



Evidence Brief: The Quality of Care Provided by Advanced Practice Nurses

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) managers and policymakers, as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout VA.

QUERI provides funding for 4 ESP Centers and each Center has an active VA affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of QUERI Central Office and the 4 ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

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EXECUTIVE SUMMARY

This evidence brief discovered little new evidence regarding health outcomes of patients receiving care from an independent advanced practice nurse (APRN) or physician. In primary and urgent care settings, there was no difference in health status, quality of life, mortality, or hospitalizations favoring either APRN or physician care, although the strength of evidence was generally low (see Table 1).

Table 1. Evidence Summary

Outcome (Setting)	Results	Strength of evidence
Health status (primary care)	No difference	Insufficient (1 study)
Health status (urgent care)	No difference	Low
Quality of life (primary care)	No difference	Insufficient (1 study)
Mortality (primary care)	No difference	Low to Medium
Mortality (CRNA)	No difference	Insufficient (high risk of bias)
Hospitalization (primary care)	No difference	Low
Hospitalization (urgent care)	No difference	Insufficient (1 study)

Recent publications promoting over-riding state scope-of-practice laws argue that a large body of evidence shows APRNs working independently provide the same quality of care as medical doctors. We found scarce long-term evidence to justify this position.

The generally low strength of evidence outlined in this brief does not necessarily mean that additional randomized trials are necessary to prove comparable health outcomes among patients cared for by APRNs and physicians. Data on performance measures and provider errors, which is routinely collected by the VA, may be a better source of information on the actual quality of care provided by independent VA APRNs.

Strong conclusions or policy changes relating to extension of autonomous APRN practice cannot be based solely on the evidence reviewed here. Although no differences in 4 outcome measures (health status, quality of life, mortality, hospitalizations) were detected, the evidence cannot rule out such differences. Published evidence about performance measures, satisfaction, resource use, and considerations of access to care—as well as the track record of VA facilities that use this model—should be considered.

INTRODUCTION

The term “Advanced Practice Registered Nurse” (APRN) encompasses the Nurse Practitioner (NP), Certified Registered Nurse Anesthetist (CRNA), Clinical Nurse Specialist (CNS), and Nurse Midwife (NM).¹

Today, most NPs practice in primary care. Autonomy or independence has always been central to the concept of a nurse practitioner as a primary care provider.² The National Council of State Boards of Nursing defines “independence” as practicing with “no requirement for a written collaborative agreement, no supervision, [and] no conditions for practice.”³ Although the authority to diagnose and prescribe are the most frequently mentioned aspects of independence, the concept encompasses other dimensions including entry into practice; authority to bill for services independently; access to diagnostic services and hospital admitting privileges; and recognition as primary care providers.⁴

Medical licensing is a state function and APRN scope-of-practice (SOP) laws vary from state to state.⁵ In 16 states, APRNs have the authority to practice without a written agreement with a supervising physician, 9 states require physician involvement to prescribe but not to diagnose and treat, and in 24 states physician oversight is required to prescribe, diagnose, and treat.⁶ The definition of “oversight,” however, varies by state, and most states allow collaboration or supervision to occur remotely.⁷ There is also variation in SOP laws regarding APRNs’ authority to supervise clinical staff. For example, one article notes a requirement in sections 2069–71 of the California Business and Professions Code that doctors and selected other professions— but not registered nurses—may supervise California medical assistants.⁸

While there is disagreement about whether APRNs should practice independently, the seemingly arbitrary variation in SOP laws among the states is nearly universally criticized. As an editorial from the Commonwealth Fund put it, “objectively interpreted data on the competencies of professionals should guide policy, not rigid, often antiquated state laws.”⁹

The National Governors Association¹⁰ and the Institute of Medicine (IOM)¹¹ have criticized variation in SOP regulations among the states, and both argue that nurses should be able to practice to the “full extent of their education and training” in order to adapt to the changing health care system after the implementation of the Affordable Care Act (ACA), which authorizes nurse-managed health clinics and other innovations. In March, 2014, a report from the Federal Trade Commission, relying in large part on the IOM report, argued that physician supervision or collaborative practice agreement requirements “may sometimes restrict competition unnecessarily, which can be detrimental to health care consumers and have broader public health consequence,” that is, “decreased access to health care services, higher health care costs, reduced

The editorial also lists additional principles for policymaking concerning APRN’s SOP: “Second, policy should be dynamic and flexible in response to changing knowledge about the roles and abilities of health care professionals, as well as changes in the organization and financing of health care. Third, patients’ preferences with respect to who provides their care should play a much more prominent role in the debate than such data have in the past. Fourth, the United States must give higher priority to the development of a high-performing primary care infrastructure if it hopes to attract and retain a competent, satisfied workforce. Finally, unless physicians and nurse practitioners collaborate to improve primary care, neither will be happy with the outcome. We urgently need a facilitated, open dialogue about the roles of physicians and nurse practitioners that includes representatives of the public.”

quality of care, and less innovation in health care delivery.”¹² In the context of the ACA, one emergent issue is whether some patient care teams should be led by a nurse practitioner instead of only a medical doctor. Other advocates for change argue that, nationally, removing restrictions on NP practice would improve access to primary care and allow NPs to emerge as leaders of the integrated teams that are an important component of new models for delivering primary care.^{8,13,14}

THE IMPACT OF STATE SOP REGULATION

Despite the strong statements from multiple groups, there has been very little formal study of the impact of SOP laws on access to and quality of care. The National Governors Association report, supporting the elimination of most SOP restrictions for APRNs, notes:

Although there is a growing body of evidence from health services research that suggests that NPs can deliver certain elements of primary care as well as physicians, there is a dearth of rigorous research that isolates the effect of NP scope of practice rules on health care quality, cost, and access at the state level.¹⁰

More restrictive SOP rules are probably associated with slower growth in the number of NPs¹⁵ and in the number of Medicare patients cared for by NPs.¹⁶ In both 2006 and 2010, the odds of having an NP as a primary care provider were 2.5 times higher in the least restrictive states compared to the most restrictive states.¹⁶ These findings have not been directly associated with overall access to primary care, and it is unclear whether SOP rules exert this effect directly, or indirectly via the policies of state and private payers. In an extensive provider survey, “at the point of care, scope-of-practice laws were not found to have substantial impact across the study states on what services NPs can deliver, despite significant differences across states in the level of NP autonomy...”¹⁷ Rather, the study found that payer policies had more impact than SOP laws on how and where NPs can practice.¹⁷ Payers in states with restrictive SOP laws often add additional restrictions, such as not recognizing NPs as primary care providers, that make independent NP practice difficult. In addition, Medicare policies do not permit a NP to order home health care or durable medical equipment, even in states in which NPs practice independently.

Other arguments made by advocates for APRNs about the adverse effects of SOP restrictions are based on hypothetical reasoning or on anecdotes concerning inefficient use of time and, in some cases, delay in needed care because a physician’s approval was required to prescribe, order equipment, or admit a patient to the hospital.

PHYSICIAN GROUP PERSPECTIVES

Physician groups that support SOP restrictions envision a system in which physicians delegate the care of less complex patients to (supervised) nurse practitioners; one physician advocacy group has estimated that “nurse practitioners and physician assistants are capable of providing 70% or more of the care required for adults and 90% in pediatrics.”¹⁸ According to J.K. Iglehart, the AMA supports team-based care but argues that teams should be led by medical doctors, as integrated systems such as Geisinger, Kaiser Permanente, and the VA have done.⁵

These groups also argue that physicians may be better able to manage complicated diagnostic problems, patients with multiple chronic conditions, and unstable patients. These claims are plausible—as Blumenthal and Abrams note, “[p]hysicians and nurse practitioners receive very

different training, and it would be surprising if their competencies were identical.”¹⁹ However, no studies have been done to examine the validity of these beliefs.

Physician groups also argue that policymakers should take into account that patients prefer having a medical doctor as a primary care provider and that use of the title “doctor” by APRNs who have completed doctoral training could confuse patients about the training of their provider.¹⁹ Evidence about patients’ preferences regarding the type of provider is conflicting.

VETERANS HEALTH ADMINISTRATION PRACTICE ENVIRONMENT AND PREVIOUS RESEARCH

In the Veterans Health Administration (VHA), the use of APRNs in the delivery of health care, including primary, specialty, acute, and home health care, expanded greatly after the implementation of the Veterans Integrated Service Network (VISN) structure in October 1995 and the Veterans Health Care Eligibility Reform Act in 1996 (Public Law 104-262).²⁰ These changes resulted in a shift to local and regional networks grounded in ambulatory and primary care,²¹ an increase in the number of patients served by the VHA, and an increase in the percentage of patients seeking primary care services: 20% in fiscal year 1994 to 76% in fiscal year 1996. In 1996, 75% of VHA primary care practices reported using NPs and by 1999, this proportion had risen to 90%.²² Today the VHA employs over 4,700 nurse practitioner full time equivalents, 786 CRNAs, and 482 CNSs.²³

Currently, although a single unrestricted license allows APRNs to work at any VA facility, the VHA observes state-by-state rules regarding prescribing and admission privileges and physician supervision for APRNs. Each VA institution establishes its own policies regarding all other aspects of scope of practice. Advocates for “federal supremacy” argue that overriding state laws would “increase access to health care services, reduce costs and improve the quality and availability of health care” for Veterans by eliminating bureaucratic complexity and “artificial barriers” such as supervisory requirements.^{23,24} They note that varying regulations for diagnosing and prescribing can delay appropriate care and waste time and resources, particularly for CNSs in cardiology and other specialties working in VA facilities that serve patients from more than one state.

Research on APRNs in the VHA has been sporadic, and has focused on NPs rather than CRNAs or CNSs. From 1995 to 1999, the VHA HSR&D conducted one single-center RCT²⁵ and several observational studies of the impact of NPs on access to specialty care, continuity of care, and resource use.²⁶⁻²⁹ Some studies demonstrated improved continuity of and access to care after implementation of an interdisciplinary firm system,²⁷⁻²⁹ however, little research was conducted in the 2000s.^{20,30} The best recent data are from a 2011 cross-sectional study of all VISN 11 primary care patients who had hypertension and/or diabetes.²⁰ VISN 11 includes 2 states (Illinois, Michigan) with very restrictive scope of practice laws and 2 states (Ohio, Indiana) with moderately restrictive laws. The main findings were:

- On average, primary care NPs cared for less complicated patients than primary care physicians. MDs were caring for the more complex patients within the study sites.

The AANP commissioned a survey that found that 70% of the US adult population would support legislation to make it easier to choose NPs as their primary care provider. At this time, we have not assessed the validity of the survey methods. The AAFP refer to a different survey conducted by the Colorado Academy of Family Physicians.¹⁹ We were not able to find any additional information about this survey.

