Protocol for evidence reviews

Evidence reviews to support the guideline on:

Sexually transmitted infections – condom distribution schemes

Stage	Date completed
Review team – draft	15th September 2015
Review team – finalised	29th September 2015
Quality assurance – approval	14th December 2015
Review team – revision	N/A

Guideline webpage	http://www.nice.org.uk/guidance/indevelopment/gid-phg93
Scope available at	As above
Committee	PHAC A

Review team
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Protocol signed off by: Fiona Glen Date: 14th December 2015

Introduction

This guideline focusses on condom distribution schemes to prevent sexually transmitted infections (STIs). This includes all schemes that provide or distribute free or cost-price condoms, femidoms and dental dams, with or without lubricant. It also includes schemes that distribute condoms together with additional advice, information or support.

Review questions

Topic: Effectiveness of different types of condom schemes

1. Are multicomponent condom schemes (that distribute free condoms, with or without lubricant, together with training, information or support) effective at increasing condom use and preventing STIs among different populations?

2. Are single component condom schemes (that only provide or distribute free condoms and lubricant) effective at increasing condom use and preventing STIs among different populations?

3. Are outlets or schemes that provide cheap condoms and lubricant effective at increasing condom use and preventing STIs among different populations?

4. Which types of condom schemes (multi-component, single component, outlet) are most effective at increasing condom use and preventing STIs among different populations?

5. What are the features (including setting, access arrangements, mode of delivery) of effective condom schemes for different populations?

6. What are the components (eg education, offer or additional services) of effective condom schemes for different populations?

Topic: Cost effectiveness of different types of condom schemes

7. Which types of condom schemes are cost effective at increasing condom use and preventing STIs among different populations?

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Review question 1	Are **outlets or schemes that provide cheap condoms and lubricant** effective at increasing condom use and preventing STIs among different populations?	This will establish which types of outlet schemes are effective, which are ineffective and where we do not have any evidence of effectiveness. It will also consider any unintentional/adverse affects.
Context and objectives	To determine the effectiveness of outlet schemes.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution) Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will	If a large number of papers are included at full text, advice will be sought from a topic expert as to

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	exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations Exclusions: • Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with

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		men, Commercial sex workers.
Intervention(s)	**Outlet schemes** or schemes providing cheap condoms for high risk groups. For example, this could include community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms. Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example, clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia).	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be

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	• Reported condom use • Intention to use condoms • Health related quality of life • Any economic outcomes Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience • User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	reported.
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found,	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on

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	references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	groups at greatest risk
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer.	

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	Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion	Exclusions	

Topic	**Effectiveness of different types of condom schemes**	
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or exclusion	• Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts • Poster presentations • Research published after the search is undertaken in September 2015	

Topic	**Effectiveness of different types of condom schemes**	
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Review question 2	Are **single component condom schemes (that only provide or distribute free condoms and lubricant)** effective at increasing condom use and preventing STIs among different populations?	This will establish which types of single component schemes are effective, which are ineffective and where we do not have any evidence of effectiveness. It will also consider any unintentional/adverse affects.
Context and objectives	To determine the effectiveness of single component schemes.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and	

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	(distribution) Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations	

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	Exclusions: • Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Single-component schemes** that provide or distribute free condoms. This will include (but will not be restricted to) online services for specific groups or areas of the country, and distribution schemes in public places where people meet to have sex (for example, clubs). Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example, clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Mexico and Turkey where there are	

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	substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms • Health related quality of life • Any economic outcomes Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be reported.

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	• User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

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	remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	

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Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts • Poster presentations • Research published after the search is undertaken in September 2015	

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Review question 3	Are **multi-component condom schemes (that distribute free condoms, with or without lubricant, together with training, information or**	This will establish which types of multi-component schemes are effective, which are ineffective and

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	support) effective at increasing condom use and preventing STIs among different populations?	where we do not have any evidence of effectiveness. It will also consider any unintentional/adverse affects.
Context and objectives	To determine the effectiveness of multi-component condom schemes.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution) Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be

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	There are no date limits for this search. See Appendix 2 for details of the search strategy.	appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations Exclusions: • Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Outlet schemes** or schemes providing cheap condoms for high risk	

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	groups. For example, this could include community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms. Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example, clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be reported.

