often than they use formally trained caregivers (Bamidele et al., 2009). Even in countries with easy access to well-established formal care, such as Singapore and South Korea, people commonly still use traditional medicine because of cultural or historical influences (WPRO, 2012). In India, most people seek care in the private sector, where providers' qualifications vary from a medical degree to one based on traditional medicine (e.g., Ayurveda) to no training at all. Most visits, however, may tend to be to underqualified providers, as indicated by a study on health-seeking behavior in rural India. That study found that 70 of every 100 visits to a health care provider were to unqualified private providers, whereas 8 of every 100 visits were to qualified public providers (MAQARI Team, 2011).

How Good Is the Care in the Informal Sector?

Health care providers of any kind—whether providing care, advising on treatment options, or dispensing medications—should ideally be trusted professionals. But the large numbers and diverse nature of IPs, who typically operate outside of regulatory oversight, raise legitimate concerns about the quality of care they provide. The default assumption tends to be that because IPs lack standard qualifications, they deliver services of substantially lower quality relative to formally trained medical doctors, nurses, and pharmacists. But actual data on that comparison are scarce, and findings are mixed. The relevant evidence is difficult to parse, in part because IPs are such a highly variable group. Some IPs, for example, act as apprentices to formal doctors for several years, while others have almost no involvement in the formal health care sector before setting up shop.

Because a large proportion of people in India seeks care from IPs, that nation has yielded some of the best data on the topic. Gautham and colleagues (2014) studied IPs in two different settings in India and found that more than two-thirds were able to manage common conditions competently, although they did prescribe more drugs than necessary. Das and colleagues (2012) used a gold standard method—standardized patients (that is, people recruited and trained to simulate symptoms and complaints)—to assess quality of care in rural and urban India across a large number of studies, and found only modest differences between trained and untrained practitioners in their adherence to approved checklists. They also found no differences in the likelihood of providing an accurate diagnosis or correct treatment (Das et al., 2012). A study in Nigeria found that medicine vendors—a common type of IP—knew about the government malaria policy, with nearly 60 percent indicating correctly that artemisinin-based combination therapy (ACT) was the first-line treatment. More than three-quarters of those studied took adequate patient histories, and nearly half prescribed ACT properly (Center for Health Market Innovations, 2010).

While the evidence suggests that IPs are only modestly less knowledgeable than formal providers, factors other than the store of knowledge also drive the quality of care. It is known, for instance, that a very large know-do gap exists in health care delivery throughout the world (see Chapter 2). That is, providers—whether formal or informal—often fail to act on knowledge that they appear to have. In low-resource settings, there can be a substantial difference between what providers appear to know in standardized testing (such as clinical vignette testing) and what they do when caring for an actual patient (see also Chapter 4) (Mohanan et al., 2015). A study conducted in Delhi, India, compared the performance of formal providers on vignettes with their performance when a standardized patient presented with the same symptoms. The researchers found that for standardized patients, the doctors were less likely to recommend appropriate tests and to make referrals than they were in the vignette-based testing (10 percent versus 73 percent) (Das et al., 2015). These results highlight that a lack of knowledge among providers is not necessarily the limiting factor for high-quality care in low-resource settings. Instead, providers often have knowledge that they do not translate into practice. Much more research is needed on how to help providers—both informal and formal—strengthen the connection between knowledge and practice.

Just as a knowledge base is insufficient to ensure high-quality care, the same is true for structural inputs alone. Studies find only very weak links between the structural inputs to health care facilities, such as medical equipment and patient loads, and the quality of care. This is the case in both rural and urban environments. Researchers argue that quality gaps cannot be closed by simply conducting more training or adding more doctors. Instead, as discussed in Chapter 2, quality improvement on all fronts will require systemic changes and proper designs to make a holistic impact on health care quality. Examples of such systemic changes include increasing accountability through community monitoring (Björkman and Svensson, 2009), finding ways to attract clinicians who are intrinsically motivated, and motivating current employees—whether in the formal or informal sector—through encouragement and scrutiny from peers (Brock et al., 2012). Since IPs operate outside of regulatory authority, the level of quality of the care they deliver is largely unknown. Countries need a national strategy for identifying these IPs and for measuring their work processes and outcomes.

What Are the Benefits and Risks of Care Received from Informal Providers?

While many organizations, especially those representing formal providers, are skeptical of IPs, the reality is that IPs represent a significant portion of providers and that efforts to eliminate them—or to ignore them—have not been successful. Whatever a nation's strategy toward IPs may be, understanding both the benefits and risks of their care is critical to making wise decisions. In countries without robust health care coverage, patients are often limited to seeing providers whose fees they can afford. Because IPs are relatively inexpensive, they are often the providers of choice for ailments that are not life-threatening. A study in Bangladesh, for example, found that the median cost of treatment by a formal physician was 5 times higher than that of a village doctor and 15 times higher than that of a traditional healer (ICDDR, B, 2009). IPs also typically have more forgiving payment policies, such as sliding scales or deferred payment options (Sudhinaraset et al., 2013).

Beyond affordability, another benefit to using IPs is that they are in some ways more accountable and more familiar. Many people choose to use IPs even when there is, at least theoretically, a public clinic nearby that provides free services. The reasons for this are complex but include the high rates of absenteeism in public clinics and the greater degree of familiarity with private IPs, since they often have strong local roots in their own communities. Although IPs may not be formally regulated, some argue that it is easier to keep them "in check" relative to formal providers since their practice depends on maintaining good relationships with their community. Their accountability is, in this sense, direct. Conversely, formal providers working in public clinics are often from outside the local community and are posted in those clinics for short periods of time. A study in India found that more than half of the IPs surveyed were born in the same block or district where they practiced, rendering them well-known and often trusted members of the community (Center for Health Market Innovations, 2010). Typically, they are cognizant of or aligned with the values and beliefs of the people in their community. They may also be more flexible than the formal care system in the services they provide. As researchers found in Uganda, for example, they may be more willing to make home visits, especially with respect to women's reproductive care (Kiapi-iwa and Hart, 2004). While this issue may become less important in the future if formal health care systems shift to become more community-based, for now, getting to a formal clinic or hospital in many places is enough of a barrier to lead patients and families to choose IPs instead. There also is typically less turnover among IPs than in formal facilities, increasing their familiarity to their community.

One example illustrating the benefits is an integral part of India's National Rural Health Mission. The goal is to provide every village in the country with an an accredited social health activist (ASHA), who acts as a trained CHW serving as a link between the community and the public health system. While their formal medical training is limited, ASHAs act as a primary source of education on health practices and aim to increase the utilization of health services (National Health Mision, n.d.). The ASHA program was launched in 2005, and its work was key in reducing the infant mortality rate from more than 50 to 34 deaths per 1,000 live births by 2016 (IANS, 2017).

Of course, care from IPs carries substantial risk. Some examples associated with traditional and complementary medicine include use of poor-quality or counterfeit products and treatment by unqualified practitioners who can miss or delay diagnoses, with dire clinical consequences. IPs can be sources of misleading information or be directly responsible for adverse medical events, such as side effects or harmful treatment interactions (WHO, 2013). A review in Bangladesh in 2009, for example, found that just 14 percent of the drugs used by IPs to treat diarrhea, pneumonia, fever, and colds were appropriate (in line with treatment guidelines) (Bhuiya, 2009). Authors of the studies described above in Bangladesh, India, and Nigeria also caution that IPs have been shown to engage in detrimental, unnecessary, and wasteful medical practices, such as conducting insufficient testing prior to diagnosis, performing unnecessary injections, and overprescribing (Center for Health Market Innovations, 2010). Of course, these problems are also found among formal providers, sometimes at nearly comparable rates.

What Can Be Done to Improve Care in the Informal Sector?

What can nations do to improve care in the informal sector? The dearth of formal research on the patterns, behaviors, and outcomes of that sector limits strong conclusions, but research does support some sensible steps. While the many different contexts and types of IPs make generalized recommendations difficult, one critical issue across the board is addressing the gap between IPs' knowledge and practice. It is also important to understand where in the scope of practice IPs can contribute positively to a health system. In the end, of course, each country needs to have a contextual understanding of how its IPs fit within and serve the country's cultures and populations. Research suggests several plausible steps toward improvement, some of which are described below: acknowledging IPs, leveraging traditional healers, defining scopes of practice, and implementing various types of interventions.

Acknowledging Informal Providers

The notion of formalizing IPs is hotly contested, but evidence supports at the very least identifying them and incorporating them to supplement the health care workforce in many areas of the world, as well as leveraging their strengths within their trusting communities (discussed in the following section). Researchers argue that the formal health care sector should design a strategy for integrating IPs into the mainstream system to ease pressure on a typically overburdened system, especially in low-resource settings such as Bangladesh (Ahmed et al., 2009). This strategy would be especially important for middle-income countries that need to reach their poor and vulnerable populations to overcome the historical inequities in their health care systems. Because drug vendors are one of the most common types of IP, working with them could be a first step in engaging the informal health care sector. Bringing them into the mainstream health care system "to provide appropriate drug dosages and referrals" could help reach poorer populations (Sudhinaraset et al., 2013, p. 9). For example, a high percentage of Tanzanian citizens obtain their medicines from private shops, often located close to their homes with convenient hours. However, prior to 2003 the sellers were often unregulated or unlicensed, illegally selling prescription-only products, or untrained (Embrey et al., 2016). In 2003, a public–private partnership—the Accredited Drug Dispensing Outlet (ADDO) program—developed an accreditation scheme and increased training, education, and supervision of staff responsible for dispensing medicines. An evaluation of ADDOs in the region of Ruvuma after 8 years of implementation showed the program to be not only successful, but also sustainable and scalable (WHO, 2014). Traditional medicine practitioners offer another entry point. Ahmed and colleagues (2009) found that using institutional training, registration, and licensing to make traditional medicine practitioners more reliable might decrease health care costs and the demand pressures faced by a health care system.

With the global shift toward person-centered health care systems, the goals of providing services near the patient, integrating care across the continuum, and linking care to community services are paramount. Although IPs are currently weakly regulated in most places, they can, if operating in the same community as formal providers, offer additional capacity for screening, referrals, coordination, and case management. Given the realities of many low-resource settings, it is unclear whether an accessible, high-quality health care system made up only of formal providers is achievable, at least in the conceivable future (Sieverding and Beyeler, 2016). While some policy makers may see a purely formal system as the ultimate goal, in the interim, acknowledging, incorporating, and improving the care of IPs may be a more pragmatic approach to a person-centered health care system. Many IPs interviewed in rural Nigeria consider themselves to be part of the village health system, and they believe they play an important role in the community's primary care (Sieverding and Beyeler, 2016). To take full advantage of that notion, it will be important to develop interventions to support collaborative working relationships between the formal and informal sectors. As a start, the committee believes countries could include IPs in counting so that more knowledge can be generated about their practices and patients. In addition, countries could train IPs, where appropriate, to help buttress a formal health care sector that badly needs additional workforce capacity.

Leveraging Traditional Healers

Traditional healers are often the first point of consultation in many communities worldwide for health issues. In some countries, they work largely within the formal system; in others, they do not (Omaswa, 2006). As of 2003, traditional medicine made up 40 percent of all health care delivered in China, 71 percent in Chile, 40 percent in Colombia, and 65 percent in rural India (WHO, 2003). In parts of Africa, herbal medication is the primary treatment for approximately 60 percent of children with febrile symptoms, and in North America and Africa up to 75 percent of people living with HIV/AIDS use traditional medicine (WHO, 2003). Even in developed countries, traditional and alternative medicines have grown in popularity.

Leveraging IPs' familiarity and access to community populations is one potential and feasible way to improve the quality of care in those communities. A Cochrane review on implementation strategies for health systems, for example, found that training traditional healers may improve their knowledge and patient management and referral practices for sexually transmitted diseases and HIV (Pantoja et al., 2017). Many countries are beginning to realize the value that traditional healers can bring to their formal health care systems. To meet this new demand, the World Health Organization (WHO) has developed an updated strategy on Traditional Medicine for 2014–2023 with two key goals:

> (1) to support member states in harnessing the potential contribution of traditional medicine to health, wellness, and person-centered health care; and (2) to promote the safe and effective use of traditional medicine through the regulation of products, practices, and practitioners. (WHO, 2013, p. 6)

These two goals could guide countries in integrating various types of IPs into their formal networks to extend their reach and coverage of populations while still ensuring safety and quality. WHO cites the projected rise in the global burden of chronic disease as the most pressing reason for strengthening this collaboration between the conventional medicine and traditional medicine sectors (WHO, 2013).

Defining Scopes of Practice

Another approach the committee believes can benefit quality of care is defining the scopes of practice of IPs. As discussed previously, highly variable and diverse groups of practitioners make up the broader IP category. For this reason, and because of the lack of acknowledgment and oversight from regulatory bodies and country governments, it is extremely difficult to tell when IPs are operating within the scope of practice in which they can perform competently. A study in South Africa, for example, found that traditional healers practice with guidelines often unwritten and legally unregulated—the opposite of the current practice of South African formal health care practitioners regulated by statute (Duvenhage and Louw, 2016). And a recent study on preeclampsia in Nigeria found that CHWs interviewed did not regularly give antihypertensives for emergency preeclampsia and eclampsia, even though such treatment is dictated by international guidelines, because many were concerned that doing so was outside of their scope of practice (Sotunsa et al., 2016).

On the other hand, some types of IPs, such as CHWs, have often had training and are familiar with their scope of practice. Many countries have standard tiers for CHW types with defined scopes of practice. Ethiopia, for example, has a two-tiered system through its Health Extension Program—the Health Development Army (HDA) volunteers and the Health Extension Workers (HEWs) (Zulliger, 2014). The HDA lower-level volunteer cadre works just a few hours a week in the community in the areas of newborn nutrition and family practices, while the HEWs, a higher-level cadre, are trained for longer, with a scope of practice that includes treatment of children with malaria, pneumonia, diarrhea, and newborn sepsis (Leon et al., 2015).

Since 2002, WHO has been calling for defined scopes of practice for traditional healers as part of a regional strategy for traditional medicine, with the responsibility for establishing standards and training resting with practitioners, educational institutions, and governments (WPRO, 2012). This may not be accomplished overnight, but together with the committee's previous call to acknowledge and formally count IPs, an important step forward would be for countries to define scopes of practice for various types of IP where possible and appropriate. With reference to the design principles set forth in Chapter 2, the transformation process the committee calls for throughout this report emphasizes continual feedback, learning, and improvement. Accordingly, those whose scope of practice is already defined could advance this transformation by connecting with other similar practitioners and providers and revisiting gaps and models, as in the Nigeria example above, to improve their country's health care quality.

Implementing Interventions

The most common recommendations for improving informal care found in the systematic review of Sudhinaraset and colleagues (2013) are for educational interventions, such as capacity-building training, patient education programs, and continuing education requirements. While these interventions would be directed at IPs, there is also a need to educate formal providers in traditional or complementary medicine to augment their understanding. Numerous universities in the Economic Community of West African States have already recognized this need and included transcendental meditation in their medical and pharmaceutical curriculum (AFRO, 2011). A large number of studies also call for oversight and regulation of IPs, as well quality assurance by way of professional associations. Process interventions were frequently recommended as well, including such activities as promoting dialogue and developing working relationships among formal and informal providers (Sudhinaraset et al., 2013).

In a separate review, Shah and colleagues (2011) present a conceptual framework for considering the types of interventions that could be implemented in the informal system (see Figure 5-1). Successful interventions for child health involve changing the environment of incentives and accountability, focusing on the higher levels of the health system illustrated in the committee's framework in Figure 2-2 in Chapter 2. In Uganda, for example, common goals and expectations for diagnosis and treatment of child illness were developed through negotiation sessions with private providers, leading to significant improvements in the majority of items measured (Tawfik et al., 2006).

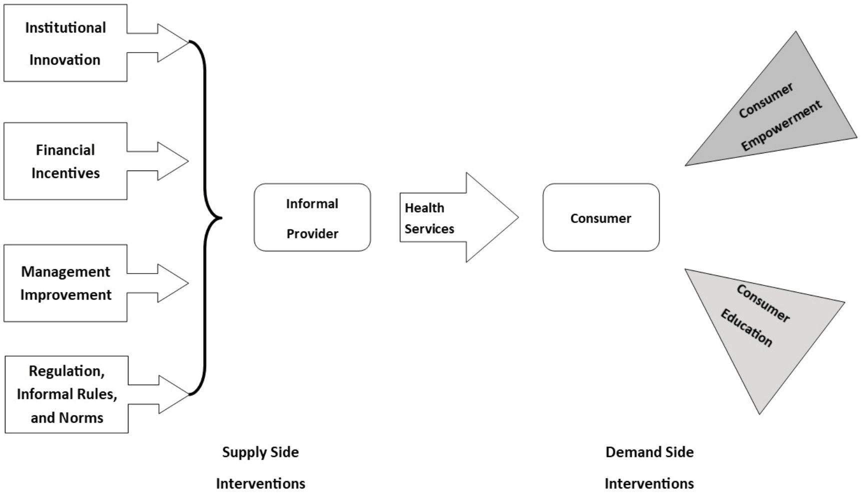

FIGURE 5-1 Interventions to improve health services in the informal sector.
SOURCE: Shah, N. M., W. R. Brieger, and D. H. Peters. 2011. Figure in "Can interventions improve health services from informal private providers in low and middle-income countries? A comprehensive review of the literature." *Health Policy and Planning* 26(4):278. By permission of Oxford University Press.

It should be noted that very few studies have called for increased access to formal providers to reduce the need for IPs, partly because such efforts are unlikely to be successful. Sudhinaraset and colleagues (2013) recommend that interventions not be reliant on individual-level behavior changes alone as they are extremely difficult to influence; rather, a combination of market-based and regulatory approaches with rigorous evaluations may prove to be successful for improving the quality of informal care. They identify quality improvement strategies that combine providing training with improving market conditions, such as provider incentives and accountability, as being most successful (Shah et al., 2011).

Supporting this finding, a 2010 review identified training as one of the most common interventions, but ineffective on its own. Training was most successful when paired with initiatives that changed institutional relationships and incentives (Shah et al., 2011). More specifically, studies employing training alone found positive outcomes just 21 percent of the time, but when training was combined with other strategies, the rate of positive outcomes was nearly 60 percent (Shah et al., 2011). While this finding does not negate the importance of training providers at the community level, more successful approaches included measurement and disclosure of performance. In a large randomized controlled trial, Das and colleagues (2016) found that a 12-week intervention that entailed training IPs substantially improved case management rates—the IPs were more likely to make the correct diagnoses and offer proper treatments. Yet, while these results are promising, the intervention unfortunately had no impact on rates of unnecessary prescribing. Truly understanding the effectiveness of training will require more rigorous research designs to document longer-term outcomes and better incorporate contextual factors (Shah et al., 2011). High-quality intervention research targeting IPs and measuring population-level outcomes is a major need.

What Is Left to Understand?

Much more is unknown than known regarding IPs, even though a very large proportion of the world's population seeks them out frequently to meet health care needs. At a foundational level, common definitions of IPs and a common understanding of what types of providers exist and what services they provide are needed. The systematic review of Sudhinaraset and colleagues (2013) calls for a better understanding of patient choices and knowledge. And crucially, research is needed to examine the quality of IPs, beyond just their knowledge base, since knowledge alone has been proven to be a poor indicator of clinical quality.

In addition, studies are needed to understand traditional medicine in greater depth to help countries develop their frameworks and strategies, especially since many countries continue to incorporate traditional healers and practitioners into their formal health care systems. This trend transcends income level; as noted earlier, many high-income countries also see growing use of alternative medicine and complementary therapies. In Australia, for example, visits to complementary health professionals increased more than 50 percent from 1995 to 2005 (Australian Bureau of Statistics, 2008). Likewise, the use of acupuncture, a traditional Chinese medicinal practice, is now recognized by 103 member states within WHO (WHO, 2013). With so many modalities from different regions being used worldwide, the assurance of quality in traditional medicine can benefit from heightened levels of cooperation among countries to define and support access to safe products and practices from this sector (WHO, 2013).

As of 2012, 73 WHO member states had established national research institutes for traditional and herbal medicine, and 119 were regulating herbal medicines. Yet, 105 member states cited "lack of research data" as a top difficulty with respect to regulatory issues related to the practices of traditional medicine, and 68 cited a lack of financial support for research on traditional medicine as a challenge (WHO, 2013). Clearly, this represents an opportunity for the global community to bring together centuries of varied experience and research and regulatory experts to improve the quality of traditional medicine.

HEALTH CARE QUALITY IN SETTINGS OF EXTREME ADVERSITY

The challenges of assuring and improving the quality of care in low-resource settings are magnified in settings of extreme adversity, defined by Leatherman and colleagues (in press) as "comprising but not limited to fragile states, conflict-affected areas, and sustained humanitarian crises." The growth in connectivity in the past decade has increased awareness of the many instances of suffering, war, and conflict in the world, as well as of the growing numbers of people displaced from their homes. In 2016, 1.8 billion people, or 24 percent of the world's population, lived in fragile contexts, a figure predicted to grow to 3.3 billion by 2050 (OECD, 2018a). The proportion of those living in extreme poverty in fragile contexts is also increasing (see Figure 5-2).

Such situations are highly nuanced and complex, and do not yet benefit from an easy definition or clear nosology. Databases such as the Fragile States Index (FSI), a tool for measuring in real time when tensions in a country outweigh the capacity to deal with them, can now provide early warning for the international community (FSI, 2017).

With the explosion of migration in recent years, many refugee camps with austere conditions have formed in countries that are not themselves considered failed or fragile states, such as France, Jordan, and recently

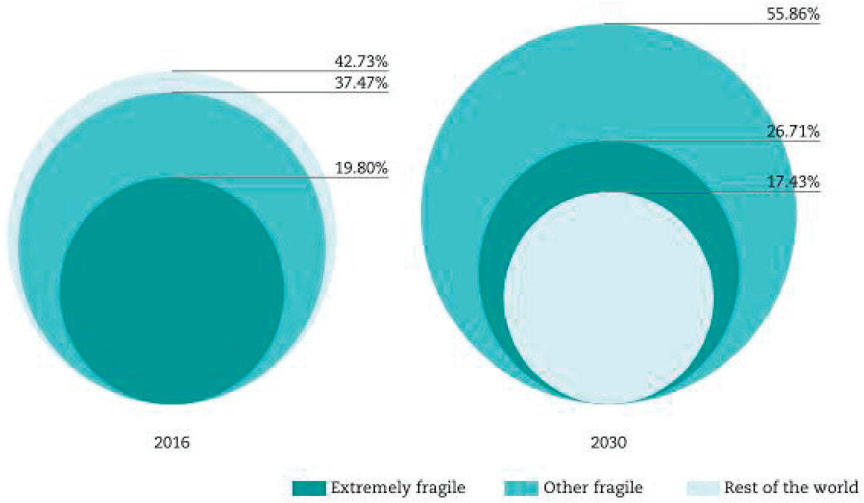

FIGURE 5-2 Proportion of populations in extreme poverty living in fragile contexts, 2016 and 2030.
SOURCE: OECD, 2018b.

Bangladesh. In countries such as Nigeria, regions of thriving economic activity with strong governance and social structure may coexist with other regions that are plagued by terrorist groups (e.g., Boko Haram) and that lack the security and services found elsewhere in the country. Countries vary along the spectrum of "fragility," leading to highly variable needs. Venezuela, for example, although historically having a strong economy, has descended into high rates of violent crime and hunger, with little access to medical supplies. At the other end of the spectrum are countries, such as Iraq and Afghanistan, that are emerging from years of war but with newly functioning governments. One obstacle these settings all have in common is their lack of reliable and timely access to high-quality health care. Some may have little to no health care at all, while others may have a fragmented mix provided by international nongovernmental organizations (NGOs) and local health care practitioners who have stayed behind when most of the well-educated population has fled. Because of the constraints and limited resources in these settings, the first priority has historically been to get any care available to the population and worry about quality afterwards, but this approach is misguided. Quality and access efforts need to be linked as any type of health care is offered, and the committee would argue that it is perhaps more important to assure quality in these settings than anywhere else. The committee has chosen to characterize these chaotic and uncertain environments as "settings of extreme adversity" so as to shine a light on the dearth of quality health care affecting a huge proportion of the global population, many of whom are women and children.

Growing Challenges in the Number and Distribution of This Population

The number of people worldwide who are currently living in some type of extreme adversity, whether for humanitarian, war, refugee, or fragile state reasons, has continued to grow in recent years as a result of ongoing sociopolitical conflicts. As this number and the number of countries involved grow, it becomes increasingly difficult for the limited scale of global resources and initiatives to address the problems adequately. Before issuing specific calls for action, however, it is imperative to understand more about these various situations, how many people are subject to what types of environment, and what their true needs are so that those in the global community can prioritize what is most needed and mobilize appropriately for action.

According to the World Bank (2018a), half of the world's poor—2 billion people—live in fragile or conflict-affected states, and more than 50 percent of all refugees in 2014 were children for whom access to education, health care, and other essential services was severely limited. Globally in 2015, the world saw a record high number of people—more than 65 million—who endured forced displacement because of conflict or persecution (UNHCR, 2016). Data from the Organisation for Economic Co-operation and Development (OECD) paint an even bleaker picture, indicating that half of the 836 million people living in poverty today globally are living in fragile contexts—a proportion projected to reach 80 percent by 2030 (OECD, 2018a). Thus, traditional avenues of development and bilateral aid and historical global health efforts are unlikely to reach the vast majority of this population.

Service Readiness and System Inputs to Health Care

Chapter 2 describes some of the basic inputs or foundations for any health care system. In most high-income settings, these foundations can be fairly assumed to be present and functional. In many low-resource settings, however, the foundations of the health care system can be variable throughout a country. In settings of extreme adversity, the quality of the inputs to the system and general service readiness is even lower, and may vary widely on a daily basis depending on the status of the power grid, existential threats (such as bombs), and the available workforce. Although it has been noted throughout this report that these types of foundations do not necessarily dictate the quality of care being provided in a particular location, their absence can certainly be expected to have a profound impact on the care that can be provided.

Although an increase in the workforce or training alone is inadequate to meet the demand for quality health care in typical low-income settings, the environmental issues that come with the lack of infrastructure and medical supplies in settings of extreme adversity compound the gaps in quality. A systematic review on surgical capacity in 21 low- and middle-income countries (LMICs), for example, revealed that less than two-thirds of hospitals regularly offering surgical care had access to a continuous electricity source or generator (Chawla et al., 2018), a point illustrated vividly during the committee's site visits to hospitals in Goma, Democratic Republic of the Congo (DRC). Lead doctors at hospitals in Goma highlighted the unstable power grid and the lack of working generators as critical causes of mortality and morbidity among their patients, especially in such settings as the neonatal ward, with babies in incubators.[1]

Quantifying the Burden of Poor-Quality Care in Adverse Environments

Looking at countries facing extreme adversity as a subset of LMICs, one finds a disproportionate burden of low-quality care for certain conditions. The team that conducted the analyses for quality dimensions in Chapter 4 also performed analyses on a subset of countries that are classified as fragile states to gain a better understanding of the quality of health care delivered in these adverse contexts, although the lack of available data limits these findings in ways similar to those discussed in Chapter 4, and these numbers thus represent the committee's best estimates. In the case of quality-related neonatal mortality (unnecessary mortality among those with access to care), for example, an estimated 22.7 percent of deaths occur in fragile states annually, even though these states represent only 8.5 percent of the LMIC population (see Table 5-1). For other measures, such as lung cancer mortality, this proportion is much smaller (0.4 percent). This differential may be due to underreporting of cancers in fragile states, shorter life expectancies, or other factors. In addition, the definition used to identify fragile states is conservative and is at the national level—all countries with an FSI of 100 or above.[2]

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[1] Personal communication, E. K. Muhindo, General Reference Hospital, North Kivu, DRC, December 15, 2017.

[2] The FSI, produced by the Fund for Peace (FFP), is a tool intended to highlight the normal pressures that all states experience and identify when those pressures may be outweighing a state's capacity. The FSI includes 178 states and is based on a triangulated approach to data collection through content analysis, quantitative data, and qualitative review (FSI, 2017). Fragile states included here and in Table 5-1 are Afghanistan, Chad, Cote d'Ivoire, Democratic Republic of the Congo, Guinea, Guinea Bissau, Haiti, Iraq, Nigeria, Pakistan, Somalia, South Sudan, Sudan, Syria, Yeman, and Zimbabwe.

TABLE 5-1 Quality-Related Deaths in Fragile States and Low- and Middle-Income Countries (LMICs) Annually

Cause of Death	Proportion of Quality-Related Deaths* in Fragile States (%)	No. of Quality-Related Deaths in Fragile States	No. of Quality-Related Deaths in LMICs (total)
Neonatal Mortality	22.7	51,173	462,131
Maternal Mortality	11.6	5,055	43,602
Lung Cancer Mortality	0.4	552	130,000

*Quality-related death is defined as excess death occurring among all patients with access to care, using high-income countries as a benchmark to define excess.
SOURCE: See Appendix D.

With regard to person-centeredness, it appears that people in the fragile states for which data are available are more dissatisfied with their care on average relative to people in all LMICs, at 29.7 percent and 24.9 percent, respectively (see Figure 5-3). With the exception of Sudan, people in fragile states also report higher rates of disrespect than the LMIC average, 59 percent versus 57.6 percent (see Figure 5-4).

While differences should be interpreted cautiously, lack of consumer choice (and the corresponding assumption that people in contexts of adversity may rate their care artificially high) is cited as a reason not to focus on or collect data on person-centeredness in these contexts. Yet, these data suggest that people faced with extreme adversity may retain the ability to pass judgment on the quality of care they receive. These data may also represent an underestimate of dissatisfaction and rates of disrespect.

Needs and Priorities in Adverse Environments

Although health care providers, including both humanitarian and local workers, try to "do no harm" and provide the best care possible given their situations and resources, caregivers in these settings of extreme adversity are likely have priorities that differ from those in more stable settings. Simply providing access to lifesaving care has historically been the priority, but as the numbers of people in extreme adverse circumstances worldwide rise and as the crises responsible for these circumstances shift to protracted status rather than being just acute emergencies, the need for health care services across the continuum from preventive to palliative care is increasingly being acknowledged.

Given the amount of violence and trauma to which both adults and children bear witness, mental and emotional health care is a top priority

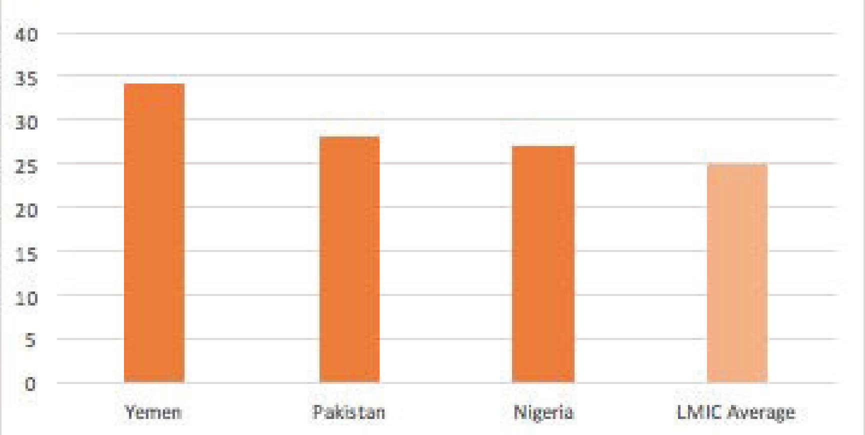

FIGURE 5-3 Poor overall patient experience in fragile states compared with all low- and middle-income countries (LMICs).
SOURCE: See Appendix D.

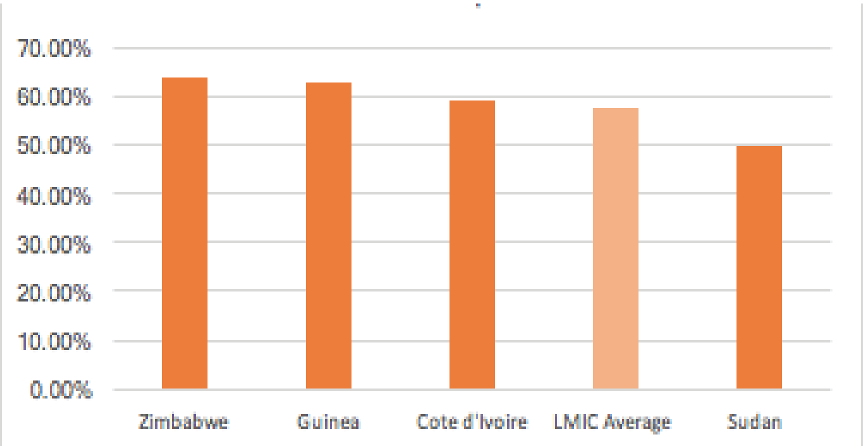

FIGURE 5-4 Experience of disrespect in fragile states compared with all low- and middle-income countries (LMICs).
SOURCE: See Appendix D.

for populations in these settings. After several years of war, nearly half of Syrian children now show signs of posttraumatic stress disorder (PTSD), and one-quarter of them face developmental challenges (Karasapan, 2016). Researchers examining health-seeking behavior in Mosul in the period immediately following ISIS (Islamic State in Iraq and Syria) occupation found that emotional and mental health problems were leading illnesses for both adults and children (Marquez, 2016). Likewise, the Rohingya refugee situation in Bangladesh has escalated in the past 12 months, with nearly 1 million refugees crossing into Bangladesh from Myanmar as of February 2018 (WHO, 2018b). Not surprisingly, large numbers of these refugees have suffered serious mental and psychosocial impacts from their displacement, as well as from violent and traumatic experiences during their journey. Humanitarian responders recognize, as with refugees from Syria, the need for increased accessibility of specialized mental health services and greater capacity for these services within the primary care workforce. But given the breadth and depth of the problem, services must go beyond meeting basic needs and leverage community-based health care systems (Marquez, 2016).

Lafta and colleagues (in press) identify as other challenges in Mosul the shortage of medications and equipment, especially pediatric medicines and medicines to treat chronic conditions; the lack of health care professionals and the collapse of their salaries (likely related); and the weak coordination among providers in shelters, with limited access to follow-up on patients referred for hospitalization (Marquez, 2016). Other conditions affecting large numbers of patients in Mosul included diarrhea, hypertension, and noncommunicable diseases (NCDs). These problems were also identified as priorities by providers in Venezuela, with National Public Radio (NPR) reporting that the entire Venezuelan health care system is on the verge of collapse (Raphelson, 2018). The Pharmaceutical Federation of Venezuela estimates that the country has a shortage of 85 percent of medicines (Reuters Staff, 2017), while some hospitals lack electricity, and more than 13,000 doctors have left the country in the past few years because of the deteriorating circumstances (Trejos, 2017). These numbers were reflected in a front page tragedy early in 2018 when a Major League U.S. baseball player died in his native Venezuela because antibiotics to treat his pneumonia were difficult to find (Raphelson, 2018).

While initial priorities upon settling the Rohingya refugees in Bangladesh are clean water and sanitation to prevent disease, nutrition is also critical. More than 400,000 of those in the refugee and host community populations require emergency nutrition interventions (WHO, 2018b). Responders worry that without immediate scale-up of interventions, nearly 150,000 children under 5 will suffer from acute malnutrition. Unfortunately, nutrition needs to be a priority in these settings beyond the aftermath of a crisis. A recent observational study in Afghanistan found the prevalence of undernutrition to be among the highest in the world, with child wasting exceeding 20 percent in high-conflict regions (Akseer et al., 2018). Stunting was extremely variable, with prevalence ranging from 4 percent to 84 percent depending on the district.

Variability and Challenges of Providing Care

While the health issues described above are the more immediate and acute ones that emerge in crisis settings, rightfully demanding attention and resources from donors and health care providers, other chronic and persistent conditions also exist. The lack of adequate knowledge or infrastructure for addressing these more chronic conditions creates gaps in already fragmented and underresourced systems. More than 80 percent of the 629,000 Syrian refugees in Jordan, for example, are settled not in camps but in communities within the country, reflecting a broader trend globally (UNHCR, 2015). As might be expected from the growing burden of NCDs worldwide, a growing percentage of displaced older populations from middle-income countries require care for their chronic conditions. This changing profile demands a different set of services than humanitarian and other responders are typically familiar with providing, and it places a heavy strain on the host country's health care system (Akseer et al., 2018). In the particular case of Syrians, the population had high rates of smoking, high body mass indexes, and elevated blood sugar before the conflict began in 2010, yet very little attention had been given to NCD prevention and health promotion (Doocy et al., 2016). Thus, with the population now spread out across various settlement locations, addressing NCDs systematically has become extremely challenging. Several experts identify a shortage of guidance on NCDs in various emergency guidelines and policies, leading to a gap in adequate health care for populations during and following emergencies (Demaio et al., 2013).

Another health care issue that has advocates but often lacks supporting data is reproductive health care and gender-based violence in contexts of conflict, humanitarian crisis, or failed states. Sexual violence is common in these settings of extreme adversity, and it is exacerbated by separation from traditional communities and a breakdown in law and order. At the 2016 World Humanitarian Summit, WHO called attention to sexual and reproductive health needs, particularly among women and girls. Of the 100 million who were targeted in 2015 with humanitarian aid, WHO estimates that 26 million, or more than one-fourth, were women and girls of reproductive age (WHO, 2018c). The disintegration of society in these settings often increases women's exposure to threats including sexual violence, unwanted pregnancy, unsafe abortion, increased rates of HIV and other sexually transmitted infections, and maternal illness or death. Thus, despite much attention in the global discourse to adolescent girls and young women, in these types of emergency contexts they are at high risk for sexual violence, as well as for human trafficking and forced marriage, and the services to help them are weak. And these issues often persist even after a conflict ends, as social norms can reinforce gender-based violence. Liberia, for example, continues to have some of the highest levels of sexual violence and abuse toward women worldwide even though its conflict ended more than 10 years ago (Samuels et al., 2017).

Reproductive health care in humanitarian settings was not seen as a priority until the mid-1990s, when donors, governments, and NGOs came together to urge increased advocacy and research and provided manuals and guidance on interventions in the field (Barot, 2017). Yet, while these efforts provided much support and encouragement, repeated evaluations, even as recently as 2014, highlighted key remaining gaps in service delivery, such as failure to immediately implement provision of the minimum initial services necessary at the onset of an emergency (IAWG, 2015). Some barriers to addressing these gaps are cultural, but many also involve a lack of relevant research and financial resources (Barot, 2017). One approach that could help fill these gaps would be to include women and girls in the planning and management of policies and programs for these types of emergencies, in accordance with the fundamental principles of person-centered design discussed in Chapter 2. This approach could be valuable not only after a crisis but also during peacetime to allow for the building of preparedness and resilience before an emergency occurs.

In addition to the challenges of the variability of illnesses and conditions in adverse settings, the vast number of health care providers and actors involved in a conflict zone or refugee camp results in an even more complex problem—coordination (see Box 5-1). For example, long-term progress in providing quality health care for all Afghan citizens will require a "combination of specific goal-oriented projects, foreign aid, domestic responsibility, and time" (WHO, 2018a). Given its history of conflict, damaged infrastructure, and dearth of providers, Afghanistan will need to utilize diverse resources to rebuild its health sector (WHO, 2018a).

Evidence Available to Guide Health Care Leaders

Both country-specific information and a general understanding of the evidence base are needed to address quality issues in contexts of extreme adversity systematically. An evidence base is lacking even for a country such as Iraq, which has a long-standing history of multiple conflicts and fragility; identification of poor-quality areas and methods with which to address deficiencies are still sorely needed (Al Hilfi et al., 2013). Some evidence is available that can be applied to similar settings to improve health outcomes.