- Provider type was not significantly associated with an elevated blood pressure or creatinine level in either diabetic or hypertensive patients nor with an elevated HbA1c in diabetics.
- Increased use of resources by NPs was not demonstrated. NPs were less likely than physicians to obtain psychiatric referrals.

A survey of VISN 11 NPs and MD providers was also part of this study. The main findings were:

- Over 80% of NPs said they assess acutely ill/unstable patients on their own, and about 70% said they also plan care and make medication changes on their own.
- VHA NPs and physicians reported a high degree of collegiality.
- Nevertheless, there were “striking differences” between physicians’ and nurses’ beliefs about the NPs’ scope of practice. About 50% of physicians (vs 21% of NPs) were apprehensive about the fact that NPs function on their own, particularly for acute/unstable patients.

A 2012 ESP report reviewed the evidence on the role of primary care providers’ skill level (MD vs NP/PA) in ambulatory care settings in influencing patient outcomes from a VHA perspective.³¹ The authors of the ESP report stated that they “did not review studies that examined the effect of skill levels on patient quality of care or patient safety as it is widely accepted that medical school or more training increases quality of care.” The best evidence the ESP identified came from 2 randomized controlled trials which consistently found no difference in patient satisfaction with provider interaction when seeing a NP/PA instead of an MD. The ESP report also noted that a large VA study of patient satisfaction among 1.6 million veterans seen in 21 VISNs provided some limited information about impact of skill level: patient satisfaction increased in 3 VISNs that hired more NP/PAs.

USE OF EVIDENCE IN POLICY DEBATES

In a policy paper, Newhouse and colleagues state “[o]nce the issue of comparability between APRN care and that delivered by physicians is set aside in favor of an integrated team concept, disciplines can focus on...overarching goals” such as developing patient-centered team care, reducing quality gaps, and educating an interprofessional workforce.³² Their recent systematic review of RCTs and observational studies supports the emphasis on team care outlined in their policy paper. Including all types of APRNs, intermediate and health outcomes, and various patient populations and settings, Newhouse et al concluded that the outcomes of care provided by APRNs in collaboration with specialist or primary care physicians are similar to, or in some cases better than, the outcomes of care provided by a physician alone.³³

Although Newhouse et al’s emphasis on the role of APRNs in integrated teams is more relevant to the current organization of primary care services in VHA, policy discussions about over-riding state SOP laws invoke the argument that APRNs working independently provide the same quality of care as medical doctors.^{11,24,34} The Institute of Medicine, for example, claims that a large body of evidence “does not support the conclusion that APRNs are less able than physicians to provide safe, effective, and efficient care.”¹¹ Similarly, a publication from the Robert Wood Johnson

Foundation (RWJF) asserts that “health outcomes are comparable for patients treated by primary care NPs and MDs.”²⁴

Most articles about the role of APRNs do not explicitly define the autonomy of the nurses, compare non-autonomous nurses with physicians, or evaluate nurse-direct protocol-driven care for patients with specific conditions.³⁵ However, studies like these are often cited in support of the claim that APRNs practicing autonomously provide the same quality of primary care as medical doctors. For example, the RWJF publication quoted above refers to a review by Naylor and Kurtzman¹⁴ that relied on 2 systematic reviews published in 2002 and 2005^{36,37} and 2 additional randomized trials published in 2009. Many of the trials included in 2 older systematic reviews were considered by Naylor and Kurtzman.^{36,37}

The first additional trial comparing NP and general physician care was conducted 2 months after the NPs successfully completed a Masters-level training program. As nurses were not permitted to prescribe independently, physicians were “always available for consultation and to validate prescriptions and referrals.”³⁸ The second randomized trial included in the Naylor and Kurtzman review evaluated a 4-visit, computer-guided, nurse-led intervention for overweight and obese patients conducted in 11 general practice (GP) locations.³⁹

Most research on APRNs has evaluated team models of care or interventions designed to enhance care for patients with specific conditions (*eg*, incontinence, bronchiectasis, heart failure, etc.).^{36,37,40,41} The evidence supporting the contributions of APRNs in team models of care, protocol-driven care and nurse-led intervention focusing on a specific patient population is relevant to VHA and reasonably up-to-date.^{33,35} VA-ESP recently published a report that concluded there is strong evidence that nurse-managed protocols help to improve health outcomes among patients with moderate severity of diabetes, hypertension, hyperlipidemia, and chronic heart failure.⁴²

Nevertheless, the issue of the comparability of health outcomes of autonomous APRNs and physicians continues to be a cornerstone of the debate regarding state SOP rules. Because no previous systematic review has focused on this issue, the VHA Office of Quality, Safety and Value commissioned the VA Evidence-based Synthesis Program (ESP) Coordinating Center to reevaluate recent, original studies that reported health outcomes.

SCOPE

The objective of this evidence brief is to assess the strength and relevance of studies comparing autonomous APRNs with physicians in primary care, urgent care, and anesthesia settings for 4 important outcomes: health status, quality of life, hospitalizations, and mortality. We did not include process of care measures (such as access to care or resource use), performance measures (eg, blood pressure or glucose control), or patient satisfaction. We did not include studies of the work of APRNs (primarily CNSs) in team-based care or in interventions designed to augment usual care, nor care provided by nurse midwives.

The ESP Coordinating Center investigators and representatives of the Office of Quality, Safety and Value worked together to identify the population, intervention, comparator, outcome, timing, setting, and study design characteristics of interest. The Office of Quality, Safety and Value approved the following key questions and eligibility criteria to guide this review:

KEY QUESTIONS

- Key Question 1. Do independent advanced practice nurses and physicians provide comparable quality of care?
- Key Question 2. Does the quality of care provided by advanced practice nurses vary by the type of care (eg, primary or specialized care) being provided or by the setting of practice?
- Key Questions 3. Does the quality of care provided by advanced practice nurses vary by their degree of autonomy?

INCLUSION CRITERIA

- Population: adults.
- Intervention: A nurse or nurses practicing primary care, urgent care, or anesthesia with a high degree of autonomy. We included advanced practice nurses (including nurse practitioners (NP), clinical nurse specialists (CNS), specially-trained nurses, and certified registered nurse anesthetists (CRNA)). We did not include studies of Nurse Midwife (NM) care since the VA does not employ these providers.
- Comparator: a physician providing patient care.
- Outcomes: hospitalizations, mortality, health status (resolution of symptoms, overall improvement, or functional status), quality of life.
- Timing: no restriction on minimum study duration.
- Setting: both inpatient and outpatient care.
- Study design: randomized controlled trials and comparative observational studies.

To address Key Question 1, we searched for evidence for the direct comparison between care provided by an advanced practice nurse and care provided by a physician. In Key Questions 2 and 3, we sought to identify the factors that mediate the relationship between type of provider (advanced practice nurse or physician) and quality of care. Potential factors that might influence this relationship include the type of care being provided, the setting of practice, or the degree of autonomy of the advanced practice nurse.

METHODS

Brief or rapid review methodology is still developing and there is not yet consensus on what represents best practice. For example, limiting the number of electronic databases, excluding studies published in languages other than English, and forgoing a specific search for gray literature could introduce bias. An evidence brief differs from a full systematic review in that the scope is narrowly defined and the traditional review methods are streamlined in order to synthesize evidence within a shortened timeframe. An evidence brief does not outline the context in which the information is to be used and does not present a comprehensive assessment of knowledge on the topic.

Reference lists from existing systematic reviews and meta-analyses provided literature dating from 1969 to 2009. Additionally, we searched PubMed and CINAHL (2008-November 2013) using terms for *advanced practice nurse* and *quality of care* (see Supplemental Materials for complete search strategies). Additional citations were identified from hand searching reference lists, and consultation with content experts. We limited the search to published and indexed articles involving human subjects available in the English language. Study selection was based on the eligibility criteria described above. Titles, abstracts, and full-text articles were reviewed by one investigator and checked by another. All disagreements were resolved by consensus.

We rated the internal validity (quality) of controlled trials using methods from the Agency for Healthcare Research and Quality (AHRQ).⁴³ We abstracted data from all included studies on intervention and patient characteristics and results for each included outcome. All data abstraction and internal validity ratings were first completed by one reviewer and then checked by another. All disagreements were resolved by consensus.

We graded the strength of the evidence based on the AHRQ version of the GRADE working group system.⁴⁴ This approach incorporates 4 key domains: risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence. It also considers other optional domains that may be relevant for some scenarios, such as a dose-response association, plausible confounding that would decrease the observed effect, strength of association (magnitude of effect), and publication bias. Strength of evidence is graded for each key outcome measure and ratings range from high to insufficient, reflecting our confidence that the evidence reflects the true effect. For example, “low” strength of evidence means “[o]ur confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.”⁴⁵

A previous version was reviewed by 4 invited peer reviewers. Reviewer comments and author responses can be found in the Supplemental Materials.

RESULTS

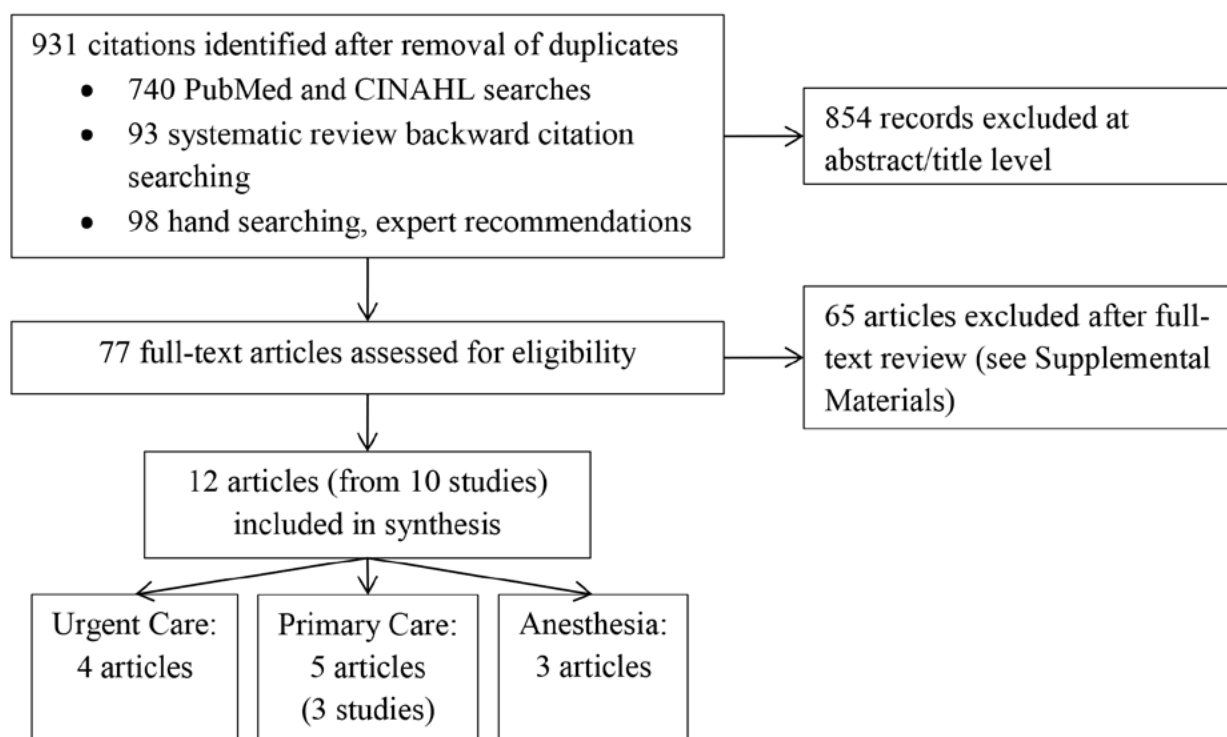
OVERVIEW

Figure 1 provides the results of the study selection process. We included 4 controlled trials conducted in urgent care settings,⁴⁶⁻⁴⁹ 3 controlled trials in primary care settings,^{25,50-53} and 3 observational studies in inpatient anesthesia care⁵⁴⁻⁵⁶ (see Data Abstraction Table in Supplemental Materials, pages 6-9).

