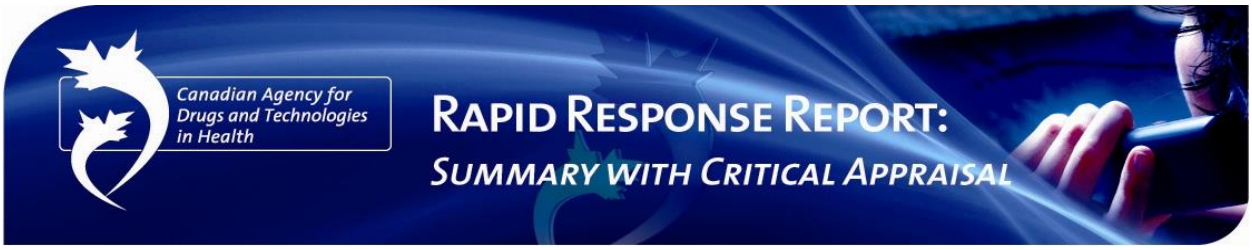

TITLE: Newborn Eye Prophylaxis: A Review of Clinical Effectiveness and Guidelines

DATE: 03 May 2016

CONTEXT AND POLICY ISSUES

Ophthalmia neonatorum (ON) is a type of conjunctivitis that occurs in up to 12% of newborns due to chemical, viral, or bacterial causes.[1] *Chlamydia trachomatis* and *Neisseria gonorrhoeae* are bacteria that have been reported to account for up to 40% and 1% of Canadian ON cases, respectively.[1] Bacterial transmission from mother to baby can occur during delivery; 30% to 50% of neonates born to mothers with a gonorrheal or chlamydial infection develop ON.[2] When untreated, gonococcal ON can progress to severe ocular damage and blindness.[2] In the late 1800s, newborn eye prophylaxis with silver nitrate was introduced in Germany and the rates of gonococcal ON and childhood blindness were substantially reduced.[1,3] Since that time, newborn eye prophylaxis has been commonly accepted as a part of neonatal care in several countries, including Canada,[3] where erythromycin is the only prophylactic agent indicated for this purpose.[2] Furthermore, this practice is mandated by law in some provinces, and British Columbia is the only province with this legal requirement that offers parents and caregivers of newborns a choice to opt out of this treatment.[2,4,5]

The Canadian Pediatric Society (CPS) recently produced a position statement challenging the requirement for universal neonatal eye prophylaxis, citing the questionable efficacy of erythromycin and reduced need for prophylaxis due to the low incidence of gonococcal ON in Canada.[2] The CPS recommends that erythromycin should not routinely be used for newborn eye prophylaxis. Instead of mandating universal newborn prophylaxis, the preventative focus should be shifted to screening pregnant women for gonorrhea and chlamydia at the first prenatal visit, or at the time of delivery if earlier screening was not performed.[2] The position statement also provides recommendations for repeat screening of pregnant women after treatment, and management of newborns exposed to *N. gonorrhoeae* and *C. trachomatis* during delivery by mothers with untreated infections. In light of this position statement, additional information may help to inform clinical best practices and clarify the need to reevaluate laws and policies mandating newborn eye prophylaxis.

The purpose of this report is to review the clinical evidence regarding the effectiveness of erythromycin for newborn eye prophylaxis, and to summarize the evidence-based guidelines for newborn eye prophylaxis and screening of pregnant women for gonorrhea and chlamydia.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of erythromycin for newborn eye prophylaxis?

2. What are the evidence-based guidelines for newborn eye prophylaxis?

3. What are the evidence-based guidelines for screening women for gonorrhea and chlamydia in pregnancy?

KEY FINDINGS

Results from one SR of low quality evidence suggested that there is no statistically significant advantage to using erythromycin over other prophylactic agents for the prevention of gonococcal ON, though erythromycin may be more effective than silver nitrate for the prevention of chlamydial ON. There was limited available evidence comparing prophylactic erythromycin to no treatment. Three evidence-based guidelines were identified that present contrasting recommendations; two guidelines recommend universal newborn eye prophylaxis, while one guideline does not recommend routine prophylaxis for newborns who are not at increased risk or showing signs of infection. Five evidence-based guidelines were identified that provide recommendations regarding screening pregnant women for chlamydia and gonorrhea. Routine screening of pregnant women is not recommended in one guideline, and three guidelines recommend screening when women are at high risk of infection or belong to a high prevalence age group. One guideline recommends the use of nucleic acid amplification tests to screen any asymptomatic individual for gonorrhea, but does not address timing or frequency of screening. The limited quantity and quality of evidence included in the single SR and supporting the guidelines regarding newborn eye prophylaxis and maternal screening for gonorrhea and chlamydia reduced confidence in the findings.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were used to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2010 and March 31, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Q1 & Q2: Newborns Q3: Pregnant women
Intervention	Q1: Erythromycin Q2: Antibiotics or other medications Q3: Screening pregnant women for gonorrhea and chlamydia
Comparator	Q1: Any comparator Q2 & Q3: None required
Outcomes	Q1: Clinical effectiveness of erythromycin for the prevention of gonorrhea or chlamydia infections in newborn eyes; safety and harms Q2: Guidelines for prophylaxis of ophthalmia neonatorum Q3: Guidelines on maternal screening for chlamydia and gonorrhea
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2010. Guidelines and recommendation statements that did not clearly report the conduct of a formal literature search and assessment of the evidence were also excluded.