BOX 5-1
Case Study: Palestinian Refugees in the West Bank

The Shuafat refugee camp sits 400 meters from the largest Israeli settlement in East Jerusalem, where medical attention is sparse and emergency response and critical care teams are few—and often delayed by traffic and checkpoints. Emergency transfers can see a delay of 27 minutes, easily the difference between life and death. The health care that does exist is gradually losing international donor funding, leaving gaps that must be filled by an uncoordinated mix of government and nongovernmental agencies, such as the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA); nongovernmental organizations (NGOs) that offer secondary and tertiary care; Palestinian Red Crescent, which provides ambulance services; and the emerging private sector.

The main clinic near the camp sees more than 2,000 refugees each month for services that include care for hypertension and chronic heart disease, dialysis, prenatal care, and psychological counseling, but it employs only 16 full-time staff. To see specialists in Jerusalem, Palestinians need visas to travel into the city, which is often complicated by staff and equipment shortages and challenges with ambulance transfers. This restricted mobility and health care system accountability and management of limited effectiveness result in a quality of care that is generally low. Having so many players involved in delivering health care in this politically and geographically complex area only adds to the difficulty of striving for any kind of streamlined care.

SOURCES: Giacaman et al., 2009; Rosen, 2018; Waterson and Nasser, 2017.

For example, health care quality fared the best in Afghanistan when both patient and provider were female (Hansen et al., 2008), likely because of the many cultural and religious challenges that surround interactions between men and women who are unmarried. Thus, just encouraging and incentivizing more female providers to increase the number practicing could improve the quality of care. Another nonhealth intervention found to be successful, also in Afghanistan, was the emergence of community councils that managed the oversight of health facilities. Likely because of their reputations in the community and the consequent accountability, their activity was a predictor of higher-quality care (Edward et al., 2012).

Some interventions, such as supervision and feedback, are found more traditionally within health care systems. In the same Afghanistan study, better supervision in the form of increased supervisory visits was associated with improvements in quality (Edward et al., 2012). Other studies have also shown supportive supervision to be a key motivating factor for provider performance (Naimoli et al., 2006). Another systemic intervention with successful outcomes in multiple postconflict settings is integrating mental health services into more routine care delivery or primary care systems, discussed below.

Integrating Mental Health in Postconflict Settings

Addressing the growing burden of mental health needs in postconflict settings will be a continual challenge, especially since many of these locations may not have a high-functioning health care system and lack resources to dedicate to these problems. Many countries have already endured similar issues and challenges and provide both failures and successes from which to learn. As an example of how dire this problem can be, data show that ongoing exposure to conflict and violence in Gaza has resulted in nearly 70 percent of adolescents developing PTSD, 40 percent having moderate to severe levels of depression, and 95 percent having severe anxiety (Elbedour et al., 2007). While these levels seem shockingly high, many studies in the Middle East region confirm this alarming burden (Dimitry, 2011). To address the problem, money for mental health care is often focused at the hospital level, leading to an uneven distribution of resources. Decision makers in Gaza have made progress, however, in moving from a hospital focus toward more community-based services, as described for future systems in Chapter 3, and slowly integrating mental health into primary health care (Saymah et al., 2015). This design is also supported for other postconflict settings, where typical efforts are narrowly focused on a population or a single intervention. Instead, it would be better if leaders of those efforts systematically took a longer-term perspective and employed multilevel care packages with entry points outside of typical health care settings, focused instead in the community (Betancourt et al., 2010; Jordans et al., 2009). Other studies also have confirmed the feasibility of having primary care workers take on mental health care in multiple postconflict settings around the world (Mendenhall et al., 2014).

Unsuccessful Interventions

The levels of some inputs to the health care delivery system, as described in the earlier discussion of service readiness, are assumed to be associated with high quality. However, research has shown that this is not always the case. In the previously described Afghanistan study looking at the quality of primary care services, for example, researchers found that neither remoteness, facility type, in-service training, nor timely salaries were associated with a change in quality (Hansen et al., 2008). Understanding what interventions have no effect, at least in a given context, is important so that countries can target limited resources toward efforts that do move the needle on outcomes and do not simply streamline processes or improve access without yielding results for patients.

Building on Lessons Learned from Other Regions

Although it has faced many years of war, Afghanistan has made important strides in reducing maternal and infant mortality despite ongoing insecurity, and that experience offers lessons for other states in similar positions. These improvements have been attributed to the Afghanistan Ministry of Health's service delivery model, investments in data collection and verification, and government ownership (World Bank, 2018b). Together with NGO Health Cluster partners and WHO, the Ministry of Health assembled an essential package of health interventions called the Basic Package of Health Services (BPHS). The BPHS defines which services should be provided by which type of primary health care facility and establishes standards that need to be met. Since its creation, BPHS services are now available to 77 percent of the Afghan population (WHO, 2018a).

As seen in countries such as Rwanda and Timor-Leste, the quickest option for providing health care services to populations following civil war or nationwide tragedy and strife is through contracting with national or international NGOs. At some point, however, this option becomes unsustainable and less attractive as the country recovers and regains ownership of its governing mechanisms. In Timor-Leste, after periods of prolonged conflict, a citizen-run interim health authority was established, which enabled donors to shift funding away from NGOs to the newly established ministry. This shift phased out the NGOs and built the local capacity needed for a strong public system. Researchers found evidence that use of health services grew during and after the ministry's implementation (Alonso and Brugha, 2006). However, such a transfer of authority and management could be precarious in these recovering settings, and additional research is needed to verify whether this transition is one that can be applied at scale and what considerations all parties will need to take into account throughout the process for it to be successful.

Established in Japan for decades, a simple tool such as a maternal and child health (MCH) handbook can be used in settings of extreme adversity, with important implications for improving care. The Japan International Cooperation Agency (JICA) began supporting the development of such a handbook in Indonesia in 1993; it was adopted nationwide and informed future iterations in more low-resource settings (Katsuma, n.d.). In 2008, an Arabic version of the handbook was introduced to refugees in Palestine in cooperation with JICA and the United Nations Children's Fund, and a modern update was digitized for smartphones. Use of the handbook in Palestine was tested for its association with quality of antenatal services in 2017. Researchers found that handbook users were significantly more likely to receive "all three kinds of medical tests and … information on five or more health education topics," even after adjusting for confounders (Kitabayashi et al., 2017, p. 2161). Such a handbook can act as a portable checklist, with the patient at the center, to promote the committee's design principles of coordination and integration and improved adherence to standards of care. This proof of concept for MCH is now being broadened to lifestyle-related diseases such as the NCD priorities mentioned previously in this chapter. If information on these conditions can be blended and accessible via smartphone, refugees can be empowered to take greater ownership of and participate in decision making on their health, managing their own health data across national borders even when their environment offers little in the way of health care infrastructure.

Multistakeholder Collaboration

To provide high-quality care in a coordinated manner in such austere and extremely chaotic settings, collaboration among stakeholders is paramount. In the Mosul study cited earlier, for example, respondents highlighted cost and transportation as top barriers to seeking formal health care (Lafta et al., in press). If services within the community are not accessible, they will not be used, making it easier for other, less qualified actors to fill the void. Afghanistan was able to have a national health policy in place just 3 years after the collapse of the Taliban. Much of that accomplishment was attributable to increased partnerships with NGOs, which led to improved quality of health care for the poorest in Afghanistan (Hansen et al., 2008). By contrast, Iraq is struggling to build a central health care system, and with no health insurance yet in place, everyone currently pays for private health care out of pocket (Al Hilfi et al., 2013). Compounding these financial challenges for the population is the fact that there are no guidelines or regulations for private hospitals, making quality difficult to assure. Although a quality unit is built into the Iraq Ministry of Health, the culture has not yet caught up with the policy change, and there are no national performance standards. With the anticipated rapid development of the private sector in health care worldwide, researchers worry that the public sector will be at a great disadvantage unless quality improvement is taken more seriously (Al Hilfi et al., 2013).

Critical Nature of Validation

Given the clear lack of evidence for quality status and improvement interventions in low-resource settings, let alone within settings of extreme adversity, the argument for more research can easily be made. However, the context is important in all situations, and is no less important here. Although rigorous observational studies and clinical trials may yield findings that could be applied in settings of extreme adversity, they need to be validated by those practicing on the ground. Experts working in the field, whether NGOs, local providers, or multilateral representatives, can serve as the source for vetting interventions and findings that are proven successful in sanitized study settings.

SUMMARY AND RECOMMENDATIONS

While the lack of available data and challenging environments make it difficult for leaders and policy makers to know where to begin, there are successes and new approaches emerging from many regions. Additional research investment can augment this knowledge base even further. In addition, global learning networks and collaboratives can provide opportunities to share lessons across countries and settings. As emphasized throughout this report, however, contextual application of evidence and interventions from various environments is critical. There will be no "magic bullet" solution to these complex problems; rather, each country and health system will need to tailor its approaches to best fit the needs of its own citizens and populations.

Care in the Informal Sector

Vast numbers of people receive care from IPs worldwide, with utilization rates in some countries exceeding 75 percent. Much is still unknown about the precise numbers of IPs and about who is using them, but the research that is available makes clear that the quality of their care is poor, although often no worse than that of the formal sector. This is a health care challenge, but one that also represents an opportunity. Researchers have identified promising interventions for addressing the quality concerns within the informal health care sector while also relieving pressure on the formal system. These include

- working with drug vendors, one of the most common types of IP, to bring them into the mainstream system so they can provide appropriate drug dosages and referrals to reach poorer populations;
- using institutional training, registration, and licensing to make traditional medicine practitioners more accountable and reduce the cost of care in the formal system;
- including IPs in counting of providers so more knowledge can be generated about their practices and patients;

- training traditional healers to improve their knowledge and patient management and referral practices for sexually transmitted diseases and HIV;
- defining scopes of practice for various types of IPs where possible and appropriate; and
- increasing opportunities for research to inform the regulation of traditional medicine.

Conclusion: Governments and leaders in the formal health care system need to acknowledge that informal providers in all countries deliver a significant proportion of health services. Bringing these providers closer to mainstream care delivery to the extent possible so they can be monitored, measured, and improved can help improve the quality of their care for large numbers of people.

Recommendation 5-1: Incorporate the Informal Care Sector in the Pursuit of Improved Care Delivery
Country governments should integrate informal care providers into their national health strategies and quality monitoring and improvement efforts. To this end, they should acknowledge that these informal providers exist and undertake efforts to assess and improve the care they provide, such as through education, training, and incentives, to the full extent possible.

Health Care in Settings of Extreme Adversity

About 2 billion people live in fragile states and conflict settings worldwide. Their access to high-quality care is unreliable at best, often nonexistent. Research on health care in these contexts is scarce, leaving health care leaders and providers with an unclear picture of what interventions lead to best outcomes and what to prioritize with limited funds. Although not robust and generalizable enough to apply in every case, evidence has emerged that offers lessons to guide leaders in improving quality in these contexts, as described in this chapter. In summary, those lessons include

- improved quality in Afghanistan when both patient and provider were female, and through the use of community councils that managed oversight of health care facilities;
- the benefit of increased supportive, supervisory visits in Afghanistan and Morocco;
- the potential to integrate mental health services into routine care delivery or primary care systems, especially with entry points in the community; and

- increased likelihood of receiving medical tests and information on health topics as a result of providing refugees in Palestine handbooks with which to track their care.

Conclusion: Assuring health care quality in chaotic, unstable, or unsafe settings where government is often weak or inconsistent in its role of delivering and overseeing public services has long been wrongly deemed a luxury. Indeed, the opposite is true. Given the extreme vulnerability of the people in these settings, providing them with high-quality care is arguably more important than is the case anywhere else. There is an urgent need to understand what interventions work to improve care under conditions of extreme adversity so they can be implemented as soon as possible to reduce mortality, harm, human suffering, and the waste of already insufficient resources.

Recommendation 5-2: Make Settings of Extreme Adversity a High Priority

National governments, multilateral institutions, nongovernmental organizations (NGOs), bilateral donors, humanitarian stakeholders, and philanthropic donors should make studying and improving the quality of care in settings of extreme adversity a high priority. More specifically:

- The international humanitarian system, multilateral organizations, and NGOs should identify priorities for assessing the quality of care in these settings and develop strategies for its improvement. Emphasis should be placed on addressing conditions that are particularly burdensome in these settings, such as treating conflict-related trauma and mental illness, optimizing the patient experience to ensure trust in providers, protecting providers from harm, and adequately managing chronic diseases.
- The National Institutes of Health (NIH) and other research funders should support primary and implementation research aimed at identifying what interventions work and in what contexts to improve health outcomes in fragile states and austere environments.
- Multilateral organizations and the United Nations System should create multistakeholder collaborations for the purposes of reviewing and vetting the available evidence; developing consensus on promising interventions for improvement; and identifying issues of leadership and accountability for quality of care in particular circumstances, such as conflict zones, humanitarian crises, and fragile states.

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6

The Critical Health Impacts of Corruption

Key Findings

- Approximately $455 billion of the $7.35 trillion spent on health care annually worldwide is lost each year to fraud and corruption. Furthermore, the Organisation for Economic Co-operation and Development estimates that 45 percent of global citizens believe the health sector is corrupt or very corrupt.
- Globally, 1.6 percent of annual deaths in children under 5—more than 140,000 deaths—can be explained in part by corruption.
- Chronic government underfunding, insufficient regulatory oversight, and lack of transparency in governance can breed corruption and reduce the quality of health care.
- Public spending for health care is inefficient in countries with poor governance. Good governance, on the other hand, is vital for national health care systems to work optimally. In fact, the quality of governance is a key mediator for whether public spending on health care influences health outcomes positively.
- Many strategies exist for reducing corruption and making environments less conducive to malpractice, including remunerating health care workers adequately, adequately financing the public health care system, ensuring social accountability, and strengthening institutions outside the health care sector.

As discussed in Chapters 4 and 5, many people around the world lack access to quality health care services. The poor state of quality in many countries and the challenges that come with health care in austere settings are exacerbated when health care systems are continually degraded through corruption and collusion. Global health care expenditures total $7.35 trillion each year, much of which comes from out-of-pocket (OOP) payments by families, insurance reimbursements, and public funding. Coupled with a lack of transparency, this makes the health sector vulnerable to corruption. Gee and Button (2015) estimate that $455 billion of this total expenditure is lost each year to fraud and corruption. Additionally, unique in this sector, the demand for health care is not always predictable in any given facility or region and usually exceeds supply (Vian, 2002). With little leverage in such scenarios, patients and public funds can easily be taken advantage of, even by people who are supposed to be trusted. This problem plagues countries at all income levels. One-third of Organisation for Economic Co-operation and Development (OECD) citizens and 45 percent of global citizens believe the health sector is corrupt or very corrupt (OECD, 2017). In fact, in polls, the health care sector has been identified as one of the most corrupt sectors in many countries (Transparency International, 2006).

Corruption is a complex and multifaceted challenge. Offenses range from smaller-scale acts by doctors and nurses who charge bribes or “informal payments” to larger-scale acts at the ministerial or hospital administrator level, when people in power siphon money or redirect resources away from those who need it for their own benefit (Transparency International, 2006). The 2006 global corruption report produced by Transparency International identifies many of these issues, providing robust evidence and calls for action (Transparency International, 2006). Yet, more than 10 years after that report was issued, many countries and health systems are dealing with the same challenges. Box 6-1 presents brief vignettes of corruption found in India, Costa Rica, Cameroon, and Albania.

This chapter first describes the effects of corruption on the health outcomes of populations. It then outlines some of the more common types of corruption found in the health care sector. Next, the chapter details the challenges to effective universal health coverage (UHC) posed by corruption, illustrating that because of the many linkages among governance, spending, and health care, achieving UHC will be impossible unless corruption is addressed. Then, the committee offers strategies for reducing corruption in various areas and making the environments where corruption has thrived less attractive for those willing to deceive with malpractices. The final section presents a summary and recommendation.

BOX 6-1
Corruption Is Widespread

In India, a nurse compels a mother to pay a fee to see her newborn girl—a charge reported to be higher had her baby been a boy.

In Costa Rica, a Congress member is bribed in exchange for introducing legislation approving a Finnish loan for the importation of hospital equipment.

In Cameroon, a village committee files a grant application to build a health clinic. With the committee's consent, the village leader increases the amount requested to cover upgrades to his house.

In Albania, a doctor prescribes an unnecessary medication as he has an arrangement with the pharmacist to split sales profits.

SOURCE: Vian et al., 2010.

THE IMPACT OF CORRUPTION ON THE HEALTH OF POPULATIONS

While an ongoing survey across 33 countries measuring public attitudes on democracy and governance provides evidence of a generally downward trend in the prevalence of corruption in Africa, the problem remains important in several countries (Kankeu, 2018). In its Quality Improvement Framework for Health 2011–2016, Tanzania acknowledges corruption as one of the major barriers to providing quality services (URT and Ministry of Health and Social Welfare, 2011). Similarly, in Uganda, participants in a 2012 study identified perceived corruption as one of the largest barriers to providing good care to injured patients (Bouchard et al., 2012). Ukraine, too, has acknowledged corruption as a cause for barriers to accessing health services and medical commodities (Mendel, 2017).

Corruption in the health sector has been found to take many forms in various areas, such as in health facility construction; equipment and supply purchasing; pharmaceutical distribution and use; health worker education; falsification of medical research; and perhaps most important for this report, the provision of health care services (Vian, 2008). The effects of corruption on a population's health may not always be clear and direct, but they are present nonetheless and can degrade the system and negatively affect the health of a community or nation in multiple ways. In the Philippines, for example, corruption undermined immunization of children, increased patient wait times, decreased patient satisfaction, and reduced accessibility of clinics for treatment (Azfar and Gurgur, 2008). Research has also linked corruption to negative health impacts. In fact, 1.6 percent of annual deaths in children under 5 globally—more than 140,000 deaths—can be explained in part by corruption (Hanf et al., 2011). Furthermore, the International Monetary Fund (IMF) has estimated that infant and child mortality in countries with high levels of corruption is almost twice as high as that in countries with low levels of corruption (Gupta et al., 2002). While many impacts of corruption can be felt through the lack of access to clean water and adequate sanitation, this report focuses on the impacts experienced in the health care delivery system, especially when the quality of care is compromised. These impacts can take the form of poor staffing at facilities and longer wait times due to absenteeism, less equitable care, poor quality or little availability of drugs, and unnecessary additional financial burden. As Hanf and colleagues (2011) argue, donors and governments need to design indicators at the macro and micro levels to monitor the impacts of corruption on health efficiently and to view health, water and sanitation, and corruption as integral components in overcoming these linkages.

TYPES OF CORRUPTION IN HEALTH CARE

There are varying types of corruption—fiscal, intellectual, and ethical—as well as potential actors who may play a role in these malpractices (see Figure 6-1). While the lack of a paper trail makes it challenging for researchers to prove causation, many surveys have revealed associations between instances of corruption and consequences for those seeking health care. Previous studies have shown that people who report dysfunctions, such as absent doctors, drug stockouts, and long wait times, are also more likely to report paying bribes (Kankeu and Ventelou, 2016; Kankeu et al., 2016; Mokhtari and Ashtari, 2012). This relationship has been found in multiple countries according to a study using nationally representative samples from 33 African countries (Kankeu and Ventelou, 2016). Furthermore, when these data are aggregated to the national level, a similar pattern emerges (Kankeu, 2018). This section explores some of the more common types of corruption in health care: absenteeism, informal payments, fraud, and mismanagement of resources and theft of supplies.

Absenteeism

One of the most commonly cited forms of corruption is absenteeism of health care workers. This often occurs because they are working another job in the private sector, one that likely pays a higher salary, so when they are dually scheduled, the public sector typically suffers. In one of the recent Afrobarometer surveys, more than 50 percent of respondents across 25 countries reported absenteeism in a recent health care experience. This number ranged from 23 percent in Burundi to as high as 90 percent

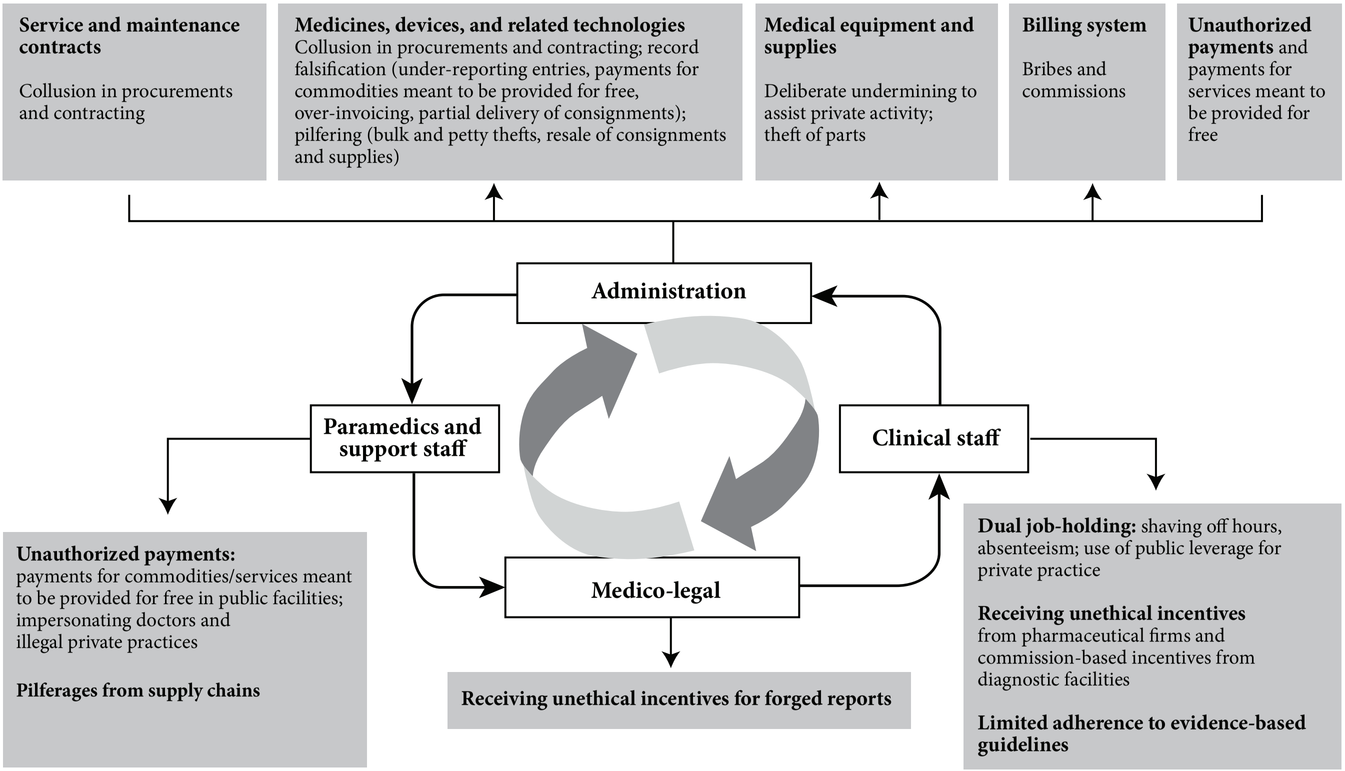

FIGURE 6-1 Chain of malpractice in publicly owned health care facilities.
SOURCE: Nishtar, S. 2010. Choked pipes—reforming Pakistan's mixed health system. *Journal of the Pakistan Medical Association* 60(4):252–253. Reproduced with permission of Oxford University Press Pakistan © Oxford University Press.

in Morocco (Kankeu, 2018). In many cases, absenteeism and the "ghost worker" phenomenon are prevalent where institutionalized corruption creates an environment that enables health care workers to be absent from duty in lieu of relinquishing a percentage of their salary, which is then shared institutionally (Nishtar, 2010). This absenteeism and the resulting uncertainty as to whether the public facilities will be properly staffed when patients need them lead to a reliance on providers in private clinics and thus the closing or underutilization of the public facilities (Nishtar, 2010). Moreover, those patients who still rely on the poorly staffed public facilities face long wait times and health care that is likely not person-centered.

Informal Payments

Informal payments (i.e., bribes or kickbacks) (Kankeu and Ventelou, 2016) are those made in kind or in cash by patients or relatives "outside official payment channels or are purchases meant to be covered by the health care system" (Lewis, 2007). These payments are often made directly to individual providers (Lewis, 2007) to either access care, avoid queues, receive more attention or better care, or even express gratitude (Kankeu and Ventelou, 2016; Maestad and Mwisongo, 2011). The payments are sometimes termed a "coping strategy" for health care workers to make up for remuneration that does not match their perceived efforts (Kankeu et al., 2016). Because health care workers' salaries can be paltry, this pattern can appear to be an understandable part of a broken system. However, it is problematic when a high percentage of OOP spending is directed toward informal payments. A study in Uganda, for example, found that health care workers embezzled 68–77 percent of user fees (McPake et al., 1999). Additionally, a study investigating informal payments across 33 countries in Africa discovered that they can be highly regressive, with demands for informal payments and actual payments being concentrated among the poorest (Kankeu and Ventelou, 2016). It is important to note, however, that the range of frequency of informal payment is large—from 3 percent in Peru to 96 percent in Pakistan. While countries in South Asia have been found to have a heavy reliance on informal payments, the trend is mixed in other regions of the world (Lewis, 2007).

Studies have linked informal payments to negative impacts on the quality, efficiency, and equity of health care provision (Lewis, 2007; Stringhini et al., 2009; Szende and Culyer, 2006). A study in Cameroon found the practice to be more common in public than in private nonprofit facilities, but the highest incidence was found in private for-profit facilities, demonstrating the need for both sector-wide and sector-specific approaches (Kankeu et al., 2016). This finding also highlights the point that although salaries differ across sectors, that differential alone is clearly not sufficient to prevent corrupt practices. Further enabling this type of malpractice is the use (and even lack of use) of paper records, which makes proper tracking of supplies and payments very difficult (Nishtar, 2010).

Fraud

Fraud appears to plague countries regardless of their income status. In the United States, for example, where significant resources are devoted to health care and automated payments are typically made to reimburse various types of insurance, fraud is well documented in the case of the national Medicaid and Medicare programs. For instance, the U.S. Department of Health and Human Services found that providers in 8 of 10 audited states received more than $27 million in Medicaid overpayments for services that were claimed after the patient had died (HHS and DOJ, 2008). Based on multiple streams of data, estimated costs of fraud and abuse in the United States range from $100 billion to $170 billion annually (Rudman et al., 2009).

Fraud is often perpetrated through false claims to insurance companies for reimbursement, but it can also manifest as administrative fabrication of patients or "padding" of orders and invoicing to divert money meant for the health care facility or system. Fraud can be committed by multiple actors within the health care system, including health care providers, government inspectors or regulators, payers (whether public or private), and even suppliers of equipment and medicines (Transparency International, 2006). Corrupt practices in the process of bidding and false invoicing or overpayment by agencies can be so well institutionalized that in many countries, a "parallel system" actually operates, sometimes even more coordinated than the one officially charged with overseeing and managing public resources (Nishtar, 2010). One of the barriers to preventing or reducing fraud is that it is often difficult to prove. A clear line cannot always be drawn between an honest mistake on an ordering form and nefarious intent.

Mismanagement of Resources and Theft of Supplies

Another form of corruption common in health care is mismanagement of resources and theft of supplies, whether drugs, diagnostic equipment, or even spare parts. Often the perpetrators are hospital administrators, who agree to deals with companies to purchase only their equipment or take money for projects or conditions that are not a need or priority for their community. The problem is illustrated by anecdotal evidence from a study in Uganda regarding a hospital administrator who was provided a $60,000 car for him to use once or twice per day—in a country where many in the population live on less than $1/day (Bouchard et al., 2012). This form of

BOX 6-2
Equipment Graveyards

Shortages of medical supplies and equipment are prevalent in low- and-middle-income countries (LMICs). However, those who provide foreign aid for the purchase of supplies and equipment often fail to consider the upkeep and appropriateness of donated materials. The resulting accumulation of unused medical donations in health care facilities around the world is denoted by the term “equipment graveyard.” The World Health Organization (WHO) reports that as much as 80 percent of medical equipment in developing countries is donated (Bhadelia, 2016), and an analysis on 16 developing countries found that about 40 percent of medical equipment was out of service (Perry and Malkin, 2011). This situation is attributable in part to inappropriate deployment of medical donations from wealthy countries (Perry and Malkin, 2011).

The Mulago National Referral Hospital in Kampala, Uganda, has firsthand experience with malfunctioning, inadequate medical donations. Its neonatal intensive care unit crams up to 80 babies in a 20 × 30 foot room where 20 incubators reside, only 7 of which work. When the unit runs out of incubators, functioning or broken, it places the babies on chairs. The instructions for one incubator are in Dutch even though Ugandans typically speak Luganda, Kiswahili, and English. A similar situation was observed at Bwindi Community Hospital in Uganda’s Bwindi Impenetrable National Forest, where the perception of donations is as “dumpings” of useless medical equipment (Miesen, 2013). A study done in the Democratic Republic of the Congo identified as an additional reason for underutilization of donated diagnostic tools a lack of treatments for the diagnosable diseases (Bauserman et al., 2015). Similar cases have been seen in Liberia, Nicaragua, Nigeria, Papua New Guinea, Sierra Leone, and many more LMICs.

While donors may have the right intentions, making this phenomenon difficult to label as purely “corruption,” these unnecessary devices and equipment continue to arrive often as the result of deals or agreements between hospital managers and companies or arrangements involving kickbacks. At other times, it is simply a symptom of poor management, weak policies and procurement mechanisms, and a lack of trained technicians (Cockerell, 2014). WHO’s published guidelines on medical equipment donations, updated in 2011, provide guidance on best practices that may be useful for both donors and solicitors of equipment donations. To further support better medical donation practices, WHO produced the 2017 Global Model Regulatory Framework for Medical Devices, which offers guiding principles and definitions, as well as specifies the attributes of effective and efficient regulations (Compton et al., 2018).

Solutions exist for increasing the utilization of aid to medical facilities. Examples include proper needs assessments, better communication between donors and recipient countries, provision of all resources needed to utilize equipment, proper training of staff, and the development and identification of equipment that can be adapted to the environment of a donation (Bhadelia, 2016).

corruption can also result in the "equipment graveyard" phenomenon, whereby practically new equipment will sit unused in a health care facility because of structural incompatibilities (e.g., voltage requirements), or the workforce and access to spare parts necessary to maintain and repair it are lacking (see Box 6-2).

Also common is the pilfering of supplies. Medicines and equipment are siphoned off along the entire supply chain, from the very first stages of their procurement to their delivery to their final destination (Nishtar, 2010). Medicines can be diverted for resale, bills or invoices can be padded with services that the patient did not use, or records can be created for "ghost patients" who allegedly received medicine. Theft of spare parts for larger hospital equipment is also commonplace. In Pakistan, for example, spare parts can easily be resold on the private or black market at lucrative rates (Nishtar, 2010). Another study in Uganda found that more than two-thirds of drugs that were supposed to be free were "lost" (McPake et al., 1999).

Publications on Corruption Across Country Lines

Interesting correlations can be found by analyzing the types of publications involving corruption in health care focused on various countries worldwide. In addition to measuring relationships and looking for associations between variables and health indicators, the committee wanted to understand what the data illustrated in terms of publications. A literature search of articles published from 2000 to 2018 identified more than 1,000 articles related to corruption and the health care sector. These publications were divided into 13 categories, with variations seen across years in the types of corruption addressed (see Figure 6-2), showing the increasing interest in recent years in better understanding this linkage and how to reduce its occurrence.

CHALLENGES TO EFFECTIVE UNIVERSAL HEALTH COVERAGE POSED BY CORRUPTION

The health care sector is unique because providers typically determine what services their customers (i.e., patients) should buy, whereas in most purchasing scenarios in other sectors, customers decide how they should spend their own money (Transparency International, 2006). The health care sector suffers from market failures due to the unique nature of the services provided. Because health care, by its nature, is complex, it is rife with information asymmetry in terms of what services should be provided and the price of those services. Although regulations are in place to control the quality of services provided (e.g., limiting reimbursement), health care markets are complicated by the frequent presence of a public–private mixed

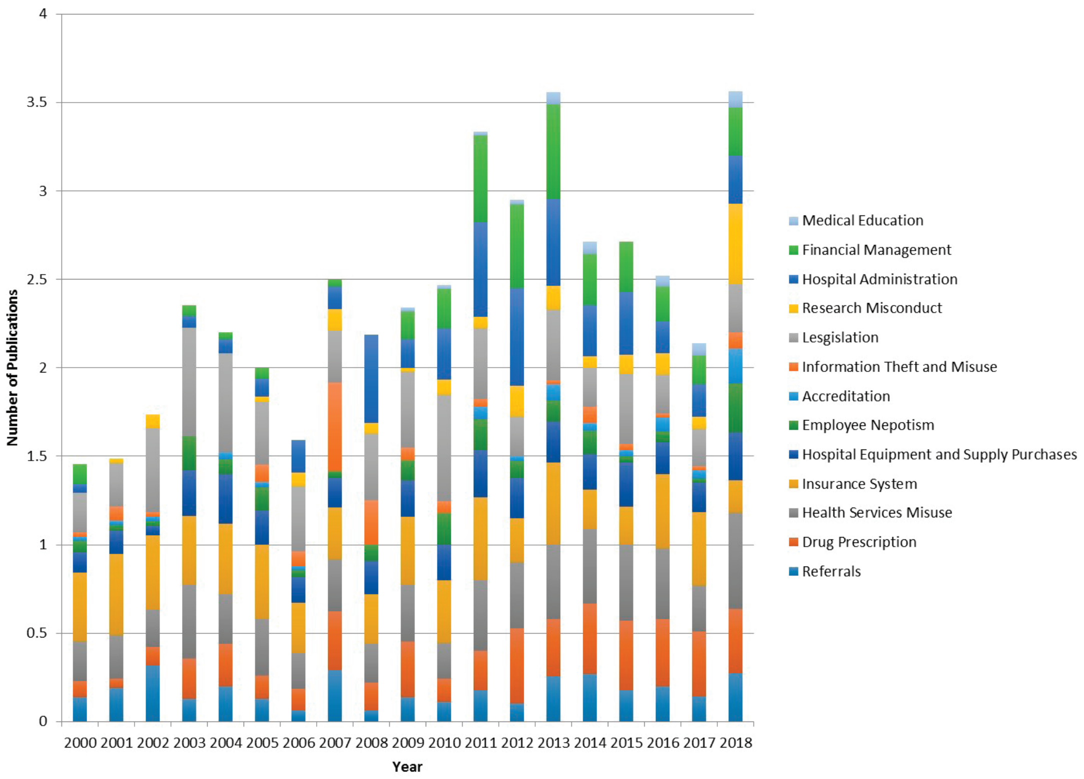

FIGURE 6-2 Publications on different types of corruption, 2000 to 2018.

system. Its large size, complex mix of actors, and asymmetrical information are relatively unique to the health care sector (Transparency International, 2006) and can make it prone to corruption and a diminished quality of governance (Holmberg and Rothstein, 2011). This problem can be exacerbated by imbalanced power dynamics that leave the general public with little voice to demand increased accountability. This section explores the determinants of corruption and the links among quality of governance, spending, and health outcomes to demonstrate why achieving UHC will always be out of reach for those countries plagued by corruption.

Determinants of Corruption

Even though health care systems worldwide are mixed,[1] private expenditures represent a higher share of overall health care spending in lower-income countries. Of private expenditures, household OOP spending is the predominant component (WHO, 2010a). In fact, OOP spending represents 24 percent of total health care expenditures worldwide, but this proportion can be more than 50 percent in some low-income countries (Regional Committee for the Eastern Mediteranean, 2004). High OOP percentages open the door to informal payments and other forms of corruption, especially if prices are not transparent, making many health care systems worldwide vulnerable. Thus, it is not surprising that the rate of informal payments is also high; more than 30 percent of survey respondents from Turkey (Ozgen et al., 2010) and Greece (Liaropoulos et al., 2008), for example, reported making informal payments. Many mixed health care systems tend to suffer from poor performance, such as a failure to achieve fairness in financing and equity in outcomes. This has been hypothesized to result from an interplay among three determinants: insufficient state funding for health, insufficient regulatory oversight, and a lack of transparency in governance (Nishtar, 2007).

The first determinant is the chronic underfunding of health infrastructure by the government. The World Health Report 2010 notes that it is difficult to achieve UHC by limiting combined government and compulsory insurance expenditures to less than 5 to 6 percent of gross domestic product (GDP), an amount required to decrease the proportion of OOP to less than 15 to 20 percent of total health care expenditures (WHO, 2010b). This OOP percentage is based on analyses indicating what is required to

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[1] Here, a mixed health care system is defined as one in which "out-of-pocket payments and market provision of services predominate as a means of financing and providing services in an environment where publicly-financed government health delivery coexists with privately-financed market delivery" (Nishtar, 2007).

reduce catastrophic health care expenditures[2] to negligible levels (Ablo et al., 2014; Xu et al., 2010). Unfortunately, this OOP level is often not met, with the average percentage being between 34 and 43 percent for low- and middle-income countries (LMICs). When the health care system is financed primarily through OOP spending, it is not surprising that services and infrastructure are unable to benefit from long-term planning and coordinated management, especially if a typical household income cannot sustain high OOP payments. This public underfunding results in providers in the public system seldom being paid adequately (Nishtar, 2010).

The second key determinant is the lack of sufficient regulatory oversight to guide the private sector in delivering social services. Regulation can play an integral role in many aspects of the health care system, whether directed at the quality and price of drugs and equipment, the qualifications and professionalization of human resources, the amount of supplies or providers needed for a particular type of facility, or even medical education (Nishtar, 2010). In many countries, the lack of oversight and incentives to prevent corruption—resulting from the absence of an adequate regulatory framework and defined roles and accountabilities—makes it easier for corrupt practices to take place. Nishtar (2010) notes that appropriate safeguards and transparent oversight can enable self-regulation of prices, quality, and numbers.

The third—and critically important—determinant is the lack of transparency in governance. This determinant has two components. The first, previously described, is the administrative and financial malpractices that can take place behind closed doors. A recent example comes from India, where some of the highest costs for patients in hospitals (up to 40–50 percent of the total cost of a stay) are for medicines and consumables (Prakash, 2018). Whether these items are necessary in each patient's case is questionable; moreover, the price of medicines is based on the highest market retail price instead of the procurement price and quality (Rao, 2018). This practice allows the hospital to make higher profit margins, but drives families further into poverty when patients must pay the bill. Another issue found is a parallel system for the posting and transfers of health care workers in the public system, which functions on political connections and side payments (La Forgia et al., 2015). The second component of this determinant is laws and policies governing an entire district or country that are formulated to benefit just a few. This practice violates the equity principle

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[2] Catastrophic health expenditure is defined as OOP spending on health care services that consumes a large portion of a household's available income, such that the household may be pushed into poverty as a result (WHO, 2005). The Sustainable Development Goals define two thresholds for catastrophic health expenditures: greater than 10 percent and greater than 25 percent of a household's available income (WHO and World Bank, 2017).

of UHC. Furthermore, this practice is compounded when it is not transparent or provides few opportunities for public input, rendering the public unaware of what laws and policies are being established (Nishtar, 2010). This lack of transparency also makes it easy for corruption to thrive and creates a disincentive for leaders in management and governance to enact any reforms. Overall, this determinant adds to the argument for inclusive community oversight and engagement of citizens in developing health care systems and goals.