The primary outcome measures in the 3 urgent care trials were cost-effectiveness,⁴⁹ patient satisfaction,⁴⁸ processes of care,⁴⁷ and health status.⁴⁶ The primary outcomes in the 3 primary care trials were cost-effectiveness,⁵⁰ resource use,²⁵ and health status,⁵³ but they also reported on quality of life,⁵⁰ mortality,^{25,50} and hospitalizations.^{25,50,53}

Classic studies such as the Burlington Randomized Trial of the Nurse Practitioner,⁵⁷ the St. John's Randomized Trial of the Family Practice Nurse,⁵⁸ and others demonstrated that advanced practice nurses in primary care could perform the activities traditionally associated with primary care physician practice and, in the short term, maintain comparable clinical outcomes among their patients.⁵⁹ However, since the 1970s, the content and complexity of primary care practice and nurse and physician education has changed substantially. These studies are now outdated and will not be considered in this evidence brief.

Figure 1. Literature Flow Chart



KEY QUESTION 1. Do independent advanced practice nurses and physicians provide comparable quality of care?

Health Status

Urgent Care. Four studies conducted in “urgent care” (same day consultation) settings that compared independent APRNs with physicians found no difference in resolution of symptoms 2 weeks after the encounter (Table 1).⁴⁶⁻⁴⁹ The urgent care practices examined in these studies included general practices ranging from rural to urban settings, serving 3,000 to over 16,000 patients, and with one to more than 5 partners, although several studies did not provide practice characteristics.⁴⁶⁻⁴⁹ Two studies compared Nurse Practitioners and physicians^{47,49} while 2 studies compared specially-trained nurses and physicians.^{46,48} The urgent care study samples were mostly female and the most common presenting condition in all 4 studies was respiratory infection or other acute conditions.⁴⁶⁻⁴⁹ Comorbidities of the patients included in the urgent care studies were not reported (see the Supplemental Materials for additional details of the patients).

None provided information on longer-term outcomes. While the studies are reassuring in that they found no differences, additional research that followed patients longer and used more detailed measures of health status might uncover differences (Strength of Evidence: low). See the Supplemental Materials for additional details of these trials.

Primary Care. A randomized controlled trial by Mundinger and colleagues is the best available evidence regarding the effectiveness of independent primary care NPs in the primary care setting.⁵³ Patients recruited from an urgent care center and 2 emergency rooms were randomly assigned to a provider in a clinic staffed exclusively by NPs or to a clinic staffed by physicians (Table 1).⁵³ There was no difference between the nurse practitioner group and the physician group in physical or mental Medical Outcomes Study Short-Form Health Survey (SF-36) scores for the 79% of enrolled patients who completed the 6-month follow-up interview (physical component summary scores (adjusted for age, sex, baseline scores, and selected chronic conditions): NP group: 40.53; physician group: 40.60; $P=0.92$).

Strengths of this large study (1,316 patients, 7 NPs, 11 physicians) were that NP and MD practices were not co-located and practitioners were not necessarily aware of patient’s involvement in the study. Patients were also new to both groups of providers and NPs had the same authority as MDs to prescribe, consult, refer, and admit patients.

The main weakness of the study was that 6 months is not an adequate follow-up time for the outcome of health status. The care provided in 6 months was too short to represent continuity care. Within the 6-month follow-up period, for example, 42% of patients had 0 or 1 primary care visits. As Sox noted in an editorial that accompanied the trial, “The short duration of the trial limits its ability to test a health professional’s competence across the broad spectrum of primary health care.”⁶⁰ After 2 years, researchers were able to contact 66% of the enrolled patients, and 55% of them had returned to their originally assigned provider.⁵² In this subsample, there were differences in NP-assigned patients ($n=222$) and the physician-assigned patients ($N=184$) in the proportion of Hispanics (94.5 vs 89.6%), Medicaid enrollees (87.4 vs 95.7%) and other characteristics, so that the benefits of randomization had been lost. Another weakness is that the data, which were collected between 1995 and 1997, are now over 20 years old.

Table 1. Effect of care by an APRN on health status

Author Year (Quality)	Study Duration	Setting	Results
Iglesias 2013 ⁴⁶ (Good)	15 days	Urgent care	Resolution of symptoms: OR nurse/physician=1.10 (95% CI: 0.84, 1.46)
Kinnersley 2000 ⁴⁷ (Fair)	2 weeks	Urgent care	Resolution of symptoms: Intervention group: 401/484 (83%) Control group: 450/529 (85%) <i>Not significant</i>
Shum 2000 ⁴⁸ (Fair)	2 weeks	Urgent care	Improved health status: Intervention group: 558/672 (83%) Control group: 546/661 (83%) <i>Not significant</i>
Venning 2000 ⁴⁹ (Fair)	2 weeks	Urgent care	“There were no differences in health status at the end of two weeks.” <i>No data shown</i>
Munding 2000 ⁵³ (Fair)	6 months	Primary care (urban community- based clinics and an academic medical center)	MOS SF-36 physical component summary (adjusted for age, sex, baseline MOS, selected chronic condition): Intervention group: 40.53 Control group: 40.60 <i>P=0.92</i>
Strength of evidence (urgent care): Low (medium risk of bias, inconsistent, direct, imprecise)			
Strength of evidence (primary care): Insufficient (medium risk of bias, consistency unknown, direct, precision unknown)			

Quality of Life

Primary Care. Information about quality of life is insufficient to draw any conclusions. Only one randomized controlled trial measured quality of life using the EQ-5D questionnaire, which captures 5 dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.⁵⁰ Respondents were asked to rate each domain using a 3 point scale (no problems, some/moderate problems, and extreme problems). The authors reported no statistically significant changes in EQ-5D scores for each of the patient groups over time or between groups, but did not provide any data.

Table 2. Effect of care by an APRN on quality of life

Author Year (Quality)	Study Duration	Setting	Results
Arts 2012 ⁵⁰ (Fair)	2 years	Primary care (academic hospital)	“EQ-5D scores remained similar over time in both groups demonstrating an equal non-significant decrease (<i>P=0.058</i>).” <i>Data not shown.</i>
Strength of evidence: Insufficient (medium risk of bias, consistency unknown, direct, precision unknown)			

Mortality

Primary Care. Two randomized controlled trials reported on mortality among patients cared for by APRNs and physicians (Table 3). These studies were not designed to test differences in mortality between the 2 groups of patients. While both studies directly compared care provided by an APRN and care provided by a physician and consistently reported no difference between the 2 groups after follow-up, small sample sizes make these estimates imprecise.

In the first study with 2 years of follow-up,⁵⁰ researchers found no difference in mortality between the nurse and physician group (5/149 (3.3%) and 4/145 (2.7%), respectively). The second study, with 1 year of follow-up,²⁵ found no statistically significant differences in mortality between patients cared for by APRNs or physicians (5/150 (3.3%) and 3/150 (2%), respectively).

Mortality is not a practical measure of quality for primary care. While the evidence on this outcome is sparse, it is *a priori* unlikely that studies comparing different practitioners (APRNs vs MDs, APRNs vs other APRNs, or MDs vs other MDs) would find differences in mortality except for very high-risk patient panels. While the available evidence is imprecise, it is unlikely that additional evidence from studies of unselected primary care patients would change the conclusion.

Table 3. Effect of care by a NP or CNS on mortality

Author Year (Quality)	Study Duration	Setting	Results
Arts 2012 ⁵⁰ (Fair)	2 years	Primary care (academic hospital)	Intervention group: 5/149 (3.3%) Control group: 4/145 (2.7%) <i>Not significant</i>
Hemani 1999 ²⁵ (Fair)	1 year	Primary care (VAMC)	Intervention group: 5/150 (3.3%) Control group: 3/150 (2.0%) <i>Not significant</i>
Strength of evidence: Low to Medium (medium risk of bias, consistent, direct, imprecise)			

Hospitalizations

Urgent Care. Information about hospitalizations in an urgent care setting is insufficient to draw any conclusions. One urgent care randomized controlled trial reported hospitalizations as an outcome (Table 4).⁴⁸ This study reported no difference in hospitalizations between the nurse practitioner and physician groups after 2 weeks (1/675 (< 1%) and 3/664 (< 1%), respectively).

Primary Care. Three primary care studies examined hospitalizations among patients treated by an APRN or a physician and found no difference between the 2 groups (Table 4).^{25,50,53} As with mortality, these studies were not designed to test differences in hospitalizations between the 2 groups of patients. All 3 studies compared care provided by an APRN and care provided by a physician and consistently reported no difference in hospitalizations between the 2 groups. However, small sample sizes make these estimates imprecise.

