Additional evidence tables - pregnancy related outcomes

At PHAC 1 the NICE technical team were asked to check whether any relevant studies with pregnancy related outcomes may have been missed in the screening process.

As a result of this the technical team confirmed that the original search strategies for database searches did not pre-specify outcome measures, as such any condom distribution schemes with pregnancy outcomes would have been identified and included in our database. The database of studies identified through systematic searches (n= 4,177) was re-searched for any items with the truncated term 'pregnan' in the title or abstract, this identified 841 items. Screening of these items was undertaken using the same methods outlined in the review protocol and applied to the original screening process¹. An additional 5 full text papers were retrieved for further scrutiny, these were checked by two reviewers. All were excluded, on the basis of not being condom distribution schemes, or not being comparative studies. 10 papers which had already been retrieved and excluded at the original screening stage were also double-checked. No further papers were identified through this process, and the technical team are confident that no relevant papers with pregnancy outcomes have been missed.

All included studies (n=22) were checked again to ensure that no pregnancy related outcomes had been missed during data-extraction. We found no pregnancy related outcomes. Table 1, below outlines the outcomes measured in all the included studies (as evidence review).

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.

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¹ Stage 1. Title abstract screening

Table 1: Included studies and outcomes measured

Study	Soft-outcomes (non-STI)	STI	Pregnancy related	Evidence statement number and Intervention type
Guttmacher et al 1997	Sexual activity Condom use	No	No	# 1 Multiple component.
	Condom use			School-based
Larsson et al 2006	Condom use	No	No	# 1
2006	Intent to use emergency contraception (ECP).			Multiple component.
	Knowledge of ECP			School-based
	Attitudes to condoms and ECP.			
	Intentions to use, discuss or buy condoms.			
	Use of ECP, and recommend ECP.			
Furstenberg et al 1997	Ever had sex	No	No	#1
1991	Condom use at last intercourse			Multiple component.
				School-based
Anderson et al	HIV-related risk behaviour	No	No	# 2
	Condom behaviours			Multiple component
	Exposure to street outreach worker			

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				Community/outreach
Reijtmeijer et al 1996	Use of condoms with occasional partners.	No	No	# 2
1990	Use of condoms with regular partners.			Multiple component
				Community/outreach
Anonymous et al	Positive movement in stages of change towards:	No	No	# 2
1999	Condom use with main partner			Multiple component
	Condom use with non-main partner			Community/outreach
	Carrying condoms			
Rhodes et al 2009	Consistent condom use in past 30 days	No	No	# 2
	HIV testing			Multiple component
	High knowledge of HIV transmission and prevention			Community/outreach
	High self-efficacy for condom use			
	High adherence to traditional masculine norms			
	High sense of mastery over circumstances			
Wendell et al	Contact with outreach worker	No	No	# 2
2003	Know where to get free condoms			Multiple component
	Last condom free			Community/outreach
	Has condom with them or at home			

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	Use condom at last encounter			
	Used the street outreach brand condom at last encounter			
Exner et al 2012	Knowledge/attitudes	No	No	#3
	Intention to use			Multiple component
	Policy and practice changes			Healthcare settings
Neumann et al	Knowledge and attitudes about HIV/STD and condom use	Incident STIs	No	#3
2011	Condom acquisition			Multiple component
				Healthcare settings
Oakeshott et al	Given condom and STI advice	No	No	#3
2000	Condom use			Multiple component
				Healthcare settings
De Rosa 2012	Student awareness of scheme	No	No	#4
	Student sexual behaviour and condom use			Single component
	Student acquisition of condoms			Improvement of existing high school scheme
	School condom orders			
Kirby et al 1999	Number of condoms obtained.	No	No	#5
	Use of school obtained condom during sex.			Single component
				High school

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Schuster et al 1998	Number of students having intercourse	No	No	#5
	Condom use every intercourse			Single component
	Intention to use condoms			High school
Wretzel et al 2011	No	Rates of gonorrhoea and chlamydia.	No	#5
		J. Marry and T.		Single component
				High school
Weatherburn et al 1998	Condom distribution by method.	No	No	#6
ui 1000	Access to and use of condoms			Single component
				Commercial venues
Cohen et al 1999	Numbers of condoms distributed	No	No	#6
	Condom knowledge			Single component
	Condom behaviours			Commercial venues
Ross et al 2004	Condom use	No	No	#6
	Knowledge of syphilis			Single component
	Sexual behaviours			Commercial venues
Dahl et al 1999	Rate of condom coupon redemption.	No	No	#7
				Reduced price

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Condoms - additional evidence tables

Senn et al 2011	Consistent condom use	No	No	#8
				Single component v multi component
Bedimo et al 2002	Both cost-utility analyses. Neither modelled costs for pregnancy. F	I IIV / STI cases averted were estin	nated.	#9
2002				Cost effectiveness
Holtgrave et al 2012				#10 cost effectiveness

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Analysis of observational studies and non-intervention studies

At PHAC 1 (March 2016) the committee noted that no evaluation studies of the C-Card or other UK multicomponent schemes had met the inclusion criteria for the effectiveness review. It was discussed that while some qualitative research may be available studies including a comparison group are not. An inclusion criteria for the evidence review, as outlined in the protocol, was that only studies with a comparison group were eligible for inclusion in the review². The decision to exclude other study designs such as qualitative research and cross-sectional surveys, was based on the questions in the review scope which are explicitly about 'what works'. Committee requested that the NICE technical team provide more information on this set of excluded studies.