These three determinants—insufficient public funding for health, insufficient regulatory oversight, and a lack of transparency in governance—diminish the quality and equity of public services. Nishtar (2010a) presents a graphical depiction of how these three determinants interact (see Figure 6-3). While a public–private mix does not guarantee poor quality, there is a need for public policies that are locally adapted so as to develop stewardship mechanisms and influence the behavior of private providers to use their services for good (Lagomarsino et al., 2009).

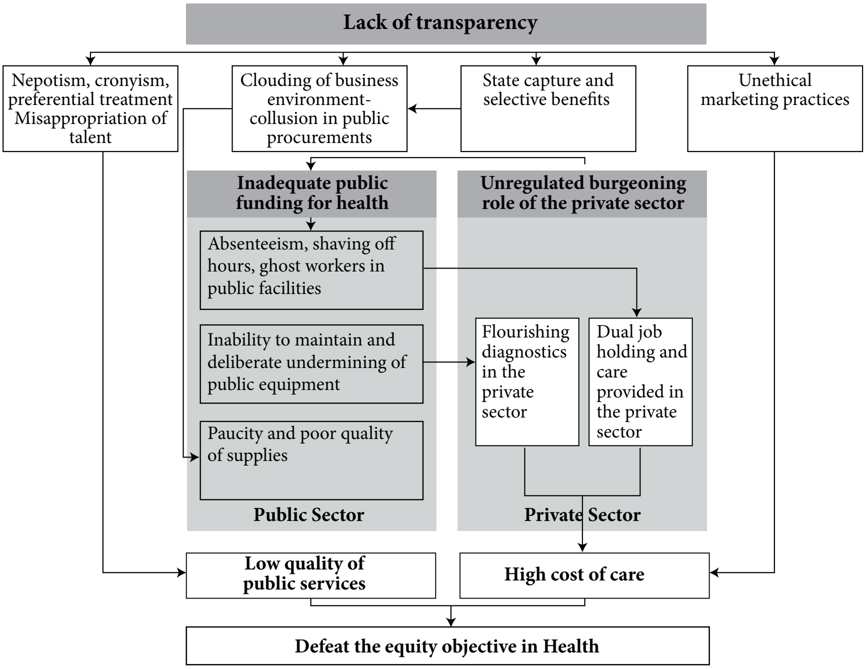

FIGURE 6-3 The public–private nexus in institutionalizing corruption.
SOURCE: Nishtar, S. 2010. Choked pipes—reforming Pakistan's mixed health system. *Journal of the Pakistan Medical Association* 60(4):252–253. Reproduced with permission of Oxford University Press Pakistan © Oxford University Press.

A Need for Leadership

Overall, ensuring that quality health care services are available regardless of the national health infrastructure will require transparent stewardship. When resources are scarce, those in power can use the lack of resources as an excuse for poor services, but in reality they may often be siphoning resources for their private gain (Otremba et al., 2015). This corruption leads to the waste of scarce resources, as well as severely compromised quality of health services (Mackey and Liang, 2012). Surveys of 23 developing countries found that more than 80 percent of respondents had encountered corrupt practices in the health care sector (Holmberg and Rothstein, 2011). Reducing corruption and improving governance are thus needed investments. While strengthening stewardship of the health care sector is important in its own right, it is linked to improved health outcomes. In fact, modeling has shown that high quality of governance is associated with higher life expectancies and lower mortality rates for mothers and children (Holmberg and Rothstein, 2011). Of course, corruption is not limited to the public sector or government leaders; numerous allegations of corruption in the private sector have emerged in LMICs as well. Regardless of where the corruption originates, however, high-quality UHC will be out of reach as long as it exists. But as the world currently lacks an international consensus around corruption in global health and a comprehensive global framework for addressing it, any independent efforts will be difficult to motivate and sustain (Mackey and Liang, 2012).

Linkages Among Quality of Governance, Spending, and Health Outcomes

The relationship between the quality of governance and how a government spends its money is not a difficult connection to make. However, the indirect relationship between the quality of governance and health outcomes is a bit more tenuous. Quality governance can be said to exist "when the exercise of public power is based on impartiality as the basic norm" (Holmberg and Rothstein, 2011, p. 532). While "there is yet no country-based precise measurement of [the quality of governance]" (Holmberg and Rothstein, 2011, p. 532), such variables as population health measures can be used to depict the relationships among governance, spending, and health outcomes.

Several studies have found a positive association between a country's quality of governance and its population health measures. Using data from 91 countries, Rajkumar and Swaroop (2008) found that quality of governance is a key mediator for whether public spending on health care effectively influences health outcomes. This finding is demonstrated by the changes the authors saw in child mortality rates: for each 1 percentage point increase in the share of GDP devoted to public health care spending, countries with high-quality governance saw their child mortality rate reduced by 0.42 percent. This effect was reduced to just 0.18 percent for countries with average quality of governance, and there was no effect at all for countries with low quality of governance (Rajkumar and Swaroop, 2008). Findings of other studies corroborate this concept, with Lewis and Lloyd-Sherlock (2009) suggesting that mortality rates are unlikely to decline unless attention is shifted to institutional health care factors. Additionally, a meta-analysis by the Center for Global Development found that good governance is necessary for national health care systems to work optimally, and that public spending for health care in countries with poor governance is not efficient (Lewis, 2006)

STRATEGIES FOR REDUCING CORRUPTION IN HEALTH CARE

Many strategies exist for reforming health care systems to reduce corruption and make environments less conducive to malpractice. These include, among others, adequate remuneration of health care workers; adequate funding and management of the public health care system; community, public, and social accountability; and the strengthening of institutions outside the health care sector. These strategies are highlighted below, and it is hoped that more action will be taken to implement them so that 10 years from now, another report calling for similar steps will not be needed. The consequences of inaction are too great.

Adequate Remuneration of Health Care Workers

When health care systems are not adequately funded, front-line health care workers are often among those that suffer. Without adequate remuneration to support themselves and their families, health care workers may use their position to increase their income. One study, for example, found that resale of pharmaceuticals provided health care workers in Uganda their greatest source of income (Ferrinho and Van Lerberghe, 2002). Accordingly, researchers and policy makers from many countries have been calling for higher salaries to make workers less likely to request tips or bribes for providing health care. Such a reform effort is currently under way in Ukraine. Historically, individuals in that country had to provide “gift” payments to physicians to access care (BBC, 2018). However, a reform effort designed to rein in corruption directly addresses this issue by providing capitation-based payments to primary care providers (Twigg, 2017). This broad reform was passed into law in late 2017 (USUBC, 2018) and will be implemented in a phased manner, with full roll-out in 2020 (Twigg, 2017;

USUBC, 2018). But simply raising salaries will not be sufficient. Such strategies need to be supported by labor laws, professionalization, adapted codes of conduct, and monitoring of payment schemes. Others have called for the modification of the structure and oversight of payments (Holmberg and Rothstein, 2011; Kabote, 2017; Transparency International, 2006). Thus, efforts to curb corrupt practices by health care workers need to be paired with similar reforms for health system management—an area discussed in the next section.

Adequate Funding and Management of the Public Health Care System

Without an adequately funded and managed health care system, ensuring staffing, procurement of needed medicines and equipment, and treatment of illnesses and injuries can be difficult to accomplish. It has been argued that limited public funding results in a mixed health care system (Nishtar, 2007) that, because of its complexity, becomes difficult to monitor and open to instances of corruption. Country health care systems have a responsibility to ensure that patient need, not the opportunity for profit, dictates the care and treatment of their populations (Transparency International, 2006). Accordingly, Kankeu and colleagues (2016) also suggest improving the ethical standards of health workers and establishing well-defined legal frameworks to better discourage informal payment practices. Strengthening management practices and controls on personnel—in the form of increased oversight and inspection, institutional independence (e.g., the ability to control staffing), and multilayered approval for procurement and/or contracting (Lewis, 2006)—has been found to be effective in reducing corruption (Gonseth and Acuna, 2018). However, this strategy must be paired with effective incentives to influence desired behavior change. Where corrupt practices are entrenched within the system, social accountability can play an effective role, which is expanded on below.

Community, Public, and Social Accountability

Accountability strategies have long been proposed as solutions to improve the performance of public institutions—through a “long route,” via elections and public officials, or a “short route,” via “direct accountability between users [patients] and providers” (Anuradha, 2013, p. S30). Similar calls have been made to decrease instances of corruption in the health sector through the use of community councils and greater public scrutiny (Transparency International, 2006). For those efforts seeking to use the “long route,” transparency is paramount, as reflected in studies and ongoing reform efforts. For example, transparency in pricing of medical supplies at hospitals in Argentina resulted in a 50 percent decline in price variation across hospitals (Transparency International, 2006). Similar reform efforts in Ukraine have sought to increase transparency and instate reference pricing for the procurement of drugs, thereby addressing the state capture and collusion that plagued the pharmaceutical supply chain, which resulted in an annual loss of $100 million out of a $250 million pharmaceutical budget (Twigg, 2017). The "short route" of accountability, however, is more heavily emphasized in areas in which democratic institutions have weakened, thus necessitating direct participation in governance (Fox, 2007). This form of accountability, also called social accountability, can involve user-centered information systems, citizen monitoring, public grievance and redress, and even participatory budgeting (Fox, 2015). Successfully tested in various sectors, these mechanisms have been found to improve health outcomes (Björkman and Svensson, 2009; Björkman et al., 2014; Gonçalves, 2014; Touchton and Wampler, 2013). At the core of these strategies is the provision of actionable and user-centered information (Fox, 2015), essential for building collective bargaining power from the bottom up.

To be successful, these efforts toward community accountability not surprisingly need to be backed by leadership and oversight. Bolivia, for example, has found lower corruption where local groups are active overseers, demonstrating the strengths of bottom-up accountability (Gatti et al., 2002). Several other initiatives have pursued similar goals through community councils. However, they may not achieve their intended results without proper oversight and authority (Lewis, 2006). Creating this type of social accountability can be nearly impossible if there is true government failure (Devarajan et al., 2014), and can have little effect if an adequate enabling environment is lacking. Ukraine was able to create such an enabling environment to roll out its reform package. The new health minister, Dr. Ulyana Suprun (an American-Ukrainian radiologist), cleared the ranks of obstructionist political appointees and hired her own leadership team—one that did not have vested interests in the corrupt system. This new environment allowed a meaningful reform agenda to move forward (Twigg, 2017). A similar tactic was used at the Abel Gilbert Pontón Hospital in Ecuador, in which an outside manager was hired to curb corrupt practices, thereby allowing it to be more responsive to community needs (Gonseth and Acuna, 2018). Thus, for accountability efforts to be successful, there needs to be a state–society synergy and a reliance on mutual empowerment (Fox, 2015), which in turn requires a strengthening of institutions across sectors.

Strengthening of Institutions Outside the Health Care Sector

Weak institutions, whether due to misuse of resources, capture by special interests, influence by political patronage, organizational volatility, or goal ambiguity (Graham, 2002), can create a milieu in which corruption can breed (World Bank, n.d.). While reform at the local and regional levels is necessary to prevent corruption, the system within which individuals and health care facilities operate needs to be strengthened. Strong institutions are necessary to detect, correct, and prevent corruption. As described by the World Bank, supreme audit institutions (SAIs) are national agencies responsible for auditing government spending and revenue (Dye and Staphenhurst, 1998; Stapenhurst and Titsworth, 2001). SAIs can promote accountability and transparency, thereby preventing corruption. Examples include the Turkish Court of Accounts, whose auditors detected falsified claims and statements and illegal bidding practices (Evans, 2008), and the Auditor General of Zambia, who identified overpayment for and nondelivery of goods and services and irregular procurement contracts. In addition to detecting corruption, efforts can be made to build systems of a well-performing government, such as the development of an apolitical civil service guided by institutional values, the development of well-functioning budget processes that are transparent and allocatively efficient, the creation of transparent financial management systems, and the diffusion of power through decentralization paired with community oversight structures (World Bank, n.d.). What route and mechanisms a country uses will highly depend on the relative accountability and capacity of its government.

SUMMARY AND RECOMMENDATION

Corruption, in all of its forms, is an enormous contributor to poor quality of care worldwide. Whether it occurs sporadically or becomes institutionalized, its effects are felt through longer wait times, poorer treatment by health care workers, threats to supply chains, higher fees for services that should be free of charge, and general misuse of funds. These malpractices lead to declining trust in governments and health care systems among citizens, as well as reduced quality of care and worsened health outcomes. Solutions lie in investments in health care infrastructure and payment of health care workers, coupled with accountability, public reporting, and strengthening of institutions outside the health care sector that may impact its practices, such as financing and regulation. While overcoming corrupt practices is a difficult and often long-term endeavor, there have been successes in various countries, and their lessons can be applied elsewhere for those striving to achieve better quality through improved governance:

- Social accountability, paired with strengthened government institutions, can leverage synergy to curb corrupt practices and improve the responsiveness of a health care system to its clients.

- Transparency in pricing of medical supplies at hospitals in Argentina resulted in a 50 percent decline in price variation across hospitals.
- Social accountability mechanisms, such as user-centered information systems, citizen monitoring, public grievance and redress, and even participatory budgeting, have been found to improve health outcomes in various settings.
- Hiring of outside individuals with no ties to a corrupt institution can roll back vested interests and create an impetus for positive change.

As with the rest of the topics discussed in this report, context and local input and leadership will be paramount in ensuring success and sustainability.

> *Conclusion: It is critical for governments and societies to create better governance structures that are accountable and transparent, build safeguards both within and outside of health care systems to decrease corruption, and improve health outcomes for populations. Until this is accomplished on a national scale for many countries, universal health care may be subverted to enrich the powerful and leave vulnerable populations without adequate care. In essence, integrity is, if not a domain of quality itself, an essential precondition for the pursuit of quality in health care.*

> **Recommendation 6-1: Address Corruption and Collusion**
> **Ministries of health should include in their national health care quality strategies, directly and clearly, safeguards against corruption and collusion and actions for improvements in integrity throughout their health care systems. The health sector should draw on expertise and resources from outside the health care system, including related core state institutions and dedicated anticorruption institutions, to combat corruption through prevention, detection, and enforcement.**

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7

Embedding Quality Within Universal Health Coverage

Key Findings

- Out-of-pocket (OOP) payment is the most inequitable and inefficient method for health care financing, often leaving vulnerable patients without access to care and further impoverished. In India, for example, OOP payments account for 70 percent of health care services and are responsible for the impoverishment of 7 percent of the population.
- Poor populations in several countries may receive care, but their inability to pay can lead to their detention in a hospital for weeks or even months afterwards, without continued care, food, or even a bed. For example, in the Democratic Republic of the Congo, approximately 54 percent of mothers at one health care facility were detained after failing to pay medical fees for giving birth.
- In markets with asymmetric information, where sellers know more than buyers about quality, quality will often be underprovided. Systematic investments in improving the quality of care in both the public and private sectors, often in partnership, are needed.
- Strategies exist for improving quality through policy and financing mechanisms, including public reporting, mobile health (mHealth), clinical decision support, workforce training, accreditation, and pay for performance. Positive evidence for these strategies has emerged in many cases, but more research is needed to understand why interventions work better or worse in various contexts.
- Ensuring accountability to health system users and building health literacy in the community are key to improving quality in any health care system.

Universal health coverage (UHC) has been at the forefront of the global health agenda for several years, with renewed enthusiasm following the issuance of the Sustainable Development Goals (SDGs) in 2015. The World Health Organization (WHO) defines UHC as

> ensuring that all people have access to needed health services (including prevention, promotion, treatment, rehabilitation, and palliation) of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user [patient] to financial hardship. (WHO, 2010)

Approaches to achieving UHC vary across different applications in different country settings. Evidence is mixed on which approaches are most successful, and unfortunately, not all of them guarantee access to care that is of high, or even adequate, quality. This uncertainty makes decisions about health care reform difficult for countries with limited resources. However, it is clear that without UHC, payment systems are often cobbled together, imposing a burden that many citizens end up bearing through an out-of-pocket (OOP) payment system. Experts agree that most successful systems employ both the public and private sectors, and often use a mix of incentives, structures, and cost containment mechanisms that can be leveraged to assure and improve the quality of care provided. Several global efforts are under way to this end, but if these efforts are not broadened and applied to all settings, including low- and middle-income countries (LMICs), they will be less effective than they could be.

With reference to the committee's framework in Figure 2-2 in Chapter 2, the discussion in this chapter addresses the "environment" level while highlighting the impacts this level can have on patients, their community, and even individual facilities when incentives are not aligned across levels. The chapter first examines the necessary link between UHC and quality and explains why simply ensuring access and financial protection—although important—is insufficient to achieve effective UHC. It then examines UHC as an opportunity for quality improvement, providing examples of policy levers that can be used within UHC to institutionalize quality in health care systems and reviewing the available evidence on various levers. The third section explores the need for government commitment to achieve quality within UHC, highlighting recent guidance from WHO on creating national quality policies and strategies and presenting illustrative examples of countries that have already undertaken these efforts. The final section presents a summary and recommendations.

THE NECESSARY LINK BETWEEN UNIVERSAL HEALTH COVERAGE AND QUALITY

As highlighted throughout this report, successfully achieving UHC requires financial risk protection and access to high-quality essential health services. Yet, while increasing numbers of people worldwide are being provided with access to health care services, the data and findings presented in Chapter 4 make clear that these services are often not of high quality. For UHC to be effective, the quality of care needs to improve across all key dimensions of quality: safety, efficiency, person-centeredness, timeliness/accessibility, effectiveness, and equity. Quality UHC is achievable with health care services that respond to people's health needs, taking into account emerging and varied health challenges within each country's context. To this end, a deliberate focus is required at all points of care—from national to subnational to community units. A 2018 joint report of WHO, the World Bank, and the Organisation for Economic Co-operation and Development (OECD) includes a similar call to action (WHO et al., 2018). After providing a perspective on the suboptimal quality of care in LMICs, the report proposes high-level actions directed at health policy makers, health system leaders, and health care workers. The report argues that these actions would facilitate the achievement of UHC—with "high-quality, people-centered" services. The committee agrees with the argument and recommendations of this joint report, and this chapter seeks to offer additional support for quality as a component of UHC. The sections below explore the interactions and interdependencies within UHC of access, financial protection, and quality—the missing link for ensuring effective UHC.

Expanding Access to Care

As countries are reforming their health care systems, they are giving special attention to incorporating UHC into their objectives. A number of LMICs in Africa, Asia, and Latin America have made substantial progress in their efforts to expand coverage to all population groups. Among the countries that have achieved what can be regarded as UHC systems are Mongolia, the Philippines, Sri Lanka, and Thailand in Asia; Gabon, Gambia, Ghana, and Rwanda in Africa; and Argentina, Chile, Costa Rica, and Cuba in Latin America. Varying levels of health care investment exist in these countries—from $56.66 annually per capita in Rwanda to $29.11 in Costa Rica in 2015 (World Bank, 2018).

Although access is a necessary condition for achieving high-quality care, however, in no way does it guarantee quality. Costa Rica's massive primary care reform of the 1990s, discussed in Chapter 3, helped reduce child and adult mortality by 13 percent and 4 percent, respectively, for every 5 years the reform was in place, compared with areas not yet covered (Starfield et al., 2005). Access was certainly part of the country's strategy, but Costa Rica went beyond access to realize these gains in health outcomes. This is not to minimize the importance of access, however, especially for those patients with complex chronic illnesses. For these patients, access to specialized care can have dramatic effects on their lives. For example, the Vajpayee Arogyashree Scheme (VAS), a social health insurance strategy in India for households below the poverty line, was rolled out in an area with more than 61 million people. Research found that VAS users had lower mortality rates thanks to increased care utilization, better-quality facilities, and earlier diagnosis (Sood and Wagner, 2018).

Reducing the Financial Burdens of Health Care

Since one of the goals of UHC is to reduce the financial hardship associated with health care, it is expected that, regardless of the quality of services in a system, high costs of care are being reduced. A key indicator to consider is the incidence of catastrophic spending.[1] Yet, even in the face of the global momentum of and political commitments to UHC, the incidence of catastrophic OOP spending globally has actually increased since 2000 at all household expenditure thresholds (WHO and World Bank, 2017; World Bank, 2016b).

Achieving effective UHC can help reduce this financial burden of health care. In the 1980s and 1990s, OOP payments became a more common method for paying for health care. Yet, of the $500 billion generated by user fees annually worldwide, the World Bank estimates that 40 percent is wasted (*The Economist*, 2018). A 2009 Rockefeller Foundation report notes that this type of spending is "the most inequitable and inefficient form of financing for health care, leaving patients" without access and further impoverished (Lagomarsino et al., 2009). Moreover, relying on high OOP payments, regardless of income level, violates the spirit of UHC by driving people into poverty and can make the achievement of effective UHC impossible. A high incidence of OOP payments in regions with low domestic funding for health care increases the fragility and instability of health systems and leaves many households vulnerable to financial catastrophe and impoverishment (Okungu, 2015). For millions, the financial burden can cause them to forego needed health care and potentially to become sicker

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[1] Catastrophic health expenditure is defined as OOP spending on health care services that consumes a large portion of a household's available income, such that the household may be pushed into poverty as a result (WHO, 2005). Sustainable Development Goals define two thresholds for catastrophic health expenditures: greater than 10 percent and greater than 25 percent of a household's available income (WHO and World Bank, 2017).

(Xu et al., 2007). In India, for example, OOP payments account for 70 percent of health care services and are responsible for the impoverishment of 7 percent of the population (Ravi and Sood, 2018). One of the reasons why the VAS example described in the previous section was successful was that it reduced the financial hardship of tertiary care for those in the program, and at a reasonable cost to taxpayers: VAS-eligible households reported 60 percent fewer OOP expenditures for hospitalizations (Sood and Wagner, 2018).

For most people without access to such insurance schemes, high OOP expenses mean that families must provide a large sum of money (relative to their incomes), using multiple avenues, before accessing care. In some parts of the world, requirements for OOP payment deviate so completely from any type of functioning financial system that they lead to detention in the hospital of patients unable to pay, with an appallingly negative impact on the quality of care received. For example, in the Democratic Republic of the Congo (DRC), approximately 54 percent of mothers at one health care facility were detained after failing to pay medical fees for giving birth (Yates et al., 2017). Although they may receive care, these patients are detained for weeks or even months afterward, without continued care, food, or even a bed (Amon, 2015). Box 7-1 describes the example of a detained woman in Uganda. And while many are quick to condemn this practice, as it is certainly a human rights violation and clearly goes against the SDGs and the goals of UHC, the factors contributing to the practice are multifaceted, complex, and not easily resolved without dedicated resources and political leadership.

A cornerstone of UHC should be to end patient detention (Otremba et al., 2015), but doing so is not a simple task. Without a global budget from a national system or mechanisms for insurance and reimbursement, health care facilities naturally rely on user fees to stay open and provide care; otherwise, facilities would go bankrupt themselves, leaving the community without access to care. One option is subsidizing fees based on income level so that OOP payments are not catastrophic for patients and their families, but the health care facility can continue operating. For example, committee members visited hospitals in Goma, DRC, and learned about a community-based health insurance scheme initiated by the Church of Christ in the Congo Baptist Church in 2016. With little investment from the national level, hospital revenues rely on patient user fees to operate. Yet, because the population is very poor, these revenues are often not enough to cover even hospital overhead, such as employee salaries and general infrastructure maintenance. To stay afloat, hospital leaders are hoping to generate more revenue while offsetting the financial risk to patients through this contributory scheme, but doing so will require a concerted and long-term effort. As of December 2017, this effort had resulted in the enrollment of nearly 5,000 members from two districts, with the insurance covering 90 percent of a

BOX 7-1
Case Study: Patient Detention

Esther Ayugi, a woman from northern Uganda, was suffering from a debilitating gynecological problem that required surgery. After years of seeking treatment with government providers who were unable to treat her, she asked her teenage son to sell some of their assets to get the money needed to see a private doctor in November. Her son accompanied her to the clinic, as many family members do in that region, to feed and take care of her while she was there. The doctor diagnosed her and treated her with some drugs for a couple of days, and on the third day she underwent an operation. She was charged the equivalent of US$200, but her family could come up with only US$135. After her family was unable to obtain the remaining US$65, the hospital's surgeon detained her. The surgeon detained Esther's son as well and forced him to guard her and other patients. He was charged a day's wage if anyone escaped. This situation lasted for nearly 6 months before Esther's case made news through a radio show, and the doctors decided to release her to reduce the negative public attention.

Unfortunately, Esther's story is not unique. The exact scale of patient detention worldwide is difficult to assess with confidence, given the lack of academic research on the topic and likely significant underreporting of detention cases outside of urban areas. Based on the research and testimonies that are available, however, it appears the practice exists largely across sub-Saharan Africa, including in Cameroon, the Democratic Republic of the Congo, Ghana, Kenya, Liberia, Nigeria, Uganda, and Zimbabwe, and is also prevalent in India and Indonesia. The articles reviewed in a 2017 report by the Chatham House identify more than 950 detention cases, with one identifying as many as 400 cases in a single hospital in Kenya. Based on these numbers, the Chatham House report suggests that the annual number of detained patients globally is in the hundreds of thousands and could be even greater because of underreporting.

SOURCES: Otremba et al., 2015; Yates et al., 2017.

standard package of services and patients being responsible for the other 10 percent.[2] However, even a 10 percent copayment can be problematic for some families, and without additional funding to subsidize the pool of payments, making this effort sustainable will be an ongoing challenge.

Even when such efforts to make medical care affordable are made, patient detention can still occur. For example, China recently rolled out an ambitious $130 billion package designed to ease the financial burden of health care. Nonetheless, many hospitals still demand payment under threat of detention, reminiscent of corrupt practices described in Chapter 6.

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[2] Personal communication, Isaac Muyonga, ComBaptist at the Center of Africa (CBCA), December 15, 2017.

A common practice in China is for hospitals to place newborn babies in holding, preventing new mothers and parents from seeing them until payments are made. With fees totaling up to $19,000, these separations can be prolonged while families try to find the money, which can be especially dangerous with respect to breastfeeding of the babies (Wee, 2018).

Changing this practice of patient detention will require systematic thought, commitment to reform, and mobilization of resources. In Burundi following advocacy against patient detention, for example, user fees for young children and women in labor were eliminated. But with no plan in place to substitute for these lost resources, facilities experienced frequent drug shortages, reduced quality of services, and strain on health care providers (Nimpagaritse and Bertone, 2011). Worse still are the unintended consequences of hospitals refusing to provide care—even emergency care—until a patient can pay. This situation is tragically illustrated by a recent example in Cameroon, where a pregnant woman was turned away at a first hospital that claimed it could not offer the care she needed and then denied service at a second hospital upon arrival with insufficient funds. Following this denial of service, she died on the doorstep of the second hospital while her family member attempted to retrieve her unborn twins from her body (Berlinger, 2016).

Such examples highlight how crucial it is to design the system and financing of health care in a way that ensures quality of care and discourages such deadly practices. While providing care regardless of funding might be considered a step in the right direction, it is not justified if receiving that care sends patients further into poverty and compromises their human rights. Financial support of hospitals is imperative, but many countries will have to grapple with the reality that resources are finite, and thus will need to balance the priorities of funded health care, improved roads, investment in education, and other determinants that may in fact impact population health. These are important trade-offs that countries will need to consider, together with their citizens, clinicians, and other stakeholders, to design the right system. Regardless of the amount of funding directed at health, the focus needs to shift from reliance on OOP payments toward government and private-sector support, in partnership, to achieve UHC. Quality safeguards and assurances need to be incorporated into care offerings. For those populations living in the fragile contexts described in Chapter 5, more global and multipartner solutions will be necessary.

The Insufficiency of Access and Financial Protection to Ensure Quality

As detailed above, while both access to care and protection from financial catastrophe are critically important for keeping people healthy and out of poverty, they are not enough to truly meet the ambitious goals of UHC. Providing access to care that is of sufficient quality requires a focus on the specific dimensions of quality, as outlined in Chapter 1. The end goals are impacted by what is being monitored and evaluated, and if the number of people accessing care and not encountering financial hardship is all that is being measured, many important elements within the dimensions of quality can be missed, leading to situations in which poor or ineffective care is provided for months or years unnoticed. In 2013, for example, Kenya abolished user fees in public health care facilities in hopes of increasing utilization rates, especially for maternal health care. While this strategy was successful in increasing utilization, which rose significantly for 2 years, maternal and neonatal mortality rates remained unchanged (Gitobu et al., 2018)—this increased access to services did not come with a commensurate increase in human resources, medical supplies, and infrastructure (Otremba et al., 2015). Furthermore, the loss of revenue that results from eliminating user fees, unless replaced by public funding or a mechanism for reimbursement, can lead to worsening quality. All of these issues need to be considered for their quality implications before efforts are made to increase access and utilization (Hercot et al., 2011). This is a key example of the need to link access to quality and to undertake coverage and quality improvement efforts in parallel.

With similar goals of prioritizing access, India created the Rashtriya Swasthya Bima Yojana (RSBY) program in 2008 to provide the rural poor with access to health care. To become empaneled RSBY providers, facilities—whether public or private—must meet certain requirements. Once people have their RSBY card and are enrolled, they can use their card at any empaneled facility, but only for inpatient costs (Upneja, 2015). In practice, however, barriers prevent this from being a successful high-quality program. Empaneled hospitals are located too far from villages to be effective; even if every inpatient hospital close to villages were empaneled, 63 percent of the rural population would still need to travel more than 5 kilometers to access inpatient care (Aitken et al., 2013). The goal of reducing the financial burdens of care for families has been shown to yield mixed benefits as well, with one analysis showing that RSBY provided no significant financial protection for poor households (Karan et al., 2017).

At the same time, however, a perhaps tertiary benefit of this program is that it collects large amounts of claims data with which to conduct evaluation and continual feedback for iterative quality improvement. Currently, the way the data are collected does not automatically make the program a good opportunity for this research, although the potential opportunities certainly exist (Morton et al., 2016). If the right efforts were undertaken using co-design approaches discussed earlier in this report, and if the metrics and indicators used were accurate reflections of quality care and health outcomes, the data collected could offer valuable insight into where resources should be targeted, and the program could be greatly strengthened. Researchers note that the absence of an accepted quality framework and national benchmarks in India remains a key constraint to adequate data capture and systematic quality measurement (Morton et al., 2016), although the recent introduction of a national patient safety framework suggests that changes may be on the horizon (Indian Ministry of Health and Family Welfare, 2017).

UNIVERSAL HEALTH COVERAGE AS AN OPPORTUNITY FOR QUALITY IMPROVEMENT

The political will and momentum of UHC offer a number of opportunities that can be leveraged to embed quality safeguards within systems and programs. UHC provides new opportunities to make system-wide improvements in health care quality. Moving toward a national health insurance scheme, for example, could help provide access to data on the care-seeking behavior of the population, which could in turn drive health system improvement. New incentives for care coordination and quality improvement could then be created because there would be a baseline understanding of what services were in high demand, where the system was lacking, and where care could be better integrated.

Similarly, the quality of care delivered by the providers and clinics within insurance programs can be monitored and held to high standards through a variety of mechanisms. For example, only hospitals that meet certain quality standards—measured not only by their infrastructure but also by health outcomes—should be available to insurance beneficiaries (Cashin et al., 2018; Mate et al., 2013). Likewise, affiliated doctors should review surgeries performed to ensure that they were warranted and follow evidence-based guidelines as a condition of reimbursement. Rwanda uses this approach to ensure quality within its Community-Based Health Insurance (CBHI) scheme (discussed in detail later in this chapter), which is available to the entire population. Each hospital has an embedded "mutuelle" from the Ministry of Health who reviews all services provided on a regular basis to ensure that they meet quality standards and accord with the essential health care package before reimbursement is issued[3] (Republic of Rwanda, 2010). Reimbursement of services using "bundled payments"[4]

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[3] Personal communication, Emmanuel Manirakiza, Gisenyi Hospital, Rwanda, December 14, 2017.

[4] Bundled payments are designed to move toward value-based care by predetermining the allowable cost expenditures for an episode of care. This method requires that providers assume some risk, and if the cost of care is higher than the predetermined amount—for example, because of hospital readmission—they will lose that money. However, if they can keep costs lower while maintaining quality standards, they can share in the savings. For more detail, see https://catalyst.nejm.org/what-are-bundled-payments (accessed July 17, 2018).

can also be tied to quality metrics, reducing the incentive to provide more care regardless of whether it is warranted. There are many policy levers for embedding quality. Those that work well for a given region or community will be contextually dependent, and will have to be applied by local leaders and citizens. A variety of these options are discussed below.

Public–Private Partnership

Experts have long debated whether private or public health care is the better answer to the world's health problems. Some believe that private health care markets will fail because key preventive and public health services often are not valued in a market transaction, and patients' lack of knowledge and health literacy can leave them vulnerable to overprescription and excessive use of diagnostics (Hanson et al., 2008). Some studies have found private care to be better than public care, while others have found the quality of care in private markets in LMICs to be very low as the result of a poor knowledge base and a lack of effort among doctors (Das et al., 2008). Studies have noted such shortcomings as private providers being less likely to prescribe oral rehydration therapy (ORT) and more likely to prescribe antibiotics (Wagner et al., 2015), newborns being less likely to receive Bacille Calmette-Guerin (BCG) vaccination in a private hospital (Sood and Wagner, 2013), and private patients less likely to be tested for HIV (Sood and Wagner, 2013).

Others have argued that no "public" system is entirely separate from the private sector when it comes to drugs, equipment, and innovation, even to the point of a blended workforce. Das and colleagues (2016) found that doctors who worked in both public and private settings in India (an arrangement that is fairly common in many countries) provided higher-quality care in the private than in the public clinics. On the whole, incentives in the public sector are no better aligned than those in the private sector to provide high-quality care. However, positive associations have been shown between government stewardship and the quality of clinics and hospitals—as demonstrated in Ghana and Kenya, where comprehensive government engagement with health care providers can be influential (Spreng et al., 2014). More research is needed to see which specific engagement strategies are most impactful. While this debate will surely continue, a much stronger evidence base on private-sector engagement is needed to enable better understanding and inform decision making for UHC schemes. It will be difficult for countries to achieve effective UHC without involving the numerous private-sector companies and providers that deliver care.

The committee was curious as to whether a business case can be made for investing in quality that would drive the private sector to improve quality for its own economic benefit. The evidence here is also mixed.

Unfortunately, no peer-reviewed studies have directly evaluated the business case for quality among private providers in LMICs. Analyzing case studies on whether quality improvement costs or saves money, Leatherman and colleagues (2003) found an unclear mix. In most cases, the patient accrued a benefit, and stakeholders benefited from predictable cost savings in the long-term. However, the investor had negligible or uncertain financial returns, making the "business case" ambiguous. This was so in part because patients/consumers were unable to discern quality differences, and in part because quality improvement required using services that were not easily billable to any payer. If benefits to patients and other stakeholders apply at a larger scale, the uncertain "business case" calls for payment reforms and policies that "reward organizations that are willing to invest in quality" (Leatherman et al., 2003). The empirical evidence on this issue is supported by theory that says quality will be underprovided in markets with asymmetric information where sellers know more about quality compared with buyers (Lagomarsino et al., 2009).

Clearly, then, there is a need for systematic investments in improving the quality of care in both the public and private sectors, often in partnership. Both sectors bring strengths and weaknesses, and countries need to bring the two together to work within their own national contexts and address their own priorities to build the right UHC system.

Tapping the Private Sector

Studies have examined very few financing and incentivizing strategies for improving the quality of care provided by the private sector, whether supported by insurance or OOP payments. The authors of a 2017 working paper from the Center for Global Development did study the effectiveness of input and output incentives for private health care providers with different skill levels in India (Mohanan et al., 2017). Focusing on maternity care, the authors found that both input and output incentive contracts resulted in a more than 20 percent reduction in postpartum hemorrhage (PPH). Additionally, they noted that with output incentives, those providers with higher skills were able to achieve large reductions in PPH, but those with lower-level skills and training failed to do so. The rate for both groups was the same with input incentives, showing that pay-for-performance schemes could focus on input incentives regardless of skill levels.

Another key financing component that can improve the quality of services is strategic purchasing (Cashin et al., 2018). Strategic purchasing, as opposed to passive purchasing, makes use of information on performance and a payment mechanism that incentivizes certain behaviors and results, such as improvements in health system performance, improved efficiency in resource use, and improved quality (Cashin et al., 2018). Strategic purchasing involves decisions on what services to buy, what service providers to choose, and how and how much to pay providers (Figueras et al., 2005). These decisions would be optimally supported by such mechanisms as monitoring the performance of providers and knowing the different institutions that have purchasing functions. Goldfarb and colleagues (2003) identify six key means by which purchasing ensures quality of services:

- collecting accurate information on provider or health plan performance;
- contracting with providers that meet the quality threshold as defined;
- partnering with providers or health plans to improve quality;
- promoting "Six-Sigma" quality, an industry-based model for minimizing errors and waste;
- enhancing consumer awareness and understanding of quality services; and
- using incentives to reward or punish providers of poor-quality services.

The committee encountered several anecdotal examples of successful high-quality care delivery by private providers that could be replicated. For example, PurpleSource in Nigeria, a private integrated health care provider, set its own goal of improving access to quality primary health care services. It used partnerships to minimize the risk of counterfeit medications and used accreditation within its clinic network for quality assurance. With a deep customer development focus and using a hybrid strategy of improving efficiencies, leveraging economies of scale, centralizing management, and lowering costs without compromising quality, it applied lean execution methods with multiple pivots until it started seeing results (Sunmonu, 2017) (see also Box 2-2 in Chapter 2).

In another example, Narayana Health in India has been able to deliver high-quality services at affordable cost through such process innovations as configuring assets in a hub-and-spoke model facilitated by telemedicine and increasing the quantity of services provided (Govindarajan and Ramamurti, 2013). Narayana Health performs more open heart surgeries than anywhere else in the world, also increasing physician productivity; surgeons at Narayana perform 400–600 procedures per year, compared with 100–200 in the United States (Taylor et al., 2017). Similarly, providers in another system in India, Aravind Eye Care, perform high numbers of eye surgeries (McKinsey's Health Systems and Services Practice, 2011). This high volume of procedures makes it possible to develop and continually update protocols for patients of varying risk levels, enabling specific and evidence-based care for every type of patient. Both of these hospitals have also used task shifting to maximize efficiency and ensure that all providers perform only "tasks they are uniquely qualified to do" (i.e., working at the "top of their scope of practice") (McKinsey's Health Systems and Services Practice, 2011; Taylor et al., 2017).

Policy and Financial Levers to Institutionalize Quality

A variety of mechanisms, especially for mixed health system stewardship, can be used to incentivize meeting quality-of-care goals among multiple players in the system (see Figure 7-1). These mechanisms have produced good outcomes in a variety of high- and middle-income countries, but have yet to be adopted in low-income countries. Pooled financing models influence health care quality in the private sector in many ways, but when they are paired with strategic purchasing, an insurer can develop a "network of preferred providers for insured patients to choose from" (Lagomarsino et al., 2009, p. 22). Through this model, insurers can assure quality by providing clinical protocols and training to approved providers and mandating that they meet basic quality standards (Lagomarsino et al., 2009). This approach can be taken a step further through pay-for-performance models that use financial incentives to foster additional quality improvements (Gottret and Schieber, 2006). If the levels of quality are not maintained by a provider, the insurer can remove that provider from the network or take other actions, such as withholding payments.

In addition, these types of active, or strategic, purchasing measures can enable cost containment, align services with population needs, and balance provider payment. Thailand's UHC scheme, for example, practices active purchasing to control costs while also being responsible for achieving impressive health outcomes (Okungu, 2015). In fact, government health expenditures in Thailand total only 3 percent of its gross domestic product (GDP) (Limwattananon et al., 2013), and the country has met the WHO recommended threshold of less than 20 percent of total health expenditures as OOP spending (Xu et al., 2010).