Munding et al found no statistically significant difference between patients assigned to the nurse practitioner and physician group at one year (68/800 (8.5%) and 50/509 (9.8%), respectively; $P=0.42$).⁵³ Another randomized controlled trial by Arts et al⁵⁰ reported no

statistically significant difference in hospitalizations between the group receiving care from a nurse specialist and the group receiving care from a physician after 2 years (43 (4.3%) and 42 (5.4%), respectively).⁵⁰ The remaining primary care study found a trend towards more hospitalizations for the nurse practitioner group, but results were not statistically significant (mean hospitalizations per patient-year for NPs=0.43, attending physicians=0.31).²⁵

Table 4. Effect of care by an APRN on hospitalization

Author Year (Quality)	Study Duration	Setting	Results
Shum 2000 ⁴⁸ (Fair)	2 weeks	Urgent care	Intervention group: 1/675 (< 1%) Control group: 3/664 (< 1%) <i>Not significant</i>
Munding 2000 ⁵³ (Good)	1 year	Primary care (urban community- based clinics and an academic medical center)	Intervention group: 68/800 (8.5%) Control group: 50/509 (9.8%) <i>P=0.42</i>
Arts 2012 ⁵⁰ (Fair)	2 years	Primary care (academic hospital)	Intervention group: 43/149 (4.3%) Control group: 42/145 (5.4%) <i>Not significant</i>
Hemani 1999 ²⁵ (Fair)	1 year	Primary care (VAMC)	Mean utilization rate (unadjusted): Intervention group: 0.43 admissions per patient-year Control group: 0.31 admissions per patient-year <i>P>0.05</i>
Strength of evidence (urgent care): Insufficient (medium risk of bias, consistency unknown, direct, precision unknown)			
Strength of evidence (primary care): Low (medium risk of bias, consistent, direct, imprecise)			

Patient case mix and policies on hospitalization vary widely among settings. For primary care, care by a NP or CNS versus a physician probably does not affect the risk of hospitalization in published studies, but applicability to the VA is limited; only one of the studies was conducted in a VA setting. With the background of this literature, observational data from current VA clinics would be valuable to assess applicability. While not as rigorous as evidence from randomized trials, observational data would reflect the quality that results from current VA policies on assignment of patients to nurse practitioners in primary and urgent care and would be applicable to VA facilities in states that do not permit independent APRN practice.

CRNAs

In anesthesia, 2 major issues are whether CRNAs should be candidates to lead teams specializing in outpatient chronic pain management and which surgical patients can be managed independently by a CRNA.

Chronic Pain Management. VA-based CRNAs have argued that an expanded SOP is needed to permit them to practice independently, particularly in pain management clinics. While nurse-led pain management clinics are described in numerous studies, we found no studies comparing a nurse-led pain clinic to one led by a physician.

Surgical and Procedural Anesthesia. VHA anesthesiologists have objected to expanding the scope of practice of CRNAs on the grounds that CRNAs lack experience in the care of higher-risk surgical patients.

No randomized trials compared outcomes of surgical patients managed by an independent CRNA with those managed by teams, anesthesiologists, or other physicians.

In 2004, a narrative review provided an excellent critical appraisal of older observational studies, concluding “it is not possible to draw a conclusion regarding differences in patient safety as a function of provider type.”⁶¹ The limitations of the older studies were “difficulty in risk adjustment, failure to define precisely how hospital anesthesia providers are utilized, and lack of consideration of resources and processes beyond the anesthesia provider model that may also affect outcomes.”⁶²

For this evidence brief, we reviewed 3 frequently cited observational studies that used claims data to compare mortality and length of stay (Table 5).⁵⁴⁻⁵⁶

The first study (Silber) analyzed Pennsylvania Medicare claims from 1991 to 1994 for 194,430 major surgical and orthopedic operations billed as “personally performed” or directed by an anesthesiologist and 23,010 not billed as performed or directed by an anesthesiologist.⁵⁶ The latter group represented a mix of cases supervised by a surgeon, a staff CRNA, or an anesthesiology resident. After accounting for hospital and patient characteristics, the adjusted 30-day mortality rate (OR = 1.08; 95% CI: 1.00, 1.15; $P < 0.04$) and the adjusted mortality rate after complications (OR = 1.10; 95% CI: 1.01, 1.18; $P < 0.01$) were higher among patients managed without medical direction by an anesthesiologist. The rates of complications were similar.

Although it is very frequently cited in debates about CRNA care,⁶³ we found this study had little relevance to the current question because the comparison group does not directly represent care provided by an independent CRNA. It is also unlikely that the methods for risk adjustment were adequate; for example, undirected cases were performed in smaller hospitals, and, by itself, hospital size does not adequately explain differences in mortality due to failure to rescue.

The second study (Pine) used 1995 -1997 Medicare claims from 22 states to compare adjusted inpatient mortality when anesthesia was provided by an anesthesiologist alone, a CRNA alone, or a team consisting of an anesthesiologist and a CRNA.⁵⁵ To avoid some of the limitations of the previous study, the sample excluded emergency cases, cases from hospitals with low surgical volumes, and cases that had no Medicare Part B data, no anesthesia bill or an incomplete bill, or ambiguous provider codes. A total of 182,000 of 586,422 potentially eligible surgeries were excluded because of these criteria. Only 33,151 (8.2%) of the remaining 404,194 cases were managed by a CRNA alone. Risk-adjusted mortality rates were not significantly different between type of anesthesia provider or practice organization.

The third study (Dulisse and Cromwell) suggests that, for patients with low complexity (surgeries comparable in complexity to a thyroid biopsy), care by a CRNA alone is comparable to care by a team or a solo MD.⁵⁴ This study compared 1999 to 2005 Medicare data from states that opted out versus states that did not opt out of a requirement for physician supervision of CRNAs. This study found:

1. In opt-out states (14 primarily rural states[‡]), surgical mortality and complication rates for

patients managed by independent CRNAs did not change after the states opted out of the CMS supervision requirement.

2. In non-opt-out states, surgical mortality among patients whose anesthesia was provided by a CRNA was lower compared with patients whose anesthesia was provided by a physician, and there was no difference in complications between these 2 groups.
3. Mortality and complication rates were lower for all patients (physician, CRNA, and team care) in opt-out states (both before and after opting out) compared with physician patients in non-opt-out states.

In general, patients managed by solo CRNAs were less complex than those managed by solo MDs. Despite adjustment for patient characteristics (age, sex, and race), procedure complexity (captured with procedure base units), and year, the methods used in the study to capture the complexity of surgery and relevant comorbidity were not adequate to exclude selection bias as an explanation for the results. That is, the lack of differences in patient outcomes might be due to triage of less complex cases to CRNAs.⁶⁴

The results of these studies do not provide any guidance on how to assign patients for management by a solo CRNA, or whether more complex surgeries can be safely managed by CRNAs, particularly in small or isolated VA hospitals where preoperative and postoperative health system factors may be less than optimal. To determine how CRNAs function within the VA or which procedures or surgeries would best be managed by which provider (CRNA, physician, or team), studies conducted within the VHA would be optimal.

Table 5. Effect of care by a CRNA on mortality

Author Year (Quality)	Study Duration	Setting	Results
Dulisse & Cromwell 2010 ⁵⁴	Retrospective	Inpatient	Odds Ratios (adjusted) Non-opt-out states: Anesthesiologist solo: 1.00 (reference) CRNA solo: 0.899* Team: 0.959* Opt-out states (before opting out, after opting out): Anesthesiologist solo: 0.797*, 0.788* CRNA solo: 0.651*, 0.689* Team: 0.708*, 0.565* * $P < 0.05$
Pine 2003 ⁵⁵	Retrospective	Inpatient	Anesthesiologist only: 121/29,718 (0.41%) Obs/ Pred = 1.049 CRNA only: 61/13,592 (0.45%) Obs/Pred = 0.897 Team: 24/8,330 (0.29%) Obs/Pred = 0.830
Silber 2000 ⁵⁶	Retrospective	Inpatient	Odds Ratios (adjusted) 30-day mortality: 1.08 (1.00, 1.15) Failure to rescue: 1.10 (1.01, 1.18)
Strength of evidence: Insufficient (consistent, indirect, precise for relatively simple operations)			

‡ Alaska, Idaho, Iowa, Kansas, Minnesota, Montana, Nebraska, North Dakota, New Hampshire, New Mexico, Oregon, South Dakota, Washington, and Wisconsin

KEY QUESTION 2. Does the quality of care provided by advanced practice nurses vary by the type of care being provided or by the setting of practice?

We did not identify any studies that were designed to study whether the quality of care provided by advanced practice nurses varies by the type of care being provided or by the setting of practice. While previous systematic reviews have included studies of APRNs in a variety of settings, none have compared outcomes across these settings. Due to the small number of included studies we cannot conclude that the quality of care provided by APRNs does or does not vary by setting of practice (eg, hospital vs free-standing clinics, multispecialty vs solo practice, or differing case mix managed by a CRNA).

KEY QUESTION 3. Does the quality of care provided by advanced practice nurses vary by their degree of autonomy?

We did not identify any studies that examined whether the quality of care provided by advanced practice nurses varied by their degree of autonomy. Such a study would compare the outcomes of care provided by advanced practice nurses who were required to have physician involvement to diagnose, treat, and prescribe; those that were required to have physician involvement to prescribe; and those that were not required to have any physician involvement. The variation in scope-of-practice regulations throughout the US may hinder the feasibility of such a study.

While there was variation among the included studies regarding the autonomy or supervision of APRNs, there were not enough studies or data to make a meaningful comparison of the quality of care provided by APRNs compared with physicians by the degree of autonomy or supervision. Two controlled trials included nurses that worked according to a protocol.^{46,50} In another study, physicians were required to review and countersign all charts but approval was not required for referrals, tests, or treatment plans.²⁵ In the 3 studies conducted in the UK, nurses required a doctor's signature in order to prescribe.⁴⁷⁻⁴⁹ Finally, in one RCT nurse practitioners and physicians had the same authority to prescribe, consult, refer, and admit patients.⁵³ In this study, nurse practitioners and physicians worked with a collaborative agreement that required 1) doctors to respond when a nurse requested consultation and 2) quarterly meetings to review charts.

SUMMARY OF MAIN FINDINGS

Table 6 summarizes the main findings of this evidence brief.

Table 6. Main findings

Outcome (Setting)	Number of studies (number of participants)	Results	Strength of evidence	Comments
Health status (primary care)	1 (1,040)	No difference favoring either APRN or physician care	Insufficient	Medium risk of bias, consistency unknown, direct, precision unknown
Health status (urgent care)	4 (4,702)	No difference favoring either APRN or physician care	Low	Medium risk of bias, inconsistent, direct, imprecise
Quality of life (primary care)	1 (294)	No difference favoring either APRN or physician care	Insufficient	Medium risk of bias, consistency unknown, direct, precision unknown
Mortality (primary care)	2 (594)	No difference favoring either APRN or physician care	Low to Medium	Medium risk of bias, consistent, direct, imprecise
Mortality (CRNA)	3 (1,103,074)	No difference favoring either APRN or physician care	Insufficient	Observational studies with high risk of bias
Hospitalization (primary care)	3 (1,903)	No difference favoring either APRN or physician care	Low	Medium risk of bias, consistent, direct, imprecise
Hospitalization (urgent care)	1 (1,339)	No difference favoring either APRN or physician care	Insufficient	Medium risk of bias, consistency unknown, direct, precision unknown

There was insufficient information on whether the quality of care provided by advanced practice nurses varies by the setting of practice to draw any conclusions. Similarly, there was no information on whether the quality of care provided by advanced practice nurses varies by degree of autonomy.

