

Review protocol for interventions for increasing uptake of hepatitis A, hepatitis B or HPV vaccinations in MSM

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Effective and cost-effective interventions to increase uptake of hepatitis A, hepatitis B and human papillomavirus (HPV) vaccination in gay, bisexual and other men who have sex with men (MSM)
2.	Review question	1.3a What interventions are effective and cost effective at increasing uptake of hepatitis A and hepatitis B vaccination in MSM? 1.3b What interventions are effective and cost effective at increasing uptake of HPV vaccination in MSM?
3.	Objective	Gay, bisexual and other men who have sex with men (MSM) are at a higher risk of hepatitis A, hepatitis B and HPV. Vaccinations have been shown to be effective in preventing these infections. The aim of this review is to establish which interventions are effective and cost effective at increasing the uptake of these vaccinations among men who have sex with men.
4.	Searches	The following databases will be searched: Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase (OVID) Medline (OVID) Medline in Process (OVID) PsycINFO (Ovid) EmCare (OVID) Web of Science (for citation searching* only, if judged to be required) *Citation searching Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading. Reference searching may also be done depending on initial database results. Websites

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		<p>5 key websites will be searched for relevant reports or publications Database functionality will be used, where available, to exclude: Non-English language papers Animal studies Editorials, letters or commentaries Conference abstracts or posters Dissertations or theses Duplicates Sources will be searched from 2009 to current. The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion. The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies. A record will be kept of number of records found from each database and of the strategy used in each database. A record will be kept of total number of duplicates found and of total results provided to the Public Health team. The full search strategies for MEDLINE database will be published in the final review.</p>
5.	Condition or domain being studied	Hepatitis A, Hepatitis B and HPV
6.	Population	<p>Gay, bisexual and other men who have sex with men (MSM) from age 16. This may also include younger people who contact or use sexual health services and are considered to be Gillick competent and satisfies the Frasier guidelines</p>
7.	Intervention/Exposure/Test	<p>Interventions with the primary aim of increasing uptake of hepatitis A and B and HPV vaccinations in MSM such as: targeted mass media campaigns for example newspapers and other printed material, radio, television, billboards education for example peer to peer programs (peer led education) – teaching or sharing of information, values, and behaviours recommendations from for example health care practitioner, sexual health adviser, community health worker</p>

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		<p>internet-based interventions for example social media, websites and banners on dating apps where the primary purpose is to increase uptake of Hepatitis A, Hepatitis B and HPV vaccinations in MSM</p> <p>interventions designed to increase recall / adherence / vaccination schedule completion, including letters, telephone calls, text message or email reminders, case management programs, accelerated schedules</p> <p>Interventions that aim to reduce any difficulties with access or expand access, such as out of hours services, delivery in clinical and non-clinical settings</p> <p>Single or multi component interventions.</p>
8.	Comparator/Reference standard/Confounding factors	<p>No intervention</p> <p>Other intervention aiming to increase uptake</p> <p>Comparator as defined by the paper</p>
9.	Types of study to be included	<p>Inclusion:</p> <p>RCTs</p> <p>Cluster RCTs</p> <p>Controlled before-and-after studies</p> <p>Prospective cohort Studies</p> <p>Systematic reviews of included study designs</p> <p>Interrupted time series</p> <p>Exclusion:</p> <p>Case control studies</p> <p>Cross-sectional studies</p> <p>Correlational studies</p>
10.	Other exclusion criteria	<p>Only papers published in the English language will be included</p> <p>Only full published studies (not protocols or summaries) will be included.</p> <p>Non-OECD countries</p>
11.	Context	<p>The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, service provision, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines.</p>

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		<p>Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility. It is therefore important to address interventions to help prevent or reduce STIs.</p>
12.	Primary outcomes (critical outcomes)	<p>Changes in uptake of hepatitis A and B vaccination in MSM Changes in uptake of HPV vaccination in MSM Uptake of initial and subsequent vaccinations</p>
13.	Secondary outcomes (important outcomes)	<p>Secondary outcomes: Safety or adverse effects Health related quality of life</p>
14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated.</p> <p>This review may use the EPPI reviewer priority screening functionality where at least 50% of the identified abstracts will be screened. After this point, screening will only be terminated if a pre-specified threshold is met for a number of abstracts being screened without a single new include being identified. This threshold is set according to the expected proportion of includes in the review (with reviews with a lower proportion of includes needing a higher number of papers without an identified study to justify termination) and is always a minimum of 250.</p> <p>A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified.</p> <p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.</p> <p>A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4).</p>
15.	Risk of bias (quality) assessment	<p>Risk of bias for individual studies will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual</p>
16.	Strategy for data synthesis	<p>Studies will be grouped by intervention type as appropriate.</p>