To identify the best options for policy and financial levers and their available evidence, the committee conducted a rapid review of current research on strategies for health care improvement being tested in countries (see Appendix B for the review protocol). More than 100 studies were analyzed for their impacts on health outcomes. The committee found that the evidence is mixed across many interventions and several countries and continents. Thus, there is clearly a need for additional research on potential interventions to show how they can be implemented sustainably at scale. (Note that the examples from various countries presented in boxes throughout this section are intended to provide additional context, but they were not included in the rapid review and should be considered separate examples of these types of incentives.)

Risk-pooling programs can combine tax revenues, private premiums, and donor expenditures into a single pool of funds. These funds are a prepayment for a defined package of services for a defined member population, whose medical risks are also pooled. Since some members pay a premium that supplants some of their previous out-of-pocket spending, risk-pooling can influence the use of those funds, which are typically not optimally spent in private unpooled markets.

With these larger pools of funding, strategic provider purchasing mechanisms can be implemented, with the goal of creating incentives to improve quality, innovation, and efficiency. Donor or government funds can also be channeled to supplement premiums for the poor, giving them access to quality providers and services they could not otherwise afford.

Pooled funds with subsidies for the poorest are a steady revenue source for providers, ideally spurring the creation and scale-up of high-quality service delivery models focused on superior care for all—not just the rich—and making healthcare businesses more attractive to lenders and investors.

To support such a platform, appropriate regulatory models are needed to set the rules of the game for financing and delivery. Government-established and enforced quality standards can protect patients and facilitate identification of quality network providers. Professional organizations can also work toward enforcing quality and pricing standards.

FIGURE 7-1 A conceptual model for mixed health system stewardship.
SOURCE: Lagomarsino, G., S. Nachuk, and S. S. Kundra. 2009. Reprinted from *Public stewardship of private providers in mixed health systems: Synthesis report from The Rockefeller Foundation-sponsored initiative on the role of the private sector in health systems in developing countries.* (p. 4), by Lagomarsino, G. S. Nachuk, and S. S. Kundra, 2009, Washington, DC: The Rockefeller Foundation. https://www.r4d.org/wp-content/uploads/Public-Stewardship-of-Private-Providers-in-Mixed-Health-Systems.pdf (accessed June 4, 2018).

Public Reporting and Community Engagement

Several studies investigated the role of public reporting and community engagement in improving patient safety and reducing risk presented by health workers (Alhassan et al., 2015; Liu et al., 2015, 2016; Tang et al., 2016; Yang et al., 2014; Zhang et al., 2014). The literature reviewed on public reporting does not lend strong evidence to support its effectiveness in reducing overprescription of antimicrobials. Overall, the evidence is highly mixed, and the only study with consistent findings found that public reporting decreased prescriptions for gastritis but increased those for hypertension. Moreover, most of the studies had a methodological weakness in that they analyzed the effects of the intervention too soon after its introduction. Liu and colleagues (2015) found a lag in the effect of public reporting on prescribing practices. Thus, the findings are uncertain in that the effects of this intervention could be undermeasured, and the sustainability of the reductions in prescribing patterns is unknown.

Alhassan and colleagues (2015) found that community engagement did appear to improve accountability and leadership, but did not have a significant impact on quality of care. The varied impact of the gender composition and type of community group on the particular risk area scores warrants further research.

Additional research is needed on public reporting, examining, for example, its sustainability and its effect on prescription practices depending on patient or provider characteristics. Additional research also is needed on community engagement, such as how the composition of community groups can influence its impact. In addition, research on the unintended consequences of both of these strategies is needed.

Mobile Health (mHealth)

mHealth is among the multiple digital health technologies and tools highlighted in Chapter 3. Because mobile phones were available across many types of settings long before broadband 3G access or smartphones, a fair amount of research has been conducted on mHealth interventions with respect to health outcomes. However, complaints often arise about too many pilots or interventions or target groups being too narrowly focused, making it difficult to generalize findings.

The committee identified two systematic reviews on mHealth interventions (Kallander et al., 2013; Stephani et al., 2016), but the small number of studies included and the settings where these interventions were implemented make it difficult to apply and generalize the findings or recommendations. The reviews did find that mHealth interventions can be effective, and can improve the accuracy of health workers' data submission and clinical decision-making skills and have positive effects on noncommunicable diseases (NCDs) (Kallander et al., 2013; Stephani et al., 2016). However, the authors also caution that these interventions can cause workers to focus too much on technology and less on the patient, potentially diminishing person-centered care. Kallander and colleagues (2013) note that few evaluations of mHealth have addressed low-income countries, and that sustainability and scalability are a challenge.

Clinical Decision Support (CDS)

CDS, which often has a technology component, has been examined as a possible intervention for quality (Ali et al., 2011; Anchala et al., 2015; Duysburgh et al., 2016; Maia et al., 2016; Mensah et al., 2015). However, many of the studies reviewed measured the impact of time spent on care or workflow, rather than the impact on health outcomes. These studies did identify positive effects on nonhealth outcomes, finding that CDS is feasible to implement, is accepted by providers, improves workflow, and is cost-effective (Anchala et al., 2015; Duysburgh et al., 2016; Maia et al., 2016; Mensah et al., 2015). Of the three studies that measured outcomes, only one found that CDS had a positive impact (Anchala et al., 2015). Although the studies identified lend weak evidence for CDS as a tool for quality improvement, they do indicate that it can improve process efficiency and cost-effectiveness. Should additional evidence on the impact of CDS on health outcomes be developed, customization and implementation of this strategy in LMICs could make it possible to leapfrog infrastructural deficits that occur in high-income countries.

Workforce Training

The committee reviewed multiple studies on workforce training (Bassuni and Bayoumi, 2015; Bazant et al., 2014; Bergh et al., 2015; Vasan et al., 2017). Although Bassuni and Boyoumi (2015) and Bazant and colleagues (2014) did not analyze health outcomes, their analysis of provider perception lends vital insight applicable to health care quality. Specifically, they highlight that providers' knowledge of care processes and the occurrence of adverse events can lead them to improve their own behavior (Bassuni and Bayoumi, 2015; Bazant et al., 2014). Vasan and colleagues (2017) report the important finding that little is known about the elements of performance improvement and training for primary care workers. Bergh and colleagues (2015), on the other hand, provide strong evidence for the introduction of emergency obstetric and neonatal training. As more countries invest in community health workers, filling this knowledge gap will be important. Bassuni and Bayoumi (2015) and Bazant and colleagues (2014) also provide valuable insight on the creation of a quality and safety culture through the eyes of providers, demonstrating that increasing skills through training and supported supervision can improve perceptions of a work environment and thus the reception of constructive feedback. This strategy can also be implemented through nurse mentorship programs to decentralize the management of disease.

These findings, however, need to be supplemented by future research on health outcomes and insights from patients. Likewise, the findings of Vasan and colleagues (2017) call for future research on comparative intervention trials and the establishment of clear global standards for professional performance initiatives. Lastly, although Bergh and colleagues (2015) did find positive results for the obstetric and neonatal training program they studied, it was adapted from a high-income setting and may not be easily transferred. Future studies are needed to investigate the contextual and socioeconomic conditions in LMICs in order to improve the adaptation of the training program.

Accreditation

Accreditation is a common mechanism for improving the quality of facilities, both within and outside the health sector around the world. The committee considered several studies, including a systematic review examining accreditation as an intervention for quality, in this review (Al Tehewy et al., 2009; Devkaran and O'Farrell, 2015; Halasa et al., 2015; Ng et al., 2013; Peabody et al., 2008; Saut et al., 2017). Collectively, the studies reviewed investigated the impact of accreditation on quality improvement, organizational and financial factors, process and health outcomes, hospital quality activities and measures, level of quality, and patient and provider satisfaction.

Saut and colleagues (2017) found that accreditation status in Brazil was significantly associated with patient safety and quality management activities. Similarly, Halasa and colleagues (2015) found that accredited hospitals compared with nonaccredited hospitals in Jordan had decreased rates of readmission to the intensive care unit (ICU) in 24 hours, reduced staff turnover, and improved completeness of medical records. Peabody and colleagues (2008), using clinical vignettes to calculate quality scores, found that accredited providers and institutions in the Philippines scored higher than nonaccredited facilities. Lastly, Al Tehewy and colleagues (2009) found that accredited health centers in Egypt had higher patient and provider satisfaction and performed better on patients' rights, information systems, compliance with care standards, and recording of patient visits in records. Although not included in this review, two nationwide accreditation programs, in Turkey and Jordan, are described in Box 7-2.

BOX 7-2
Examples of Nationwide Accreditation Programs Designed to Improve Quality

Turkey

In Turkey, establishment of a quality culture at health care facilities began with the issuance of quality standards in 2005. The Ministry of Health started with a list of 100 facilities, which grew to 621 by 2011. The goal of these standards was to ensure systematic improvement, and implementation of these standards is now mandatory at all hospitals. The International Society for Quality in Health Care (ISQua) began endorsing these standards in 2013, and since then has accredited Turkish hospitals, which in turn have established ISQua-endorsed training programs for surveyors who assess whether facilities are meeting the standards. As of 2014, surveyors had evaluated 1,200 of the 1,491 hospitals in Turkey. This progress led to the implementation of regulations that established Turkey's Institute for Quality and Accreditation in Healthcare. Although the institute's standards are based on those endorsed by ISQua, it will still formally seek ISQua organizational accreditation. To support this accreditation effort, the institute established a web-based system to monitor the outcomes of its efforts, and results will be tracked as they become available.

Jordan

In 2003, the Minister of Health and leaders from the public and private health sectors sought technical assistance from the U.S. Agency for International Development (USAID) to establish a national accreditation body. By 2007, the Health Care Accreditation Council (HCAC) had been formed, comprising representatives from the Ministry of Health (MoH), the Private Hospital Association (PHA), teaching hospitals, medical and nursing councils, the insurance commission, and members of the public. HCAC currently holds accreditation by ISQua for its organization, surveyor training programs, and standards. HCAC works at the micro level by training hospital employees to become agents of change, and at the meso level by helping facilities establish quality management and patient safety systems. The effects of these changes can be seen in a USAID study indicating increased service usage at accredited versus nonaccredited institutions. Study findings also show that patients at accredited institutions managed diabetes and hypertension better than patients at nonaccredited institutions. At the meso level, HCAC is now able to self-organize around issues that matter to its members, and lobbies for enforcement of licensure requirements, malpractice legislation, and linkage of continuing education to relicensure. As a result, the MoH has increased its commitment to quality to ensure that accreditation requirements are met. By 2014, the MoH had 5 hospitals and 102 primary care centers accredited. Future goals include adding HCAC accreditation at an additional 11 hospitals and 27 primary care centers. The PHA aims to achieve accreditation at all private hospitals by 2020.

SOURCES: Araj and Chappy, 2018; Berktas and Kayral, 2018.

These positive results, however, need to be qualified. Although Saut and colleagues (2017) found positive associations with accreditation, they did not find a correlation between accreditation and monitoring of safety goals, nor did they measure outcomes. Ng and colleagues (2013) found clinical impacts that included improved patient safety, reduced medical errors, and increased public reporting. However, some findings contradicted these results, which were not deemed to provide strong evidence for the use of accreditation. Devkaran and O'Farrell (2015) found perhaps the most mixed results. They analyzed the impact of accreditation on a set of quality measures that included patient assessment, laboratory safety, surgical procedures, medical errors, anesthesia and sedation use, use of and access to patient records, infection control, reporting of mortality and morbidity, and safety goals. While they found a significant improvement in quality leading up to accreditation, 26 percent of the measures had reduced scores postaccreditation, with only 2 percent showing improvement.

Ng and colleagues (2013) also report on a variety of factors that can affect the impact of accreditation on quality improvement. Teamwork culture, for example, is important for the willingness of staff to undertake improvement efforts, and if supplemented by leadership, can increase the likelihood that accreditation will advance quality improvement.

Overall, the studies reviewed provide a growing base of evidence that accreditation can create a safety and quality culture in addition to yielding real improvements in health outcomes. However, the study results are mixed. Peabody and colleagues (2008) attempted to investigate these mixed results, but their study's small sample size made it difficult to do so. Overall, the results do not support accreditation as a tool for quality improvement in all settings, nor do they support its use for quality improvement in isolation. The latter point is crucial. Although not always the case, third-party payers may contract exclusively with accredited institutions. Yet, the influence of accreditation standards is not fully explored in the literature. There is a chance that meeting these standards is merely done as a formality and not as a result of a quality improvement culture. Additional research is needed on how accreditation can create a quality improvement culture, on the linkage between accreditation and clinical indicators, on compliance with the standards, and on innovative ways to track improvements (beyond standards set by accreditation requirements).

Pay for Performance (P4P)

Whether the various financing strategies in use in health systems around the world have significant impacts on quality remains uncertain. Among these, P4P has been the subject of extensive research using a mix of methods and has been analyzed across several systematic reviews (Eichler et al., 2013; Suthar et al., 2017; Witter et al., 2012). While P4P has been shown to improve utilization of services, quality of care, and patient outcomes, the strength of the evidence is weak, and more studies with strong research designs are needed to understand the impact of P4P on quality of care. Furthermore, given that P4P is not a uniform strategy and can involve making several design choices, more studies are needed to document the implementation of P4P programs. Lastly, more studies are needed to understand the potential unintended consequences of P4P schemes. Box 7-3 describes examples of P4P schemes in different countries and their effects on quality (although these studies were not included in the committee's rapid review).

Other Mechanisms for Financing Health Care

The starting point for health care financing is understanding what is possible and what level and mix of funding are available, what the channels are for health care expenditures, and how sustainable they will be over time (Xu et al., 2018). The main sources of revenue for health care systems are currently tax revenue, mandatory social health insurance contributions, voluntary private insurance, or a mixed system (World Bank, 2016a). Public sources can include government revenue, social security contributions, and even external resources from international donor countries and organizations. However, some countries, even those of low-income status, elect to provide national health insurance instead of directly providing care, and can build in methods for ensuring that the insurance is used only where services meet quality standards. An example of a national health insurance fund is Rwanda's CBHI program, referred to previously with respect to its use of the "mutuelle," which is based on a partnership between the national and local governments (through their districts) and the community (see Box 7-4).

A Framework for Improvement in Health Care Quality

Clearly the path to effective UHC is not straightforward, and every country encounters challenges along the way, especially in covering its poorer populations, who often work in the informal sector and thus lack access to typical employer insurance. The committee understands that the pursuit of UHC is a difficult and multifaceted process, but again strongly emphasizes the need to include and evaluate quality along with the important issues of access, coverage, and financial protection. Much of the research conducted throughout various health systems is focused on the results of efforts addressing access, equity, and utilization rates. Very few studies have looked at health outcomes, patient or family well-being, or other quality indicators, making it difficult to understand which approaches

BOX 7-3
Pay-for-Performance Schemes

A 2013 working paper from the National Bureau of Economic Research (NBER) explores pay for performance in developing country health programs, focusing on what, whom, and how to reward, as well as potential unintended consequences of these programs. The findings of the NBER paper support those of the committee's rapid review—that there is little evidence demonstrating the value of pay for performance, despite its widespread use. The NBER paper identifies only two pay-for-performance schemes that rewarded good health outcomes. Those examples are highlighted below.

China

Researchers in rural China aimed to reduce anemia in children by issuing incentive contracts to school principals if they were able to do so. Students' hemoglobin concentrations were measured at the beginning and end of the school year, and the incentive was issued shortly after the beginning of the year. Principals responded in creative ways, and in addition to changing school lunches and providing micronutrient supplements, they engaged families at home and worked with them to feed their children healthier meals. By the end of the school year, anemia prevalence had fallen by nearly 25 percent (Miller et al., 2012).

India

Researchers in urban slums in India partnered with workers across 145 daycare facilities to reduce malnutrition scores among children enrolled in the facilities. They first took anthropometric measurements of the children, and then issued incentive contracts for lower scores, taking the measurements again 3 months later. The researchers also provided nutrition information to the mothers of the children in the study. Looking just at the incentive contract for workers, no change was seen; the same was true for the intervention of just giving mothers the nutrition information. However, when the two strategies were used in combination, with daycare workers visiting mothers' homes and promoting the use of the nutrition booklets, malnutrition scores decreased by 4.2 percent in just 3 months—an effect equivalent to raising an average household income by approximately 51 percent (Singh, 2011).

Overall Findings

In summary, authors of the NBER working paper note that despite the amount of research on pay-for-performance schemes, very little of this research focuses on the conceptual areas covered: choice of contracted outcomes, at which organizational level to offer incentives, the structure of incentives, and unintended consequences. They conclude that direct comparison across schemes is difficult because of the heterogeneity of environments, such as levels of autonomy accorded to those incentivized. Finally, there are also equity implications for these types of schemes, as well as unintended consequences that are currently poorly understood. Additional research in these areas is necessary to make it possible to leverage this tool equitably across settings and countries for improved quality of care.

SOURCE: Miller and Babiarz, 2013.

BOX 7-4
Case Study: Rwanda's Community-Based Health Insurance Program (CBHI)

The government of Rwanda started this program in 1999 with successful pilots in three districts, after demonstrating feasibility. With the national rollout of this scheme, coverage of the target population increased from 7 percent in 2003 to 74 percent in 2013 (Kalisa et al., 2015). While the program initially operated with a flat premium fee, a 2011 reevaluation resulted in the introduction of staggered premiums which were less regressive and more equitable. Category 1 members are the poorest, and 100 percent of their premiums are paid by the government. Category 2 and 3 premiums are based on income and paid in part by the member[a] (Kalisa et al., 2015). Because this is a national system, the branches that see a surplus of funds at the end of the year transfer 60 percent of that surplus to the district pooling risk to compensate for those health centers that had a shortage of funds, and 20 percent is transferred to national pooling risks for hospitals that could not pay their bills (Kalisa et al., 2015).

Successes and Challenges

According to interviews with those involved in the design of the program, CBHI has contributed to healthier families through improved access to and utilization of health care services. For example, infant mortality decreased by 70 percent from 2000 to 2014, and maternal mortality decreased by 80 percent during the same period (Collins et al., 2016). Based on household survey responses, equity in utilization of services has also been noted, with most facilities and hospitals showing the richest and poorest quintiles of the population using the services at nearly the same rate.

The program has also reduced catastrophic patient costs, although issues with premiums and hospital copayments being unaffordable remain. Challenges exist as well with respect to patient understanding of the system, as those who do not get sick in a given year do not agree in principle with risk sharing and do not renew membership because they do not want to subsidize others who did get sick (Kalisa et al., 2015).

Mechanisms for Ensuring Quality

Since the program's rollout, many reforms and changes have been implemented. Rwanda adopted a performance-based financing approach to improve quality of care by rewarding health care facilities for good performance, and health care providers receive bonuses on top of their salaries. After this approach was scaled nationwide, along with a rigorous evaluation program, significant positive impacts on quality with respect to targeted maternal and child health outcomes were seen (Kalisa et al., 2015).

The government of Rwanda uses contractual mechanisms between health facilities to hold them accountable for their levels of quality care. It also established a standardized set of essential health care services that must be provided (including lab tests and medicines) before a facility can join the CBHI program. While some respondents have concerns about the management of CBHI, the program was recently transferred from the Ministry of Health (MoH) to Rwanda's social security board, which was viewed as a good opportunity to achieve improved management and allowing the MoH staff to focus on ensuring quality (Kalisa et al., 2015).

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[a] Personal communication, Zuberi Muvunyi, Ministry of Health, Rwanda, December 13, 2017.

result in higher-quality care and better health for populations, versus cost savings or improved efficiency.

Regardless, knowing that most countries will have a mix of insurance, government, and private-sector roles in health care, a framework is needed to understand how quality, coverage, and financial protection can be considered and accounted for as systems reform. Mate and colleagues (2013) developed a framework for improvement in health care quality that considers how insurers interact with other stakeholders to promote a cohesive national strategy within a country (see Figure 7-2). This framework can serve as a guide to policy makers as they think about quality improvement in the context of UHC. Depending on the country and employment demographics, the disease burdens, and the political leadership, the mix of options in the "ideas" and "execution" circles of Figure 7-2 will differ. But regardless, the stakeholders that need to contribute "will" to improvement efforts are likely the same, and within the same context of working to improve the quality of health care for their populations. Yet, political will for improving quality may occur slowly without adequate advocacy and public demand. The following are some of the questions policy makers need to ask in seeking to advance improvement:

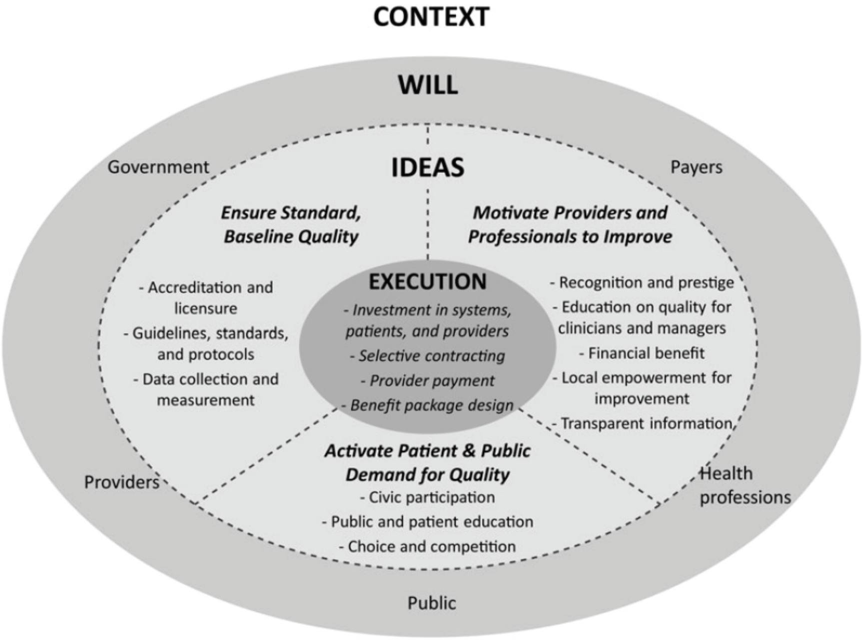

FIGURE 7-2 Framework for improvement in health care quality.
SOURCE: Mate et al., 2013.

- Do we have leadership and will to improve health care quality?
    - Is improving health care quality a national priority?
- What are we doing to motivate and equip health care professionals to improve quality?
    - Do providers have the technical skills to provide high-quality care?
    - Do providers have the right incentives? Are higher-quality providers rewarded in terms of prestige, reputation, or financial benefit?
    - Are providers working in learning health care organizations that have a mission to improve quality of care and empower providers to do so?
    - Do providers have access to decision support tools based on evidence-based guidelines?
- What are we doing to activate patient demand for quality?
    - Do patients have adequate health literacy?
    - Do patients understand what level of care is to be expected?
    - Do patients understand the consequences of poor-quality care?
    - Do they have the tools and resources to distinguish between high-quality and poor-quality providers?
    - Do they have the ability to choose high-quality rather than low-quality providers?
    - Is high-quality care affordable?
- Are payers focused on improving quality?
    - Does insurance cover high-quality care?
    - Are we using selective contracting and provider payment to improve quality?
    - Are payers monitoring quality and reducing the use of inappropriate or poor-quality care?
- Do we have a regulatory or legal framework for ensuring access to high-quality care?
    - Do we have a robust system for licensing and accreditation of providers?
    - Do we have a system for reducing counterfeit or substandard products?
- Do we have the leadership and organizational structure to provide quality health care?
    - Do different parts of the system coordinate care?
    - Is there accountability?

THE NEED FOR GOVERNMENT COMMITMENT TO QUALITY WITHIN UNIVERSAL HEALTH COVERAGE

Taking on the challenge of UHC requires a deep commitment from a country's leaders to serving all of its people. Among those countries that have seen successes, an overarching characteristic is strong political leadership for stewarding coverage expansion policies. In Ghana, Sri Lanka, and Thailand, for example, a populist political process (established initially for election purposes) created the momentum for free health care at the point of service (Agyepong and Adjei, 2008; Gunatilleke, 2009; Missoni, 2010). Other important examples include Sri Lanka's social welfare program (Gunatilleke, 2009) and Thailand's health system development, which includes maintenance of institutional knowledge via retention of key personnel (Missoni, 2010; Tangcharoensathien et al., 2010).

Systems that are in such dire straits that patients—most often women and their newborn babies—are being detained for payment need multifaceted and immediate interventions. The Chatham House report (Yates et al., 2017) emphasizes the need for policy interventions that can deliver immediate impact, such as banning the practice of patient detention completely with enforcement to follow, as well as compulsory public financing mechanisms to steer countries away from direct-charge mechanisms that contribute to hospitals serving as debt prisons and toward prepayment. As countries transition from severely underfinanced health systems to those that have sustainable and equitable funding sources, leaders will be key in ensuring that UHC policies help improve quality.

Leadership and Stewardship

Leadership for quality can manifest in different ways. In the case of Nigeria, the success of the National Quality Strategy (NQS) is attributable to the involvement of the leadership of the Federal Ministry of Health (FMOH) and its broad group of stakeholders in the strategy's implementation (Wickham et al., in press). Stakeholders represented regulatory agencies, implementing partners, the private sector, and patient groups. The many different workshops, meetings, interviews, and activities undertaken by the FMOH and nongovernmental organization (NGO) partners helped increase the demand for high-quality care. Stakeholders who were engaged from the beginning are now starting to carry out their own quality-of-care initiatives in line with the country's overall strategy, ranging from accreditation regulations, to patient empowerment through information access, to compulsory data reporting (Wickham et al., in press). Stakeholders reported a clear commitment at the state level and increases in demand, openness, and trust—all likely contributing to the success of the NQS implementation. However, it was national-level leadership and commitment from the Minister of State for Health that drove the success.

On a broader scale, in addition to commitment from leadership and a clear vision for improvement, country experiences have shown that structures at the national, regional, and hospital levels are needed to coordinate and lead the implementation of activities related to a national strategy (Wickham et al., in press). During Ethiopia's journey toward an NQS, for example, the federal government established a new Health Service Quality Directorate. A Steering Committee for National Quality was also created to convene multiple stakeholders and agencies on a regular basis to review progress in implementing the NQS. Furthermore, the country is developing a Quality Technical Working Group to bring together a broader set of partners supporting quality-related work. This example is being duplicated at the subnational level, with quality units being formed within regions; focal persons being assigned to coordinate implementation at the zonal level; and hospitals and health centers, respectively, being expected to have quality units and committees (Wickham et al., in press). Further supporting these newly established structures will be well-trained experts in quality who are able to operationalize the strategy and continue to iterate in a continual improvement process. This expertise, if not found in house, can be sought through linkages with academia and other health partners. Government structures and dedicated personnel, however, will have limited effectiveness if there is high administrative turnover or loss of institutional memory.

Beyond commitment and the establishment and maintenance of government structures, the success of UHC designs and payment systems will depend on the political acceptability and sustainability of the financing system. In fact, it has been found that UHC is less likely in societies with low social solidarity (e.g., political or economic divisions) (Stuckler et al., 2010). The institutional universalism described by Okungu and colleagues (2018) as making a noncontributory financing approach successful requires a high level of collective responsibility among the population, which in some countries, regardless of income level, is difficult to imagine.

National Quality Policy and Strategy Development

With so many countries at various stages of quality control and improvement and a clear need for many systems to deliver better care, WHO recently developed a handbook with country-level input to support those countries interested in improving their health care systems (WHO, 2018a). While improvement is traditionally viewed as a linear process, the handbook makes an argument for moving toward a more triangular or circular process whereby "implementation experience drives policy and strategy development [and] can build a sense of ownership among those implementing to ensure products are grounded in realities" (WHO, 2018a, p. 11). This argument aligns with the committee's call for systems thinking, integrated co-design, and meaningful engagement with stakeholders in evaluating and improving any health care process, as outlined in the design principles presented in Chapter 2 of this report. Ongoing relationship building and engagement with the entire health care team, including patients and families and blending top-down and bottom-up approaches, are needed to ensure that interventions tested in the real world are being incorporated into policies and strategies.

The WHO team reviewed more than 20 existing quality strategies across LMIC settings in developing the handbook, which is intended to guide countries in the development and implementation of their National Quality Policy and Strategy (NQPS). The process is organized into three stages: policy development, strategy development, and tools and resources. Eight key elements are identified as requirements in the policy and strategy development stages: (1) national health priorities, (2) local definition of quality, (3) stakeholder mapping and engagement, (4) situational analysis, (5) governance and organizational structure, (6) improvement methods and interventions, (7) health management information systems and data systems, and (8) quality indicators and core measures (see Figure 7-3). This committee endorses that list.

Because the handbook is intended for use by authorities, stakeholders, and external partners involved in the development of an NQPS, the guidelines account for the fact that countries are in different stages in the development and implementation of national initiatives. The handbook provides guidance on how to develop a national quality policy, either as a stand-alone document or incorporated into the overall national health policy.

The policy development stage of the process aims to acknowledge the existing systems and factors that will contribute to the national quality policy. The handbook states that the national policy should be based on agreed ambitions that should intentionally become the agreed course of action (WHO, 2018a). The strategy development stage entails the process by which the policy is enacted. It should include a time frame for the various activities to be launched and consider and plan for the various practical concerns that may arise when translating the policy into action. The same eight elements included in the policy development stage should also be applied in this stage, and even simultaneously when appropriate. WHO acknowledges that advocacy efforts may be required to incorporate goals and priorities related to quality successfully across the health care system and ensure that they are present in national health planning and budgeting in addition to the NQPS. This, again, will require commitment and political will from the highest levels of leadership—whether at the level of a health

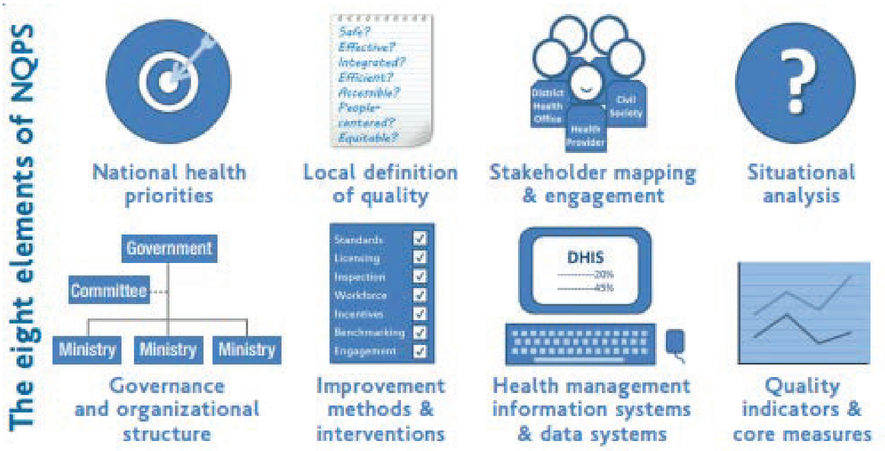

FIGURE 7-3 The eight elements of a National Quality Policy and Strategy.
NOTE: NQPS = National Quality Policy and Strategy.
SOURCE: WHO, 2018b.

care facility, care delivery network, or national government entity (WHO, 2018a). The "Tools and Resources" section of the handbook describes how to access and select the tools needed to implement and sustain successful NQPS strategies.

A strength of the WHO handbook is the adaptability of strategies to countries regardless of their stage in the design and implementation of an NQPS (WHO, 2018a). For example, Ghana developed an NQPS for 2017–2021 through a collaborative approach, led by a steering committee, managed by a Ministry of Health team, and evaluated by patients and providers (Ghana Ministry of Health, 2016). This collaborative effort is intended to encompass the entire health care system, categorized by country priorities: maternal health, child health, malaria, epidemic-prone diseases, NCDs, mental health, and geriatric care. Included are measures of improvement in health outcomes, strengthening of systems, and patient-centeredness. The guiding principle of the strategy is to improve health care coordination, so it incorporates the public and private health care sectors, emphasizes partnership with patients and providers, and establishes feedback loops to guide quality improvement at all levels (Ghana Ministry of Health, 2016).

Not every country's policy and strategy will be the same. Depending on the emphasis placed on certain areas—based on national priorities—plans will manifest differently to address certain gaps. The selection of goals may also be related to recent outbreaks or events that are fresh in a country's collective mind. For example, Ethiopia's ultimate aim is to "consistently ensure and improve the outcomes of clinical care, patient safety, and patient-centredness, while increasing access and equity for all segments of the Ethiopian population, by 2020" (WHO, 2018a, p. 35). Namibia's strategy, on the other hand, is aimed instead at providing a framework for the implementation of quality management initiatives at all levels using four key objectives as a guide: (1) improve quality management systems and accountability, (2) ensure client-centered care and empowerment of consumers, (3) improve patient and health worker safety, and (4) improve clinical practice (WHO, 2018a). Different still, is the strategy of Sudan, where quality is defined as "providing the best possible patient-centred care using available resources and evidence-based practice" (WHO, 2018a, p. 36).

Accountability

These processes of quality improvement are thoughtful methods of care management. During his testimony to the committee in Nairobi, Maina Boucar, from University Research Company's Regional Office for Francophone Africa, highlighted several instances of low-resource countries implementing quality improvement efforts with corresponding success. He noted that tangible improvement is possible where leadership is strong, but that these types of interventions cannot be seen as an external effort, and need to be owned by and implemented within organizations. He stressed that accountability for this improvement and assurance of quality is crucial. One of his final reflections was on how to gain buy-in from local leaders and managers, as well as solicit the voices of consumers, to achieve the long-term sustainability of these quality efforts, which otherwise would certainly be in question.

The authors of a 2009 report on public stewardship of private providers in mixed systems also support the notion of accountability, and highlight the importance of "educating and incentivizing patients to demand the most beneficial services," increasing the "supply of high-quality services," and reducing "inappropriate provider behavior" (Lagomarsino et al., 2009, p. 6). Examples of such educating and incentivizing interventions include social marketing; conditional cash transfer; rural cooperatives; and trusted sources of knowledge within the community, such as consumer associations or citizen complaint lines. At the core of these efforts, however, is the aim to build health literacy.

Building Health Literacy

Health literacy, or "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (IOM, 2004, p. 4), is vital to building public demand for quality. While individuals with low health literacy can understand what poor-quality care looks like, they may not be able to articulate what level of quality is expected. Beyond such vital aspects as good communication and respect, other indicators of high-quality care may be unknown to the general population. For example, people in many countries can often associate such things as cleanliness or wait times with quality instead of evidence-based care or correctly prescribed antibiotics. Other indicators of quality may include providers knowing that ORT is needed for diarrhea or when it is necessary to provide intravenous fluid. Of course, the attainment of full health literacy on all treatments is unrealistic. However, an understanding of what services should be delivered and what providers should be present and available is not. While achieving this level of health literacy may require robust community outreach and education efforts, it will offer some balance to the asymmetry that exists around the world between the patient and the physician. In most places, when people seek care from a health care facility, they are reliant on the provider for all knowledge about their condition, and they are unable to actively choose to avoid underperforming providers (Miller and Babiarz, 2013).

Absent an ability to articulate what is expected during a visit, or in response to certain illnesses, a population will have diminished bargaining power and may mistakenly continue using facilities of poor quality. A similar line of logic was used by researchers at the Massachusetts Institute of Technology to address an equity issue in a rice distribution program in Indonesia. Although the program targeted the poorest in the country, in reality only 50 percent of its volume was reaching those individuals. Through the phased introduction of an eligibility postcard, which informed individuals what they were entitled to, beneficiaries were able to demand their full ration. In fact, following this intervention, it was found that experimental village beneficiaries had received 26 percent more rice than those in control villages (Beaubien, 2018). In line with the committee's suggested principles of co-design and empowered users at the center of the health care system, building the health literacy levels of populations will be a critical factor in raising levels of quality in all settings.

Generating Public Demand

Neither public- nor private-sector leaders will likely change of their own accord, as is fundamentally called for in this report, without a corresponding demand for better care from their populations. Accordingly, it will be necessary to generate stronger demand for high quality, educate patient populations in health literacy, and create incentives for change that will be attractive to all parties. It is important to note that for a significant portion of this work, the onus is on patients or users of the system to increase their health literacy, even though they are the ones falling through cracks within a complex system of policies and institutions (Hudson and Rikard, 2018). Nonetheless, as with other market-driven solutions, the responsibility for improvement should fall on companies and providers. A review of strategies for preventing stillbirth found that demand creation at the community level was a successful strategy for improving uptake of services, but it was most effective when coupled with supply-side efforts to improve quality of care and system strength (Bhutta et al., 2009).

Embracing the technological advances and shifts to consumer ownership of health data and health care decision making described in Chapter 3 will require that the health care industry transform its business models to incentivize providers to enhance the care experience, reduce waste, and improve quality (Hudson and Rikard, 2018). For example, Chinese consumers are some of the most digitized in the world, and spend more than one-fourth of their online time on medical-related matters (Guo, 2017). As they have become more perceptive in exploring their conditions, their treatments, and even their physicians' professional work, they have been driving the demand leading to a more joint decision-making model between physicians and patients. In some cities, a survey found that 47 percent of patients requested a prescription change, with 42 percent of their physicians approving the change (Guo, 2017). This trend will likely spread to other countries as they increase their connectivity and digital familiarity, but ensuring that patients possess high levels of health literacy to inform their shared decision making will be crucial to ensuring that high-quality care is provided.

Use of Coverage to Develop Learning Health Systems

Aside from OOP payment schemes, the majority of health systems are backed by some type of insurance coverage or government or donor investment. Health system leaders need to think about how this funding for health care facilities and providers, often as reimbursements for services, can be leveraged for improved quality. As discussed in this chapter, there are contractual and other mechanisms that can be used to build quality assurance and improvement into coverage systems, but they need to be supported by strong political commitment and leadership, as well as accurate metrics and measurement to demonstrate effects on quality and health outcomes. To be most effective, these metrics should be tracked over time, not just at a single point in time, to show rates of improvement. Those measuring and tracking also need to be sensitive to how the results are being used, ensuring that they are being used to drive continual improvement, incentives, and feedback, not for punishment and reprisal.

Using the previous example of PurpleSource in Nigeria, its leaders realized that achieving their goal of access to high-quality primary care services for mostly poor and informal workers in their network would be a long-term effort. As part of that process, they employed the principles of co-design and human-centered design discussed in Chapters 2 and 3 to include their employees in the design and implementation of any new experiments or changes in care delivery. They also spent time learning about their patients and where bottlenecks existed in the patient journey and the health care delivery process that were costing money and leading to poorer health outcomes. From these efforts, they were able to define a small set of traction metrics and focus on the right product–market fit for primary care in their densely urban context. As they learned, they incorporated those lessons back into their model and pivoted where necessary to continue to improve. The result has been up to 80 percent of primary care hospital visits costing 40 percent less and taking less than one-fourth of the time (Sunmonu, 2017).

Similarly, Thailand's experience attests to the potential impact of continual research, monitoring, and updating of a universal coverage program (Missoni, 2010). Chapter 8 explores this concept of a learning health care system in greater detail, with specific examples of how it can be operationalized in various contexts.