DISCUSSION

This evidence brief found that evidence regarding 4 important outcomes of patients cared for by a nurse working autonomously is inconclusive. Other systematic reviews have noted the small body of evidence regarding health outcomes of patients receiving care from an APRN or physician.^{37,41,61}

The studies we reviewed did not demonstrate a difference between APRN care and physician care in primary and urgent care settings with regard to health status, quality of life, mortality, or hospitalizations. However, these studies were not large enough, and did not follow patients long enough, to exclude a possible difference. Only 2 controlled trials^{46,53} determined their necessary sample size based on the outcomes included in this evidence brief. While one study was conducted in a VAMC,²⁵ the applicability of the findings of other studies may be limited given that the VA population has poorer health status and a higher rate of comorbidities compared with other patient populations.⁶⁵ A study of all General Internal Medicine Clinic patients (n=5,478) at 7 VAMCs reported that patients had an average of 3.79 comorbidities, 23.6% had diabetes, 59.4% had hypertension, and 19.2% had coronary artery disease.⁶⁶ The proportion of hypertensive patients was much lower in 2 studies reporting this condition.^{25,53} Similarly, in the study that was not specifically recruiting diabetic patients, the proportion of diabetic patients was lower.⁵³ One included study focused on patients with type 1 and 2 diabetes recruited from an inpatient setting, but excluded more complex patients that the investigators thought should not be treated by a CNS.⁵⁰ Again, this demonstrates the higher complexity of VA patients compared with other populations.

The lack of rigorous new evidence comparing care provided by an autonomous primary care APRN versus a physician alone is not surprising. Well-publicized, well-conducted randomized trials conducted in the 1970s proved the concept that an autonomous primary care APRN can deliver care comparable to that provided by a primary physician. These studies may have made further proof of equivalence seem unnecessary, particularly since independent APRN practice in primary care and urgent care were widely implemented in many states and throughout the VA, where rigorous quality assessment has been applied since the 1990s.

It is less clear why the practice of anesthesiologists and CRNAs has not been evaluated in prospective studies. We identified 3 observational studies, the largest and most recent of which suggest that there is not an increased risk of mortality due to CRNA care.^{54,55} However, these studies have a number of limitations, as described above. Our findings were similar to those of Newhouse et al, who characterized the available evidence regarding independent practice by nurse anesthetists as “sparse data from single observational studies of low quality.”³³

The generally low strength of evidence outlined in this brief does not necessarily mean that additional randomized trials are necessary to prove comparable health outcomes among patients cared for by APRNs and physicians. The historical studies and recent literature provide little reason to suspect that there is a difference between APRN care and physician care in primary and urgent care settings with regard to health status, quality of life, mortality, or hospitalizations. Data on performance measures and provider errors, which is routinely collected by the VA, may be a better source of information on the actual quality of care provided by independent VA APRNs.

We did not address the roles of advanced practice nurses in teams, nurse-managed protocols, or nurse-led interventions supplemental to usual care. These roles are well-accepted and have been shown to improve target outcomes.^{33,42} These roles of APRNs are well-accepted. The decision to expand the use of such models within the VA should be based on the results of the review by Newhouse et al and on quality and performance data from VA facilities that employ such models (eg, VA Patient Aligned Care Teams (PACTs)).

Instead, our focus was on major health outcomes of patients cared for by a nurse working autonomously because arguments against scope-of-practice regulations are predicated on the argument that the quality of care provided by APRNs is no different from that provided by physicians. We did not find any papers that evaluated nurse-led patient care teams similar to the VA-PACT or medical home model.

This review also addresses a narrower range of outcomes than may be of interest to broader audiences of healthcare providers and policymakers, such as resource use beyond hospitalizations, processes of care, and intermediate outcomes. The evidence outlined in this brief is not the only pertinent information relating to independent APRN practice within the VA. All but 2 of the studies were designed to evaluate measures we did not evaluate: resource use, patient satisfaction, or processes of care. A review on resource use, patient satisfaction, quality measures, or errors among APRNs and physicians would have included additional studies beyond those evaluated here.

Strong conclusions or policy changes relating to extension of autonomous APRN practice cannot be based solely on the evidence reviewed here. Although no differences in 4 outcome measures (health status, quality of life, mortality, hospitalizations) were detected, the evidence cannot rule out such differences. Published evidence about performance measures, satisfaction, resource use, and considerations of access to care—as well as the track record of VA facilities that use this model—should be considered.

SUPPLEMENTAL MATERIALS

The following supplemental materials are available on the ESP website with this Evidence Brief:

1. Search Strategies
2. List of Excluded Studies
3. Evidence Tables
 - a. Data Abstraction
 - b. Quality Assessment
 - c. Review Comments/Responses

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Evidence Brief: The Quality of Care Provided by Advanced Practice Nurses

SUPPLEMENTAL MATERIALS

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U.S. Department of Veterans Affairs
Veterans Health Administration
Quality Enhancement Research Initiative

SEARCH STRATEGIES

CINAHL Search (November 26, 2013)

Advanced Nursing Practice

(MH “Anesthesia Nursing”) OR (MH “Advanced Nursing Practice+”) OR (MH “Advanced Practice Nurses+”) OR (MH “Scope of Nursing Practice”) OR (MH “Nurse Practitioners+”) OR (MH “Clinical Nurse Specialists”)

AND

Assessment

(MH “Quality of Health Care+”) OR (MH “Fatal Outcome”) OR (MH “Treatment Failure”) OR (MH “Treatment Outcomes+”) OR (MH “Outcome Assessment”) OR (MH “Nursing Outcomes”) OR (MH “Medical Futility”) OR (MH “Outcomes (Health Care)+”) OR (MH “Quality Assessment”) OR (MH “Program Evaluation”) OR (MH “Clinical Indicators”)

Limits

English Language

Peer Reviewed

Research Article

NOT children

NOT (MH “Midwifery+”)

2008 to present

PubMed Search (November 26, 2013)

((("Outcome and Process Assessment (Health Care)"[Mesh]))

AND

(((((APRN[Title/Abstract]) OR NP[Title/Abstract]) OR CRNA[Title/Abstract])) OR (((("Nurse Practitioners"[Mesh]) OR "Nurse Clinicians"[Mesh]) OR "Nurse Anesthetists"[Mesh])) OR "Advanced Practice Nursing"[Mesh])) NOT ("Midwifery"[Mesh] OR "Nurse Midwives"[Mesh])

AND

(((((("Cohort Studies"[Mesh]) OR "Controlled Clinical Trial"[Publication Type]) OR "Case-Control Studies"[Mesh])) OR ((("Evaluation Studies"[Publication Type]) OR "Comparative Study"[Publication Type])) OR ((("Comparative Study"[Publication Type]) OR "Follow-Up Studies"[Mesh])

OR

evaluation studies[pt] OR evaluation studies as topic[mesh] OR program evaluation[mesh] OR validation studies as topic[mesh] OR (effectiveness[tiab] OR (pre-[tiab] AND post-[tiab])) OR (program*[tiab] AND evaluat*[tiab]) OR intervention*[tiab]

OR

"Case-Control Studies"[Mesh] OR "Control Groups"[Mesh] OR (case[TIAB] AND control[TIAB]) OR (cases[TIAB] AND controls[TIAB]) OR (cases[TIAB] AND controlled[TIAB]) OR (case[TIAB] AND comparison*[TIAB]) OR (cases[TIAB] AND comparison*[TIAB]) OR "control group"[TIAB] OR "control groups"[TIAB]

OR

((("Veterans Health"[Mesh])) OR (((VA OR Veteran OR VAMC OR Veterans)) OR ("Veterans"[Mesh] OR "United States Department of Veterans Affairs"[Mesh] OR "Hospitals, Veterans"[Mesh]))

Limits

NOT children

2008 to present



LIST OF EXCLUDED STUDIES

(testing nurse-led intervention supplemental to usual care, intervention not compared to physician care, study population not relevant to VA, clinical outcomes not reported)

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EVIDENCE TABLES

Data Abstraction of Included Studies by Setting

First Author Year	Country	Setting	Age in Years	Target Condition	Study Duration	Intervention and Comparator	APRN Supervision	Design
Sponsoring Organization	Included in Newhouse Review?	N Participants	Female (%) Race/Ethnicity (%)	Patient Complexity No. Consultations	Outcomes Reported		APRN Training	
<i>Primary Care</i>								
Arts 2011	The Netherlands	One academic hospital	Internist group: 58.4 years Nurse Specialist group: 59.5 years	Patients with diabetes mellitus types 1 and 2 requiring more extensive monitoring and specialist care than patients in a primary care setting	2 years Quality of Life (3 point scale (EQ-5D) assessing mobility, self-care, usual activities, pain/discomfort, anxiety/depression) Hospitalizations Mortality	Patients allocated to nurse care (4 Registered Nurse Specialists) Patients allocated to physician care (5 Physicians)	Nurses worked according to a protocol Nurse specialists: doctoral or master's prepared RNs who focused on specific patient populations	RCT
No external funding	No	Internist group: 145 patients Nurse Specialist group: 149 patients	Internist group: 64.8% female Nurse Specialist group: 62.4% female Race/ethnicity not reported	Baseline Characteristics (MD vs Nurse): BMI (kg/m ²): 29.5, 29.9; EQ-5D: 0.82, 0.86; HbA1c: 8.07%, 7.97% Excluded more complex patients Nurses: 1,003 Physicians: 679				
Hemani 1999	US (MD)	Baltimore VAMC primary care clinic	Attending Physician group: 60 years Nurse Practitioner group: 62 years	New primary care patients	1 year Hospitalizations Mortality	Patients allocated to nurse care (9 Nurse Practitioners w/ > 6 mos experience (mean 13 yrs experience)) Patients allocated to Resident Physician care (35 2 nd or 3 rd year residents) Patients allocated to Attending Physician care (10 Attending Physicians)	"...newly graduated NPs are required to present every patient to the attending physicians during the first 6 months of their appointment" "...physicians are required to review and countersign all nurse practitioner and resident visit charts. However, approval of the attending physician is not required for referrals, tests, or treatment plans." APRN Training not discussed	Controlled Trial
No external funding mentioned	No	Attending Physician group: 150 patients Resident Physician group: 150 patients Nurse Practitioner group: 150 patients	Attending Physician group: 1% female Nurse Practitioner group: 1% female	Baseline Characteristics (MD vs NP): hypertensive: 52%, 42%; diabetic: 19%, 20%; coronary artery disease: 19%, 18%; congestive heart failure: 7%, 5%; COPD: 9%, 5%; chronic conditions per patient: 1.5, 1.3 Nurses: 5.7 half-day sessions per week Physicians: 2.4 half-day sessions per week				
Mundinger 2000	US (NY)	Four community-based primary care clinics (MD) and one primary care clinic at an academic medical center (NP)	Physician group: 46.7 years Nurse Practitioner group: 45.5 years	New primary care patients eligible for Medicaid	6 months Health status (SF – 36 Item Short-Form Health Survey) Hospitalizations at 6 mos and 1 yr	Patient allocated to nurse care (7 Nurse Practitioners) Patient allocated to physician care (17 physicians)	"The primary care nurse practitioners and physicians had the same authority to prescribe, consult, refer, and admit patients." "New York State law allows nurse practitioners to practice with a collaboration agreement that requires the physician to respond when the nurse practitioner seeks consultation...requires only quarterly meetings to review cases..." APRN Training not discussed	RCT
Division of Nursing, Health Resources and Services Administration, US Department of Health and Human Services; The Fan Fox and Leslie R. Samuels Foundation; and the New York State Department of Health.	Yes	Physician group: 510 patients Nurse practitioner group: 806 patients	Physician group: 78.2% female Nurse Practitioner group: 75.9% female Physician group: 91.0% Hispanic, 5.5% Black, 1.5% White Nurse Practitioner group: 89.3% Hispanic, 8.1% Black, 0.8% White	Baseline Characteristics: Mean physical function (MD vs NP): 37.2, 37.9 Mean mental health summary score (MD vs NP): 40.2, 41.1 Prevalence of asthma (MD vs NP): 16.1%, 17.9% Prevalence of diabetes (MD vs NP): 14.3%, 11.5% Prevalence of hypertension (MD vs NP): 38.0%, 33.9% No significant difference in number of primary care visits				