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		<p>Data from eligible studies will be meta-analysed (combined) if studies are judged to be similar enough in terms of population, interventions, outcomes, study design or risk of bias.</p> <p>It is anticipated that meta-analysed studies will be heterogeneous. Where appropriate, heterogeneity will be explored by conducting subgroup analyses and incorporated by performing random-effect analyses.</p> <p>If studies are found to be too heterogeneous to be pooled statistically, a narrative approach with sufficient information to make judgements about study effectiveness will be conducted.</p> <p>Tables and other forms of visual presentation may be used to summarise data where appropriate.</p> <p>Dichotomous data will be pooled where appropriate and the effect size will be reported using risk ratios in a standard pair-wise meta-analysis.</p> <p>Continuous outcomes reported on the same scale will be pooled in a standard pair-wise meta-analysis using mean difference where possible.</p> <p>Continuous outcomes not reported on the same scale will be pooled using a standardised mean difference in a standard pair-wise meta-analysis.</p> <p>Where appropriate, the quality or certainty across all available evidence will be evaluated for each outcome using an the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/</p> <p>Network meta-analysis maybe conducted where appropriate</p>
17.	Analysis of sub-groups	<p>Where evidence allows, sub-group analysis will be conducted to include:</p> <ul style="list-style-type: none"> People from a Black African or Caribbean family background People with low socio-economic status Older age groups People with learning disabilities Trans and non-binary people Migrant communities <p>Where evidence allows, sub-group analyses will also be used to answer questions about the effectiveness of intervention types, including:</p> <ul style="list-style-type: none"> Mode of delivery
25.	Review team members	<p>A multidisciplinary committee including the Public Health England Topic Advisor (PHETA) will be involved in developing the evidence review.</p> <p>NICE Public Health guideline development technical guideline team:</p> <p>Technical lead: Robby Richey</p>

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		Technical analyst: Jonathan Nyong Information specialist: Daniel Tuvey Project Manager: Adam O'Keefe
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
32.	Keywords	Hepatitis A, Hepatitis B, HPV, vaccine, vaccination, intervention, promoting uptake, sexually transmitted infections, STIs.

Review protocol for barriers to, and facilitators for, increasing uptake of hepatitis A, hepatitis B or HPV vaccinations in MSM

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0.	PROSPERO registration number	Not registered
1.	Review title	Barriers to, and facilitators for, uptake of hepatitis A, hepatitis B and HPV vaccination in gay, bisexual and other men who have sex with men (MSM)
2.	Review question	1.4a What are the barriers to, and facilitators for, uptake of hepatitis A, and hepatitis B vaccination in MSM? 1.4b What are the barriers to, and facilitators for, uptake of HPV vaccination in MSM?
3.	Objective	Gay, bisexual and other men who have sex with men (MSM) have a higher risk of hepatitis A, hepatitis B and HPV. Vaccinations have been shown to be effective in preventing these infections. The aim of this review is to establish the barriers to and facilitators for vaccine uptake in MSM.

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4.	Searches	<p>The following databases will be searched:</p> <ul style="list-style-type: none"> Cochrane Central Register of Controlled Trials (CENTRAL) Cochrane Database of Systematic Reviews (CDSR) Embase (OVID) Medline (OVID) Medline in Process (OVID) PsycINFO (Ovid) EmCare (OVID) Web of Science (for citation searching* only, if judged to be required) <p>*Citation searching</p> <p>Depending on initial database results, forward citation searching on key papers may be conducted, if judged necessary, using Web of Science (WOS). Only those references which NICE can access through its WOS subscription would be added to the search results. Duplicates would be removed in WOS before downloading.</p> <p>Reference searching may also be done depending on initial database results.</p> <p>Websites</p> <p>5 key websites will be searched for relevant reports or publications</p> <p>Database functionality will be used, where available, to exclude:</p> <ul style="list-style-type: none"> Non-English language papers Animal studies Editorials, letters or commentaries Conference abstracts or posters Dissertations or theses Duplicates <p>Sources will be searched from 2009 to current.</p> <p>The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.</p> <p>The guidance Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations and a rationale for them will be recorded alongside the search strategies.</p>