SUMMARY AND RECOMMENDATIONS

Political will and committed executive and operational leadership are essential to financing and suitably equipping the health sector to deliver effective UHC. However, the methods and pathways for pursuing this goal are numerous, and will require contextual application and engagement and co-design with citizens to develop the best system for each country. India saw success with its VAS social health insurance program, in which patients experienced lower mortality rates thanks to increased care utilization, better quality facilities, and earlier diagnosis, as well as 60 percent fewer OOP expenditures for hospitalizations. Costa Rica undertook massive primary care reform, helping to reduce child mortality by 13 percent for every 5 years the program was in place. Even more countries are now starting on their journey to improve the quality of their health care. Global resources and learning networks exist, providing technical and policy guidance on how to establish NQPSs, as well as lessons learned from other countries that are working toward these goals.

Regardless of the options chosen, a focus solely on access and financial protection is insufficient to enable effective UHC. Quality assurance and improvement need to work in tandem with the SDGs goal of achieving UHC. As yet, evidence and research on the quality outcomes of various financial and policy strategies employed in pursuing UHC at scale are still deficient, but several interventions have proven successful in specific contexts. The following illustrative strategies and interventions have been highlighted in this chapter:

- A maternity care experiment in India indicated that input and output incentive contracts resulted in a more than 20 percent reduction in PPH.
- mHealth interventions can be effective and have improved the accuracy of data submission by health workers, improved clinical decision-making skills, and had positive effects on NCDs (although caution is needed to ensure person-centeredness).
- Clinical decision support is feasible to implement and accepted by providers, improves work flow, and is cost-effective.
- Demand creation at the community level was a successful strategy for improving the uptake of antenatal services, but it was most effective in reducing rates of stillbirth when coupled with supply-side efforts to improve the quality of care and system strength.

Overall, the studies reviewed on accreditation also provide a growing base of evidence that this strategy can create a safety and quality culture, in addition to yielding real improvements in health outcomes:

- Accreditation status in Brazil was significantly associated with patient safety and quality management activities.
- Accredited hospitals compared with nonaccredited hospitals in Jordan saw decreased rates of next-day readmission to the intensive care unit, reduced staff turnover, and increased medical record completion.
- Accredited providers and institutions in the Philippines scored higher than nonaccredited facilities.
- Accredited health centers in Egypt had higher patient and provider satisfaction and performed better on patients' rights, information systems, compliance with care standards, and recording of patient visits in records.

The committee wishes again to emphasize the importance of context and culture in all quality interventions, and although the above examples show many successes, they may not be easily translated to another country or institutional environment. We urge health system and country leaders to employ the design principles outlined in Chapter 2 when considering these policy and financial levers for improving quality, and hope that additional, tailored research can lead to stronger evidence and greater generalizability for promising interventions.

Conclusion: All countries need to commit to achieving universal quality care to truly realize the benefits of UHC. This commitment will require investment and, equally challenging, changes in culture and beliefs among health care leaders and professionals and the public. It will require rethinking about how to achieve better-quality care in all settings, such as by employing systems thinking, ensuring the reliable use of evidence-based guidelines, fostering innovation in care delivery, empowering the workforce and patients to participate in the improvement of care systems, and building accountability into the system to address collusion and corruption so the system is responsive to and meets the needs of patients. This commitment will also require setting bold aims for ongoing improvement in all domains of quality, and revisiting and updating those aims frequently over time. Finally, since no health system is entirely "public," partnership and collaboration with the private sector will be necessary to realize this vision and truly improve quality for all citizens.

Recommendation 7-1: Make Accountability for Quality a Top Priority
Ongoing improvement of the quality of care in all dimensions should be the daily work and constant responsibility of health care leaders, including, but not limited to, ministries of health. The committee endorses the recent Global Quality report and recommendations of the World Health Organization, the World Bank, and the Organisation for Economic Co-operation and Development, and further recommends the following steps:

- Every ministry of health should develop a national health care quality strategy, together with supporting policies, and should agree to be held accountable for progress.
- Every ministry of health should adopt goals for achieving high-quality care, adapted to their national context, but considering all the dimensions of quality highlighted in this report.
- The United Nations System or a respected global civil society organization should maintain an independent accountability mechanism with which to monitor and report on the progress of nations toward achieving high-quality care.
- Governments, international agencies, and private-sector partners should activate public demand for high quality care through education on patient rights and health literacy, provider choice, measurement, and transparency.

Conclusion: Quality and UHC are not sequential or separate; they are inextricably linked. Without quality, UHC is an empty vessel. Specific *policy levers exist to help embed quality into UHC, but they need to be used as a package of interventions to promote quality improvement. These approaches have not yet shown successful outcomes at scale. As countries move toward UHC, governments will need to use the mechanisms inherent in UHC as levers to accelerate care improvement. These policy levers include, but are not limited to, actively considering quality when making decisions on what services and products to commission or purchase, to whom they will be provided, and how much to pay.*

Recommendation 7-2: Use Universal Health Coverage (UHC) as a Lever to Improve the Quality of Care

As ministries of health and health care leaders implement UHC, they should work with payers and providers to improve quality by institutionalizing evidence-based policy levers and systematically assessing their effects on quality. Countries should gather and report on quality metrics in global frameworks and across a range of quality dimensions. Steps within nations should include:

- using financing and coverage mechanisms in UHC that support the provision of high-quality care, such as strategic commissioning and purchasing of services and products, selective contracting, and paying for the value of care;
- carrying out monitoring and evaluation, including clinical audits, community involvement and co-design, and customer satisfaction surveys, to generate data that can be used to ensure that UHC resources are fostering high-quality, continuously improving care; and
- conducting research and evaluation on the impact of policy levers on the quality of care received to improve the evidence base on what interventions lead to better care at a systems level.

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8

Establishing a Culture of Continual Learning

Throughout this report, the committee has called for leaders to rely on systems thinking approaches to guide their efforts to restructure health care to improve quality and put patients at the center of care. But what does "systems thinking" really mean? And what beliefs, behaviors, and investments does it call upon? This chapter elucidates the concept and offers suggestions for putting it into practice, using the lens of a "learning health care system" (LHCS), a concept established in the National Academy of Medicine's Learning Health System Series (NAM, 2018). In effect, an LHCS is an organization that uses continuous cycles of learning and reflection to inspire growth and development, involving all stakeholders—staff, managers, executives, clinicians, patients, communities, and others—in that enterprise. While the label and terminology of an LHCS are used most commonly in the United States and, more recently, in Europe, the fundamental components of such an organization are global, and examples exist in many countries.

Technologies and proper financing can be key technical tools to support an LHCS. The advances in digital technology in health care explored in Chapter 3 will be invaluable—indeed essential—in the health care systems of the future. So, too, can smart payer and government financing strategies that incentivize high-quality care, especially using universal health coverage (UHC) as a lever, as explored in Chapter 7. However, an LHCS's most significant, core characteristics are not technical but cultural. The essence of an LHCS is an organizational ecosystem that enables and encourages continual learning, information exchange, and improvement, illustrated in the third level of the committee's framework in Figure 2-2. The committee believes an LHCS may be the best possible vehicle for health care leaders who choose to act on the recommendations offered in this report.

The first section of this chapter describes an LHCS, its underlying philosophy of continual improvement, how it is supported by sociotechnical systems theory and principles of human factors, and its benefits. The chapter then describes the essential components of an LHCS and suggests how these components shape the work of organizational leaders, using examples from around the world. Finally, the committee has highlighted areas throughout the report in which information and research are lacking. The third section of the chapter outlines a research and development agenda to provide the information needed to improve the picture of health care quality around the world. The chapter closes with a summary and recommendations.

WHAT IS A LEARNING HEALTH CARE SYSTEM?

According to the Institute of Medicine, an LHCS is a system in which "science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practice for continuous improvement in health and health care" (IOM, 2011a, p. 1). An LHCS seeks to transform clinical care and better align people, processes, and technology by weaving continuous, rapid, and systematic evidence generation into routine medical practice (Smoyer et al., 2016). Although LHCSs have been implemented in various forms and at various scales, they all follow a cycle of "assembling, analyzing, and interpreting data, followed by feeding it back into practice" (Foley and Fairmichael, 2015, p. 4) to support productive change. Figure 8-1 depicts the learning cycle that characterizes an LHCS. Collecting data from routine patient care and using proper analytic techniques, learning organizations can feed back valuable and timely information to clinicians, public health officials, health care managers, and patients to help them continually improve the quality of health care (Foley and Fairmichael, 2015).

Although the LHCS label is relatively new, the concepts underlying an LHCS have a long history in the enterprise of health care quality improvement. In fact, the cycle depicted in Figure 8-1 is nearly identical to the "Plan, Do, Study, Act" cycle (AHRQ, 2015) that is familiar to many quality improvement experts and used worldwide in many industries. A "decision to study" lies at the base of the LHCS cycle, after which an LHCS will support the assembly and analysis of relevant data, ideally coming directly from routine work processes, patients, and health care workers. Interpretation of the data can provide lessons based on experience, which are immediately available for clinical decision support (Friedman and Macy, 2014).

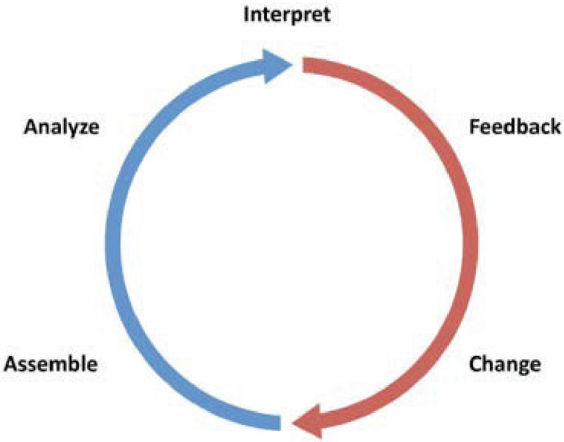

FIGURE 8-1 The learning health care system cycle.
SOURCE: Foley and Fairmichael, 2015.

This cycle of continual learning and action is rare today in health care systems around the world, despite the level of resources available. In some cases, resource-constrained environments are poised to become learning systems and generators of frugal innovations because they have no other choice. However, their growth will require time and investment, especially in the face of approaches that treat health system solutions as "magic bullets" instead of recognizing the need for long-term institutional and behavioral change (Morain et al., 2016). Conventionally, health care organizations rely on clinical research or health systems and services research to determine how to change care practices. However, this process of evidence generation and passive uptake can take years to develop and make its way into clinical practice. Conversely, an LHCS is a "change machine," seeking to close the gap between knowledge and action and quicken the pace of change, supporting the rapid testing of best practices and lessons and their incorporation into routine clinical practice (IOM, 2011b). However, even these lessons will not happen overnight. In a *Harvard Business Review* article, the authors examine three innovation models at top health care institutions, finding that all of them report a challenge of navigating pressures to show immediate value (Bhatti et al., 2018). The committee recognizes that these organizational changes are not a quick fix and may take time to show return on investment. However, that does not mean they are not worth pursuing, as several health systems are already doing (see Box 8-1).

BOX 8-1
Case Studies of a Learning Health Care System

Kenya's Clinical Information Network (CIN)

Kenya developed the CIN in 2013 as part of its new strategy for improving hospital care for children nationwide. Kenya points to the CIN as a mechanism for promoting continual improvement, implementing new practices, and conducting locally relevant research to optimize interventions, arguing that these issues are often tackled separately. One challenge is that a data management and clinical team needs to be supported to build the partnership and ensure that learning is shared, but it is difficult to secure funding for these purposes. Instead, quick fixes are often prioritized, but their long-term absorption and learning are not. CIN leaders also are increasingly aware of the need to consider health care as a complex adaptive system, and to build into change efforts soft skills in leading multidisciplinary teams, reflection on the dynamics of an intervention, and flexibility for pivoting instead of viewing cause and effect as always being a direct linear process (Irimu et al., 2018).

Baobab Health

Baobab Health is a Malawi-based nongovernmental organization that uses technology and tools to improve health care for HIV treatment, antenatal care, chronic care, and trauma care. Its key innovations include software development, touch screen computers, and bar codes for patient registration. Its touch screen interfaces are designed to be used by those with limited technology experience and to guide health workers through guidelines for HIV/AIDS approved by the World Health Organization (WHO) and the Malawian Ministry of Health. Furthermore, the touch screen interfaces are linked with a clinical application, the Baobab Antiretroviral Therapy System, which

The Application of Principles of Sociotechnical Systems and Human Factors

Given the complex interplay among technologies, patients, health care workers, behavior, and organizational decision making (Friedman et al., 2015), an LHCS can best be achieved when fully informed by sociotechnical systems and human factors theories. In fact, an LHCS is a sociotechnical system (Foley and Fairmichael, 2015). Mastering and implementing the sociotechnical frameworks presented in Chapter 2, such as the Systems Engineering Initiative for Patient Safety (SEIPS) model,[1] will help

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[1] The SEIPS model is a sociotechnical systems model that builds on the traditional Donabedian model of health care (Structure + Processes = Outcomes). By introducing sociotechnical systems theory, it expands on each component of the Donabedian model. The first, redubbed the "Work System," is composed of technology, the organization, the environment, tasks, and the person. The second, still called "Processes," takes into account care and other processes, such as administrative rules. The third, still termed "Outcomes," takes into account patient and organizational outcomes (Carayon et al., 2006).

aids health workers in diagnosis and prescription. The patient registration system allows all data to be recorded so they can be retrieved for all future visits. Baobab uses other clinical modules, such as an antenatal module, a maternity module, a diabetes and hypertension module, and a chronic care module. Each of these modules allows Baobab to collect demographic information, manage laboratory results, enhance case management and discharge, and manage chronic care needs longitudinally (Baobab Health, n.d.; Center for Health Market Innovations, 2018a). Although Boabab has yet to use its extensive data collection to improve care iteratively, it makes valuable use of the data to inform clinical decision making and care continuity.

Proqualis

Launched in 2009 by the Oswaldo Cruz Foundation, the Collaborative Center for Quality of Care and Patient Safety (Proqualis) contributes to the implementation of effective quality improvement in health care organizations in Brazil (Braithwaite et al., 2017b). Hospitals with recognized success are invited to join the network and share their quality improvement experiences, highlighting the "Safety II" appoach described in Chapter 2. These are compiled into an easy-to-use repository that is managed and kept up to date to ensure that the most current information is being accessed. Proqualis' organization of communities of practice encourages user participation and provides a model for locally contextualized health system information in other similar countries. This facilitation of shared learning allows providers and hospitals to compare performance and continually improve their learning processes. To truly take this initiative to the next level and build a resilient health care system, the network will need to continue adapting to changing care requirements, as well as have the ability to identify, assess, and share emerging conceptual and practical approaches to improvement (Braithwaite et al., 2018).

hospitals and health care facilities become LHCSs. The goal of an LHCS is to improve the work system and processes so as to improve outcomes by transforming clinical care. In addition to identifying failures and striving to reduce their occurrence, LHCSs can employ the elements of the "Safety II"[2] approach toward resilient health care and work to understand what makes things go right in a complex, nonlinear health care system, leading to successful outcomes. An LHCS can engage with clinicians and all providers to identify and promote the characteristics and circumstances that lead to good care, and then make that information available to others to extend the network of learning. As argued in Chapter 2, an ideal health care system will strive for joint optimization, to the extent possible, for patients, health care workers, and the health care organization, rather than optimizing one at the expense of the others. Thus, an LHCS focuses its goals on the inner

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[2] Safety II is a new approach to understanding safety that acknowledges a provider's "ability to succeed under varying conditions, so that the number of intended and acceptable outcomes is as high as possible" (Hollnagel et al., 2015).

two circles of the committee's framework in Chapter 2 to optimize health care quality, often driven by circumstances in the outer circle.

As discussed in Chapters 2 and 3, a systems thinking approach to designing a health care system requires acknowledging human factors, which involve constant interactions among information, technology, and people (Roth et al., 2016). Human factors science can help everyone in an organization understand the strengths and vulnerabilities of human performance, help shape work processes to better support the people involved, and help present information in ways that make its interpretation and use easier and more reliable (Roth et al., 2016). Mastery of human factors science can result in far better designs that are much more capable of assuring quality.

Experience suggests that establishing LHCSs in low-resource settings is feasible. It may become even more feasible in the near future as digital health technologies burgeon, bringing technical expertise more quickly and at lower cost to places that formerly lacked such access.

Benefits of a Learning Health Care System

Although traditional approaches to improving health care quality, such as auditing, accreditation, inspections, and public reporting (when used in conjunction) are essential and have important and generally favorable effects on basic quality assurance (that is, reducing egregiously bad care), they are double-edged. When too heavily relied upon, surveillance, reward, and punishment can sometimes negatively reinforce quality improvement, and they can breed unwanted behaviors, such as misreporting of outcomes and bias in case selection. Moreover, if not used appropriately, they can create a culture of fear and blame, leading to health care that is compliant with minimal standards and reactive to adverse events. Furthermore, if such tools are not paired with feedback and guidelines for improvement, they can seem unnecessary and burdensome for health care workers, leading to disengagement with quality improvement efforts.

An LHCS is different, using positive reinforcement, long-term investment, and the celebration of teamwork to breed a culture of learning, not fear. An LHCS confers benefits to both providers and patients by emphasizing feedback and learning rather than mere surveillance (Wollaston, 2013). In addition, because LHCSs acknowledge that people are fallible and prone to making mistakes, they create a culture in which people freely report hazards, errors, and defects in care, opening the door to improvement and giving life to the Japanese phrase "every defect is a treasure" (IHI, 2018). Thus, with learning as a foundation, an LHCS will strive not just to meet quality benchmarks but to achieve improvements beyond them. It will measure not just static achievements but also rates of improvement over time.

THE COMPONENTS OF A LEARNING HEALTH CARE SYSTEM

Figure 8-1 depicts an LHCS as having five main components: (1) assembly of data, (2) analysis, (3) interpretation, (4) feedback, and (5) change. To support these components, an LHCS should be comprise various technical and system-level characteristics. These foundational elements of an LHCS are described in Table 8-1.

These LHCS components align well with and reinforce the committee's design principles articulated in Chapter 2. Each has strong implications for the activities and investments by leaders in both wealthy and resource-limited settings. The committee's remarks below elucidate which design principles these components particularly support and how they can function when resources are low.

Real-Time Access to Knowledge and Digital Capture of the Care Experience

The new digital era, as explored in Chapter 3, holds enormous promise for extending subject-matter expertise, such as specialty medical consultation, into low-income and austere environments far faster and at far lower cost relative to conventional care. The LHCS components of real-time access to knowledge and digital capture of the care experience embody an essential feature of the future of health care envisioned by the committee: Continuous feedback and learning generates knowledge to make decision making evidence-based and locally relevant, anticipatory, and cognizant of true sources of adverse events. This vision requires knowledge that is gathered rapidly and implemented quickly. Access to near-real-time knowledge (not just raw data) will bridge the "know-do" gap and act as the engine for the learning cycle. An LHCS attempting to offer real-time information collects information steadily from its own care processes. Information management is integrated into the workflow, rather than being layered on top of it. The result is that information is fresher, cleaner, and easier to interpret, and collecting it is far less burdensome.

However, paper-based records and reporting are still all too common in low- and middle-income countries (LMICs), impeding rapid reflection, adjustments, and growth. Digitizing the data and knowledge now commonly contained in paper-based records can make decision making and care delivery adjustments quicker and safer. For example, the Mobile Triage app developed by The Open Medicine Project in South Africa uses patient information to help nurses triage patients in emergency rooms. Typically, nurses use paper charts and calculate triage scores from memory, but as many as one in four patients in some settings may be incorrectly triaged

TABLE 8-1 Components of a Learning Health Care System

Science and Informatics	
Real-time access to knowledge	A learning health system continuously and reliably captures, curates, and delivers the best available evidence to guide, support, tailor, and improve clinical decision making and care safety and quality.
Digital capture of the care experience	A learning health system captures the care experience on digital platforms for real-time generation and application of knowledge for care improvement.
Patient–Clinician Partnership	
Engaged, empowered patients	A learning health system is anchored on patient needs and perspectives and promotes the inclusion of patients, families, and other caregivers as vital members of the continuously learning care team.
Incentives	
Incentives aligned for value	A learning health system has incentives actively aligned to encourage continuous improvement, identify and reduce waste, and reward high-value care.
Full transparency	A learning health system systematically monitors the safety, quality, processes, prices, costs, and outcomes of care, and makes information available for care improvement and informed choices and decision making by clinicians, patients, and their families.
Continual Learning Culture	
Leadership-instilled culture of learning	A learning health system is stewarded by leadership committed to a culture of teamwork, collaboration, and adaptability in support of continuous learning as a core aim.
Supportive systems competencies	A learning health system constantly refines complex care operations and processes through ongoing team training and skill building, systems analysis and information development, and creation of the feedback loops for continuous learning and system improvement.

SOURCE: Excerpted from NASEM, 2016, p. 121.

(The Open Medicine Project, 2014). The app can assist otherwise underresourced emergency centers in accurately screening and prioritizing patients, and it is already being used in 63 countries worldwide.

Related design principles:

- Decision making is evidence based and context specific.
- Care makes optimal use of technologies to be anticipatory and predictive at all system levels.
- Problems are addressed at the source, and patients and health care staff are empowered to solve them.
- The transformation of care delivery is driven by continuous feedback, learning, and improvement.

Engaged, Empowered Patients

The committee has spoken repeatedly about the centrality of the patient experience, the importance of streamlining the entire patient journey, and the value of co-design and co-production of health care systems with patients and communities. A commitment to these precepts requires both culture change, to shift the balance of power between those who give and those who receive care, and practice change, to support ongoing, authentic conversations among patients, caregivers, and the organizations that serve them. Empowerment, at the end of the day, comes from refocusing health care from the conventional question of "What is the matter with you?" to the modern question of "What matters to you?" (DiGloia et al., 2016).

Thus, the information needed by LHCSs includes not only clinical data but also information on the needs and perspectives of patients, families, and communities. This could include, for example, information on patients' ability or inability to receive maternal and neonatal care at the same facility. Taking into account people's perspectives, however, requires that the health care organization have the ability to inquire about what matters to them, and to incorporate their perspectives and those of their communities into the operations of the health care system at all levels, from clinical encounters, to improvement projects, to governance. This approach can lead to the development of a network of integrated health centers, such as was accomplished by Aprofe, a not-for-profit provider in Ecuador. Originally a provider of sexual and reproductive health care, Aprofe now provides surgical, maternal, and rural health care. This diversification of services occurred in part in response to demand from patients. The quality of services and patient-centered care provided at Aprofe clinics benefit the organization, as its customer base expands predominantly through patient referrals. In fact, Aprofe regularly implements improvements to person-centered care, such as by conducting patient flow analysis to reduce wait times (Innovations in Healthcare, 2012).

Engaging and empowering patients, especially by leveraging digital tools they are already using, can also create opportunities to collect data, helping an LHCS better prioritize patients' needs on their journey, determine how to structure care such that it is integrated and coordinated, and create a space for patients and health care workers to co-design care transformation. As a result, the purposeful act of empowering and engaging patients will help create a system that is easy and transparent to navigate.

Related design principles:

- Care delivery prioritizes the needs of patients, health care staff, and the larger community.
- Care is integrated and coordinated across the patient journey.
- Navigating the care delivery system is transparent and easy.
- Patients and health care staff co-design the transformation of care delivery and engage together in continual improvement.

Incentives Aligned for Value

The committee has emphasized the importance of systems thinking in redesigning care and the need for alignment of leadership, policy, culture, and incentives to deliver value. However, value can take on many meanings. In traditional quality discussions, value has the meaning of "value for money," a catchphrase that has driven financing and payment away from volume and toward outcomes, as evidenced by the numerous pay-for-performance schemes now emerging globally. However, "value" can vary depending on the local context, necessitating contextually appropriate trade-offs.

To be able to deliver value, an LHCS will embrace and encourage new system designs that align the incentives of all parties. All too often, different parties (patients, health workers, administrators, and leaders) have competing priorities, which can foster fragmentation and myopia and inhibit learning. By striving for the joint optimization of outcomes among patients, health care workers, and the health care organization, an LHCS can improve value. For example, consider PurpleSource Healthcare in Lagos, Nigeria, described in Chapter 7. In Lagos, private health care is highly fragmented, with 90 percent of facilities being sole proprietorships. Poor management capacity, lack of quality assurance, and lack of access to finance lead to unsustainable business performance and poor patient outcomes. PurpleSource aggregates such facilities and deploys financial management, SafeCare quality certification, and technology solutions to integrate care across facilities. It also works with its patients to understand what matters to them, and builds its services around those priorities. This alignment of patient and organizational needs places PurpleSource on the path to becoming one of the largest networks of health care providers in Nigeria (Center for Health Market Innovations, 2018b; Innovations in Healthcare, 2018; PharmAccess Foundation, 2016).

The value created can be further improved by capturing the care experience; providing real-time knowledge; and giving voice to patients, their families, and their communities. An LHCS will best thrive when payment methods support and reward alignment, teamwork across boundaries, and truly person-centered care. Thus, an LHCS should also embrace forms of financing that reward such activities and cooperation among caregivers. The era of UHC bodes well for smarter payment if nations leverage the potential of UHC policy and financial mechanisms, as discussed in Chapter 7.

Related design principles:

- Systems thinking drives the transformation and continual improvement of care delivery.
- Care delivery prioritizes the needs of patients, health care staff, and the larger community.
- Trade-offs in health care reflect societal values and priorities.
- Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote integrity, stewardship, and accountability.

Full Transparency

An LHCS should align and make transparent incentives to create value. Monitoring of information on quality, prices, and outcomes needs to be complemented by an effort to share the information. Without that dual effort, continuous feedback and learning cannot be achieved. Furthermore, without full transparency, investigation of adverse events will likely revert to outmoded root-cause point analysis instead of tracing the problem to longitudinal system sources.

Thus, transparency for an LHCS is a prerequisite for improvement. It can not only identify priority areas for focused improvement by highlighting problems, but also support identification of so-called "positive deviants,"[3] organizations and systems that significantly outperform expectations. These

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[3] Positive deviancy denotes a behavioral and social change approach based on the observation that in a group or organization, individuals may use uncommon but successful strategies to deliver better solutions than their colleagues despite facing similar challenges and having no extra knowledge resources (Sternin and Coo, 2000). Positive deviancy thus serves as an asset-based approach (Baxter et al., 2015), and lessons developed from so-called "positive deviants" can be particularly valuable (Lawton et al., 2014).

organizations merit special study since they may offer breakthrough models and lessons on which others can build. For example, the positive deviance approach was used to identify and disseminate information that improved compliance with hand hygiene in Brazil (Marra et al., 2010), nurse–patient communication in Indonesia (Kim et al., 2008), and newborn care practices in Pakistan (Marsh et al., 2002). Sharing this information freely can facilitate broad uptake of the lessons as providers attempt to better themselves and patients self-select higher-performing providers. Similarly, transparency in an LHCS can serve as a foundation for productive exchange between providers and patients. In essence, it illuminates what matters in the patient journey and can direct where to strengthen efforts to simplify navigating the care process.

Transparency in an LHCS can produce positive externalities. For example, those who believe in the power of market forces to energize improvement will want patients, families, and health insurers (public or private) to see the relative performance of the providers from whom they can choose. Regulators will want to know which providers to inspect more thoroughly or with whom to intervene. And transparency can shine a light on corruption, which is a toxic impediment to the accountability, trust, and integrity of a system on which learning depends.

Related design principles:

- Navigating the care delivery system is transparent and easy.
- The transformation of care delivery is driven by continuous feedback, learning, and improvement.

Leadership-Instilled Culture of Learning

Developing an LHCS is a structural commitment to a culture of continual learning and improvement that has implications for all parties interacting with the health care system. In fact, many of the components of an LHCS can feel threatening and unwelcome. Empowered patients bring new demands and expectations. Measurement and transparency can be perceived as threats of blame and punishment. Incentives can seem like unjust sources of pressure. Improvement requires change, which a workforce can oppose if it seems infeasible or is not implemented strategically—or, most important, if it is not supported by an invested leadership. If an LHCS is to strive for continual learning and improvement, empowerment of patients, and transparency, a shift in organizational culture is needed. A key component of culture change for an LHCS is building a supportive and motivating culture, which takes time to accomplish. Without such a culture, obtaining buy-in from staff will be arduous, and changes made will not be sustainable. If done well, however, the building of such a culture can have positive and encouraging results. Project Fives Alive! in Ghana, for example, focused on harnessing the creativity of front-line workers and managers and having them solve problems at their level (Twum-Danso et al., 2012). It also used local data to identify problems and adapt the design of the system to improve, seeing mortality among children under 5 and infant mortality decline by one-third (Sodzi-Tettey et al., 2015).

The potential of this culture change has been demonstrated in a systematic review analyzing 62 studies (Braithwaite et al., 2017a). In more than 90 percent of the studies, the authors found organizational and workplace culture to be correlated with a range of patient health outcomes across multiple settings, nearly three-quarters of which were positive. For example, patient mortality rates were nearly 48 percent lower in hospitals with better nurse work environments in South Korea (Cho et al., 2015). These changes in culture offer tremendous opportunity for improvement. Finally, culture change must be led by motivated and dedicated leaders prepared to invest the appropriate resources (Morain et al., 2016). Health care leaders who want to cross the quality chasm documented in this report will consciously nurture the beliefs and behaviors essential for learning, such as curiosity, mutual trust, a willingness to try, systems knowledge, and transparency. They will do so by modeling such norms in their own daily behaviors and by coaching those who work for them to do the same. The committee sees no reason why these basic characteristics are any less applicable to leaders in resource-constrained settings than to those in wealthy ones. Indeed, one can find a growing number of examples in low-income settings of organizations that have begun to practice continual improvement and have reaped the benefits, as described previously in Box 8-1.

Related design principles:

- Leadership, policy, culture, and incentives are aligned at all system levels to achieve quality aims, and to promote integrity, stewardship, and accountability.
- Problems are addressed at the source, and patients and health care staff are empowered to solve them.
- The transformation of care delivery is supported by invested leaders.

Supportive System Competencies

Culture may be the “soft side” of transformation to an LHCS. Its partner is the “harder” side of supportive systems, both human and technological. To participate actively in continual improvement, the entire workforce can benefit from skills in understanding systems and processes; statistical thinking and data interpretation; teamwork; approaches to testing changes on a small scale (e.g., "Plan-Do-Study-Act" cycles locally); and the establishment of new, more balanced relationships with patients and families. To streamline and improve processes, for example, Senegal recently tested the well-known 5S management method for improving the quality of health care services, and included it in its national strategy following a successful pilot project (Kanamori et al., 2015). Leaders can learn to study and assess their own work locally—right at the "sharp end" of care—and to embrace measurement as a friendly tool, not an outside threat. Modernized data systems, including new digital applications and telemedicine, can be invaluable, but they must be implemented with a systems approach in mind. Piecemeal pilots and ad hoc digital interventions over the past 15 years have proven that potential can be wasted if implementation, evaluation, and sustainability are not well designed at the outset. Methods for better analyzing and displaying data can help, as can collaborative structures within and among organizations in which people grappling with similar problems can exchange lessons, discovering that they know more together than they do separately. For example, the newly established program on Developing Excellence in Leadership, Training and Science Africa is aiming to shape and drive a locally relevant research agenda among 21 countries across the continent, creating a network of researchers poised for collaboration and information sharing (AESA, 2017). Such learning collaboratives have thrived in many low-resource settings, and have very likely accelerated improvement among their members.

Related design principles:

- Systems thinking drives the transformation and continual improvement of care delivery.
- Decision making is evidence based and context specific.
- Care is integrated and coordinated across the patient journey.
- The transformation of care delivery is driven by continuous feedback, learning, and improvement.
- The transformation of care delivery is a multidisciplinary process with adequate resources and support.

A RESEARCH AND DEVELOPMENT AGENDA

Throughout this report, the committee has identified gaps in knowledge about the prevalence, patterns, costs, and causes of and remedies for quality defects in global health care. Closing those gaps through research would help better inform policy, management, and practice, all of which should ideally be based on sound evidence. LHCSs generate and use evidence mainly in cycles of pragmatic, local action and reflection in real-world settings, rather than deriving evidence from formal experimental trials (English et al., 2016). The distinction between the former evidence and that obtained through traditional randomized controlled trials and other formal designs is important, and sometimes controversial. The committee recognizes that both forms of evidence are valuable in pursuit of better care (Massoud et al., 2016). Additionally, given the massive increase in connectivity and the globalized nature of the world today, the research and development agenda outlined here need not be applied in silos across the world. Instead, to support the existing and emerging learning networks and collaboratives aiming to improve health care quality, there is also great potential for bidirectional information sharing, as discussed in Chapter 1. It is increasingly recognized that while countries may be different, health challenges and populations across borders can be quite similar. Researchers at the University of California, for example, are testing models for improving birth outcomes and have created sister programs in Fresno County, California, and five districts in Rwanda, partnering with the country's Ministry of Health and universities (Evangelista, 2018). Together, they can compare models with similar populations and share lessons that emerge during the study. The Fresno program learned from Rwanda the importance of stakeholder engagement, for example, and the Rwandan team is interested in Fresno's lessons on mental health, reduction of stress, and provision of psychosocial care. In this pursuit for better quality of care and better health outcomes globally, borderless research provides great opportunity (Evangelista, 2018).

Applying the findings from the research and development agenda outlined below will be another important step. The aims of an LHCS have much in common with the arena of study that has recently become known as "implementation science," defined as

> the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within certain settings (NIH, n.d.);

and

> the study of methods to promote the integration of research findings and evidence into healthcare policy and practice (NICHSR, 2018).

Implementation science is thus about how to move good models into widespread use. And this is what an LHCS is about: generating practice-based evidence (from its own studies and those of others) and translating that knowledge into evidence-based practice that applies to the local contexts of the system. This relatively new discipline has the potential to develop and identify effective, evidence-based strategies and speed the translation of knowledge into practice. Examples of its application and utility in low-resource settings are already emerging, such as the integration of implementation research into Population Health Implementation and Training partnership projects in five African countries. Ghana's experience resulted in successful scale-up of effective practices, including reduction of neonatal mortality and improved data utilization, and added to understanding of the role of mentoring and coaching in improving the quality of care (Awoonor-Williams and Appiah-Denkyira, 2017). The committee supports the further development of and investments in implementation science.

Reflecting on findings in prior chapters, the committee proposes the following set of important research topics for the next decade to support the acceleration of care improvement globally. These topics fall into four general categories: (1) digital health care and measurement of quality, (2) applications and adaptations in LMICs, (3) payment and policy strategies to motivate and support improvement, and (4) organizational and clinical interventions to accelerate improvement.

Research on Digital Health Care and Measurement of Quality

Chapter 4 summarizes much of what is known about the prevalence and patterns of high and low quality globally. However, the endeavor to gather that information repeatedly encounters a dramatic deficit in reliable, high-quality data. Without such data, it will be difficult to target resources and interventions effectively. Along with that need is the complementary challenge of creating and adopting helpful metrics, especially in the coming age of digital health, as highlighted in Chapter 3. In the future the committee envisions, in which digital health care and traditional health care as a whole increasingly overlap, measuring the impact of digital health care on health outcomes will become vital. The committee highlights the following two questions in these arenas:

- What is the impact of the digitization of health care on population health outcomes?
- What innovative or proven models exist for local use of measurement for improvement?

Research on Applications and Adaptations in Low- and Middle-Income Countries

Questions about the quality of global care assume special forms in the context of LMICs. Effective forms of quality management and improvement in those settings need to be better understood. One particularly important related topic is corruption and its impact on health care quality, as emphasized in Chapter 6. Unfortunately, corruption, by its nature hidden and opaque, does not lend itself to easy measurement or research, and thus its impact on care is not well understood. The committee is interested in the following four questions, the answers to which would yield a better understanding of the determinants of and some remedies for poor quality:

- What is the role of various actors in quality management across LMICs?
- Which digital health technologies can best contribute to better quality of care in resource-constrained settings?
- Do private markets reward higher quality?
- To what degree does corruption have effects on the quality of health care delivered in various settings? How can these effects best be mitigated?

Research on Payment and Policy Strategies to Motivate and Support Improvement

Chapters 5 and 7 identify several areas of major deficits in knowledge about strategies for improving the quality of care in specific settings and using specific levers. Chapter 5 identifies these deficits for settings of extreme adversity and for the informal sector, while Chapter 7 highlights uncertainties about the effects of policy and payment tools and raises questions about the roles that patients could play in demanding improvements in health care quality. The recent 2018 joint report of the World Health Organization (WHO), the World Bank, and the Organisation for Economic Co-operation and Development (OECD) (WHO et al., 2018) highlights seven categories of interventions employing policy, clinical, and cultural levers and represents a major step forward, but many questions continue to loom large. Six related questions emerged as of special interest to the committee:

- What 10 interventions are most likely to improve health care quality in settings of extreme adversity?
- What 10 interventions are most likely to improve the quality of care in the informal sector?
- What are the best strategies for addressing quality in fragmented settings, where most patients pay out of pocket?
- What strategies can reduce overuse of health care delivery services in low-resource settings, especially when regulatory capacity is limited or absent?
- How can strategic purchasing best help improve the quality of care delivery?
- What strategies are most effective in engaging patients and people in general to demand high-quality (and, especially, safe) care for themselves and their families?

Research on Organizational and Clinical Interventions to Accelerate Improvement

Much more needs to be known about optimizing strategies in local contexts and organizations. This is an area in which the LHCS and implementation science can become especially useful. Chapter 2 emphasizes the importance of using a systems approach to designing health care. But what, more precisely, does that mean for the daily work of health care leaders? Chapter 3 calls for a workforce with a vastly different skill set to meet the needs of the digital age in health care. But what skills are most valuable? Key questions for optimizing organizational strategies for quality improvement include the following:

- How can leaders implement a systems approach for improving the quality of health care in LMICs effectively and efficiently?
- What skill sets for the workforce are linked to better health outcomes for patients, especially in the coming digital age of health care?

SUMMARY AND RECOMMENDATIONS

The basic technical principles of systems thinking, quality improvement, and a learning organization are generic in that they apply to improvement at all levels and in all sizes of systems, from very local enterprises, such as one's chess game or weaving, to very large-scale enterprises, such as national policy frameworks or the strategy of corporations. In the case of health care quality, this means the same approaches that can help improve antibiotic use in a clinic or pain control in surgery can also be used at the level of health care policy and finance. While this chapter on creating a learning culture focuses mainly on the clinical level—or the inner circles of the committee's framework in Chapter 2—great opportunity lies in doing the same in the outer circle, with a focus on the environment affecting care. Clearly, conducting learning cycles at such a large scale can be daunting, but it is not out of reach for leaders who want to ensure that policy, like practice, is based to the extent possible on evidence and the continual growth of knowledge. Indeed, a nation that fails to learn from its trials of new policies and tactics is thereby at a disadvantage compared with nations that learn. For a health system, this cycle of learning will require a skilled clinical and nonclinical workforce able to actively co-design and co-produce care with patients and communities. In most nations and most organizations, the development of such a workforce will in turn require a profound cultural shift from reliance on inspection and punishment of "bad actors" and failures to investments in transparency, openness, learning, and improvement. Examples of this potential already exist, as mentioned throughout this chapter:

- The positive deviance approach was used to identify and disseminate information that improved hand hygiene compliance in Brazil, nurse–patient communication in Indonesia, and newborn care practices in Pakistan.
- A project in Ghana focused on harnessing the creativity of front-line workers and managers, having them solve problems at their level, and used local data to identify problems and adapt the design of the system to improve. As a result, infant and child mortality declined by one-third.
- In South Korean hospitals where nurses experienced better work environments, patient mortality rates were nearly 48 percent lower.

At the same time, however, as with the many other topics across quality health care discussed in this report, context is important. The existing evidence and examples offer ideas and inspiration for other similar countries, but each learning health care system must take the elements outlined here and adapt them to its own local needs and priorities to see success.