First Author Year	Country	Setting	Age in Years	Target Condition	Study Duration	Intervention and Comparator	APRN Supervision	Design
Sponsoring Organization	Included in Newhouse Review?	N Participants	Female (%) Race/Ethnicity (%)	Patient Complexity No. Consultations	Outcomes Reported		APRN Training	
<i>Primary Care</i>								
Lenz 2004 <i>Subset of Mundinger 2000</i>	US (NY) Yes	Four community-based primary care clinics (MD) and one primary care clinic at an academic medical center (NP) Physician group: 184 patients Nurse practitioner group: 222 patients	Physician group: 57.1% 40-64 years Nurse Practitioner group: 57.7% 40-64 years Physician group: 15.2% female Nurse Practitioner group: 20.7% female Physician group: 89.6% Hispanic, 7.7% Black Nurse Practitioner group: 94.5% Hispanic, 4.5% Black	Subset of Mundinger (2000) patients Target conditions (MD vs NP): asthma (16.3%, 19.4%), diabetes (13.0%, 10.4%), hypertension (37.5%, 37.4%) Mean physical function (MD vs NP): 37.49, 38.94 Mean mental health summary score (MD vs NP): 39.88, 38.94 Unknown	2 years Health status Hospitalizations	Patient allocated to nurse care (unclear # Nurse Practitioners) Patient allocated to physician care (unclear # physicians)	“The primary care nurse practitioners and physicians had the same authority to prescribe, consult, refer, and admit patients.” “New York State law allows nurse practitioners to practice with a collaboration agreement that requires the physician to respond when the nurse practitioner seeks consultation...requires only quarterly meetings to review cases...” APRN Training not discussed	RCT
Lenz 2002 <i>Subset of Mundinger 2000</i>	US (NY) Yes	Four community-based primary care clinics (MD) and one primary care clinic at an academic medical center (NP) Physician group: 59 patients Nurse practitioner group: 86 patients	54.8 years 66.2% Female 91.5% Hispanic 84% of subjects were enrolled in Medicaid.	Subset of Mundinger (2000) patients with type 2 diabetes Baseline Characteristics: 64.1% BMI ≥ 27 Mean physical function (MD vs NP): 33.48, 37.11 Mean mental health summary score (MD vs NP): 39.20, 40.91 Unknown	6 months Health status Hospitalizations	Patient allocated to nurse care (unclear # Nurse Practitioners) Patient allocated to physician care (unclear # physicians)	“The primary care nurse practitioners and physicians had the same authority to prescribe, consult, refer, and admit patients.” “New York State law allows nurse practitioners to practice with a collaboration agreement that requires the physician to respond when the nurse practitioner seeks consultation...requires only quarterly meetings to review cases...” APRN Training not discussed	RCT
<i>Urgent Care</i>								
Kinnersley 2000	UK No	10 general practices ranging from 6,000 to 16,300 patients General Practitioner Group: 716 patients Nurse Practitioner Group: 652 patients	GP group: 16-35: 30%; 36-55: 25% NP group: 16-35: 28%; 36-55: 22% GP group: 58% female NP group: 61% female Race/ethnicity not reported	Patients requesting same day appointments Presenting illness (GP, NP): respiratory system (29%, 29%), nervous system and sensory organs (15%, 14%), skin (12%, 11%), musculoskeletal system (9%, 7%), digestive system (9%, 8%), allergic, endocrine, nutritional, and metabolic (6%, 8%), genitourinary (5%, 5%), miscellaneous (16%, 18%) Unknown	2-4 weeks Resolution of symptoms and concerns (5 pt. Likert-type scale (2 wks)) Hospitalizations for same problem (4 wks)	Patients allocated to nurse care (10 NPs) Patients allocated to physician care (unknown # of GPs)	“General practitioners were always available to prescribe when necessary.” Nurse practitioners: nurses employed in general practice who had completed the nurse practitioner diploma course at one of two colleges at least one year prior to start of study	Controlled Trial



First Author Year	Country	Setting	Age in Years	Target Condition	Study Duration	Intervention and Comparator	APRN Supervision	Design
Sponsoring Organization	Included in Newhouse Review?	N Participants	Female (%) Race/Ethnicity (%)	Patient Complexity No. Consultations	Outcomes Reported		APRN Training	
<i>Urgent Care</i>								
Shum 2000	UK No	Five general practices ranging from semi-rural to urban, Physician group: 915 patients Nurse group: 900 patients	Physician group: 29.1 years Nurse group: 26.0 years Physician group: 60.3% female Nurse group: 60.0% female Race/ethnicity not reported	Patients requesting same day appointments (minor illnesses) Presenting condition (GP vs NP): respiratory infection (52.4%, 48.1%), musculoskeletal problems (13.5%, 13.0%), skin condition (9.5%, 11.0%), abdominal pain (4.6%, 4.5%), eye condition (3.6%, 4.6%), diarrhea or vomiting (3.7%, 2.6%), urinary infection (2.4%, 3.7%), gynecological (2.3%, 2.4%), contraception (1.6%, 1.2%). Unknown	2-4 weeks Self-reported health status at two weeks (cured, improved, same, worse) Return to surgery Attendance at an "accident and emergency" out of hours call to emergency Hospitalizations	Patient allocated to nurse care (5 specially trained nurses) Patient allocated to physician care (19 general practitioners)	Prescriptions required a doctor's signature Training: nurses participated in a course on managing minor illnesses over 3mos. Team developed an academically accredited degree level course in managing minor illnesses as none of the nurses had experience in this area.	RCT
Venning 2000	UK No	20 general practices ranging from urban to rural, 1 to >5 partners, and 3,000 to >12,000 practice list size General practitioner group: 651 patients Nurse practitioner group: 641 patients	Physician group: 69.4% > 16 years Nurse Practitioner Group: 64.6% > 16 years Physician group: 57% female Nurse Practitioner group: 58% female Race/ethnicity not reported	Patients requesting same day appointments (points of first contact in primary care) Presenting condition: upper respiratory tract infection (36.8%), viral illness (11.4%), no specific diagnosis (11.0%), minor injuries (9.2%), eye and ear conditions (7.6%) Unknown	2 weeks Health status (SF-36 at baseline and two weeks after appointment)	Patient allocated to nurse care (20 nurse practitioners) Patient allocated to physician care (unknown # GPs)	Prescriptions required a doctor's signature Nurses had a one or two year nurse practitioner training, BSc, or MSc. Median time as nurse practitioners= 3 yrs. Median time as registered nurse=22 yrs.	RCT
Iglesias 2013	Spain No	38 practices belonging to the main primary care provider in Catalonia General practitioner group: 708 patients Nurse group: 753 patients	Physician group: 38.6 years Nurse group: 39.0 years Physician group: 61.2% female Nurse group: 61.0% female Race/ethnicity not reported	Patients requesting same day appointments Presenting condition (GP vs nurse): upper respiratory symptoms (56.2%, 54.6%), acute diarrhea (16.0%, 17.4%), low back pain (11.2%, 10.6%), injury (10.6%, 9.4%) Unknown	15 days Health status improvement (yes/no)	Patient allocated to nurse care (155 specially trained nurses) Patient allocated to physician care (142 general practitioners)	Nurse supervision was not explicitly discussed, although nurses were free to consult with and refer patients to a general practitioner Nurses were trained to follow guidelines developed during the study's preparation phase	RCT



First Author Year	Country	Setting	Age in Years	Target Condition	Study Duration	Intervention and Comparator	APRN Supervision	Design
Sponsoring Organization	Included in Newhouse Review?	N Participants	Female (%) Race/Ethnicity (%)	Patient Complexity No. Consultations	Outcomes Reported		APRN Training	
<i>Inpatient Care</i>								
Silber 2000	US (Pennsylvania)	Pennsylvania Medicare general and orthopedic surgical admissions claims 1991-1994	9.9% older than 85 years 34.7% male Race/ethnicity not reported	Elderly Medicare patients general and orthopedic surgical admissions History of: congestive heart failure (2.6%), arrhythmia (2.9%), aortic stenosis (1.8%), hypertension (6.6%), cancer (24.2%), COPD (12.1%), type 2 diabetes (10.6%), type 1 diabetes (1.7%) ED admission: 34.4% Unknown	Mortality within 30 days of admission (identified vial HCFA Vital Status file) Failure-to-rescue (deaths after complications) identified using a set of 41 events – ICD-9-CM	194,430 patients whose surgery was directed by an anesthesiologist 23,010 patients whose surgery was undirected by an anesthesiologist	Adjusted for: 11 hospital characteristics (> 200 beds, RNs/bed ratio, % anesthesiologist staff board certified, % surgical staff board certified, trauma center, lithotripsy facility, MRI facility, solid organ/kidney transplant unit, residency training program, council of teaching hospitals member), 64 patient characteristics and interaction terms (demographics, history, transfer, ER admissions, 42 diagnosis-related group categories)	Retrospective
Funding: Methodology development partially supported by a grant from AHRQ and a grant from the American Board of Anesthesiology	No	245 hospitals						
Pine 2003	US (22 states)	Medicare surgical admissions claims 1995-1997 in 22 states obtained from part B Medicare billing data (404,194 cases)	Patient Characteristics not reported	Patients undergoing 1 of 8 procedures: Carotid endarterectomy (14.09%), Cholecystectomy (13.53%), Herniorrhaphy uncomplicated (3.90%), Hysterectomy for benign disease (7.56%), Knee replacement (27.49%), Laminectomy (7.17%), Mastectomy (6.78%), Prostatectomy (19.47%) Unknown	Inpatient mortality (risk-adjusted)	Anesthesiologist alone (33.2% of cases) Certified Registered Nurse Anesthetists alone (8.2% of cases) Team of an anesthesiologist and CRNA (58.6% of cases)	Adjusted for: case mix, clinical risk factors*, hospital characteristics, geographic location *used NY SPARCS database to screen potential clinical risk factors (used Medicare dataset to verify)	Retrospective
Funding: The American Association of Nurse Anesthetists Foundation	No							
Dulisse and Cromwell 2010	US (14 opt-out states, unknown # non-opt-out states)	Medicare surgical admissions claims 1999-2005 in opt-out and non-opt-out states (481,440 cases)	Opt-out states: CRNA solo: 51% ≥ 75; MDA solo: 48% ≥ 75; Team: 45% ≥ 75 years Non-opt-out states: CRNA solo: 44% ≥ 75; MDA solo: 47% ≥ 75; Team: 44% ≥ 75 years Opt-out states: CRNA solo: 41%; 45%; Team: 44% male Non-opt-out states: CRNA solo: 43%; MDA solo: 45%; Team: 44% male Opt-out states: CRNA solo: 1%; MDA solo: 2%; Team: 2% African American Non-opt-out states: CRNA solo: 8%; MDA solo: 7%; Team: 11% African American	All Medicare surgical diagnosis-related groups Procedure Base Units: Opt-out states: CRNA solo: 7.2; MDA solo: 8.3; Team: 7.6 Non-opt-out states: CRNA solo: 7.2; MDA solo: 8.4; Team: 7.6 Excluded patients with more than one hospitalization in a quarter Unknown	Inpatient mortality	In opt-out and non-opt-out states: Anesthesiologist alone (42%, 44.5%) Certified Registered Nurse Anesthetists alone (21%, 9.7%) Team of an anesthesiologist and CRNA (37.0%, 45.8%)	Adjusted for: patient characteristics (age, sex, race), procedure complexity (anesthesia base units), year, opt-out status, indicators for the ten highest-mortality diagnosis-related groups	Retrospective
Funding: The American Association of Nurse Anesthetists	No							