All studies in the database that had been excluded on a criteria that related to study design (i.e. coded as 'not an intervention study', or 'no comparison group') were identified and examined. 64 studies were identified, 26 of which were UK studies. 17 studies related to the C-Card and 9 to other UK schemes. It should be noted that many of the C-Card papers referred to here were not intended to be rigorous evaluations, and as such do not have distinct methodologies.

All of the C-Card papers describe issues about implementation: who they are reaching, issues of acceptability, numbers of users and condoms distributed, quality of services provided. Many also report the views and experiences of providers and users of services. However these were rarely collected as part of a qualitative study with reported methods – in fact only one of these papers was published in a peer reviewed journal (Cheetham et al 2014). Implementation and quality issues for providers of C-Card schemes are covered in The Brooks & PHE England Publication *C-Card condom distribution schemes : why, what and how?* This report also includes information from Cheetham et al (2014) *The social meanings of the C-Card scheme: The importance of friends and peers.*

- 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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² Type of study to be included: Any comparative study type, including:

UK based observational studies

Author	Title	Study	
Non C-Card Schemes (n=9)			
Baraitser et al (2011)	Do it yourself' sexual health care: the user experience	Views and experiences - users	
Adams, J., Neville, S., Dickinson, P. (2013)	Evaluation of Bro Online: An Internet-based HIV prevention initiative for gay and bisexual men	Google analytics and user survey	
Hughes,D., Morris,S.(1996)	The cost-effectiveness of condoms in the prevention of HIV infection in England and Wales: should condoms be available on prescription?	Probability study - not based on effectiveness data	
Thompson,C., Smith,H. (2001)	'Condom club': An interface between teenage sex and genitourinary medicine		
		Retrospective case note review	
Welfare, W.S., Lighton, L.	Mapping of sexual health promotion in North West England, 2008	Sexual health promotion activity and resources	
Wiles,R., Austin,J. (2011)	City of Sunderland College positive practice	Survey of needs	
Woolf,L., Jackson,B.(1996)	Coffee & condoms': the implementation of a sexual health programme in acute psychiatry in an inner city area	Overview of service	
Wright,S., Tobin,R., Kell,P., Franks,J. (2001)	A novel condom policy for young attenders at a sexual health clinic	Retrospective case note review	
Lesbian and Gay Foundation (2010)	Proud to be safer: 16 years of the free condom and lube distribution scheme in Greater Manchester	Survey.	

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C-Card Schemes (n=17)		
Anonymous (2014)	An Evaluation of the All Wales C-Card Standards (Public Health Wales)	Survey of staff and users
Brook & PHE (2014)	C-Card condom distribution schemes : why, what and how	Views and experiences - implementation
Cheetham, et al (2014)	The social meanings of the C-Card scheme: The importance of friends and peers	Views and experiences - young people. Include in Brook & PHE Report above,
Cross,R, Kinsella,K, South,J (2011)	An evaluation of the C-Card Scheme in Bradford District	Evaluation - no comparison group
Dean,L. (2009)	Promoting safer sex in young people	Protocol for delivery
Hurrell,Z and Wheeler,K (2014)	C Card Progress Report 2013-14 (Bath and North East Somerset)	Audit and views and experiences
Hutchinson,Laura and Evans,David (2012)	Brighton & Hove C-Card Evaluation	Views and experiences
Ingram, Jenny, Salmon, Debra (2010)	Young people's use and views of a school-based sexual health drop-in service in areas of high deprivation	Views and experiences - young people
Jones,Adam (2012)	All Wales C-Card (Condom-Card) Scheme Standards	Service delivery model
Jones,Geinor Medi (2008)	What do you think? An evaluation of the Ceredigion card scheme: the perceptions of the young people and distributors	Views and experiences
Kinsella,Karina, Cross,Ruth, South,Jane (2014)	An evaluation of the condom distribution scheme (C-Card) with young people in Northeast England	Non-comparative evaluation, plus views and experiences

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Condoms - additional evidence tables

Kraszewski,S. (2006)	Free condoms for teenagers	Overview of administration
Lincolnshire County Council Childrens Services in Partnership with NHS Lincolnshire (2011)	C Card Condom Scheme - Evaluation July 2009 - July 2010	Views and experiences, and costs
MacDonald,G., Nehammer,S. (2001)	A evaluation of users' views of a piloted free condom distribution scheme	Views and experiences - users
Ryder,Hollie, Aspden,Trudi, Sheridan,Janie (2015)	The Hawke's Bay Condom Card Scheme: a qualitative study of the views of service providers on increased, discreet access for youth to free condoms	Views and experiences - providers
Smith,H. (1999)	Contraception and young people: the condom club	Views and experiences
Snowhill, Felicity (2013)	Condom distribution for young people in Tayside: review 2013	Overview of scheme

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