Additionally, an enormous number of questions related to quality and the strength of the evidence supporting interventions remain unanswered. Given these gaps in knowledge and the importance of people's health, the amount of funding directed toward quality control and quality improvement in health care, compared with that in other industries, is too low, and multifaceted and interdisciplinary investments are needed.

> *Conclusion: Realizing the benefits of a learning health care system will require a culture change in which learning is institutionalized and systemically rewarded. There are no "magic bullet" solutions. Instead, long-term investment and behavior change will be needed, adapted to the local context. All of those who work in a learning system help drive improvement of the system as a whole on behalf of the people and communities the system serves. And all understand what the desired outcomes are; how they contribute to these outcomes; and how and why to avoid suboptimizing their own department, specialty, or local organization at the expense of the whole.*

> **Recommendation 8-1: Encourage a Culture of Learning to Fundamentally Redesign Health Care**
> **Health care leaders in all settings should master and adopt the vision and culture of a learning health care system, striving for continual learning and avoiding an approach that relies primarily on blame and**

shame. This learning system should extend beyond hospitals and providers to include patients, payers, administrators, community health workers, and others involved in health.

- Country governments should implement policies designed to effectively educate and supply health care professionals who are trained to provide high-quality care. These professionals should include a cadre of clinical and nonclinical leaders that are versed in creating a culture that rewards openness, transparency, and a commitment to improvement.
- Governmental and organizational leaders should ensure that efforts to create accountability in the health care system, though fundamental, do not create a culture of fear and reaction, which is inimical to system improvement and change. Performance in all domains of quality should be measured and reported transparently, and the results should be widely available to patients to encourage feedback and improvement over time.
- Governmental and organizational leaders should learn and use modern approaches to improving science, practice, and organizational culture.
- Nations, regions, and health systems should establish and maintain programs to facilitate shared, collaborative learning about improvements and innovations in health care.
- Leaders should ensure that health care systems harness new digital health technology to help reduce costs and improve care through real-time use of data.

Conclusion: There is a clear need for a much more locally relevant, robust research agenda related to quality of care. Investments are required to fund this agenda, which could have exponentially positive effects. A parallel investment to create a global learning community surrounding quality that can mobilize to share lessons and to understand what strategies and interventions to employ would multiply the benefits of that research.

Recommendation 8-2: Define and Mobilize a Research and Development Agenda

The U.S. National Institutes of Health, philanthropic organizations, and other bilateral donors, as well as low- and middle-income country (LMIC) governments and other stakeholders, should increase investments in research and development on interventions that would improve the quality of care at the system level, encompassing both primary and implementation research. The following questions should be priorities:

- What is the impact on population health outcomes of the digitization of health care?
- What innovative or proven models exist for local use of measurement for improvement?
- What are the roles of various actors in quality management across LMICs?
- Which digital health technologies can best contribute to better quality of care in resource-constrained settings?
- Do private markets reward higher quality?
- To what degree does corruption have effects on the quality of health care delivered in various settings? How can these effects best be mitigated?
- What 10 interventions are most likely to improve health care quality in settings of extreme adversity?
- What 10 interventions are most likely to improve the quality of care in the informal sector?
- What are the best strategies for addressing quality in fragmented settings where most patients pay out of pocket?
- What strategies can reduce overuse of health care services in low-resource settings, especially when regulatory capacity is limited or absent?
- How can strategic purchasing best help improve the quality of care delivery?
- What strategies are effective in engaging patients and people in general to demand high-quality (and, especially, safe) care for themselves and their families?
- How can leaders effectively and efficiently implement a systems approach for strengthening the quality of health care in LMICs?
- What skill sets for the workforce are linked to better health outcomes for patients, especially in the emerging digital age of health care?

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A

Public Meeting Agendas

COMMITTEE MEETING ONE
October 18, 2017
Washington, DC

1:00–1:15 pm	Welcoming Remarks Donald Berwick, Co-Chair
1:15–2:30 pm	Sponsor Briefing: Discussion of the Committee's Charge Anne Katherine Wales (via telecom) Medtronic Foundation Gianluca Fontana (via video) Institute of Global Health Innovation, Imperial College London Peter Kilmarx Fogarty Institute, National Institutes of Health Kelly Saldana Office of Health Systems, U.S. Agency for International Development (USAID)

	Steven Towers U.S. President's Emergency Plan for AIDS Relief
2:30–3:00 pm	Sponsor Q&A with Committee
3:00–3:15 pm	Break
3:15–4:15 pm	Advising the Committee on Quality Efforts
	Pierre Barker Chief Global Partnerships and Programs Officer, Institute for Healthcare Improvement
	Joe McCannons Co-Founder and CEO, The Billions Institute
4:15–5:00 pm	Discussion with Committee: Reaction Panel
	Jishnu Das Lead Economist, Development Research Group, World Bank
	Nana Twum-Danso (via video) Founder and CEO, MAXA
	M. Rashad Massoud Senior Vice President, University Research Co.
5:00–5:30 pm	Public Comment
5:30 pm	Adjourn

COMMITTEE MEETING TWO
December 18, 2017
Nairobi, Kenya

1:00–1:05 pm	Opening Remarks to Public Audience
	Donald Berwick, Co-Chair

1:05–1:15 pm	Welcome Annah Wamae Quality Assurance and Regulation, Kenya Ministry of Health
1:15–2:00 pm	Current Challenges in Health Care Mondher Letaief Eastern Mediterranean Regional Office, World Health Organization (WHO) Maina Boucar Regional Director, USAID Prosper Tumusiime Africa Regional Office, WHO
2:00–2:45 pm	Discussion with Committee
2:45–3:00 pm	Break
3:00–3:45 pm	Ignite Session: Innovations Supporting Quality Millicent Olulo Country Director, Pharmaccess Kenya Christian Rusangwa Partners in Health, Rwanda Olivia Koburongo MamaOpe, Uganda Femi Sunmonu PurpleSource Healthcare, Nigeria
3:45–5:15 pm	Discussion with Committee
5:15 pm	Adjourn

COMMITTEE MEETING THREE
March 14, 2018
London, United Kingdom

9:00–9:10 am	Opening Remarks to Public Audience Donald Berwick, Co-Chair Sania Nishtar, Co-Chair
9:10–9:25 am	Welcome and Keynote Address Ara Darzi Director, Institute of Global Health Innovation, Imperial College London
9:25–10:15 am	Commissioned Paper Presentations How Will Technology Support or Change Health Systems in the Future? Alain Labrique Johns Hopkins University What Is the Implication for Health Care Redesign: Human Factors? Peter Buckle Imperial College London
10:15–10:45 am	Discussion with Committee
10:45–11:00 am	Break
11:00 am–12:50 pm	Interactive Workshop: Helix Centre
12:50–1:00 pm	Concluding Remarks Donald Berwick, Co-Chair Sania Nishtar, Co-Chair
1:00-1:30 pm	Break
1:30–3:00 pm	Working Lunch and Reflections from Invited Guests

B

Methods for Rapid Review

OBJECTIVE

The objective of this rapid review was to accumulate evidence on strategies being used by governments and insurers to improve health care quality.

Types of Studies Included

- Randomized controlled trials (RCTs), including cluster randomized controlled trials (CRCTs)
- Quasirandomized trials (QRTs), including cluster quasirandomized trials (ClQ-RCTs) using methods of allocation such as alternation or allocation by case note number
- Observational designs with a comparison group, such as cohort or case-control designs (cross-sectional designs excluded)
- Case series in which a comparison can be made before and after the implementation of a strategy

Types of Participants: Patients, health care consumers, and health care providers, including organizations (e.g., hospitals, practices, and individual health care professionals), without any restriction by type of health care professional, provider, setting, or purchaser.

Types of Outcome Measures: Primary: Improvement in a quality-of-care metric (i.e., safety, effectiveness, timeliness, patient-centeredness, equity, or efficiency) at any follow-up time.

SEARCH STRATEGY AND DATABASES USED

All terms within Table B-1 below were searched with an OR command between them, while terms across columns were searched with an AND command between them. The search was first conducted with terms from all columns being used. A secondary search was then conducted with column D excluded, and all duplicates were deleted.

TABLE B-1 Search Strategy

Databases: Scopus, Web of Science, Medline (Ovid), Embase (Ovid), and Pubmed

A	B	C	D
All low- and middle-income countries as identified by the World Bank	• "health system" • "health care" • "health care delivery" • "health care services"	• "provider network" • "empanelment" • "prior authorization" • "pay for performance" • "performance-based financing" • "clinical audits" • "death audits" • "accreditation" • "inspection" • "licensing" • "safety standards" • "minimum quality" • "safety protocol" • "quality improvement protocol" • "clinical decision support" • "public reporting" • "shared decision making" • "provider reimbursement" • "results based financing" • "selective contracting" • "strategic contracting" • "strategic purchasing" • "purchaser strategies"	• "healthcare quality" • "health care quality" • "quality improvement"

NOTE: The search terms were developed based on an initial reading of the literature and feedback from the committee.

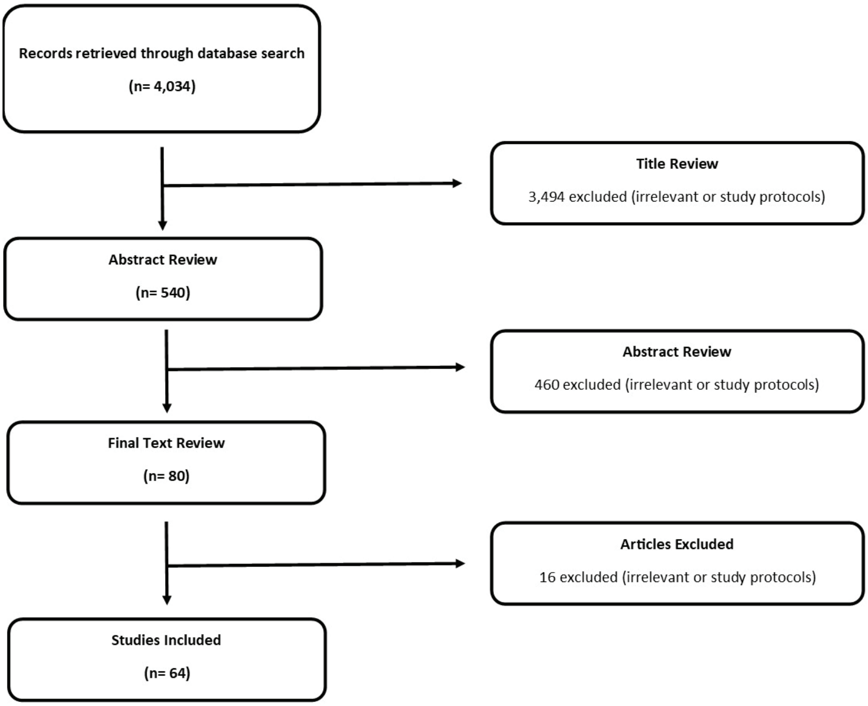


FIGURE B-1 Article exclusion flow chart.

DATA COLLECTION AND ANALYSIS

Selection of Studies

All titles and abstracts were downloaded into Excel. Articles were excluded in three phases: title review, abstract review, and document review. One reviewer conducted the title review. Two reviewers conducted the abstract review. Articles included for document review were the combination of those abstracts deemed eligible for inclusion. Multiple reviewers then conducted the last phase as articles were read for content.

Data Management

In the final phase of document review, all papers were categorized to streamline synthesis of data. Fourteen categories were identified: accreditation, conditional cash transfers, community engagement, public report, payment reform (general), workforce training, clinical monitoring and auditing, care coordination, clinical decision support, pay for performance, mHealth, quality improvement (general), strategic purchasing and contracting, and financial incentives (general).

Data Extraction

Data from each study were extracted on type of study, intervention, and clinical outcome being investigated; magnitude of the effect; the study's importance for quality; and areas of knowledge still needed.

ARTICLES INCLUDED

The flow chart depicted in Figure B-1 illustrates the articles initially identified in the literature search and each step of the exclusion process.

C

Committee Member Biosketches

Donald M. Berwick, M.D. (*Co-Chair*), is president emeritus and senior fellow at the Institute for Healthcare Improvement, as well as former administrator of the Centers for Medicare & Medicaid Services. With a background as a pediatrician, Dr. Berwick has served on the faculty of Harvard Medical School and Harvard School of Public Health, and on the staffs of Boston's Children's Hospital Medical Center, Massachusetts General Hospital, and Brigham and Women's Hospital. Additionally, he has served as vice chair of the U.S. Preventive Services Task Force; the first "independent member" of the American Hospital Association Board of Trustees; a member of the Board on Global Health Board at the National Academies of Sciences, Engineering, and Medicine; and chair of the National Advisory Council of the Agency for Healthcare Research and Quality. He served two terms on the Institute of Medicine's Governing Council and served on President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Dr. Berwick is acknowledged as a leading authority on health care quality and improvement and has received numerous prestigious awards for his contributions. In 2005, he was appointed Honorary Knight Commander of the British Empire by Her Majesty, Queen Elizabeth II, as a result of his work with the British National Health Service. Furthermore, he is an elected member of the American Philosophical Society. He has authored or co-authored more than 160 scientific articles and 6 books. Dr. Berwick received his B.A. from Harvard College and both his M.D. from Harvard Medical School and his M.P.P. from the John F. Kennedy School of Government at Harvard University in 1972. He currently serves as a lecturer in the Department of Health Care Policy at Harvard Medical School.

Sania Nishtar, SI, F.R.C.P., Ph.D. (*Co-Chair*), is a Pakistani physician and former federal minister of the Government of Pakistan. She has strong civil society credentials as founder of Heartfile in Pakistan. Born in Peshawar, Dr. Nishtar graduated from Khyber Medical College with 16 distinctions, setting a college record. She holds a Fellowship of the Royal College of Physicians of London and a Ph.D. from King's College London. Dr. Nishtar has been involved with many international agencies in various capacities and is described by the World Health Organization (WHO) as "a widely respected global health expert." She was founding chair of the United Nations Secretary-General's Independent Accountability Panel for the Global Strategy on Women's, Children's and Adolescents' Health and has served as co-chair of the WHO Commission on Ending Childhood Obesity. She has also served as board member of the WHO Alliance for Health Policy and Systems Research and Gavi, the Vaccine Alliance. She is currently co-chair of the World Economic Forum's (WEF's) Global Future Council on Health and Healthcare and is also a trustee member of WEF's Health Global Challenge initiative. She is also a member of the Lancet and Rockefeller Foundation Commission on Planetary Health and the Lancet and Harvard Commission on Pain and Palliative Care. In addition, Dr. Nishtar is a member of the Steering Committee of the Emerging Markets Symposium, an initiative of the Green Templeton College, Oxford University. She has published extensively internationally and is the author of six books. She is a regular keynote speaker at international events and is the recipient of many national and international awards, including the Pakistani civil award Sitara-i-Imtiaz (star achiever) and the Global Innovation Award. Dr. Nishtar has been included in the list of the top 20 women in science in the Muslim world. In 2017, she was one of the three shortlisted nominees for director-general of WHO.

Ann Aerts, M.D., M.P.H., is based in Switzerland and serves as head of the Novartis Foundation, an organization committed to ensuring quality health care in low- and middle-income countries. Her overseas career began in 1991 as a district health officer in Angola and as an emergency physician in Burundi, the Democratic Republic of the Congo, East Timor, Ivory Coast, Mozambique, Rwanda, and Sudan. Dr. Aerts is the former franchise medical director critical care for Novartis Pharma in Basel and therapeutic area head cardiovascular and metabolism in Novartis Pharma Belgium. Prior to joining Novartis, she served as director of the Lung and Tuberculosis Association in Belgium from 2002 to 2006 and as head of the Health Services Department of the International Committee of the Red

Cross (ICRC) in Geneva and health coordinator of the ICRC in numerous countries. Dr. Aerts holds a degree in medicine and a master's in public health from the University of Leuven, Belgium, as well as a degree in tropical medicine from the Institute of Tropical Medicine in Antwerp, Belgium. Her global health work has earned her numerous awards and recognition, including a nomination by PharmaVOICE as one of the 100 Most Inspiring People in the life science industry in 2014. In addition to the publications she has authored and the studies she has conducted, she is a member of various boards, such as the Global Health Group Advisory Board of the University of California, San Francisco, NetFWD of the Organisation for Economic Co-operation and Development Advisory Board, and a member of the International Telecommunication Union/United Nations Educational, Scientific and Cultural Organization Broadband Commission for Sustainable Development and of the Governing Council of the Technology Bank for the Least Developed Countries.

Mohammed K. Ali, M.D., M.B.A., M.Sc., is associate professor in the Hubert Department of Global Health and Department of Epidemiology at Emory University's Rollins School of Public Health. He is a physician scientist and has expertise in epidemiology, health services research, and implementation sciences. His research interests focus on diabetes, global health, and cardiovascular disease. He helped design and leads several large National Institutes of Health-funded studies in South Asia: a large three-city cohort study, two large pragmatic trials of quality improvement, a study evaluating the implementation of workplace wellness programs, and a large quasi-experimental study to transform and strengthen chronic disease management in rural areas in India. Dr. Ali was responsible for co-leading the expert group on diabetes complications for the Global Burden of Disease Study and is associate director of the Georgia Center for Diabetes Translation Research. He consults for the U.S. Centers for Disease Control and Prevention, where he helps manage a program that uses natural experiment designs to evaluate diabetes prevention and control policies in the United States. He also serves as a scientific advisor for the National Diabetes Prevention Program. Dr. Ali's work and teaching have earned him numerous honors, including the Consortium of Universities for Global Health Velji Award for Excellence in Teaching in 2013, election to the Delta-Omega Public Health Honor Society in 2013, and the Pfizer-Association of Schools and Programs of Public Health Early Career Teaching Award in 2013, and he was named a fellow of the American Heart Association in 2014. He received his M.D. from the University of Cape Town in 2003, his M.Sc. in cardiovascular medicine and M.Sc. in global health sciences from the University of Oxford in 2007, and his M.B.A. from Emory University in 2012.

Pascale Carayon, Ph.D., is Procter & Gamble Bascom professor in total quality in the Department of Industrial and Systems Engineering and director of the Center for Quality & Productivity Improvement, an interdisciplinary research center, at the University of Wisconsin–Madison. She leads the Systems Engineering Initiative for Patient Safety (SEIPS) and is founding director of the Wisconsin Institute for Healthcare Systems Engineering at the University of Wisconsin–Madison. In 1984, Dr. Carayon received her engineering diploma from the École Centrale de Paris, France, and she received her Ph.D. in industrial engineering from the University of Wisconsin–Madison in 1988. Her research interests focus on human factors and systems engineering in health care and patient safety. She has developed human factors and systems engineering methods and the SEIPS model to improve patient safety and health information technologies in complex health care settings. Her research has been funded by the Agency for Healthcare Research and Quality, the National Science Foundation, the National Institutes of Health, numerous foundations, and private industry. She has produced more than 140 journal publications and received numerous awards and honors. She is the chair of the National Academies of Sciences, Engineering, and Medicine's Board on Human-Systems Integration, a recipient of the 2007 College of Engineering Ragnar E. Onstad Service to Society Award, recipient of the 2012 International Ergonomics Association Triennial Distinguished Service Award, and recipient of the 2015 John M. Eisenberg Patient Safety and Quality Award for Individual Achievement. She is a fellow of the Human Factors and Ergonomics Society and of the International Ergonomics Association. In 2015 and 2016, Dr. Carayon was named by *Becker's Hospital Review* as one of 50 experts leading the field of patient safety. She is the editor of the *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety* and was a member of the Institute of Medicine Committee on Diagnostic Error in Health Care.

Margaret Amanua Chinbuah, Ph.D., M.P.H., M.B.Ch.B., is based in Ghana and currently serves as a newborn care technical advisor for PATH, an organization leading global health innovations especially as applied to women and children. Dr. Chinbuah has worked as a medical officer providing clinical care in Ghana and has been responsible for managing several implementation studies supporting various programs, including the Child Health program and the National HIV/AIDS, Malaria, and Tuberculosis programs. She is directly responsible for the technical component of the Making Every Baby Count Initiative. In her role as newborn care advisor, she is deeply involved with the development of policies and guidelines that impact the mother and child, such as guidelines for kangaroo mother care in Ghana, child health guidelines, and sick newborn monitoring charts. Dr. Chinbuah received her medical degree from the University of Ghana Medical School and a master's of public health from the School of Public Health, University of Ghana. She obtained a master's of health science, specialization in epidemiology, from Erasmus University in Rotterdam, Netherlands, and a Ph.D. in epidemiology from the University of Amsterdam, Netherlands. Dr. Chinbuah is fluent in English, is a member of the Ghana College of Surgeons and Physicians, the National Newborn Subcommittee, the National Child Health Committee, and the Chlorhexidine Study group, among others. She has co-authored several publications, made many presentations at national and global conferences, and served as a resource person for various national task teams.

Mario Roberto Dal Poz, Ph.D., M.D., M.S., is a Brazilian-based physician and researcher who is a full professor at the Social Medicine Institute of the Rio de Janeiro State University and editor-in-chief of the *Human Resources for Health* journal. He formerly worked as coordinator of the Human Resources for Health department at the World Health Organization. Dr. Dal Poz was invited to deliver a Regency Lecture on the "Global Response to the Health Workforce Crisis" at the Global Center for Health Economics and Policy Research of the University of California in 2008 and was awarded the Oswald Cruz Gold Merit Medal from the Brazilian president for his contributions to public health. He has published numerous books, as well as articles and commentaries in leading medical journals such as *The Lancet*, *PLoS*, and *Health Affairs*. Dr. Dal Poz obtained his medical degree in 1975 from Rio de Janeiro State University, followed by a master's in social medicine in 1981 and a doctorate in public health in 1996 from the Oswaldo Cruz Foundation. He receives research grants from the National Research Council and the Research Foundation of Rio de Janeiro.

Ashish Jha, M.D., M.P.H., is the K.T. Li Professor of Global Health at Harvard University and director of the Harvard Global Health Institute. He is a practicing general internist and a professor of medicine at Harvard Medical School. Dr. Jha received his M.D. from Harvard Medical School and then trained in internal medicine at the University of California, San Francisco. He completed his general medicine fellowship at Brigham and Women's Hospital at Harvard Medical School and received his M.P.H. from the Harvard T.H. Chan School of Public Health. His research focuses on improving the quality and costs of health care systems, with a specialized focus on the impact of policies. Dr. Jha has published more than 200 papers in prestigious journals and produces a personal blog focused on using statistical data research to improve health care quality. He is a member of the National Academy of Medicine.

Sheila Leatherman, CBE, Hon FRCP, is a professor at the Gillings School of Global Public Health, University of North Carolina. She conducts research and policy analysis internationally focusing on quality of care, health systems reform, and methodologies for evaluating the performance of health care systems. In the international field of health care quality and health systems strengthening, she has advised on and assisted in the development of national programs and strategies in countries such as Afghanistan, Canada, Ethiopia, Mexico, Nigeria, Saudi Arabia, Singapore, South Africa, Sudan, the United Kingdom, and the United States. Ms. Leatherman is the lead advisor for the 5-year World Health Organization National Quality Policy and Strategy initiative supporting low- and middle-income countries in designing and implementing national quality strategies (2015–2019). She is both a principal investigator and advisor for research and implementation projects in multiple countries, and she contributes to multiple humanitarian and global health international nongovernmental organizations, including serving as the quality advisor for Doctors Without Borders/OCP. In 2002 she was elected to the National Academy of Medicine and in 2006 she was made an honorary fellow of the Royal College of Physicians. In 2007, she was awarded the honor of Commander of the British Empire by Queen Elizabeth II for her work over the past decade in the National Health Service. Ms. Leatherman has authored numerous articles and books. Her broad background in health care management in U.S. state and federal health agencies includes the role of chief executive of a health maintenance organization and a senior executive of UnitedHealth Group, where she founded and directed a research center.

Tianjing Li, M.D., Ph.D., M.H.S., serves as assistant professor of epidemiology at the Johns Hopkins Bloomberg School of Public Health (JHBSPH) and as associate director for the U.S. Cochrane Center, 1 of 14 centers around the world that facilitate the work of the Cochrane Collaboration. The aim of Dr. Li's research is to develop, evaluate, and disseminate efficient methods for comparing health care interventions and to provide sound evidence for decision making. The focus areas of her research include methodologies for systematic reviews, network meta-analysis, randomized controlled trials, comparative effectiveness research, and patient-centered outcomes research. Dr. Li's accomplishments and research efforts earned her the inaugural Society for Research Synthesis Methodology Early Career Award in 2016. She serves as editor-in-chief for the journal *Trials* and associate editor for the journal *Ophthalmology*. She has received grant support from the National Eye Institute, Patient-Centered Outcomes Research Institute, Food and Drug Administration, and Agency for Healthcare Research and Quality. Dr. Li continues to teach graduate-level courses at the JHBSPH on clinical trials, systematic review, epidemiology, and biostatistics, as well as advanced doctoral seminars and courses in grant writing.

Vincent Okungu, Ph.D., M.P.H., M.A., is a health economist, researcher, and lecturer. His research interests include health care financing and policy, costing studies and economic evaluation, health equity analysis, and the economics of noncommunicable diseases. His key research outputs include modeling the cost of universal health coverage in Kenya, health financing strategies for the informal sector, fiscal space analysis, access barriers, and policy communication, among others. He currently heads the research unit at PharmAccess Foundation (Kenya) and is a visiting research fellow at the African Population & Health Research Centre. Dr. Okungu has been heavily involved in international, national, and county health policy design and program interventions and evaluation. Working with a number of local and international organizations, he has played leading roles in key health systems design and strengthening interventions. These include sustainable financing for HIV/AIDS; sustainable health financing for informal-sector populations; and health system leadership and governance, including budget analysis, public expenditure review, program-based budget, and resource allocation. He has also designed health financing and monitoring and evaluation curricula for the Ministry of Health, Kenya, where he serves as a technical committee member on capacity building. Dr. Okungu is a case writer in social entrepreneurship in health and teaches this subject as a visiting scholar at Duke University.

Neeraj Sood, Ph.D., is professor and vice dean for research at the University of Southern California (USC) Sol Price School of Public Policy. He is also a faculty member at the USC Schaeffer Center and research associate at the National Bureau of Economic Research. He serves on the editorial board of the *Journal of Health Economics, Health Services Research* and *Forum for Health Economics and Policy*, and is on the board of directors of the American Society of Health Economists. His prior work has focused on the economics of innovation, HIV/AIDS, health care financing, and global health. His research has been published in several peer-reviewed journals and books, including leading journals in economics, medicine, and health policy. He has testified frequently on health policy issues, and his work has also been featured in several media outlets, including *The New York Times*, *The Washington Post*, *U.S. News & World Report*, and *Scientific American*. Dr. Sood was the finalist for the 16th and 21st Annual National Institute for Health Care Management Foundation Health Care Research Award, recognizing outstanding research in health policy. He was also the 2009 recipient of the Eugene Garfield Economic Impact Prize, recognizing outstanding research demonstrating how medical research impacts the economy. Prior to joining USC, Dr. Sood was a senior economist at the RAND Corporation and professor at the Pardee RAND Graduate School.

Jeanette Vega, Ph.D., M.D., M.P.H., has been based in Santiago, Chile, as general director of the National Chilean Public Health Insurance Agency since March 2014. With 20 years of experience in international health, her expertise lies in the social determinants of health, health equity, and health systems. Dr. Vega began her career as a medical doctor practicing family medicine and holds a master's degree in public health from the Universidad de Chile and a Ph.D. in public health from the University of Illinois at Chicago. Since obtaining her degrees, she has served in prominent public health leadership roles, such as vice minister of health in Chile; director of the Center of Public Health Policy at the Universidad del Desarrollo; and director at the World Health Organization in Geneva, where she headed the organization's health equity agenda. In 2012, Dr. Vega joined The Rockefeller Foundation to lead its health-related work, including its Transforming Health Systems Initiative.

Marcel Yotebieng, Ph.D., M.D., M.P.H., has worked in multiple countries in sub-Saharan Africa as clinician, public health practitioner, and researcher. He has served as principal investigator on multiple grants funded by the National Institutes of Health (NIH) (two RO1s), the Gates Foundation, and the World Health Organization (WHO). He has also served as co-investigator on large cooperative agreements (UO1 or U2) from NIH and the Centers for Disease Control and Prevention. This funding has allowed him and his collaborators to build strong research infrastructures in the Democratic Republic of the Congo (DRC), including a centrally located office with more than 20 full-time staff, cars, and freezers, all supporting ongoing data collection in 106 health facilities across the entire province of Kinshasa. His work has informed national and international guidelines on tuberculosis management and treatment of HIV in children. Results from one of his recently completed trials have led to calls for WHO to revisit its policy of almost three decades on breastfeeding promotion. His expertise is well recognized at both the national and international levels. He has served as a member of the scientific committee that advises the National TB Program in the DRC on guidelines since 2011. He has been invited to chair a discussion section at the Conference on Retroviruses and Opportunistic Infections and to participate on panel discussions at other regional and international meetings. As lead for the pediatric work for the Central Africa International Epidemiologic Database to Evaluate AIDS, he has been a key member of the Collaborative Initiative for Pediatric HIV Education and Research Cohort Collaboration since its inception. Recently, he was invited to join the Global Burden of Disease Network, and more important, he was nominated by NIH to serve on the ad hoc committee that conducted the present study.

D

Methods for Chapter 4

PART 1: MODELING

Contents

SAFETY

Unsafe and Harmful Medical Care

Assumption

1. Disability weights, duration, and mortality from Jha and colleagues (2013) are still applicable.

We estimated the burden of unsafe and harmful medical care as a continuation of the published work from Jha and colleagues (2013). We combined studies from Jha et al. (2013) with an updated literature search, and excluded studies that were missing population information and those that focused only on intensive care unit (ICU) patients. For each safety indicator, we calculated a weighted average incidence rate and age from this new sample of studies. We used the same mortality rates, disability weights, distribution of short-/long-term disability, and duration of disability as those used by Jha et al. We calculated disability-adjusted life years (DALYs) for six safety events: adverse drug events, thromboembolism from medical care, falls in hospital, pressure sore and decubitus ulcers, ventilator-associated pneumonia, and urinary tract infections. We updated the formula used by Jha et al. by removing social weights and age discounting. We obtained an updated estimate of total hospitalizations in low- and middle-income countries (LMICs) (estimated to be 531 million) from a forthcoming Institute for Health Metrics and Evaluation (IHME) publication.

When calculating the burden of ventilator-associated pneumonia we focused exclusively on ventilated patients in the ICU, which necessitated the use of a separate denominator. To calculate the appropriate denominator, we assumed that ICU beds in LMICs were 1.5 percent of total hospital beds, based on literature. We obtained the total number of hospital beds (13.4 million) using data from the World Bank from 2000 up to the most recent year available, and multiplied this by 1.5 percent to obtain the number of ICU beds (0.2 million). The estimate of 531 million hospitalizations implies a use rate of 11 percent given our estimate of hospital beds. We assumed that this use rate was the same for ICU beds, thus calculating an estimated 8 million number of ICU hospitalizations in LMICs. Data from the International Nosocomial Infection Control Consortium (INICC) suggests that the ratio of ventilator to ICU days is 0.38, which we applied to ICU hospitalizations to obtain the total number of ventilated ICU hospitalizations (3.1 million). This number was used as the denominator for ventilator-associated pneumonia while total hospitalizations were used for all other safety indicators.

In addition, we did not update the literature search for urinary tract infections but used the studies that were included in Jha et al., excluding those that were exclusively in the ICU.

Falsified and Substandard Medications

Assumption

1. Those receiving counterfeit or substandard drugs are considered untreated.

The main approach to estimating the burden of falsified medications was informed by estimates of falsified medication from a 2017 World Health Organization (WHO) report, *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products* (WHO, 2017). These data provide a lower, middle, and upper-end approximation that we use to provide a range of uncertainty for our estimates.

We applied the burden of falsified medications to the HIV/AIDS and tuberculosis (TB) indicators. Estimating the burden of falsified medications varied somewhat for each indicator. In every case, we assumed that the rate of falsified medications identified in the WHO report was equivalent to that share of patients receiving falsified medications, which most likely overestimates the number of patients affected. However, this bias is counter to that attributable to the conservative definition of substandard drugs used by WHO. To simplify the analysis, we assumed that patients receiving falsified medication had the same outcomes as the untreated population.

Detailed methods for applying falsified estimates can be found below in the HIV/AIDS and TB methods.

COMMUNICABLE DISEASES

HIV/AIDS Morbidity and Mortality

Assumptions

1. People dying from HIV/AIDS were not retained in treatment, and those who were retained in treatment do not die from HIV.
2. Mean age of death from untreated HIV/AIDS was assumed to be the same regardless of whether status was known.
3. Mortality rate among the untreated is the same regardless of known status.
4. Adherence and counterfeit rates are the same between low-, middle-, and high-income countries.
5. Outcomes for the nonadherence and those on counterfeit medications are equivalent to those who were untreated.
6. Those on substandard or falsified medications are untreated.

Variable Definitions

Variable	*Definition*	*Source*
Prevalence	Number of diagnosed and undiagnosed HIV/AIDS cases	IHME
Known status	Of all HIV/AIDS patients, share that know their status	UNAIDS, AIDSInfo
Treated	Of all HIV/AIDS patients, share that are on antiretroviral therapy (ART)	UNAIDS, AIDSInfo
Deaths	Deaths from untreated HIV/AIDS	IHME
Age of death	Mean age of death from untreated HIV/AIDS	IHME
Disability weights	Disability attributable to HIV/AIDS	Global Burden of Disease (GBD) Study, 2016

The percent of people with known HIV/AIDS status and the share receiving ART (both as a share of *all* HIV/AIDS patients) in LMICs was identified using the UNAIDS AIDSInfo 2016 database. A total of 71 LMICs (52 percent) reported data on known HIV status, and 114 (83 percent) reported data on treatment status. Where treatment status was available and known status was not, we used the share on treatment as a proxy for known status, with the understanding that this is an underestimate. We used the sample of countries for which data were available (83 percent) to extrapolate to the population of all LMICs. Notably, extrapolation has a minor effect on our results, since the countries within our sample account for 99.9 percent of the population in LMICs.

Prevalence of HIV, deaths attributed to HIV, and mean age of death were obtained from IHME's 2014 GBD database. We assumed that people dying from HIV/AIDS were all untreated and those who are treated do not die from HIV. Mean age of death from untreated HIV/AIDS was assumed to be the same regardless of whether status was known. The midpoints for age bins were used as single-year age estimates. The average age of death was weighted for the number of HIV deaths by country. A half-cycle correction was applied by adding 0.5 years to the mean age of death (equivalently, we can subtract 0.5 years from the remaining life expectancy) to account for double counting between years lived with disability (YLD) and years of life lost (YLL).

Disability weights for HIV/AIDS were obtained from GBD, 2016. We used a weighted average of the weights provided for HIV (0.33) and AIDS (0.66) based on the natural history of disease progression in which 94 percent of time is spent with HIV and 6 percent with AIDS.

Additionally, we sought to include estimates of the effect of substandard and falsified medications, as well as adherence, on HIV/AIDS mortality and morbidity. To obtain estimates of adherence, we conducted a literature search, and estimate that 73 percent of patients adhere to HIV medications. To obtain estimates of falsified medication, we rely on the *Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Products* (WHO, 2017). The review includes 1,018 HIV samples. We used a falsified range of 3.1 percent, 4.2 percent, and 5.7 percent. Our primary estimates use the midpoint of this range. We apply these percentages to the number of patients on treatment to obtain the number of patients who are on falsified medication. To incorporate these estimates, we assume that those on falsified medications and those who are nonadherent are effectively untreated.

Our baseline calculation uses the following formulas:

YLL Components

$$\textit{Deaths Among Diagnosed Untreated} = (\%\textit{known status} - \%\textit{treated}) / ((1 - \%\textit{known status}) + (\%\textit{known status} - \%\textit{treated})) * \textit{deaths}$$

$$\textit{Remaining Life Expectancy} = 83.5 - (\textit{age of death} + 0.5)$$

$$YLL = deaths * remaining\ life\ expectancy$$

YLD Components

$$Prevalence\ Among\ Untreated\ Diagnosed = (\%known\ status - \%treated) * prevalence$$

$$YLD = prevalence\ among\ untreated\ diagnosed * disability\ weights$$

To incorporate falsified drugs we adjust our treatment variable by subtracting the share of falsified drugs from the treatment rate to come up with a falsified-adjusted treatment rate. To incorporate nonadherence into this estimate, we multiply the adherence rate (conditional on treatment) by the baseline treatment rate and subtract the share of falsified drugs. We then recalculate YLL and YLD as above with the new adherence- and falsified-adjusted treatment rate.

To calculate excess we hold adherence and counterfeit medicine rates constant and adjust for differences in population as follows, where outcome is defined as either YLD, YLL, or deaths:

$$Excess\ Outcome = \frac{Outcome_{LMIC}}{Population_{LMIC}} - \frac{Outcome_{LMIC}}{Population_{LMIC}}$$

Tuberculosis (TB) Morbidity and Mortality

Assumptions

1. Average age of death for those treated and untreated for TB is the same.
2. Incidence-based case detection rate is applicable to prevalence.
3. All those on falsified medications are effectively untreated.

Variable Definitions

Variable	*Definition*	*Source*
Prevalence	Number of diagnosed and undiagnosed TB cases, excluding latent TB infection	IHME
Untreated	Patients lost to follow-up as a proxy for nontreatment, conditional on diagnosis	WHO Global Tuberculosis Report Database

Variable	*Definition*	*Source*
Case detection rate	The number of new and relapsed TB cases notified to WHO in a given year, divided by WHO's estimate of the number of incident tuberculosis cases for the same year, expressed as a percentage	WHO Global Tuberculosis Report Database
Mortality rate	Mortality from TB, varying by smear positive versus smear negative and HIV status	Literature search
Age of death	Mean age of death from untreated TB	IHME
Disability weights	Disability attributable to TB	GBD, 2016

Data on case detection rate, treatment, and the percentage of TB patients co-infected with HIV were obtained from the WHO Global Tuberculosis Report Database. We used patients lost to follow-up as a proxy for nontreatment (4.7 percent). Given that the WHO report only provides incidence data, we obtained prevalence of drug-susceptible, drug-resistant, and extensively drug-resistant TB from the IHME GBD 2014 database. We multiplied the case detection rate from WHO by the IHME prevalence to obtain the number of diagnosed TB cases.

We calculated the number of untreated TB patients co-infected with HIV as a share of total untreated patients (7.6 percent) to account for differences in disability weights between those infected (0.43825) and not infected with HIV (0.33). We calculated a weighted disability weight of 0.338.

Average remaining life expectancy was calculated by obtaining YLL from the IHME database and dividing by deaths in the IHME database. The key assumption made here is that the average age of death for the treated and untreated is the same.

We obtained a range of estimates of mortality rates by smear positive and HIV status from the literature and from a WHO publication. The absence of data on the untreated in the WHO database is why we look to alternative sources for an untreated mortality rate. We allowed average age of death to vary between types (drug susceptible 31.05 years, multidrug-resistant [MDR] 30.74 years, and extensively drug resistant [XDR] 30.13 years) of TB, based on data in the IHME database. While we do not allow mortality rates to vary by TB type, we note that MDR TB only accounts for 3.4 percent of global TB cases, and XDR accounts for 0.17 percent of global TB cases. Thus, even allowing mortality rates to vary would have little effect on our estimates.