Quality Assessment of Included Controlled Trials

Author Year	Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?	Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Were the outcome assessors blinded to the intervention or exposure status of participants?	Were outcomes assessed/defined using valid and reliable measures, implemented consistently across all study participants?	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Was attrition unacceptably high? Was attrition unacceptably differential? Was intention-to-treat analysis performed?	Quality Rating
Arts 2011	Yes "Patients who were considered eligible for participation and who gave written informed consent were enrolled in the study by unrestricted randomization, i.e. drawing lots."	Yes "Researchers were blinded with regard to allocation."	Yes, except for the percentage of participants with diabetes-related complications was higher in the intervention group (47%) than in the control group (42%).	Deaths and hospitalizations: No "Adverse events [including hospitalizations and deaths] were registered per patient visit by the participating physicians and nurse specialist." Quality of life: Unclear	Deaths and hospitalizations "were registered per patient visit by the participating physicians and nurse specialist." Quality of life: EQ-5D generic health index, ascertainment unclear.	Intervention (nurse) group: Randomized: 169 Enrolled: 169 (100%) Used in analysis (per outcome): 149/169 (88%) Control (physician) group: Randomized: 168 Enrolled: 168 (100%) Used in analysis (per outcome): 145/168 (86%)	No No No	Deaths: Fair Hospitalizations: Fair Quality of life: Fair
Kinnersley 2000	No "In practices using randomization by day, all patients consulting on a particular day saw the same type of practitioner." "Some of the practices that chose to randomize patients within day had appointments for same day patients fitted in throughout the day while others had unbooked consulting sessions." Order of appointments was organized according to block randomization.	Not reported	Yes Adjusted for the effect of cluster randomization.	Resolution of symptoms: No, self-report. Hospitalizations: Unclear	Resolution of symptoms: Use of a self-administered questionnaire at two week-follow-up. Likert-type scales. Hospitalizations: Yes. "...patients medical records were checked for reattendance or hospital admission for the same problem.	Total sample: Requesting same day consultation: 1757 Randomized: 1465/1757 (83%) Used in analysis: 1368/1757 (78%) Intervention group: Enrolled: 652 Used in analysis (per outcome): Resolution of symptoms: 491/652 (75%) completed postal questionnaire (two week follow-up). Hospitalizations: 583/652 (89%) audit sheet completed from medical records. Control group: Enrolled: 716 Used in analysis (per outcome): Resolution of symptoms: 533/716 (74%) completed postal questionnaire (two-week follow-up). Hospitalizations: 639/716 (89%) audit sheet completed from medical records.	No No No	Resolution of symptoms: Fair Hospitalizations: Fair



Author Year	Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?	Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Were the outcome assessors blinded to the intervention or exposure status of participants?	Were outcomes assessed/defined using valid and reliable measures, implemented consistently across all study participants?	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Was attrition unacceptably high? Was attrition unacceptably differential? Was intention-to-treat analysis performed?	Quality Rating
Shum 2000	Yes "Allocation to being seen by a doctor or nurse was determined using random permuted blocks of four, with sequentially numbers, non-resealable, opaque envelopes."	Yes	Yes, except for the percentage of patients classified as having "other" conditions in each group.	Resolution of symptoms: No, self-report. Hospitalizations: Unclear.	Health status: Yes "Self-reported health status was measured using the scale developed by Murphy et al." Critical events: "Data on critical events, attendance at accident and emergency departments, and out of hours calls were collected from the medical records of those who did not respond to the postal questionnaire."	Intervention group: Randomized: 900 Enrolled: 860/900 (96%) Used in analysis (per outcome): health status: 672/900 (75%) critical events: 675/900 (75%) Control group: Randomized: 915 Enrolled: 853/915 (93%) Used in analysis (per outcome): health status: 661/915 (72%) Critical events: 664/915 (73%)	No No Resolution of symptoms: No Hospitalizations: Yes	Resolution of symptoms: Fair Hospitalizations: Fair
Mundinger 2000	Yes	Yes	Yes	Health status: No Hospitalizations: Unclear	Health status: "Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)." (self-reported) Hospitalizations: "...obtained from the medical center computer records" at 6 months and at one year.	Intervention group: Randomized: 1181 Enrolled: 806/1181 (68%) Used in analysis (per outcome): Health status at 6 month follow-up 649/1181 (55%) Hospitalization data: 800/1181 (68%) Control group: Randomized: 800 Enrolled: 510/800 (63%) Used in analysis (per outcome): Health status at 6 month follow-up 391/800 (49%) Hospitalization data: 509/800 (64%)	No No Health status: No Hospitalizations: Yes	Health status: Fair Hospitalizations: Good
Lenz 2004 <i>Subset of Mundinger 2000</i>	Yes	Yes	Yes, except for Medicaid status at baseline.	Health status: No Hospitalizations: Unclear	Health status: "Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)." (self-reported) Hospitalizations: "...obtained from the medical center computer records" at 6 months and at one year.	Intervention group: Randomized: 1181 Enrolled: 806/1181 (68%) Used in analysis (per outcome): 222/1181 (19%) Control group: Randomized: 800 Enrolled: 510/800 (63%) Used in analysis (per outcome): 184/800 (23%)	Yes No Health status: No Hospitalizations: No	Poor



Author Year	Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?	Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Were the outcome assessors blinded to the intervention or exposure status of participants?	Were outcomes assessed/ defined using valid and reliable measures, implemented consistently across all study participants?	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Was attrition unacceptably high? Was attrition unacceptably differential? Was intention-to-treat analysis performed?	Quality Rating
Lenz 2002 <i>Subset of Munding 2000</i>	Yes	Yes	Unclear, no data given. “NP and MD patients with type 2 diabetes did not differ demographically and were similar to the larger sample.”	Health status: No Hospitalizations: Unclear	Health status: “Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).” Self-reported. Hospitalizations: “...obtained from the medical center computer records” at 6 months and at one year.	Total sample: (subset of a larger study) Randomized: 1981 Eligible: 1316/1981 (66%) Total sample: Used in analysis: 145/1981 (7%) Intervention group: Randomized: 1181 Enrolled: 806/1181 (68%) Used in analysis (per outcome): Completed MOS SF-36 questionnaire at 6 month follow-up: 71/1181 (6%) Hospitalizations at 6 months after baseline: 86/1181 (7%) Control group: Randomized: 800 Enrolled: 510/800 (63%) Used in analysis (per outcome): Completed MOS SF-36 questionnaire at 6 month follow-up: 48/800 (6%) Hospitalizations at 6 months after baseline: 59/800 (7%)	Yes No Health status: No Hospitalizations: No	Poor
Venning 2000	Yes “A method of coded block randomization was developed ... neither the receptionist nor the patient could determine the group to which a patient had been allocated at the time of booking. ... generated from random number tables.” For walk-in: “...randomized patients after they had consented...”	Yes “The randomization code was broken by one of the researchers at the start of each experimental session, at which point it became apparent which patient would see which practitioner.”	Yes	No	Health status: Yes Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). Self-reported.	Intervention group: Randomized: 651 Enrolled: 641/651 (98%) Used in analysis (per outcome): 503/651 (77%) Control group: Randomized: 665 Enrolled: 651/665 (98%) Used in analysis (per outcome): 502/665 (75%)	No No No	Health status: Fair



Author Year	Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?	Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?	Were the groups comparable at baseline on key prognostic factors (e.g., by restriction or matching)?	Were the outcome assessors blinded to the intervention or exposure status of participants?	Were outcomes assessed/ defined using valid and reliable measures, implemented consistently across all study participants?	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Was attrition unacceptably high? Was attrition unacceptably differential? Was intention-to-treat analysis performed?	Quality Rating
Hemani 1999	No “All new primary care referrals were reviewed by a nurse practitioner who assigned them to a physician, nurse practitioner, or any available provider, depending on the severity of the problems listed on the referral.” “Patients assigned to “any available provider” who fulfilled the eligibility criteria... were divided into two groups.”	Unclear	Yes, except for chronic renal insufficiency.	Unclear	Hospitalizations: Yes. VA medical records.	Intervention group: Randomized: 150 Enrolled: 150 (100%) Used in analysis (per outcome): 150 (100%) Control group: Randomized: 150 Enrolled: 150 (100%) Used in analysis (per outcome): 150 (100%)	No No Yes	Deaths: Fair Hospitalizations: Fair
Iglesias 2013	Yes “Participants were randomly assigned... using an automatic probabilistic function which assigns one group or another using a probability of 0.5.”	Yes “The sequence was concealed until groups were assigned because the application generated the sequence just after the patient gave oral and written consent...”	Yes	Health status: No	Health status: self-report of symptom resolution (yes/no)	Intervention group: Randomized: 753 Enrolled: 753 Used in analysis (per outcome): 710/753 (94%) Control group: Randomized: 708 Enrolled: 708 Used in analysis (per outcome): 641/708 (91%)	No No No	Health status: Good