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5.	Condition or domain being studied	Hepatitis A, Hepatitis B and HPV
6.	Population	<p>Gay, bisexual and other men who have sex with men (MSM) from age 16.</p> <p>This may also include younger people who contact or use sexual health services and are considered to be Gillick competent and satisfies the Frasier guidelines</p>
7.	Intervention/Exposure/Test	<p>Any barrier or facilitator that may impact on vaccine uptake?</p> <p>To consider both person-specific and system level barriers and facilitators (Ideally this will include interventions or strategies identified in RQ1.3, but is not restricted to these)</p>
8.	Comparator/Reference standard/Confounding factors	Not applicable
9.	Types of study to be included	<p>Qualitative studies</p> <p>Mixed methods studies with relevant qualitative data.</p>
10.	Other exclusion criteria	<p>Only papers published in the English language will be included.</p> <p>Only studies from the Organisation for Economic Cooperation and Development (OECD) countries will be included.</p> <p>Only full published peer-reviewed qualitative studies will be included. Non-OECD countries and the USA.</p>
11.	Context	<p>The Department of Health and Social Care in England has asked NICE to update the guideline on sexually transmitted infections and under-18 conceptions: prevention (PH3), published in 2007. Changes in policy and commissioning, financial pressures and new evidence identified through the surveillance process led to the decision to update this guideline. The updated guideline will focus solely on the reduction of sexually transmitted infections (STIs), as prevention of under-18 conceptions is covered in other guidelines</p> <p>Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2017 and 2018. STIs can affect personal wellbeing, mental health and relationships and can also lead to serious health problems including pelvic inflammatory disease, ectopic pregnancy or infertility.</p> <p>It is therefore important to address interventions to help prevent or reduce STIs. Such interventions will be delivered in settings where sexual health services are provided, including:</p>

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12.	Primary outcomes (critical outcomes)	<p>Outcomes will include attitudes, experiences and views of people receiving the interventions people delivering the interventions The attitudes, experiences and views relating to barriers and facilitators to increasing uptake of hepatitis A, hepatitis B and HPV vaccinations in MSM may include:</p> <ul style="list-style-type: none"> Affective attitude How an individual feels about the intervention Burden The perceived amount of effort that is required to participate in the intervention Ethicality The extent to which the intervention has good fit with an individual's value system Coherence The extent to which the participant understands the intervention and how it works Perceived effectiveness The extent to which the intervention is perceived as likely to achieve its purpose
13.	Secondary outcomes (important outcomes)	<p>Changes in vaccination uptake related;</p> <ul style="list-style-type: none"> Knowledge Beliefs Attitudes Acceptance
14.	Data extraction (selection and coding)	<p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated.</p> <p>This review may use the EPPI reviewer priority screening functionality. At least 50% of the identified abstracts will be screened. After this point, screening will only be terminated if a pre-specified threshold is met for a number of abstracts being screened without a single new include being identified. This threshold is set according to the expected proportion of includes in the review (with reviews with a lower proportion of includes needing a higher number of papers without an identified study to justify termination) and is always a minimum of 250.</p> <p>A random 10% sample of the studies remaining in the database when the threshold is met will be additionally screened, to check if a substantial number of relevant studies are not being correctly classified by the algorithm, with the full database being screened if concerns are identified.</p>

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15.	Risk of bias (quality) assessment	<p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual</p>
16.	Strategy for data synthesis	<p>The key findings from the studies will be categorised into themes relevant to the review across all studies using a thematic analysis. Supporting quotations and summaries of data may be included.</p> <p>Where appropriate, the quality or certainty across all available evidence will be evaluated for each outcome using the GRADE CERQual approach.</p> <p>A mixed methods synthesis including studies from question 1.3.</p> <p>Where evidence allows, a synthesis matrix will be produced to combine results from the two different analytical approaches. Findings from one analytical approach will be compared to findings from the second approach, and outcomes paired up if they provide relevant information on the same underlying topic (for example, barriers to, and facilitators for may be paired up with interventions from 1.3). The agreement between the findings of the two approaches will be qualitatively assessed, with each paired set of findings put into categories relating to the strength of the identified correlation.</p> <p>The results may be presented as a narrative summary or diagram with quantitative findings mapped onto the qualitative ones.</p>
17.	Analysis of sub-groups	<p>Where evidence allows, sub-group thematic analysis will be conducted to include:</p> <ul style="list-style-type: none"> People from a Black African or Caribbean family background People with low socioeconomic status People with learning disabilities Older age groups Trans and non-binary people Migrant communities
25.	Review team members	<p>[Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.]</p> <p>From the [Insert Development centre]:</p>

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		<p>[Tech lead] [Tech analyst] [Health economist] [Information specialist] [Others]</p>
26.	Funding sources/sponsor	This systematic review is being completed by Public Health guideline development, NICE.
27.	Conflicts of interest	<p>All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.</p>
28.	Collaborators	<p>Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].</p>
32.	Keywords	Hepatitis A, Hepatitis B, HPV, vaccine, vaccination, intervention, promoting uptake, sexually transmitted infections, STIs.