Additionally, we sought to include estimates of the effect of substandard and falsified medications on TB mortality and morbidity. To obtain estimates of substandard and falsified medication, we rely on the *Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Products* (WHO, 2017). The review includes 4,920 TB samples. We used a falsified range of 6 percent, 6.7 percent, and 7.4 percent. Our primary estimates use the midpoint of this range. We apply these percentages to the number of patients on treatment to obtain the number of patients who are on falsified medication. To incorporate these estimates, we assume that those on falsified medications are effectively untreated.

For the main calculation, we calculated total extrapolated prevalence across each TB category, then multiplied by the case detection rate (62 percent) and untreated rate (4.7 percent) to calculate a total diagnosed-untreated prevalence in LMICs. We developed a set of two mortality rates using different estimates of smear-positive and smear-negative TB distribution, and different estimates of mortality among the HIV+ population.

The first mortality rate (46.6 percent) is a weighted average of four mortality rates, that are in turn weighted for the distribution of smear-positive (SM +) and smear-negative (SM –) TB, based on the 2013 WHO TB report (WHO, 2013) and Tiemersma and colleagues' (2011) work.

- HIV negative, smear positive = 70 percent
- HIV negative, smear negative = 20 percent
- HIV positive, smear positive = 83 percent
- HIV positive, smear negative = 74 percent

The second mortality rate (36.7 percent) is also made up of four mortality rates; however, these mortality rates rely on data from (Dowdy and Chaisson, 2009), which has different estimates of the distribution of smear negative and smear positive, and different mortality rates for HIV positive/negative status:

- HIV negative, smear positive = 50 percent
- HIV negative, smear negative = 16.5 percent
- HIV positive, smear positive = 100 percent
- HIV positive, smear negative = 100 percent

We calculate the weighted average mortality rate using the following formula:

$$(((Mortality_{HIV^-,SM^+} * (SM^+\%)) + (Mortality_{HIV^-,SM^+} * (SM^-\%))) * HIV^-\%)$$
$$+ (((Mortality_{HIV^+,SM^+} * (SM^+\%)) + (Mortality_{HIV^+,SM^+} * (SM^-\%))) * HIV^+\%)$$

The final two mortality rates (46.7 percent and 36.7 percent) were used to develop a range of DALY estimates. We used a half cycle correction to adjust for double counting between YLD and YLL. The population accounted for in the data represented 99 percent of the LMIC population, meaning that extrapolation had little effect on our estimates.

Between HIV status, we calculated a weighted average disability weights using the HIV infected-patient share of untreated patients.

The final calculations were as follows:

$$YLL = prevalence * case\ detection\ rate * \%untreated * mortality\ rate * (83.5 - (age\ of\ death + 0.5))$$

$$YLD = prevalence * case\ detection\ rate * \%untreated * disability\ weights$$

To incorporate falsified drugs we subtract diagnosed untreated prevalence (calculated by multiplying the untreated rate by diagnosed prevalence) from diagnosed prevalence (this gives us diagnosed treated prevalence) and multiply by the falsified drug rate, which gives us an estimate of counterfeit-treated prevalence. All other calculations are carried on as above.

Pneumonia (PN) Inpatient Mortality (under 5 years old)

Assumptions

1. Average age of death for children less than 5 is 2.5 years old.
2. Care seeking for PN among children is a proxy for PN hospitalization rates in LMICs.
3. Sampling distribution of mortality rates follows a beta distribution.

Variable Definitions

Variable	*Definition*	*Source*
Prevalence (of lower respiratory illness)	Total diagnosed and undiagnosed PN cases, under 5 years old	IHME

Variable	*Definition*	*Source*
Care seeking	Children under 5 with symptoms of pneumonia taken to a health care provider; used as proxy for hospitalizations	UNICEF aggregation of Demographic and Health Surveys (DHS), Multiple Indicator Cluster Surveys (MICS), National Universities Commission Surveys (NUCS), and other data sources
Mortality rate, LMIC	Inpatient PN mortality rate in LMICs	Literature search
Mortality rate, HIC	Inpatient PN mortality rate in HICs	National Inpatient Sample
Hospitalizations	Proxied by care-seeking variable	UNICEF aggregation of DHS, MICS, NUCS, and other data sources
Age of death	Mean age of death from inpatient PN among children under 5 assumed to be 2.5 years	N/A

For this indicator, we are not focused on treatment status but rather quality of treatment. That is, we assumed deaths attributable to PN among those who sought care are in excess of the high-income country (HIC) rate and thus preventable.

The percent of children under 5 with pneumonia symptoms taken to a health care facility was identified using data on care seeking for pneumonia symptoms from a UNICEF aggregation of survey data. We used care seeking as a proxy for hospitalization. A total of 119 LMICs (87 percent) reported data on pneumonia care-seeking status. When multiple years of data were available for a country, we used the most recent year. We used the sample of countries for which data were available to extrapolate to the population of all LMICs. The population in our sample countries includes 74 percent of the population in LMICs. Prevalence of pneumonia was obtained from IHME's 2014 GBD database by using lower-respiratory illness as a proxy.

We multiplied the care-seeking percentage by prevalence estimates to determine the number of care-seeking cases (862,324). We extrapolated this to the overall LMIC population, giving us 1,158,896 care-seeking cases.

A literature search was conducted for pneumonia mortality rates among child under 5 years in LMICs. After applying exclusion criteria, a total of 16 study-country observations were included. We assumed mean age of death to be 2.5 years old.

To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates.

For mortality, we used the study population weighted average mortality rate (6.01 percent) and standard deviation (2.01) to come up with beta distribution parameters (8.302, 129.910) using the *-betaprior-* user-written program for Stata. We then ran 2,000 draws with 1,500 observations each with randomly generated mortality rates that follow this parameterization. For each draw we calculated a mean mortality rate. The range of mean mortality rates defines the range of Monte Carlo–based YLL estimates we report. Thus, we end up with 6,000 values of YLL.

Our final calculation uses the following formula:

$$YLL = prevalence_{LMIC} * \%care\ seeking_{LMIC} * \\ mortality\ rate_{LMIC} * (83.5 - 2.5)$$

Assuming that YLL in HICs is the expected burden conditional on provision of high-quality medical care, we calculate YLL from PN under 5 years old in HICs to estimate the excess burden in LMICs. We do so by first obtaining PN mortality rates (for the under 5) and PN hospitalizations from the National Inpatient Sample, 2014. The final calculation is performed as above for low-income countries.

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * \\ care\ seeking\ prevalence_{LMIC}$$

$$Excess\ YLL - (mortality_{LMIC} - mortality_{HIC}) * \\ care\ seeking\ prevalence_{LMIC} * (83.5 - 2.5)$$

Diarrhea Mortality (under 5 years old)

Assumptions

1. Average age of death for children less than 5 is 2.5 years old.
2. All deaths from diarrhea among the care-seeking population are preventable.

Variable Definitions

Variable	*Definition*	*Source*
Care seeking	Child was taken to a medical facility for treatment of the diarrhea; this usually includes being taken to all public-sector facilities and all medical private sector facilities except for pharmacy	UNICEF
Untreated	Not prescribed oral rehydration salts (ORSs), oral rehydration therapy (ORT), zinc, or ORS + zinc among those care seeking	DHS
Age of death	Mean age of death from diarrhea among children under 5 assumed to be 2.5 years	N/A

The percent of children under 5 with diarrhea taken to a health care facility was identified using data on care seeking for diarrhea from a UNICEF aggregation of survey data. A total of 103 LMICs (74 percent) reported data on diarrhea care-seeking status. When multiple years of data were available for a country, we used the most recent year. We used the sample of countries for which data were available to extrapolate to the population of all LMICs. The population in our sample countries includes 64 percent of the population in LMICs. Because the countries in our sample were higher-mortality countries than the full LMIC sample, we adjusted our estimate as follows: We first extrapolated total diarrhea-related deaths within our sample. We then calculated a ratio of our estimated total quality-related deaths to total deaths from diarrhea, and multiplied this ratio by total deaths attributable to diarrhea in the IHME sample of LMICs.

Prevalence of diarrhea and deaths from diarrhea was obtained from IHME's 2014 GBD database. For each country in our sample, we then multiplied the care-seeking percentage by the number of deaths and the percentage untreated to determine the number of care-seeking untreated deaths (79,862). We extrapolated this to the overall LMIC population with the adjustment noted above, giving us 88,402 care-seeking untreated deaths.

We assumed that all deaths among the care-seeking population are preventable, implying that treatment prevents death. That in turn implies that all deaths from diarrhea are among the untreated. We assumed mean age of death to be 2.5 years old. Our final calculation uses the following formulas:

$$\textit{Untreated Deaths} = \textit{deaths} * \%\textit{care seeking} - \%\textit{untreated}$$

$$\textit{YLL} = \textit{untreated deaths} * (83.5 - \textit{age of death})$$

NONCOMMUNICABLE DISEASES

Lung Cancer Mortality

Assumption

1. Excess mortality attributable to quality of care is a function of LMIC status after controlling for prevalence, pollution, and smoking rates.

Variable Definitions

Variable	*Definition*	*Source*
Fine particulate matter (PM 2.5) air pollution	Mean annual exposure to fine particulate matter pollution	World Bank
Male smoking rate	Prevalence of smoking any tobacco product among males aged ≥15 years	WHO
Lung cancer deaths per 100,000	Number of lung cancer deaths per 100,000 population	WHO GLOBOCAN
Lung cancer incidence per 100,000	Incidence of lung cancer per 100,000 population	WHO GLOBOCAN
Lung cancer prevalence per 100,000	Prevalence of lung cancer per 100,000 population	IHME

Our measure of excess mortality for lung cancer uses high-income countries as a benchmark. In particular, our approach examines the extent to which lung cancer deaths are greater in LMICs controlling for air pollution, smoking rates, incidence of lung cancer, and geographic region. Our analytic dataset accounts for 91 percent of the LMIC population. Our method relies on the following linear specification:

$$\textit{Lung Cancer Deaths per } 100{,}000 = \beta_0 + \Pi_{controls} + \gamma_{region} + \alpha_{income} + \varepsilon$$

Where *controls* is a vector that includes air pollution, smoking rates, and lung cancer incidence; *region* is an indicator for geographic region;

income is a dummy variable taking on 0 for high income and 1 for low and middle income, and ε is a stochastic error term. This specification is weighted for prevalence of lung cancer (per 100,000).

To obtain the excess deaths in LMICs, we take the coefficient α, divide it by 100,000 and multiply by population in each country. This gives us the estimated number of deaths attributable to low- and middle-income status, controlling for the variables noted above. This approach extrapolates to the full sample of LMICs.

Acute Myocardial Infarction (AMI) Inpatient Mortality

Assumptions

1. Sampling distribution of mortality rates follows a beta distribution.
2. Sampling distribution of age follows a normal distribution.

Variable Definitions

Variable	*Definition*	*Source*
Mortality rate, LMIC	Inpatient AMI mortality in LMICs	Literature search
Mortality rate, HIC	Inpatient AMI mortality in HICs	OECD Stat, National Inpatient Sample
Hospitalizations	Hospitalization rates per 100,000 people for AMI in LMICs	OECD Stat, literature search
Age of death	Mean age of death from inpatient AMI	Literature search

A literature search was conducted for mortality rates and average age of death in LMICs. After applying exclusion criteria, a total of 28 study-country observations, which contained both mortality rates and either average or median ages, were included. Only two studies included an average age of death. To approximate an age of death for other studies, we calculated a weighted average ratio of average age of death to average/median age and used this ratio to extrapolate an age of death for the remaining studies.

To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates and ages of death.

For mortality, we used the study population weighted average mortality rate (8.493812 percent) and standard deviation (3.369868) to come up with beta distribution parameters (5.728, 61.714) using the *-betaprior-*

user-written program for Stata. Similarly, for age, we used the study population weighted average age of death (61.31981) and the standard deviation (2.812404). Instead of a beta distribution, we used a normal distribution to calculate a range of uncertainty for age. We then ran 2,000 draws with 1,500 observations each with randomly generated mortality rates and ages of death that follow these parameterizations. For each draw we calculated a mean mortality rate and a mean age of death. The range of mean mortality rates and ages of death defines the range of Monte Carlo–based YLL estimates we report.

The remaining variable required is the number of AMI hospitalizations in LMICs. We obtained four estimates, from databases and literature, to generate a range and a country population weighted average hospitalization rate. We extrapolated this rate to the LMICs population (6,093,361,757) to calculate a minimum, average, and maximum number of hospitalizations.

Our final calculation uses the following formula for each value of hospitalizations:

$$YLL = mortality_{LMIC} * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Thus, we end up with 6,000 values of YLL (2,000 for each estimate of hospitalizations). We report the minimum, average, and maximum for each estimate of hospitalizations.

Assuming that YLL in HICs is the expected burden conditional on provision of high-quality medical care, we use the difference in mortality rates between HICs and LMICs to calculate excess burden. We do so by first obtaining AMI mortality rates (for the 45+ population) from the Organisation for Economic Co-operation and Development (OECD) Stat (data for the United States was obtained from the National Inpatient Sample). We then use the difference in OECD and LMIC mortality rates to calculate excess deaths and YLL. The final calculation is as follows:

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{HIC}$$

$$Excess\ YLL = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{HIC} * (83.5 - age\ of\ death_{LMIC})$$

Congestive Heart Failure (CHF) Inpatient Mortality

Assumptions

1. Sampling distribution of mortality rates follows a beta distribution.
2. Sampling distribution of age follows a normal distribution.

Variable Definitions

Variable	*Definition*	*Source*
Mortality rate, LMIC	Inpatient congestive heart failure mortality in LMICs	Literature search
Mortality rate, HIC	Inpatient congestive heart failure mortality in HICs	National Inpatient Sample, literature search
Hospitalizations	Hospitalization rates per 100,000 people for congestive heart failure in LMICs	OECD Stat, literature search
Age of death	Mean age of death from inpatient congestive heart failure	Literature search

A literature search was conducted for mortality rates and average age of death in LMICs. After applying exclusion criteria, a total of 42 study countries that included both mortality rates and either average or median ages were included. Only eight studies included an average age of death. To approximate an age of death for other studies, we calculated a weighted average ratio of average age of death to average/median age and used this ratio to extrapolate an age of death for the remaining studies.

To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates and ages of death.

For mortality, we used the study population weighted average mortality rate (14.353804 percent) and standard deviation (3.14044) to come up with beta distribution parameters (18.170, 106.813) using the *-betaprior-* user-written program for Stata. We then ran 2,000 draws with 1,500 observations each with randomly generated mortality rates that follow this parameterization. For each draw we calculated a mean mortality rate. The range of mean mortality rates defines the range of Monte Carlo–based YLL estimates we report.

Similarly, for age, we used the study-population-weighted average age of death (68.63382) and the standard deviation (2.579883). Instead of a beta distribution, we used a normal distribution to calculate a range of uncertainty for age.

The final analytic dataset was created by combining values with equal rank (from 1 to 2,000) for each variable (e.g., the smallest value of age was combined with the smallest value of mortality).

The remaining variable required is the number of CHF hospitalizations in LMICs. We obtained three estimates, from databases and literature, to generate a range and a country population weighted average hospitalization rate. We extrapolated this rate to the LMICs' population (6,093,361,757) to calculate a minimum, average, and maximum number of hospitalizations.

Our final calculation uses the following formula for each value of hospitalizations:

$$YLL = mortality_{LMIC} * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Thus, we end up with 6,000 values of YLL (2,000 for each estimate of hospitalizations). We report the minimum, average, and maximum for each estimate of hospitalizations.

Assuming that YLL in HICs is the expected burden conditional on provision of high-quality medical care, we use the difference in mortality rates between HICs and LMICs to calculate the excess burden. We do so by first obtaining CHF mortality rates from the U.S. National Inpatient Sample and other HICs and from the literature. We then use the difference in HIC and LMIC mortality rates to calculate excess deaths and YLL. The final calculation is as follows:

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC}$$

$$Excess\ YLL = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Ischemic and Hemorrhagic Stroke Inpatient Mortality

Assumptions

1. Sampling distribution of mortality rates follows a beta distribution.
2. Sampling distribution of age follows a normal distribution.

Variable Definitions

Variable	*Definition*	*Source*
Mortality rate, LMIC	Inpatient stroke mortality rate in LMICs	Literature search
Mortality rate, HIC	Inpatient stroke mortality rate in HICs	OECD Stat, National Inpatient Sample
Hospitalizations	Hospitalization rates per 100,000 people for stroke in LMICs	Literature search

Variable	*Definition*	*Source*
Ischemic stroke share of observations	Share of ischemic stroke observations	Literature search
Age of death	Mean age of death from inpatient stroke	Literature search

A literature search was conducted for mortality rates and average age of death in LMICs. After applying exclusion criteria, a total of 48 study-country observations, which included both mortality rates and population ages for ischemic stroke (IS) and/or hemorrhagic stroke (HS), were included. Below, we discuss methods for IS and HS separately. Age of death was obtained from eight study-country observations, and the same age of death was used for both IS and HS. To approximate an age of death for other studies, we created a ratio of the age of death to the age of the overall study population. We multiplied a study population weighted ratio by the overall population age in each study.

Ischemic Stroke

Fifty-eight study-country observations had mortality and age data for IS. To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates and ages of death. For mortality, we used the study population weighted mortality rate (10.72 percent) and standard deviation (6.66) to calculated beta distribution parameters (2.207, 18.374) using the *-betaprior-* user-written program for Stata. For age, we similarly used the study population weighted average of death (68.92) and standard deviation (3.90). Instead of a beta distribution, we used a normal distribution to calculate a range of uncertainty for age. We then ran 2,000 draws with 1,500 observations each, pulling randomly generated mortality rates and ages of death simultaneously. For each draw we calculated a mean mortality rate and a mean age of death.

The remaining variable required is the number of IS hospitalizations in LMICs. We obtained 12 estimates, from databases and literature, to generate a range and a country population weighted average hospitalization rate (103.32 per 100,000). Seven studies of hospitalization included the share of IS hospitalizations. We used the range of identified hospitalization rates (extrapolated this rate to the LMICs population [6,093,361,757]), multiplied by the country population weighted share of IS hospitalizations (84.6 percent) to calculate a minimum, average, and maximum number of hospitalizations.

Our final calculation uses the following formula for each value of hospitalizations:

$$YLL = mortality_{LMIC} * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Thus, we end up with 6,000 values of YLL (2,000 for each estimate of hospitalizations). We report the minimum, average, and maximum for each estimate of hospitalizations.

To calculate excess burden, we took the following approach. Assuming that YLL in high-income countries is the expected burden conditional on provision of high-quality medical care, we calculate YLL from IS in HICs to estimate the excess burden in LMICs. We do so by first obtaining stroke mortality rates for IS (for the 45+ population) from OECD Stat (data for the United States was obtained from the National Inpatient Sample). Excess YLL for IS is thus calculated as follows:

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC}$$

$$Excess\ YLL = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Hemorrhagic Stroke

Thirty-eight studies had data on HS. We used the same study-reported age of death for IS and HS because the vast majority of studies did not report them independently.

To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates and ages of death. For mortality, we used the study population weighted mortality rate (23.63 percent) and standard deviation (14.37) to calculate beta distribution parameters (2.207, 18.374) using the *-betaprior-* user-written program for Stata. For age, we similarly used the study population weighted average of death (64.37) and standard deviation (4.94). Instead of a beta distribution, we used a normal distribution to calculate a range of uncertainty for age. We then ran 2,000 draws with 1,500 observations each, pulling randomly generated mortality rates and ages of death simultaneously. For each draw we calculated a mean mortality rate and a mean age of death.

The remaining variable required is the number of HS hospitalizations in LMICs. Using the same estimated hospitalization rates for all stroke as above, we assumed that the remaining hospitalizations were all HS (15.4 percent of all stroke hospitalizations).

Our final calculation uses the following formula for each value of hospitalizations:

$$YLL = mortality_{LMIC} * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Thus, we end up with 6,000 values of YLL (2,000 for each estimate of hospitalizations). We report the minimum, average, and maximum for each estimate of hospitalizations.

As for IS, we used data from OECD and NIS (for the United States) to obtain HS mortality rates. The calculation for excess YLL thus becomes:

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC}$$

$$Excess\ YLL = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Chronic Obstructive Pulmonary Disease (COPD) Inpatient Mortality

Assumptions

1. Sampling distribution of mortality rates follows a beta distribution.
2. Sampling distribution of age follows a normal distribution.

Variable Definitions

Variable	*Definition*	*Source*
Mortality rate, LMIC	Inpatient COPD mortality in LMICs	Literature search
Mortality rate, HIC	Inpatient COPD mortality in HICs	National Inpatient Sample, literature search
Hospitalizations	Hospitalization rates per 100,000 people for COPD in LMICs	OECD Stat, literature search
Age of death	Mean age of death from inpatient COPD in LMICs	Literature search

A literature search was conducted for mortality rates and average age of death in LMICs. After applying exclusion criteria, a total of 15 study-country observations, which contained both mortality rates and either average or median ages, were included. Only six studies included an average age of death. To approximate an age of death for other studies, we calculated a weighted average ratio of average age of death to average/median age and used this ratio to extrapolate an age of death for the remaining studies.

To account for uncertainty in our estimates, we used a Monte Carlo model to simulate variation in mortality rates and ages of death.

For mortality, we used the study population weighted average mortality rate (10.97603 percent) and standard deviation (5.73249) to come up with beta distribution parameters (3.154, 25.581) using the *-betaprior-* user-written program for Stata. We then ran 2,000 draws with 1,500 observations each with randomly generated mortality rates that follow this parameterization. For each draw we calculated a mean mortality rate. The range of mean mortality rates defines the range of Monte Carlo–based YLL estimates we report.

Similarly, for age, we used the study population weighted average age of death (75.18683) and the standard deviation (6.120001). Instead of a beta distribution, we used a normal distribution to calculate a range of uncertainty for age.

The final analytic dataset was created by combining values with equal rank (from 1 to 2,000) for each variable (e.g., the smallest value of age was combined with the smallest value of mortality).

The remaining variable required is the number of COPD hospitalizations in LMICs. We obtained five estimates, from databases and literature, to generate a range and a country population weighted average hospitalization rate. We extrapolated this rate to the LMICs population (6,093,361,757) to calculate a minimum, average, and maximum number of hospitalizations.

Our final calculation uses the following formula for each value of hospitalizations:

$$YLL = mortality_{LMIC} * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Thus, we end up with 6,000 values of YLL (2,000 for each estimate of hospitalizations). We report the minimum, average, and maximum for each estimate of hospitalizations.

Assuming that YLL in HICs is the expected burden conditional on provision of high-quality medical care, we use the difference in mortality rates between HICs and LMICs to calculate the excess burden. We do so by first obtaining COPD mortality rates from the U.S. National Inpatient Sample and other HICs and from the literature. We then use the difference in OECD and LMIC mortality rates to calculate excess deaths and YLL. The final calculation is as follows:

$$Excess\ Deaths = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC}$$

$$Excess\ YLL = (mortality_{LMIC} - mortality_{HIC}) * hospitalizations_{LMIC} * (83.5 - age\ of\ death_{LMIC})$$

Diabetes Morbidity

Assumption

1. Averaging disability weights adequately captures the distribution of disability.

Variable Definitions

Variable	*Definition*	*Source*
Prevalence of diabetes	The number of adults 18+ years old with diagnosed diabetes mellitus	International Diabetes Federation
Untreated	The percent of diagnosed persons with diabetes who are on not on any medication (oral or insulin)	WHO STEPS
Average disability weights	Disability attributable to diabetes	GBD, 2016

The number of adults 18+ years old with diagnosed diabetes mellitus was identified using data from the International Diabetes Federation, 2017. A total of 136 LMICS (98 percent) had data on diabetes diagnoses. The population in our sample countries includes 99 percent of the population in LMICs. The percent of diagnosed persons with diabetes who are on not on any medication (oral or insulin) was identified using WHO STEPS published reports. We included LMICs that had reports in English, French, or Spanish. When multiple years of data were available for a country, we used the most recent year. A total of 55 LMICS (40 percent) had data on treatment status, accounting for 44 percent of the LMIC population. We used the sample of countries for which data were available to extrapolate to the population of all LMICs for both diagnosis and treatment status.

We developed a disability weight by taking the average of all disability weights for diabetes listed in GBD (2016). Disability weights included neuropathy, varying severity of retinopathy, and varying severity of nephropathy.

Our final calculation uses the following formula:

$$YLD = \textit{prevalence diabetes} * \%\textit{untreated} * \textit{average disability weights}$$

Excess Trauma-Related Mortality

Assumption

1. Difference in mortality rates between LMICs and HICs is attributable to quality of care.

Variable Definitions

Variable	*Definition*	*Source*
Deaths attributable to injury	Number of deaths attributable to injuries	IHME
Prevalence of injuries	Prevalence of injuries	IHME
Years of life lost attributable to injuries		IHME
Remaining life expectancy	Remaining life expectancy among those dying from trauma; calculated as YLL divided by number of deaths	IHME/calculated
Mortality rate	Deaths attributable to injuries divided by prevalence of injuries	Calculated

To calculate excess deaths attributable to injuries, we obtained data on deaths, incidence, and prevalence of injuries, excluding those attributable to adverse effects of medical care, war, natural disasters, and terrorism. We calculated a mortality rate for LMICs as well as high-income countries by dividing the number of deaths by prevalence. We use the difference between these two mortality rates multiplied by total LMIC prevalence to obtain an estimate of excess deaths. To calculate excess YLL, we obtained remaining life expectancy by dividing the YLL from IHME by the number of deaths from IHME. We then used this remaining life expectancy multiplied by excess deaths to obtain excess YLL.

Mental Health (adult)

Variable Definitions

Variable	*Definition*	*Source*
12-month prevalence	For 12-month prevalence we use both: Low estimate (IHME): Prevalence (annual) for all adults, defined as 19 years or older by condition as reported in the IHME database High estimate (WMHS): 12-month prevalence reported for DSM-IV/CIDI disorders in the 2009 publication of data in the WMH surveys; an (unweighted) average of the LMIC 12-month prevalences reported by the WMH Survey as published by Kessler et al. (2005) (Brazil, Bulgaria, Colombia, India, Lebanon, Mexico, Romania, and Shenzhen, China) The rate for schizophrenia (0.33 percent) was taken from a literature review and is a global estimate, not limited to LMICs, owing to limited data	IHME, WMHS, published data and literature
Care seeking	Care seeking is currently taken from the WHO (2004) publication *The Treatment Gap in Mental Health Care*, where service use was defined as seeking assistance from any medical or professional service provider, specialized or not, public or private	Literature search

Variable	*Definition*	*Source*
Percentage not in treatment	Percentage not in treatment is 1 - "proportion in treatment" (of those with a mental health disorder) as a composite measure for all DSM-IV categories from 2004 publication of data in the World Mental Health (WMH) surveys Request for data disaggregated by condition pending	WMHS, published data

Our goal is to quantify the YLD attributable to poor quality mental health care of common and serious mental health conditions. To do so, we use the following equation:

$$YLD = prevalence * care\ seeking * share\ of\ severity * \%untreated * average\ disability\ weights$$

Using data from the World Mental Health Survey (WMHS), the estimated range of the share of adults 18+ years in LMICs with major depressive disorders is 1.89–12 percent; 2.66–9 percent with anxiety; 0.45–0.46 percent with bipolar disorder; and 1.27–4.1 percent with alcohol disorder. The 12-month prevalence is an average of the LMIC 12-month prevalences reported by the WMH Survey as published by Kessler et al. (2005) (Brazil, Bulgaria, Colombia, India, Lebanon, Mexico, Romania, and Shenzhen, China). The range for schizophrenia (0.27–0.33 percent) was taken from Ferrari and colleagues' (2012) literature review and is a global estimate, not limited to LMICs. We use the midpoints of each of these ranges for our calculations.

Distribution of severity is taken from individual studies published using WMHS data. We use population-weighted averages of Lebanon and South Africa where data were available to calculate the distribution of severity for anxiety, depression, and alcohol use disorder. Where this was not possible, as for bipolar disorder, we use data from the United States. For schizophrenia, we use data from a review that included estimates on the distribution of severity from five countries, as noted in Table D-2.

We use the indicator "those retained in treatment" from the WMHS, and take the midpoint of the ranges provided.

We calculate disability weights (DWs) by taking a weighted average of the DWs provided for each of the relevant mental health subconditions, as published by Solomon and colleagues (2015). We calculate DWs for each severity category individually. We exclude moderate severity for anxiety, depression, and alcohol use disorder because of variance in the recommended standard of care.

All estimates are applied to the adult LMIC population.

TABLE D-1 Rates for Mental Health YLD Calculations

		Prevalence *(for LMIC population)*	Distribution of Severity *(for 12-month prevalence)*	Care Seeking *(of those with condition)*	Percentage Not in Treatment *(of those diagnosed, by severity)*	Disability Weights
Common mental health	*Major depressive disorder*	1.89–12.0%	Moderate: 48.7%	46.1%	90.3–81.4%	Moderate: .396
			Severe: 28.4%		85.4–76.3%	Severe: .658
	Anxiety	2.66–9.0%	Moderate: 34.6%	42.5%	90.3–81.4%	Moderate: .133
			Severe: 29.5%		85.4–76.3%	Severe: .523
Serious mental health	*Bipolar disorder*	0.45–0.46%	Moderate: 17.1%	49.8%	90.3–81.4%	Residual: .032
			Severe: 82.9%		85.4–76.3%	Manic: .492
	Schizophrenia (and nonaffective psychoses)	0.27–0.33%	Residual: 63%	68.9%	90.3–81.4%	Residual: .588
			Acute: 37%		85.4–76.3%	Acute: .778
Addictive disorders	*Alcohol use disorder*	1.27–4.1%	Moderate: 10.9%	21.9%	90.3–81.4%	Moderate: .373
			Severe: 27.5%		85.4–76.3%	Severe: .570

NOTE: See “variable definitions” table above for sources.

TABLE D-2 Distribution of Severity as a Percent of Total National Prevalence

	United States	Lebanon	South Africa	Japan	Metropolitan China
Anxiety	Mild: 43.5	Mild: 43.6	Mild: 35.1	Mild: 35.3	Mild: 41.3
	Mod: 33.7	Mod: 36.7	Mod: 34.4	Mod: 46.4	Mod: 44.6
	Sev: 22.8	Sev: 19.7	Sev: 30.5	Sev: 18.3	Sev: 14.1
Depression	Mild: 19.5	Mild: 8.2	Mild: 20.3	Mild: 26.6	Mild: 32.4
	Mod: 50.1	Mod: 49.3	Mod: 45.4	Mod: 53.4	Mod: 51.1
	Sev: 30.4	Sev: 42.5	Sev: 34.3	Sev: 20.0	Sev: 16.5
Bipolar disorder	Mild: 0.00	Mild: 0.00	Mild: no data	Mild: 57.4	Mild: 0.00
	Mod: 17.1	Mod: 0.00	Mod: no data	Mod: 30.9	Mod: 0.00
	Sev: 82.9	Sev: 100	Sev: no data	Sev: 11.7	Sev: 100
Alcohol use disorder	Mild: 31.5	Mild: 63.3	Mild: 61.5	Mild: 63.5	Mild: 59.9
	Mod: 39.7	Mod: 4.2	Mod: 11.6	Mod: 8.0	Mod: 18.1
	Sev: 28.9	Sev: 32.6	Sev: 26.9	Sev: 28.5	Sev: 22
Source	Kessler et al., 2005	Karam et al., 2006	Herman et al., 2009	Ishikawa et al., 2016	Shen et al., 2006

SOURCE: Kessler et al., 2005.

TABLE D-3 Distribution of Severity for Schizophrenia as a Percent of Total National Prevalence

	United States	Tanzania	China	Russia	Germany	Pooled
Schizophrenia	Residual: 38 Acute: 62 Residual: 31 Acute: 69	Residual: 40 Acute: 60	Residual: 49 Acute: 51	Residual: 50 Acute: 50	Residual: 25 Acute: 75	Residual: 37 Acute: 63

NOTE: Source for schizophrenia is not limited to LMICs, but uses a pooled estimate from Ferrari et al., 2012.

MATERNAL AND CHILD HEALTH

Excess Maternal Mortality Among Attended Births

Assumption

1. High-income maternal mortality rates are the same among attended and unattended births.

Variable Definitions

Variable	*Definition*	*Source*
Maternal mortality ratio (MMR)	Maternal deaths per live birth	WHO Bayesian Maternal Mortality Estimation model
Maternal deaths	Maternal deaths	Calculated
Live births	Number of live births	UN World Population Prospects (WPP)
Share of attended births (SAB)	Share of births that are attended by a skilled professional	WHO Global Health Observatory (GHO)

Our approach to estimating excess maternal mortality among attended births relies primarily on data from WHO's recent modeling efforts. WHO uses a multilevel model with region and country random effects to estimate a maternal mortality ratio as a function of the share of attended skilled births, gross domestic product (GDP) per capita, and the general fertility rate. These estimates are then entered into a Markov chain Monte Carlo model to generate uncertainty intervals.

We use the range of output from this model (at the 10th, 50th, and 90th percentiles), maternal mortality rates per live birth, as the outcome in our approach. We sought to measure the excess mortality in LMICs of attended births. A key assumption is that the maternal mortality rate among unattended births in high-income countries is the same as it is for attended births.

After using the Markov chain model to generate maternal mortality rates, we multiply these estimates to the total number of live births by country to generate an estimate of total maternal deaths:

$$\mathit{Maternal\ Deaths} = \mathit{MMR} * \mathit{Live\ Births}$$

We also multiply the share of attended births by the number of live births to generate a total number of attended births.

$$\textit{Attended Births} = \textit{SAB} * \textit{Live Births}$$

We then run a bivariate linear regression model with the following specification, restricted to LMICs:

$$MMR = \beta_0 + \beta_1 SAB + \varepsilon$$

The results of this model are then used to generate predicted values of MMR (referred to as $\overline{MMR}$) assuming that SAB is set to 100 percent for all countries. This SAB-adjusted MMR represents our estimate of MMR if all births were attended. This removes the effect of SAB on MMR, with the remaining differences between countries attributable to other quality-related factors. We then take the difference between the mean SAB-adjusted MMR for LMICs and the standard MMR for HICs, and multiply by the number of attended births to generate the excess maternal mortality caused by non-SAB-related quality differences. The final calculation takes the following form:

$$\textit{Excess Maternal Deaths} = \textit{attended births} * (\overline{MMR} - MMR_{HIC})$$

Excess Neonatal Mortality Among Attended Births

Assumption

1. The difference in mortality rates between HICs and LMICs after controlling for relevant factors and attended births is attributable to quality of care.

Variable Definitions

Variable	*Definition*	*Source*
Share of attended births	Share of live births attended by a health care professional	WHO GHO
Neonatal mortality rate	Neonatal mortality rate per 1,000 live births	World Bank Development Indicators (modeled)
Live births	Total number of live births	UN WPP

We first calculated the total number of attended births by multiplying the share of attended births by the number of live births. Then, we ran a linear regression with the following specification weighted for country-level population, restricted to the LMICs, where *SAB* is the share of attended births:

$$\text{Neonatal Mortality Rate} = \beta_0 + \beta_1 SAB + \varepsilon$$

We then generated a prediction for low- and middle-income neonatal mortality rate conditional on *SAB* being 100 percent. This provides us with a neonatal mortality rate for attended births. We took the difference between this and the neonatal mortality rate among high-income countries and multiplied it by the number of estimated attended births in each LMIC to obtain an estimate of excess neonatal mortality.

VACCINATIONS

Vaccine-Preventable Mortality

Assumption

1. All deaths that occur due to diseases that are vaccine preventable are preventable deaths.

Variable Definitions

Variable	*Definition*	*Source*
Deaths	Number of deaths from vaccine-preventable disease	IHME
Age of death	Mean age of death from vaccine-preventable disease	IHME

We developed a set of vaccine-preventable causes of death (those with vaccine efficacy of more than 90 percent): liver cancer attributable to hepatitis B, cirrhosis and other chronic liver diseases attributable to hepatitis B, other hepatitis B-related deaths, cervical cancer, diphtheria, H influenza type B meningitis, measles, whooping cough, and tetanus. We obtained deaths and YLL estimates from the IHME GBD 2014 database. We estimated an average age of death by dividing YLL by the number of deaths, and recalculated YLL using this age of death, top-coded at 83.5. Ninety-nine percent of LMICs were represented in the data, which means that extrapolation had little effect on our estimates.

The final calculation was as follows:

$$YLL = \text{deaths} * (83.5 - \text{age of death})$$

Rotavirus Mortality (under 5 years old)

Assumption

1. All rotavirus deaths are preventable.

Variables Definitions

Variable	*Definition*	*Source*
Deaths	Number of deaths from rotavirus	WHO
Age of death	Mean age of death from rotavirus among children under 5 assumed to be 2.5 years	N/A

We obtained the number of rotavirus-attributable deaths for the under 5 population in 2013 (the last year of data available) from the WHO surveillance database. Data on 137 (99 percent) of LMIC countries were available. The countries included in our sample represented 99 percent of the LMIC population, which means that extrapolation had relatively little effect on our estimates. We assumed that all rotavirus deaths were preventable. We used 2.5 as the mean age of death.

Our final calculation uses the following formula:

$$YLL = deaths * (83.5 - age\ of\ death)$$

PATIENT CENTEREDNESS AND TIMELINESS

To address patient centeredness we look at both how it is currently measured and what the state of patient-centered care is, posing the following questions:

- Where is the data, and who does it represent?
- What is the quality of that data?
- What is the actual level of patient-centered care?

We first reviewed existing national and international databases with a focus on three areas of patient experience: overall rating (primary focus), communication, and respect (or disrespect). Where possible, we pulled this data to come up with point estimates for each country, using the most recent data available. We then conducted a systematic review of the literature on patient experience in all LMICs over the past 10 years.

To assess where data were collected and who the data represents, we created binary variables to categorize the studies pulled through the systematic review. For example, we looked at the following: was any care in the study provided by a private facility or provider, did the study assess care quality in a hospital setting, and were rural populations represented? We also organized studies by disease or patient population focus (e.g., HIV, TB, emergency care).

To determine the quality of the data in the literature on patient centeredness, we focused specifically on survey tools. Where available, we pulled the following information on methods regarding both survey administration and analysis: was the survey based on a previous tool, what research was done to inform the survey prior to administration, what was the sampling strategy, where were patients interviewed/how was the survey administered, were tests of internal consistency conducted (e.g., Cronbach α coefficient), and was content or construct validity assessed?

In quantifying the actual level of satisfaction, we pulled data on overall rating and other questions that were used to assess patients' experience with care. We calculated a weighted "experience" average for each country based on the population represented in each study for a given country. If a factor analysis was conducted, we pulled the results from each of the subquestions to see which factors influenced overall experience in a given context and how those factors might differ by context.