REVIEW COMMENTS/RESPONSES

REVIEWER	COMMENT	RESPONSE
1. Are the objectives, scope, and methods for this review clearly described?		
1	Yes.	N/A
2	<p>No.</p> <p>1. The language of the primary question seems somewhat vague: the phrase “comparative quality of care” seems less than precise. A more precise question might be: “Do independent advanced practice nurses and physicians provide equivalent quality of care?” Note that this specific wording implies an equivalence test, rather than either an inferiority or superiority perspective.</p> <p>2. Additionally, it’s not clear to me, given the phrase “independent advanced practice nurses” in the main question why level of supervision would pertain. Are you treating “independence” as a continuous variable, or as a binary one? Some other term may be necessary to suggest that there is a continuum (as there is in fact) in degree of autonomy.</p> <p>3. Finally, it’s not clear to me why the initial questions did not include workload as a factor that might mediate the comparison between APRN and physician care.</p>	<p>1. We changed the phrasing of Key Question 1 to reflect that we did not hypothesize physician or APRN care to be either inferior or superior.</p> <p>2. We changed Key Question 3 to include the phrase “degree of autonomy.”</p> <p>3. None of the included studies explicitly considered workload as a mediating factor between provider care and patient outcomes. We information in the Supplemental Materials detailing the number of consultations completed in each provider group.</p>
3	Yes. One minor suggestion is to make the Key questions 1, 2 and 3. It’s not a problem, but just a bit easier for the reader.	Key Questions were renumbered 1,2, and 3.
4	AHRQ quality indicators were purportedly used to assess quality of studies, but the resulting “grades” don’t measure up to what I know of some of the studies; because quality of the study is so crucial and central to everything else, it would be wise to show on a grid how and why each study was graded on the AHRQ measures	We show the details and rationale for the grades on a quality assessment table located in the Supplemental Materials. In preparing this grid, we reconsidered the grades and changed some grades through consensus.
2. Is there any indication of bias in our synthesis of evidence?		
1	No.	N/A
2	<p>Yes.</p> <p>I’m not sure this really constitutes bias, but the lack of any information about the physicians against whom the APRNs providing care were contrasted suggests a lack of concern about the comparator. There is some range in the type of physicians providing care, and in many of the settings described in the report, there would be a need to care for all ages, for example, in contrast to VA care where only adults receive care. I think the report would be somewhat richer if there were some brief discussion about the physician comparators, rather than assuming they all are equally comparable.</p>	Unfortunately, none of the included studies provided information specifically on the physician comparators apart from those outlined in the Supplemental Materials. We directed the reader to the Supplemental Materials in the overview of the results.
3	No. Not that I can identify. Your methods and synthesis appear to be thorough and of high quality.	N/A



4	Not sure if there was a lot of “adjudication” to reach consensus among the 4 authors or not. Perhaps initial individual author perspectives should have been noted	We resolve disputes regarding grading via consensus.
3. Are there any published or unpublished studies that we may have overlooked?		
1	No.	N/A
2	No. I think the report is primarily evidence of how little rigorous work has been done in this field.	N/A
3	For inclusion in your analyses, none that I can identify. I’ve provided suggestions below for references in your introduction and discussion.	N/A
4	None that I know of	N/A
4. Please write additional suggestions or comments below. If applicable, please indicate the page and line number from the draft report.		
1	<p>1. Page 3, Line 20: what does “type of care being provided” mean? (also seen on p.4, L.2; p.12, L21; p.12,L25). Does it refer to cardiac care, diabetic care, anesthesia care, etc? I couldn’t find any citations that explain that, which is a part of Question 1(a).</p> <p>2. Another important factor would be objective risk profiling of the patients, so comorbidities would be known. Was that done? If not, that is information that would help evaluate results. Were the sicker patients excluded from controlled trials? The RCTs apparently did not have the same potential exclusion/inclusion bias. However, all the studies (except the ones involving CRNAs) were done in outpatient offices or urgent care clinics – a somewhat self-selected sample of lower-complexity medical issues, one would think, given the low incidence of hospitalizations and mortalities.</p> <p>3. P. 11 ff: I found the whole discussion of opt-in, opt-out states and the results presented in the subsequent paragraphs confusing and hard to follow, although I read it several times trying to understand the differences that were being described. Does that entire discussion help with the policy questions being considered?</p> <p>4. P. 14, Line 16: “. . . in no way suggest that there is a difference” seems too strongly worded and smacks of political correctness. How about using “. . . did not demonstrate a difference”? I have no trouble with the wording on P. 15, Line 19-22.</p> <p>5. P.16, L1-3 seems awkwardly worded. How about: “The available evidence is insufficient to draw strong conclusions or support policy changes relating to extension of independent NP practice. Although no differences in four outcome measures (health status, quality of life, mortality, hospitalizations) were detected, current evidence is not sufficient to rule out such differences.”</p>	<p>1. We changed Key Question 1(a) to clarify the meaning of “type of care being provided.”</p> <p>2. We added detail on the reported comorbidities in the discussion section. While one of the primary care studies was conducted in a VAMC, comorbidities in the urgent care studies were not reported. It is unknown whether these populations are comparable to VA populations in need of urgent care services.</p> <p>3. We revised this discussion to clarify the findings of the study.</p> <p>4. We changed this sentence to: “. . . did not demonstrate a difference. . .”</p> <p>5. We changed this phrase to: “Although no differences in four outcome measures (health status, quality of life, mortality, hospitalizations) were detected, the evidence reviewed here is not sufficient to rule out such differences.”</p>



2	<p>1. In Table 1, the Mundinger 2000 study is recorded twice with exactly the same information.</p> <p>2. I think the issue of degree of supervision (or, conversely, degree of autonomy) is interesting, but the fact that there is really no evidence on the topic isn't sufficiently made clear in the report. I think this needs to be more clearly highlighted. The inconsistency across the US, at least, in scope of practice and autonomy, limits our ability to do rigorous studies in this area. In the supplemental materials, it becomes clear that the definition of "independence" or "supervision" is not entirely clear. Does "works under protocol" mean the same as "all notes must be signed by a supervising physician"? I would suggest not; and a key question is where the protocol comes from, who defines it, and whether it's one that is also, perhaps, used by physicians in the same setting?</p>	<p>1. Corrected.</p> <p>2. We clarified the findings of Key Question 3 to highlight the lack of evidence on this topic, including the following statement: "The variation in scope-of-practice regulations throughout the US may hinder the feasibility of such a study." Again, we changed the phrase "level of supervision" to "degree of autonomy" as suggested above.</p>
3	<p>1. I would recommend in your background adding in the IOM report on nursing and their suggestion to have nurses of all levels practice to the full extent of their training.</p> <p>2. In your introduction you also include the nurse midwife, however this seems to disappear. Were there no studies on midwives vs. physicians? It would be good to introduce this back in the discussion.</p> <p>3. To help give context it would be useful to include a couple sentences on the changes in federal health policy, such as the Affordable Care Act, that are providing more access to medical care for people.</p> <p>4. I feel it is important to discuss the difference between the NP and CNS scope of practice. You lump them together, but they aren't quite the same. Many CNS do not have prescriptive rights, though some do. That may make a significant difference in being able to make a comparison with the decision making and authority of a physician. The NP performs much more like a physician than a CNS.</p> <p>5. The discussion sets the reader up to focus on primary care settings and the comparison between the NP and physician. You briefly talk about primary care and its importance, but nothing on the acute care setting where many NPs also work. This makes the following section on CRNAs and anesthesiologists not fit.</p> <p>6. In the discussion paragraph on the difference between anesthesiologists and CRNAs, you say that your findings are similar to those of Newhouse et al. and that there is sparse data to make conclusions. However, you need to guide the reader here. A sentence is needed saying what studies do suggest. For example, the study by Dulisse, 2010 (your reference 28) suggests no additional harm to patients.</p> <p>7. You briefly discuss team models of care. Some mention of the PACT model is warranted in both the introduction and discussion.</p>	<p>1. We added a sentence to the introduction: "The National Governors Association and the Institute of Medicine have criticized variation in scope-of-practice regulations among the states, and both argue that nurses should be able to practice to the "full extent of their education and training" in order to adapt to the changing health care system after the implementation of the Affordable Care Act..."</p> <p>2. We did not include studies comparing Nurse Midwife and physician care since the VA does not employ NMs. This was clarified in the scope.</p> <p>3. We added a sentence: "The Institute of Medicine has criticized scope-of-practice regulations, arguing that nurses should be able to practice to the full extent of their education and training in order to adapt to the changing health care system after the implementation of the Affordable Care Act."</p> <p>4. We grouped outcomes by setting, rather than by APRN title. We added the following language to the inclusion criteria: "A nurse or nurses practicing primary care, urgent care, or anesthesia with a high degree of autonomy. We included advanced practice nurses (including nurse practitioners (NP), clinical nurse specialists (CNS), specially-trained nurses, and certified registered nurse anesthetists (CRNA))." We include a discussion of degree of autonomy in KQ 3.</p> <p>5. We clarified this in the discussion section. We removed the first sentence in the second discussion paragraph referring to primary care as the paragraph refers to the body of evidence in primary and urgent care.</p> <p>6. We added two sentences in the discussion: "We identified three observational studies, the largest and most recent of which suggest that there is not an increased risk of mortality due to CRNA care. However, these studies have a number of limitations, as described above."</p> <p>7. We added the example of the VA PACTs in the discussion.</p>



4	<p>1. I don't believe the review group is sufficiently aware of the scope of Mundinger (2000); clearly it was a large study of undifferentiated patients, and the NP's were explicitly using the same scope of practice as the MD's with whom they were compared. It is the only RCT to date that has the scope and comparability and size of population to be influential.</p> <p>2. Why do you say Mundinger (2000) was six months in duration in one box of statistics, and one year in another? One of the Lenz pubs is over more than one year...</p> <p>3. Mortality in a short term study, especially in primary care, is not a valid measure of primary care effectiveness. Health status is an important measure of assuring comparable populations in NP and MD practice, but it is not a valid measure of outcomes; health status takes a long time to change, and is related to education, financial resources, culture and a lot more. Looking at compliance, or other indicators (change in blood glucose for diabetics) that are related to the medical care are far better. Leaving out resource use and process of care and intermediate outcomes take away from a valid comparison of NP's and MD's. These are the most important indicators of short term effectiveness.</p> <p>4. Why in your intro do you state on p.1 line 29 that the public is wary of NP's practicing beyond their training?</p>	<p>1. We added a paragraph to page 10 that better describes the strengths of this study.</p> <p>2. In this study, health status follow-up was 6 months while hospitalizations follow-up was 1 year. We rated the Lenz papers low quality and did not consider the results in our synthesis.</p> <p>3. We agree that mortality is not an ideal outcome in primary care and short term studies. We include a statement in the discussion that other outcomes, such as resource use, processes of care, and intermediate outcomes, are important considerations to healthcare providers and policy makers and were not included in this brief.</p> <p>4. We don't say that the public is wary, but do cite a study of VA provider attitudes about the role of APNs.</p>
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