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	• Health related quality of life • Any economic outcomes Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience • User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

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	two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any	

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	differences in quality grading will be resolved by discussion or recourse to a third reviewer.	
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses	

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	• Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts • Poster presentations • Research published after the search is undertaken in September 2015	

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Review question 4	Which **types of condom schemes (multi-component, single component, outlet) are most effective** at increasing condom use and preventing STIs among different populations?	This will establish which types of schemes are most effective. This will include any direct comparisons of multi-component, single component and outlet schemes.
Context and objectives	To determine which types of schemes are most effective for different populations.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution)	

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	Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations Exclusions:	

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	• Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Multi-component schemes** that distribute free condoms together with information or other support. This will include (but will not be restricted to) the C-Card scheme for young people (for details see C-Card condom distribution schemes Public Health England), peer educators distributing free condoms and advice to men who have sex with men. **Single-component schemes** that provide or distribute free condoms. This will include (but will not be restricted to) online services for specific groups or areas of the country, and distribution schemes in public places where people meet to have sex (for example, clubs). **Outlet schemes** or schemes providing cheap condoms for high risk groups. This will include (but will not be restricted to) community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms.	

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	Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example, clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms • Health related quality of life • Any economic outcomes	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be reported.

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	Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience • User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

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	one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	

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Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts	

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	• Poster presentations • Research published after the search is undertaken in September 2015	

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Review question 5	What are the **features** (including setting, access arrangements, mode of delivery) of effective condom schemes for different populations?	This will establish the features of effective schemes. This will also explore the impact of these features on awareness and uptake of schemes.
Context and objectives	To determine the features of effective schemes.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution) Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey	

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	literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations Exclusions: • Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	

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Component of protocol	Description	Additional comments
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Multi-component schemes** that distribute free condoms together with information or other support. This will include (but will not be restricted to) the C-Card scheme for young people (for details see C-Card condom distribution schemes Public Health England), peer educators distributing free condoms and advice to men who have sex with men. **Single-component schemes** that provide or distribute free condoms. This will include (but will not be restricted to) online services for specific groups or areas of the country, and distribution schemes in public places where people meet to have sex (for example, clubs). **Outlet schemes** or schemes providing cheap condoms for high risk groups. This will include (but will not be restricted to) community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms. Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example,	

Topic	Effectiveness of different types of condom schemes	
Component of protocol	Description	Additional comments
	clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms • Health related quality of life • Any economic outcomes • Awareness of services • Numbers of condoms distributed. • Numbers of people accessing schemes	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be reported.

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience • User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

Topic	Effectiveness of different types of condom schemes	
Component of protocol	Description	Additional comments
	one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	• Poster presentations • Research published after the search is undertaken in September 2015	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Review question 6	What are the **components** (eg education, offer or additional services) of effective condom schemes for different populations?	This will establish the components of effective schemes. This will also explore the impact of these components on awareness and uptake of schemes.
Context and objectives	To determine the components of effective schemes.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution) Sources to be searched: see Appendix 1. Supplementary search techniques include: web searching for grey	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Any comparative study type, including: • Randomised or non-randomised controlled trials • Cohort studies • Before and after studies • Process evaluations Exclusions: • Non-comparative studies • Systematic reviews will not be included but will be used as a source of primary studies only (see also search strategy)	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Multi-component schemes** that distribute free condoms together with information or other support. This will include (but will not be restricted to) the C-Card scheme for young people (for details see C-Card condom distribution schemes Public Health England), peer educators distributing free condoms and advice to men who have sex with men. **Single-component schemes** that provide or distribute free condoms. This will include (but will not be restricted to) online services for specific groups or areas of the country, and distribution schemes in public places where people meet to have sex (for example, clubs). **Outlet schemes** or schemes providing cheap condoms for high risk groups. This will include (but will not be restricted to) community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms. Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online services and public places where people meet to have sex (for example,	

Topic	Effectiveness of different types of condom schemes	
Component of protocol	Description	Additional comments
	clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Primary outcomes • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms • Health related quality of life • Any economic outcomes • Awareness of services • Numbers of condoms distributed. • Numbers of people accessing schemes	The primary outcomes reflect the stated aims of the scope. The secondary outcomes reflect the broader outcomes that may be reported.