Variable Definitions

Variable	*Definition*	*Source*
Overall rating (primary)	"Overall experience," or "overall rating" is a global rating of the patient's (or in cases of pediatric care, a caregiver's) assessment of their care interaction For high-income countries, this is taken from Commonwealth Fund, and is taken from the following question: "Opinion of regular doctor in past 12 months," taking a composite negative score from the answers "fair" or "poor"	LMICs: Literature; HICs: Commonwealth Fund (CWF) International Health Policy Survey

Variable	*Definition*	*Source*
Overall rating (primary) (continued)	The responses across all items were summed and converted into a percentage of the maximum possible score to yield an overall experience score, with a potential range of 0–100, where 100 represents the best possible experience. The scores obtained from positive expressions were added to the score in the reverse direction (1 – x)	
Communication	Examples: Patients reporting having received easy-to-understand explanations by their regular doctor (OECD); did not have a problem with the amount of explanation received during this visit (Service Provision Assessment [SPA])	Surveys: International Development Bank (IDB), CWF, OECD, SPA (DHS) Literature
Respect	Examples: Patients reporting having been "treated with respect during consultation" or "respect was shown by my provider"	Literature
Timeliness	Data on ratings of wait time was collected throughout the literature review, a summary of which can be found in Table 4-9; additional data on time with physician was collected through existing survey tools Examples: Did not have a problem with the wait time at this visit (SPA); patients reporting having spent enough time with any doctor during the consultation (OECD)	Surveys: IDB, CWF, OECD, SPA (DHS) Literature

Variable	*Definition*	*Source*
Other	Examples: Privacy, abuse, decision making, continuity of care, etc.	Literature

ACCESSIBILITY: HIV/AIDS

To calculate the burden of access to HIV/AIDS, we relied on data from the HIV/AIDS calculations above. Issues attributable to access were measured by examining the portion of the population with HIV/AIDS who do not know their status and proceeding with calculations as above. Our final calculation was as follows:

$$YLD = (1 - \%knownstatus) * prevalence * average\ disability\ weights$$

$$YLL = total\ deaths - untreated,\ undiagnosed\ deaths$$

COSTING

For the low and high estimates of the cost attributable to poor quality care, the average gross national income (GNI) per capita for all LMICs was taken from the World Bank. This average GNI ($4,667) was multiplied to each individual death, YLL, and YLD for each condition where the burden of poor care was calculated. The calculations used to estimate cost are as follows:

$$Cost\ of\ Excess\ Deaths = deaths * avg.\ GNI$$

$$Cost\ of\ Excess\ YLL = excess\ YLL * avg.\ GNI$$

$$Cost\ of\ Excess\ YLD = excess\ YLD * avg.\ GNI$$

Variance, or high and low estimates, of cost were informed by variation in incidence, mortality, and age of the underlying indicators. In addition, for certain indicators (such as TB), variation was informed by estimates from different sources of mortality (e.g., owing to comorbidity with HIV status).

PART 2: LITERATURE REVIEW METHODS

Contents

LITERATURE REVIEW METHODS SUMMARY

As noted in the chapter text, two main sources of data were used to estimate the burden of poor quality for each domain: where available, data were obtained from national or international databases including, but not limited to, data from the Global Burden of Disease (GBD), the Demographic and Health Surveys (DHS), and the World Health Organization STEPS data.

Where there were no available data for indicators of interest, the team obtained estimates by carrying out systematic reviews of the peer-reviewed, published, English language literature primarily over the past decade (2006–2016). Detailed data sources for all variables used are outlined below, including details on literature review results and methods. The process was as follows:

- **Indicator definition:** Case definitions for indicators were primarily based on how each was defined in the literature, accounting for modest variations among these definitions based on availability of literature.
- **Exclusion criteria:** Cross-cutting inclusion and exclusion criteria were set for the studies. This included study type, study size, and relevant clinical populations for exclusion, among other considerations.
- **Search terms:** Targeted search terms were created for each indicator and, using automated machine learning, abstracts and descriptive information on each article were pulled through PubMed. For each indicator, a unique search was conducted for every country of interest (196).
- **Search:** The search was performed on PubMed to extract all relevant articles.
- **Screening:** Articles were then manually screened (titles and then abstracts) for relevance using the predetermined inclusion and exclusion criteria to assess fit. Results of this process, for each indicator, are shown in a PRISMA diagram.
- **Abstraction:** With the final set of articles, key data were abstracted including a point estimate of the indicator of interest, the population to which this number applied, and descriptive characteristics of the studies within which they were collected.

SAFETY

Summary Methods

We conducted reviews on key safety indicators as a continuation of the published work from Jha et al. (2013), *The Global Burden of Unsafe Medical Care: Analytic Modeling of Observational Studies*. We conducted new systematic reviews for five safety events: adverse drug events, thromboembolism from medical care, falls in hospital, pressure sores and decubitus ulcers, and ventilator-associated pneumonia; we used the earlier Jha and colleagues (2013) analysis for catheter-associated urinary tract infections. Additional information on our approach to safety can be found in Part 1 of this appendix.

Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Timing	• The literature search is limited to studies published between 2011 and 2016	• The study is outside the designated time frame
Country	• World Bank defined low- and middle-income countries	• The study groups multiple countries and does not provide individual country-level data
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• Decubitus (pressure) ulcers	• The study does not look at decubitus (pressure) ulcers
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)
Clinical population of interest	• Defined study population • Admitted patients to the health care facility for any cause	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Health system • Inpatient care • Facilities can include anything within the health system including hospitals, nursing homes, clinics, health centers	• Setting is specifically stated to be outside the health system • Population-based studies (e.g., asthma prevalence and treatment among the general population)
Mortality rate	• If the study reports data on patients diagnosed with the target indicator and die as a result of said indicator	• A mortality rate is recorded but the cause of death is not specified as caused by the target indicator

Content	Inclusion	Exclusion
Age of death	• Age of death reported specifically for those who died from the target indicator	• Does not include age of death if cause of death is not specified to the target indicator

Pressure Ulcers

Indicator Definition

Decubitus ulcers, also called pressure ulcers, are defects in the skin that often occur when skin is pressed against a firm surface. These ulcers can result from combinations of external factors such as pressure, force, moisture, and friction, as well as internal factors such as fever, anemia, and malnutrition. Pressure ulcers can often occur in surgery patients during the procedure (Jha et al., 2013).

Exclusion Criteria

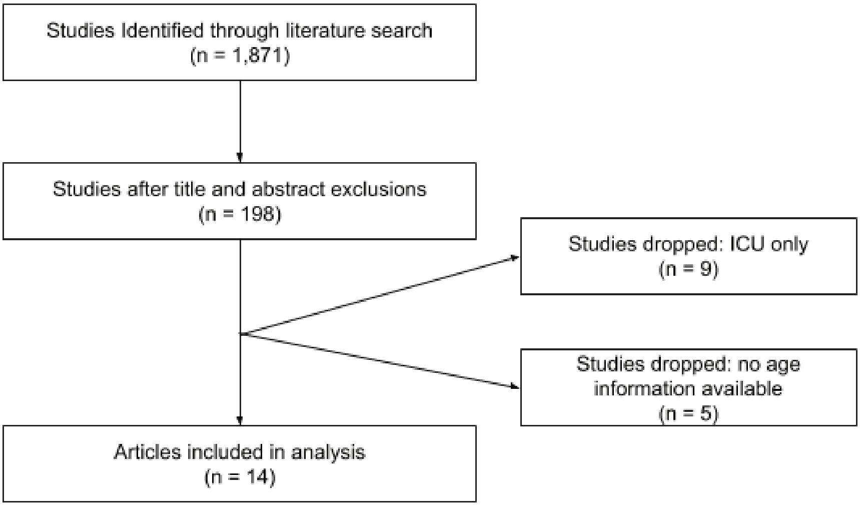
Content	Inclusion	Exclusion
Indicator	• Presence of the indicator in the article's text: **Numerator:** Patients diagnosed with a decubitus (pressure) ulcer **Denominator:** All patients in the study admitted to the health care facility(ies) in the study	• The indicator is not included in the full text • The clinical setting was the intensive care unit (ICU)
Exceptions		

Search Terms

Title/Abstract	MESH
Decubitus Ulcer*	Pressure Ulcer
Pressure Ulcer*	Pressure Ulcer
Pressure AND Ulcer	Pressure Ulcer
hospital* AND pressure ulcer	Pressure Ulcer
hospital* AND ulcer	Pressure Ulcer
Decubitus Ulcer*	Pressure Ulcer OR Ulcer
Pressure Ulcer*	Pressure Ulcer OR Ulcer
Decubitus Ulcer*	Iatrogenic Disease AND Pressure Ulcer
Pressure Ulcer*	Iatrogenic Disease AND Pressure Ulcer

Title/Abstract	**MESH**
Decubitus Ulcer*	Ulcer AND Iatrogenic Disease
Pressure Ulcer*	Ulcer AND Iatrogenic Disease
HAC AND Ulcer*	Ulcer AND Iatrogenic Disease
hospital acquired condition AND ulcer*	Ulcer AND Iatrogenic Disease
hospital AND acquired AND ulcer*	Ulcer AND Iatrogenic Disease
HAC AND ulcer*	Pressure Ulcer
hospital acquired condition AND ulcer*	pressure Ulcer
hospital AND acquired AND ulcer*	Pressure Ulcer

PRISMA Diagram



Falls

Indicator Definition

Inpatient falls are defined when a patient unintentionally falls to the ground or floor while conscious and in the care facility (Jha et al., 2013).

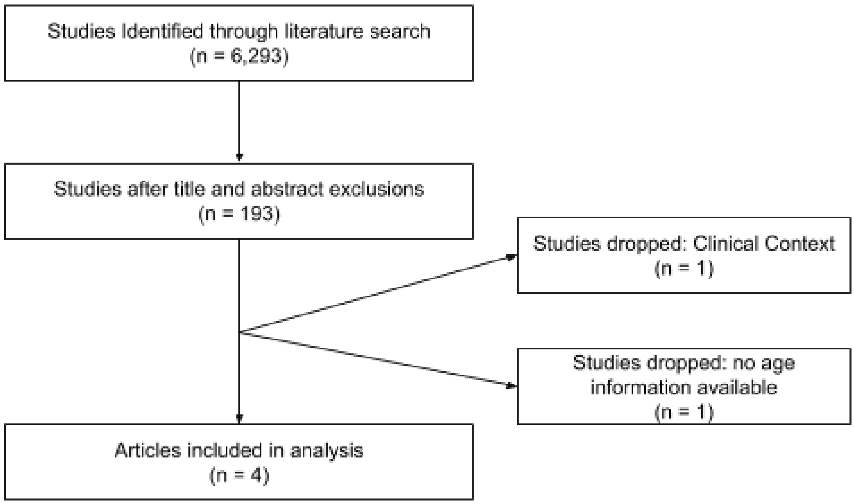
Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Indicator	• Presence of the indicator in the article's text: **Numerator:** Patients who experience a fall in hospital (inpatient falls) **Denominator:** All patients in the study admitted to the health care facility(ies)	• The indicator is not included in the full text • The clinical setting was ICU only
Exceptions		

Search Terms

Title/Abstract	**MESH**
Accident* AND fall*	Accidental Falls
Fall* AND hospital*	Accidental Falls
Fall* AND in AND hospital*	Accidental Falls
accident*	Accidental Falls
Fall*	Accidents OR Accidental Falls

PRISMA Diagram



Adverse Drug Events

Indicator Definition

Adverse drug events (ADEs) are unintended and undesired events that result from errors that relate to the administering, ordering, transcribing, or dispensing of medications. These errors can result in serious harm or death, with other costs related to extended stays and treatment (Jha et al., 2013).

Exclusion Criteria

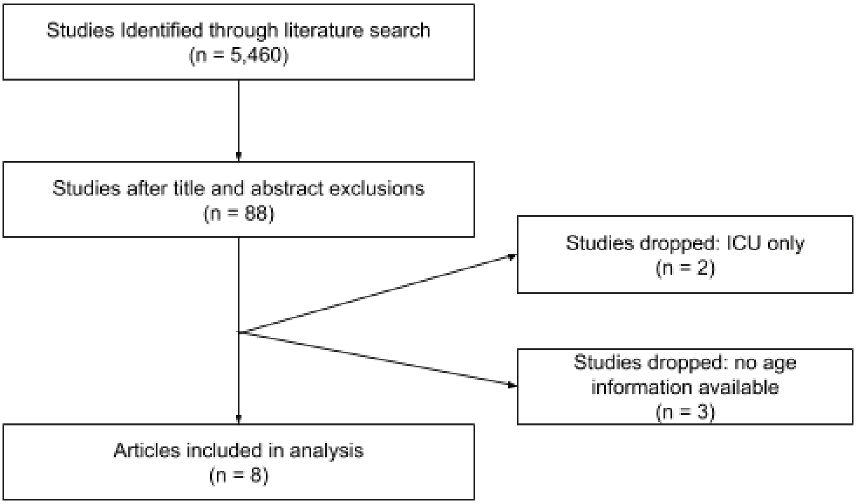
Content	**Inclusion**	**Exclusion**
Indicator	• Presence of the indicator in the article's text: **Numerator:** Inpatients experiencing an adverse drug event **Denominator:** All hospitalized patients in the study	• The indicator is not included in the full text • ADE excluded if following criteria applies: 1. Primary diagnosis for hospitalization 2. Occurred in the outpatient setting 3. Focused only on rates of drug-specific ADEs 4. Occurred due to patient noncompliance • The clinical setting was the ICU
Exceptions		

Search Terms

Title/Abstract	**MESH**
Adverse Drug Event*	Drug-Related Side Effects and Adverse Reactions
Adverse AND drug*	Drug-Related Side Effects and Adverse Reactions
medic* AND error*	Drug-Related Side Effects and Adverse Reactions
Adverse AND event* AND drug*	Drug-Related Side Effects and Adverse Reactions
medic* AND react* AND adverse	Drug-Related Side Effects and Adverse Reactions
drug AND react* AND adverse	Drug-Related Side Effects and Adverse Reactions
ADE*	Drug-Related Side Effects and Adverse Reactions

Title/Abstract	MESH
drug AND error*	Drug-Related Side Effects and Adverse Reactions
prescri* AND error*	Drug-Related Side Effects and Adverse Reactions

PRISMA Diagram



Venous Thromboembolisms (VTEs)

Indicator Definition

Venous thromboembolisms (VTEs) includes both deep vein thrombosis (DVT) and pulmonary embolisms (PEs). These incidents occur from combinations of hereditary and acquired risk factors, and presents with pain, tenderness, swelling, and erythema of the affected limb. VTEs can result in complications such as thromboembolic pulmonary hypertension and post-thrombotic syndrome (Jha et al., 2013).

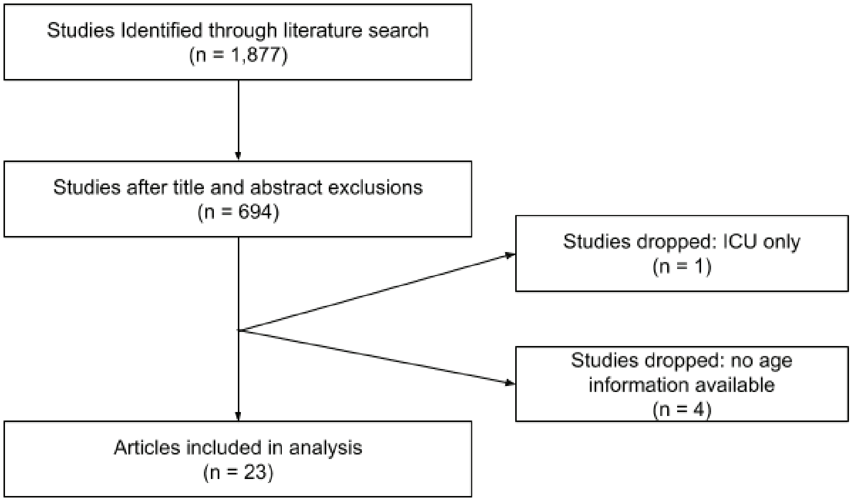
Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Indicator	• Presence of the indicator in the article's text: **Numerator:** Patients contracting a VTE during their admission to a health care facility **Denominator:** All patients in the study admitted to the health care facility(ies) in the study	• The indicator is not included in the full text • The clinical setting was the ICU
Exceptions		

Search Terms

Title/Abstract	**MESH**
Venous Thromboembolism	Venous thromboembolism
VTE	Venous thromboembolism
Hospital acquired AND venous thromboembolism	Venous thromboembolism
Hospital AND venous thromboembolism	Venous thromboembolism
Venous Thromboembolism	Venous thromboembolism AND Iatrogenic Disease
VTE	Venous thromboembolism AND Iatrogenic Disease
Hospital acquired AND venous thromboembolism	Venous thromboembolism AND Iatrogenic Disease
Hospital AND venous thromboembolism	Venous thromboembolism AND Iatrogenic Disease
VTE AND hospital	Venous thromboembolism
Venous Thromboembolism	Iatrogenic Disease
VTE	Iatrogenic Disease
Hospital acquired AND venous thromboembolism	Iatrogenic Disease
Hospital AND venous thromboembolism	Iatrogenic Disease

PRISMA Diagram



Ventilator-Associated Pneumonia (VAP)

Indicator Definition

Ventilator-associated pneumonia (VAP) is an infection in the lungs that occurs in people who are on ventilators. Ventilators are machines that help critically ill patients breath by providing oxygen through a tube directly into the patient's mouth, nose, or neck. Infections can occur as germs move through the tube and enter the patient's lungs (CDC, 2012).

Exclusion Criteria

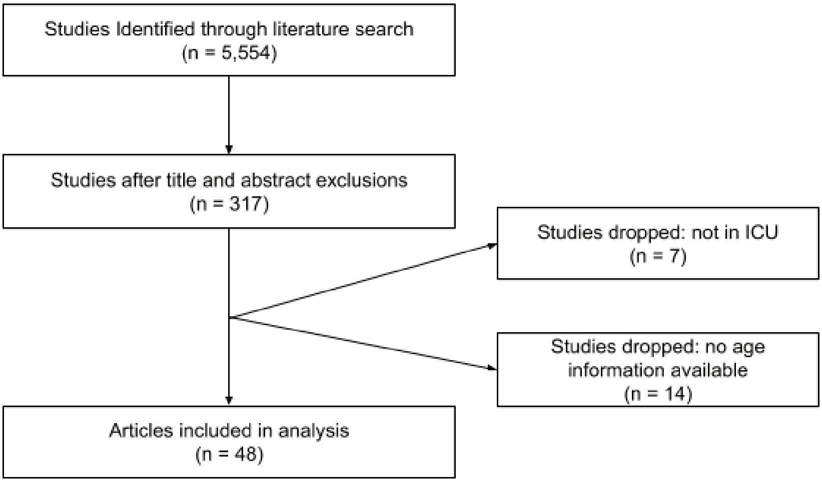
Content	Inclusion	Exclusion
Indicator	• Presence of the indicator in the article's text: **Numerator:** Ventilated patients in the ICU diagnosed with ventilator-associated pneumonia **Denominator:** All ventilated patients in the ICU during the study period	• The indicator is not included in the full text • The pneumonia is not specified as hospital-acquired • The clinical setting is outside the ICU
Exceptions		

Search Terms

Title/Abstract	**MESH**
Nosocomial pneumonia	Pneumococcal Infections
Nosocomial PN	Pneumococcal Infections
Nosocomial pneumonia	Iatrogenic Disease
Nosocomial PN	Iatrogenic Disease
Nosocomial pneumonia	pneumonia AND Iatrogenic Disease
Nosocomial PN	pneumonia AND Iatrogenic Disease
Hospital acquired AND pneumonia	pneumonia AND Iatrogenic Disease
Hospital acquired AND nosocomial pneumonia	pneumonia AND Iatrogenic Disease
Hospital acquired AND nosocomial pneumonia	Pneumococcal Infections
Hospital acquired AND nosocomial pneumonia	pneumonia
Hospital acquired pneumonia	pneumonia
Hospital acquired AND pneumonia	pneumonia
Hospital acquired AND PN	pneumonia
Hospital Acquired AND PN	pneumonia AND Iatrogenic Disease
in hospital AND pneumonia	pneumonia
hospital AND pneumonia	Pneumonia
in-hospital AND pneumonia	Pneumonia
Ventilator associated pneumonia	Pneumonia, Ventilator-Associated
ventilator-associated pneumonia	Pneumonia, Ventilator-Associated
ventilator-associated AND pneumonia	iatrogenic Disease
ventilator associated AND pneumonia	iatrogenic Disease
Ventilator associated pneumonia	pneumonia AND iatrogenic Disease
ventilator-associated pneumonia	pneumonia AND iatrogenic Disease
ventilator-associated AND pneumonia	Pneumonia, Ventilator-Associated
ventilator associated AND pneumonia	Pneumonia, Ventilator-Associated
Hospital acquired AND ventilator-associated	pneumonia AND iatrogenic Disease
Hospital acquired AND Ventilator associated pneumonia	pneumonia AND iatrogenic Disease
Hospital acquired AND ventilator-associated pneumonia	Pneumococcal Infections

Title/Abstract	**MESH**
Hospital acquired AND Ventilator associated pneumonia	Pneumonia
Hospital-acquired AND ventilator-associated	pneumonia AND iatrogenic Disease
Hospital-acquired AND Ventilator associated pneumonia	pneumonia AND iatrogenic Disease
Hospital-acquired AND ventilator-associated pneumonia	Pneumococcal Infections
Hospital acquired AND Ventilator associated pneumonia	Pneumonia
in-hospital AND pneumonia	Pneumonia, Ventilator-Associated
hospital AND pneumonia	Pneumonia, Ventilator-Associated
in-hospital AND pneumonia	Pneumonia, Ventilator-Associated
VAP	Pneumonia, Ventilator-Associated

PRISMA Diagram



COMMUNICABLE DISEASES

Overview

First we have selected a range of inpatient and outpatient conditions that represent a high burden of illness across the globe, and where quality of care can be captured by well-defined outcome or process measures. Next, in consultation with clinicians and global health researchers we have been refining a set of these metrics that can be used to assess the quality of health care globally. We focus on indicators that are able to examine the quality of services received by people who have access to care. While access is a performance domain that is critically important in its own right, we have focused this review on quality of care within the system, and thus do not examine issues of access to the health system or issues of distribution of services within the health system. We also focus the search in countries defined as low or middle income by the World Bank.

Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame
Country	• Any World Bank defined low- and middle-income country	• The study groups multiple countries and does not provide individual country-level data • The country of interest is designated high income by the World Bank
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• Community-acquired pneumonia (CAP)	• The main diagnosis is a condition other than community-acquired pneumonia • Exclude hospital-acquired pneumonia
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)

Human Immunodeficiency Virus (HIV) (adherence focus)

Indicator Definition

Treatment adherence is an important factor for patients with HIV to both control the virus as well as prevent drug resistance. Adherence is defined as sticking closely to the regimen as given by a health care provider. Poor adherence can be caused by a number of external factors and be greatly affected by environmental factors, patient–physician relationships, and treatment complexity (NIH, 2018).

Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame
Country	• Any World Bank defined low- and middle-income country	• The study groups multiple countries and does not provide individual country-level data • The country of interest is designated high income by the World Bank
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• HIV/AIDS	
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)
Indicator	• Presence of the indicator in the article's text: **Numerator:** HIV patients who adhere to treatment (as defined in the study) **Denominator:** All patients in the study given HIV treatment	• The indicator is not included in the full text • Outcomes with a value that is difficult to interpret (i.e., it is unclear what the unit of analysis is or which population it captures, or no sample size)
Study population or population of interest	• Defined study population • Patients who have sought care for HIV and received treatment	• The study provides no, or an unclear, population size • The entire study population is not from the study country (e.g., medical tourists)

Content	**Inclusion**	**Exclusion**
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Single site or multiple sites of care delivery	• If setting is specifically stated to be outside the health system • Population-based studies (e.g., HIV mortality among the general population)

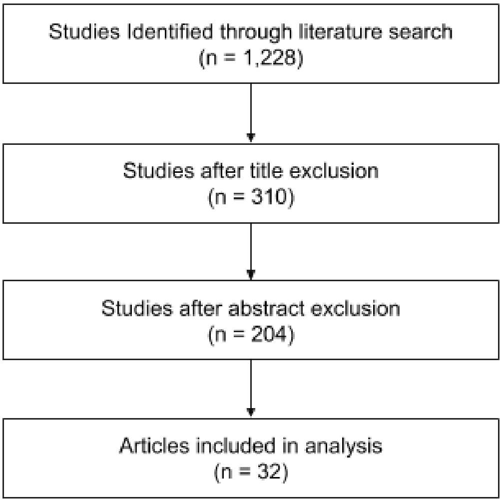
Search Terms

Title/Abstract	**MESH**	**Full Text**
Quality of Care	HIV	
Quality of Care AND HIV		
Quality of Care AND human immunodeficiency virus		
HIV	HIV AND Viral load	viral load
Human immunodeficiency virus	HIV AND Viral load	viral load
HIV AND Viral load	HIV	
HIV AND Viral load	HIV AND Viral load	
	HIV	virologic failure
	HIV	late diagnos*
	HIV	stage 3
	HIV	stage three
	HIV	ART*
	HIV AND antiretroviral agents	antiretroviral*
	HIV AND antiretroviral therapy, highly active	ART* and prescri*
	HIV AND antiretroviral therapy, highly active	antiretroviral* and prescri*
	HIV AND antiretroviral agents	ART* and prescri*

Title/Abstract	MESH	Full Text
	HIV AND antiretroviral agents	antiretroviral* and prescri*
	antiretroviral therapy, highly active	ART* and prescri*
	HIV AND antiretroviral agents	ART* and prescri*
	HIV AND antiretroviral therapy, highly active	
	HIV	ART AND prescri*
	HIV	antiretroviral AND prescri*
	HIV	PCP Prophylaxis
HIV	pneumonia, pneumocystis	pneumocystis pneumonia
HIV	pneumonia, pneumocystis	pneumocystis AND pneumonia
	HIV AND pneumonia, pneumocystis	pneumocystis AND pneumonia
	HIV AND pneumonia, pneumocystis	pneumocystis pneumonia
	HIV AND pneumonia, pneumocystis	pneumocystis pneumonia AND prophylaxis
HIV	pneumonia, pneumocystis	pneumocystis pneumonia AND prophylaxis
HIV	prevention & control	antiretroviral* AND prescri*
HIV	HIV AND prevention & control	antiretroviral* AND prescri*
HIV	HIV AND prevention & control	antiretroviral*
HIV	prevention & control	antiretroviral*
	prevention & control AND HIV	PCP Prophylaxis
	prevention & control AND HIV	PCP Prophylaxis AND prescri*
	drug resistance AND HIV	drug resistance AND testing
	HIV AND drug resistance	drug resistance AND test*
	HIV	drug resistance
HIV	HIV AND antiretroviral therapy, highly active	pregnant AND antiretroviral*

Title/Abstract	MESH	Full Text
	HIV AND antiretroviral agents	pregnant AND antiretroviral*
HIV	HIV AND antiretroviral therapy, highly active	pregnant AND ART*
	HIV AND antiretroviral agents	pregnant
	x-dign-CD4 protein, human AND HIV	
	HIV AND x-dign-CD4 protein, human	CD4 test*
	HIV	lipid panel AND ART*
	HIV AND antiretroviral agents	lipid panel
	HIV AND antiretroviral therapy, highly active	lipid panel
	HIV	lipid panel AND antiretroviral*
	HIV	lipid panel AND antiretroviral*
HIV	HIV AND Tuberculosis	tuberculosis screen
	HIV	TB screen*
	HIV	tuberculosis screen*

PRISMA Diagram



Community-Acquired Pneumonia

Indicator Definition

Pneumonia is an infection that occurs in a patient's lungs. Air sacs in the lungs can fill with fluid or pus (purulent material), which affects one's ability to breathe and often results in severe coughing and fever. Pneumonia ranges in severity and can result in death if left untreated. It most often results in more serious complications in vulnerable populations, including the elderly and children. Our review focuses on pneumonia acquired in the community rather than in a hospital, and specifically looks at the burden among the under 5 population (Mayo Clinic, 2018d).

Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Indicator	• Presence of the indicator in the article's text: **Numerator:** CAP patients who died **Denominator:** All patients in the study with a primary diagnosis of CAP or who sought care for CAP	• The indicator is not included in the full text • Outcomes with a value that is difficult to interpret (i.e., it is unclear what the unit of analysis is or which population it captures, or no sample size)
Study population or population of interest	• Defined study population	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often does not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Single site or multiple site of care delivery	• If setting is specifically stated to be outside the health care system • Population-based studies (e.g., PN mortality among the general population)
Age of death of those who died from CAP	• Age of death reported specifically for those who died of CAP	

NONCOMMUNICABLE DISEASES

Acute Myocardial Infarctions (AMIs)

Indicator Definition

Acute myocardial infarctions (AMIs), or heart attacks, occur when blood flow to the heart is blocked, often by fat, cholesterol, or other substance buildup. These substances form plaque that can break away and clot, which prevents blood flow. AMI can destroy or damage muscles in the heart if treatment is not administered in a timely manner (Mayo Clinic, 2018b).

Exclusion Criteria

Content	**Inclusion**	**Exclusion**
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame
Country	• Any World Bank defined low- and middle-income country	• The study groups multiple countries and does not provide individual country-level data • The country of interest is designated high income by the World Bank
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• Acute myocardial infarction (AMI) • Acute coronary syndrome (ACS)	• The main diagnosis is a condition other than AMI or ACS
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)
Indicator	• Presence of the indicator in the article's text: **Numerator:** Patients with AMI or acute coronary syndrome (ACS) admitted to the health facility who die **Denominator:** All patients in the study admitted to a health facility with a primary diagnosis of AMI or ACS	• The indicator is not included in the full text • Outcomes with a value that is difficult to interpret (i.e., it is unclear what the unit of analysis is or which population it captures, or no sample size)

Content	Inclusion	Exclusion
Study population or population of interest	• Defined study population • Patients who have sought care for AMI or ACS	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Single site or multiple site of care delivery	• Setting is specifically stated to be outside the health system • Population-based studies (e.g., AMI mortality among the general population)
Age of death of those who died from AMI	• Age of death reported specifically for those who died of AMI	• Age of death is not specifically due to AMI
Hospitalization rate	• Hospitalization rate for AMI among diagnosed patients	• Do not exclude hospitalization rate for any cause, only if it specifically states the hospitalization was for AMI

Stroke

Indicator Definition

Strokes occur when blood flow to the brain is stopped or reduced and prevents transmission of oxygen. There are multiple kinds of strokes that can occur, including ischemic strokes and hemorrhagic strokes. Ischemic strokes occur when arteries in the brain become interrupted. Hemorrhagic stroke occurs when blood vessels rupture and leak blood into the brain (Mayo Clinic, 2018e).

Exclusion Criteria

Content	Inclusion	Exclusion
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame
Country	• Any country not a member of the Organisation for Economic Co-operation and Development	• The study groups multiple countries and does not provide individual country-level data
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• Stroke • Hemorrhagic or ischemic	• The primary diagnosis is a condition other than stroke
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)
Indicator	• Presence of the indicator in the article's text: **Numerator:** Stroke patients admitted to the health facility who die **Denominator:** All patients admitted to the health facility for stroke	• The indicator is not included in the full text
Study population or population of interest	• Defined study population • Patients who have sought care for stroke	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data

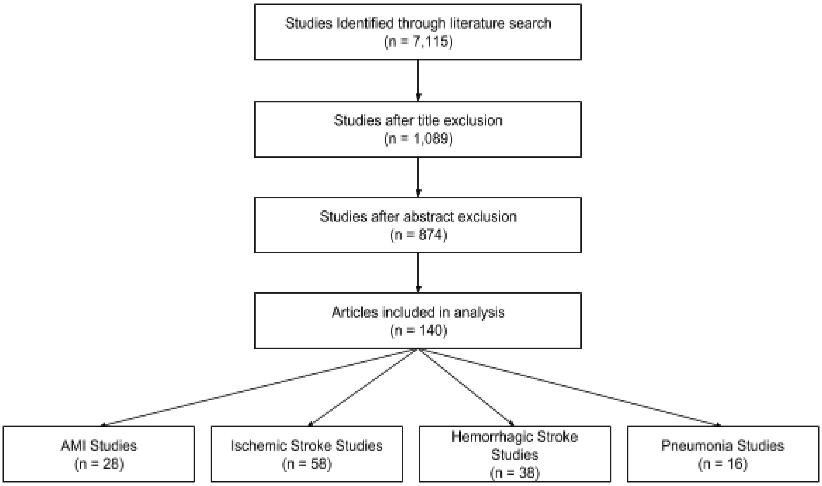
Content	**Inclusion**	**Exclusion**
Clinical setting	• Health system, health care facility	• Setting is specifically stated to be outside the health system • Population-based studies (e.g., stroke mortality among the general population)
Age of death of those who died from stroke	• Age of death reported specifically for those who died of stroke	• Do not include age of death if cause of death is not specified to stroke

Search Terms: CAP, AMI, and Stroke

Title/Abstract	**MESH**	**Full Text**
Quality of Care	Myocardial Infarction	mortality
Quality of Care	Stroke	mortality
Quality of Care	Pneumonia	mortality
Quality of Care AND ami		mortality
Quality of Care AND stroke		mortality
Quality of Care AND pneumonia		mortality
Quality of Care AND acs		mortality
Quality of Care AND acute myocardial infarction		mortality
Quality of Care AND acute coronary syndrome		mortality
inpatient mortality	Myocardial Infarction	
inpatient mortality	Stroke	
inpatient mortality	Pneumonia	
in-hospital mortality	Myocardial Infarction	
in-hospital mortality	Stroke	
in-hospital mortality	Pneumonia	
hospital mortality	Myocardial Infarction	
hospital mortality	Stroke	
hospital mortality	Pneumonia	
mortality	Myocardial Infarction	

Title/Abstract	MESH	Full Text
mortality	Stroke	
mortality	Pneumonia	
inpatient mortality AND ami		
inpatient mortality AND acs		
inpatient mortality AND acute myocardial infarction		
inpatient mortality AND acute coronary syndrome		
inpatient mortality AND stroke		
inpatient mortality AND pneumonia		
in-hospital mortality AND ami		
in-hospital mortality AND acs		
in-hospital mortality AND acute myocardial infarction		
in-hospital mortality AND acute coronary syndrome		
in-hospital mortality AND stroke		
in-hospital mortality AND pneumonia		
hospital mortality AND ami		
hospital mortality AND acs		
hospital mortality AND acute myocardial infarction		
hospital mortality AND acute coronary syndrome		
hospital mortality AND stroke		
hospital mortality AND pneumonia		
mortality AND ami		
mortality AND acs		
mortality AND acute myocardial infarction		
mortality AND acute coronary syndrome		
mortality AND stroke		
mortality AND pneumonia		

PRISMA Diagram for CAP, AMI, and Stroke



Congestive Heart Failure

Indicator Definition

Congestive heart failure (CHF) occurs when a person's heart muscle is unable to pump enough blood through the body. Various conditions can cause CHF including narrowed arteries in the heart or high blood pressure. CHF is not always life threatening, but can cause death in severe circumstances when not properly managed (Mayo Clinic, 2018c).

Exclusion Criteria

Content	Inclusion	Exclusion
Indicator	• Presence of the indicator in the article's text: **Numerator:** CHF patients who died **Denominator:** All patients in the study diagnosed with CHF or who sought care for CHF	• The indicator is not included in the full text

Content	Inclusion	Exclusion
Study population or population of interest	• Defined study population • Patients who have sought care for CHF (CHF may be primary or secondary diagnosis)	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Health system (because the indicator is inpatient mortality, the patients must have sought care)	• If setting is specifically stated to be outside the health system • Population-based studies (e.g., CHF mortality among the general population)
Age of death of those who died from CHF	• Age of death reported specifically for those who died of CHF	• Do not include age of death if cause of death is not specified to CHF

Chronic Obstructive Pulmonary Disease (COPD)

Indicator Definition

Chronic obstructive pulmonary disease (COPD) is a chronic lung disease that results from inflammation in the lungs that reduces airflow. This inflammation can lead to difficulty breathing, coughing, and wheezing. Environmental factors often cause COPD, which leads to high rates of other comorbidities such as lung cancer and heart disease amongst COPD patients (Mayo Clinic, 2018a).

Exclusion Criteria

Content	Inclusion	Exclusion
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame

Content	Inclusion	Exclusion
Country	• Any non-OECD country	• The study groups multiple countries and does not provide individual country-level data
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Condition	• Chronic obstructive pulmonary disease (COPD)	• The main diagnosis is a condition other than COPD and data specifically for the COPD population is not available
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)
Indicator	• Presence of the indicator in the article's text: **Numerator:** COPD patients who died **Denominator:** All patients in the study diagnosed with COPD or who sought care for COPD	• The indicator is not included in the full text
Study population or population of interest	• Defined study population • Patients who have sought care for COPD (COPD may be primary or secondary diagnosis)	• The study provides no, or an unclear, population size • The population is outside of the designated age range • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data
Clinical setting	• Health system (because the indicator is inpatient mortality, the patients must have sought care)	• Setting is specifically stated to be outside the health system • Population-based studies (e.g., COPD mortality among the general population)

Content	Inclusion	Exclusion
Age of death of those who died from COPD	• Age of death reported specifically for those who died of COPD	• Does not include age of death if cause of death is not specified to COPD

PATIENT CENTEREDNESS

Overall Rating

Indicator Definition

"Overall experience," or "overall rating" is a global rating of the patient's (or in cases of pediatric care, a caregiver's) assessment of their care interaction. For high-income countries, this is taken from the Commonwealth Fund (CWF), and is taken from the following question: "Opinion of regular doctor in past 12 months," taking a composite negative score from the answers "fair" or "poor." The responses across all items were summed and converted into a percentage of the maximum possible score to yield an overall experience score, with a potential range of 0–100, where 100 represents the best possible experience. The scores obtained from positive expressions were added to the score in the reverse direction (1 – x).

Exclusion Criteria

Content	Inclusion	Exclusion
Timing	• The literature search is limited to studies published between 2006 and 2016	• The study is outside the designated time frame
Country	• Any non-OECD country	• The study groups multiple countries and does not provide individual country-level data
Database	• PubMed	• The study has been pulled from any other database
Language	• Full text in English	• The full text is not available in English
Focus	• Patient experiences of care	• The focus of the paper is not patient experience or perceptions of care
Study population	• Human subjects	• Animal subjects • Lab-based research with no human subjects (e.g., biological samples)

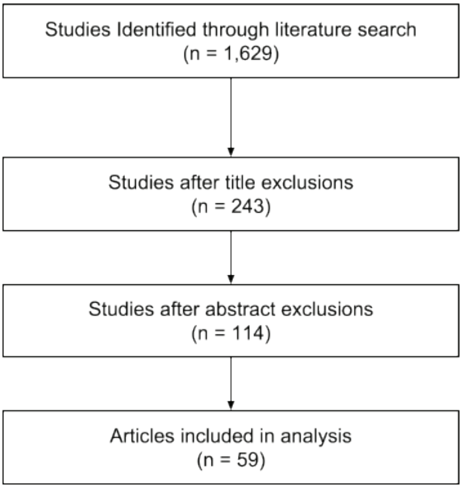
Content	**Inclusion**	**Exclusion**
Study population or population of interest	• Patients or caregivers of pediatric patients	• The study includes no data collected from patients or caregivers • The study provides no, or an unclear, population • The entire study population is not from the study country (e.g., medical tourists)
Study type	• All original research studies not noted for exclusion	• Case studies (unless cases have multiple patients) • Study protocols • Consensus papers (often do not use original data) • Meta-analyses or case studies • Intervention studies that do not provide control group data • Studies assessing satisfaction with a specific medical technology
Clinical setting	• Health system	• Setting is specifically stated to be outside the health system (e.g., population-based studies regarding overall perceptions of the health system, but the study subject has not been a patient) • Plastic surgery • Dental care

Search Terms

Title/Abstract	**MESH**	**Full Text**
patient experience*	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*
patient satisfaction	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*
patient responsive*	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*

Title/Abstract	**MESH**	**Full Text**
responsiveness to patient*	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*
patient engagement	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*
patient reported	Patient-Centered Care OR patient satisfaction	recommend* OR rate OR rating OR communicat* OR underst* OR explanation* OR explain* OR respons* OR dignity OR respect* OR disrespect* OR abus*

PRISMA Diagram



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