Review protocol for increasing STI testing in very high-risk groups

ID	Field	Content
0.	PROSPERO registration number	CRD42021243652
1.	Review title	Effective and cost-effective interventions to increase frequent STI testing in very high-risk groups
2.	Review question	What interventions are effective and cost effective at increasing frequent STI testing in very high-risk groups?
3.	Objective	STI testing, diagnosis and treatment are central to STI prevention strategies. The purpose of this review is to establish effective and cost-effective strategies or interventions for increasing 3 monthly STI testing in very high risk groups.
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)

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		• 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. Websites 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 2010 to current. The searches will be re-run 6 weeks before final submission of the review and further studies retrieved for inclusion.

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		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.
5.	Condition or domain being studied	Sexually transmitted infections including HIV, genital herpes, chlamydia, genital warts, gonorrhoea, syphilis, *Mycoplasma genitalium, Lymphogranuloma venereum* (LGV), *Trichomonas vaginalis* (TV)
6.	Population	People from age 16 at very high risk of STIs requiring 3 monthly testing: - commercial sex workers - people with multiple sex partners (>10 partners within 3 months) - People engaging in so-called chemsex

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		- gay, bisexual and other men who have sex with men (MSM) previously diagnosed with a bacterial STI (in the last year)
7.	Intervention/Exposure/Test	Interventions or strategies that have a stated primary aim of increasing the rate of 3 monthly STI testing in very high risk groups, including but not limited to: **Interventions delivered in healthcare settings:** • Emails or text messages from healthcare providers with invites for testing or testing reminders • Mobile or digital e-health reminder approaches from healthcare providers • Testing in spoke or satellite clinics • Changes in service provision and delivery that may improve access to sexual health services and testing accessibility such as reduced waiting times, extended clinic opening hours, short notice appointments, appointment booking systems. whether services meet 'You're Welcome' youth friendly criteria

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		Interventions delivered in non-healthcare settings: • Testing services delivered in non-clinical community settings such as voluntary or community organisations • Testing services delivered in outreach settings such as bars, clubs, faith-based settings, saunas, sex on premises venues • Online testing services • STI self-sampling and/or self-testing kits Excluded: Interventions where the primary objective is not specifically to increase the frequency of STI testing in the specified groups Interventions designed to improve the frequency of HIV testing, Hepatitis A or Hepatitis B Interventions designed to improve the uptake of STI vaccinations (e.g. HPV, Hepatitis A and Hepatitis B vaccinations). Interventions relating to partner notification strategies.

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		Condom distribution schemes. Clinical interventions for the diagnosis, treatment or management of STIs. Interventions delivered in schools.
8.	Comparator/Reference standard/Confounding factors	• Another intervention • No intervention
9.	Types of study to be included	Inclusion: <u>Effectiveness studies:</u> • RCTs • Cluster RCTs • Systematic reviews of included study designs Exclusion (if sufficient RCT evidence): • Controlled before and after studies • Cohort studies

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		• Case control studies • Cross-sectional studies • Correlational studies
10.	Other exclusion criteria	Only papers published in the English language will be included Only full published peer-reviewed studies (not protocols or summaries) will be included. Dissertations or theses will be excluded. Only studies carried out in the UK will be included for healthcare setting interventions. Only studies carried out in OECD countries will be included for non-healthcare setting interventions.
11.	Context	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. Data from Public Health England show the overall number of STI diagnoses increased by 5% between 2018 and 2019. 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.

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12.	Primary outcomes (critical outcomes)	• Frequency of STI testing and re-testing • STI re-infection rates • Proportion of people in very high risk groups receiving STI testing at least once every 3 months
13.	Secondary outcomes (important outcomes)	• Safety or adverse effects • Unintended consequences (e.g. availability of STI testing appointments, waiting time for diagnosis and/or treatment) • Awareness of STI testing and testing services • The number of people at risk who intend to have an STI test • Condom use • Changing STI diagnosis rate
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. This review will not use the EPPI reviewer priority screening functionality because it will not be effective in identifying the different subgroups or intervention types (e.g. evidence for a particular subgroup may be deprioritised by the algorithm in favour of other groups identified early in the screening, which could lead to evidence being missed unless the whole search result is sifted).

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		All records will be screened on title and abstract. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised template will be used to extract data from studies (this is consistent with the Developing NICE guidelines: the manual section 6.4). Information in interventions will be extracted using the TIDieR checklist. The additional checks that are used to ensure that relevant records are not missed will be applied. These include checking reference lists of included systematic reviews (even if these are not used as a primary source of data) and checking with the PHAC that they are not aware of any relevant studies that have been missed.
15.	Methodological (quality) assessment	Risk of bias for individual studies will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual
16.	Strategy for data synthesis	Studies will be grouped by intervention type as appropriate. 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.

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		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. 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. Tables and other forms of visual presentation will be used to summarise data where appropriate. Dichotomous data will be pooled where appropriate and the effect size will be reported using risk ratios in a standard pair-wise meta-analysis. Continuous outcomes reported on the same scale will be pooled in a standard pair-wise meta-analysis using mean difference where possible. Continuous outcomes not reported on the same scale will be pooled using a standardised mean difference in a standard pair-wise meta-analysis. 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/

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17.	Analysis of sub-groups	Where evidence allows, sub-group analysis will be conducted to include those disproportionately burdened with STIs, including: • Men who have sex with men • Young people age 16 to 24 years • People from a Black African or Caribbean family background • Trans and non-binary people • Older adults age 65 and over • People with low socioeconomic status • People with learning disabilities • Migrant communities