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	Secondary outcomes • Unprotected sex, including HIV serodiscordant sex • Unintended or harmful effects, eg condom failure, earlier onset of sexual activity • Attitudes towards condom use • Awareness of services • Provider experience • User experience. • Knowledge of how to use condoms correctly and negotiate use. • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence (data screening)	Stage 1. Title abstract screening All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by	As noted above, if large numbers of papers are identified and included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts	

Topic	**Effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	• Poster presentations • Research published after the search is undertaken in September 2015	

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Review question 7	What are the most cost effective **condom distribution schemes (multi-component, single component, outlet)** at increasing condom use and preventing STIs among different populations?	This will establish which types of schemes are cost effective. This will include any direct comparisons of multi-component, single component and outlet schemes.
Context and objectives	To determine which types of schemes are cost effective for different populations.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the "Developing NICE Guidelines Manual" (October 2014). Relevant databases and websites will be searched systematically to identify relevant qualitative, quantitative and cost effectiveness evidence using a combination of: (Condoms or dental dams or femidoms) and (distribution) Sources to be searched: see Appendix 1.	

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	Supplementary search techniques include: web searching for grey literature; checking reference lists of relevant systematic reviews; checking reference lists of all included studies to identify further relevant primary research; and searching citations of included studies using Web of Science. Limits: An English language filter will be placed on the searches if available. Additional limits to be placed on the searches, if available, will exclude studies on animals, as well as editorials, news items and letters. There are no date limits for this search. See Appendix 2 for details of the search strategy.	If a large number of papers are included at full text, advice will be sought from a topic expert as to whether a date cut off should be implemented. It may be appropriate to include a date cut off after 1996 due to widespread availability of HAART after this date.
Types of study to be included/excluded	Inclusions: Any economic evaluation or analysis presenting costs and consequences such as: • Cost benefit analyses • Cost effectiveness analysis • Cost minimisation analysis • Cost utility analysis Exclusions: • Non-comparative studies •	

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Participants/population	All groups at risk of an STI.	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk. This will include (but will not be restricted to): People aged under 25, Men who have sex with men, Commercial sex workers.
Intervention(s)	**Multi-component schemes** that distribute free condoms together with information or other support. This will include (but will not be restricted to) the C-Card scheme for young people (for details see C-Card condom distribution schemes Public Health England), peer educators distributing free condoms and advice to men who have sex with men. **Single-component schemes** that provide or distribute free condoms. This will include (but will not be restricted to) online services for specific groups or areas of the country, and distribution schemes in public places where people meet to have sex (for example, clubs). **Outlet schemes** or schemes providing cheap condoms for high risk groups. This will include (but will not be restricted to) community schemes that provide cost-price condoms to sex workers and online services that offer cost-price condoms. Any settings where condoms can be provided or distributed. This includes but is not restricted to: pharmacies, sexual health centres, schools, online	

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	services and public places where people meet to have sex (for example, clubs). Only interventions from OECD countries will be included, with the exception of Chile, Japan, Korea, Turkey where there are substantial cultural differences, particularly related to sexual norms. In addition, Cuba will be included because it has been flagged as having a similar free at point of care schemes with sex workers.	
Comparator(s)/control	Comparators that will be considered are: • No intervention • Usual care • Other interventions to prevent STIs, including alternative condom distribution schemes, or other sexual health interventions.	
Outcome(s)	Reporting costs as well as one or more clearly identifiable outcomes in relation to condom distribution scheme effectiveness: • Condom preventable STI incidence (e.g. HIV, gonorrhoea, syphilis, chlamydia). • Reported condom use • Intention to use condoms • Health related quality of life • Numbers of condoms distributed. • Numbers of people accessing schemes	
Selecting evidence	Stage 1. Title abstract screening	As noted above, if large numbers of papers are identified and

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
(data screening)	All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above. Where no abstract is available and the title or keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone. A randomly selected initial sample of 10% of records will be screened by two reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Where abstracts meet all the criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved. Stage 2. Full text screening Full-text screening will be carried out by two reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion. Reasons for exclusion at full paper will be recorded. Inter-rater agreement will be recorded.	included at full text, the following may be implemented: • Consideration of a date cut off (on advice of topic expert as available and appropriate) • Prioritising evidence on groups at greatest risk

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
Data extraction and quality assessment	Data extraction of included studies will be conducted using approaches described in Developing NICE guidelines: the manual. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer. Quality assessment for all included studies will be conducted using the tools in Developing NICE guidelines: the manual. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.	
Strategy for data synthesis	Data will be grouped and synthesised into concise evidence statements in line with Developing NICE guidelines: the manual. See below for potential a priori groupings. If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.' All outcomes of direct relevance to the scope, including any adverse outcomes, will be reported.	
Analysis of subgroups or subsets	Appropriate groupings for data synthesis may be based on the following: • Components of the scheme • Setting (country, community, healthcare setting, online, etc.) • Population (MSM, young people, etc.) Further groupings will be considered once included studies have been	

Topic	**Cost effectiveness of different types of condom schemes**	
Component of protocol	Description	Additional comments
	identified. Any 'post hoc' or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.	
Any other information or criteria for inclusion or exclusion	Exclusions • Not English language • Dissertations and theses • Opinion pieces (e.g. letters, editorials, commentaries) • Conference abstracts • Poster presentations • Research published after the search is undertaken in September 2015	

Appendix 1 – Sources to be searched

A systematic search of relevant databases and websites (listed below) will be carried out to identify relevant studies.

Databases

- MEDLINE and MEDLINE in Process (via OVID)
- Embase (via OVID)
- BNI (via ProQuest)
- CENTRAL (via Wiley)
- Cochrane Database of Systematic Reviews (via Wiley)
- DARE (via Wiley)
- EconLit (via OVID)
- Health Management Information Consortium (HMIC) (via OVID)
- PsycINFO (via OVID)
- Social Policy and Practice (via OVID)
- Education Resources Information Center (ERIC) (education) (via ProQuest)
- Web of Science (includes Science Citation Index, Social Science Citation Index & Arts & Humanities Citation index) as listed in 'other methods'
- Trials Register of Promoting Health Interventions (TRoPHI)
- NHS EED (via Wiley as a legacy database)

Websites

- NICE Evidence (with appropriate limits) http://www.evidence.nhs.uk/
- OpenGrey http://www.opengrey.eu/
- Google / Google Scholar, (with appropriate limits and looking specifically for reports or evaluations of condom distribution schemes in the UK) https://www.google.co.uk/ and http://scholar.google.co.uk/
- *SIGMA Research* http://www.sigmaresearch.org.uk/
- PopLine http://www.popline.org/

Appendix 2 – search strategy

Database: Ovid MEDLINE(R) <1946 to August Week 4 2015>

Search Strategy: Final strategy 7 Sept 15

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1 condoms/sd (224)

2 Condoms, Female/sd [Supply & Distribution] (18)

3 Rubber Dams/sd [Supply & Distribution] (1)

4 or/1-3 (240)

5 ((condom* or femidom*) adj5 (distribut* or scheme* or program* or initiative* or system* or outreach or access or provision or provid* or outlet*)).tw. (1708)

6 ((rubber dam or rubber dams or dental dam or dental dams) and (distribut* or scheme* or program* or initiative* or system* or outreach or access or provision or provid* or outlet*) and sex*).tw. (9)

7 ((free or freely or "cost price" or cost-price or reduc* price or "low cost" or low-cost or "cut price" or cut-price or subsidy or subsidi?e* or coupon*) adj5 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (324)

8 (("public sector" or commission* or local authorit* or "voluntary sector") and (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (162)

9 ((GP or "general practice" or general practitioner* or "primary care" or prescription or prescribe* or dispens*) adj5 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (66)

10 ((pharmacy or pharmacies or chemist) adj5 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (34)

11 ((school or schools or peer educator* or youth club* or youth worker* or public place*) adj5 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (216)

12 ((online or on-line or internet or web) and (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (387)

13 ((social market* or social network*) adj5 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams")).tw. (115)

14 ("come correct" or "condom card" or c-card or "c card" or medivend or "medi vend" or "medi+vend").tw. (3)

15 or/4-14 (2635)

16 ((multifacet* or multi facet* or multicomponent* or multi component* or multitarget* or multi target* or multisector* or multi sector* or multipartner* or multi partner* or multidisciplin* or multi disciplin* or multiagency or multi agency or interagency or inter agency or cross sector* or crosssector* or multiprofessional or multi professional) adj3 (intervention* or program* or initiative* or collaborat* or coordinat* or counsel* or educat* or learning or informat* or communicat* or advice* or advis* or literacy or publication* or curriculum* or curricula* or teach* or trainer* or training or resource* or session* or workshop* or material* or outreach)).tw. (10284)

17 (condom* or femidom* or "rubber dam" or "rubber dams" or "dental dam" or "dental dams").tw. (16514)

18 16 and 17 (44)

19 15 or 18 (2666)

20 (condom adj3 catheter*).tw. (176)

21 19 not 20 (2650)

22 animal/ not (animal/ and human/) (4014157)

23 21 not 22 (2650)

24 (letter or historical article or comment or editorial).pt. (1726079)

25 23 not 24 (2598)

26 limit 25 to english language (2422)

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