Critical Appraisal of Individual Studies

The included systematic reviews were critically appraised using the AMSTAR tool[6] and guidelines were assessed with the AGREE II instrument.[7] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 465 citations were identified in the literature search. Following screening of titles and abstracts, 457 citations were excluded and eight potentially relevant reports from the electronic search were retrieved for full-text review. An additional 12 potentially relevant publications were retrieved from the grey literature search. Of these potentially relevant articles, 12 publications were excluded for various reasons, while eight publications met the inclusion criteria and were included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest, including guidelines that did not meet inclusion criteria, are provided in Appendix 5.

Summary of Study Characteristics

Detailed study characteristics are presented by study type in Appendix 2.

Study Design

One systematic review (SR)[3] was identified for the question on the clinical effectiveness of erythromycin for ophthalmia neonatorum (ON) prophylaxis. The literature search strategy identified studies published in MEDLINE from 1966 to January 2008, and in the Cochrane Central Register of Controlled Trials, EMBASE, and CINAHL according to a similar strategy (search date range not specified). Eight primary studies were selected for inclusion in the SR, including seven randomized controlled trials (RCTs) and one quasi-RCT published from 1980 to 2007.

Seven evidence-based guidelines[8-14] were identified regarding ON prophylaxis and/or screening pregnant women for chlamydia and gonorrhea. One SR[15] was identified that was a companion publication to update the United States Preventive Services Task Force (USPSTF) Recommendations: Screening for Gonorrhea and Chlamydia.[9] Overall, 12 new studies were identified for this update; however, no studies of pregnant women were identified for the section of the systematic review that specifically focused on screening for gonorrhea and chlamydia in this special population. One guideline from the National Institute for Health and Care Excellence (NICE) was published in 2008 but was reviewed in 2013 and no new evidence was identified to alter the recommendations.[14] This guideline was put on the static list in February 2014.

Country of Origin

The two SRs were published by authors or groups in Canada[3] and the United States.[15]

Four guidelines were developed by the following groups based in the United States: the Centers for Disease Control and Prevention (CDC),[8] the USPSTF,[9,13] and the Institute for Clinical Systems Improvement (ICSI).[11] The remaining three guidelines were produced by NICE[12,14] and the British Association of Sexual Health and HIV (BASHH)[10] in the United Kingdom.

Guideline Development and Methodology

Most guidelines used a SR process to identify relevant evidence,[8,9,12-14] though the selection[10] and/or search criteria[10,11] were unclear in two guidelines. The evidence was assessed using a variety of methods, including: the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach[12] or a modified GRADE approach,[11] expert consensus and USPSTF methods,[9,13] a different rating scheme provided in the guideline,[10,14] or an informal discussion of the evidence, not otherwise described.[8] The CDC guidelines followed the USPSTF rating system and considered other guidelines to develop recommendations,[8] and four guidelines described following formal and/or informal consensus methods to produce recommendations.[10-12,14] The two USPSTF guidelines were the only guidelines that consistently rated the strength of the recommendations.[9,13]

SR Patient Population

The SR relevant to the clinical effectiveness question included studies of newborns in hospital settings, in some cases limited to those born to mothers with known gonorrhea or chlamydia infection.[3] The primary studies were conducted in the United States, Mexico, France, Kenya, Zaire, and China.

Guideline Intended Users and Target Population

Intended users of the included guidelines were clinicians involved in the care of pregnant women or newborns,[9,11-14] health care providers interacting with individuals at risk for sexually transmitted infections (STIs),[8,10] and policy and decision makers responsible for planning related health care services.[12,14] The applicable health care settings in which the guidelines should be used were generally broad, though some guidelines were intended for use in outpatient or clinic-based settings,[11] specifically sexual health clinics in one case.[10]

The target populations for the guidelines were all pregnant women,[11] healthy women with an uncomplicated singleton pregnancy,[14] pregnant women and caregivers of newborns with or at risk of early-onset neonatal infection,[12] all newborns,[13] persons at risk of or requiring treatment for STIs, including pregnant women,[8] and all sexually active adolescents and adults, including pregnant women.[9] The scope of the target population was not clearly defined in the BASHH Guideline for Gonorrhea Testing;[10] however, pregnant women were listed as a risk group who could be considered for screening as heterosexual women would be, suggesting that they were not an excluded population from this guideline.

Interventions and Comparators

The SR by Darling and McDonald[3] included studies that evaluated comparisons of one prophylactic agent versus another, or versus placebo, or versus no treatment; these selection criteria identified comparisons of erythromycin with silver nitrate, povidone-iodine, and no prophylaxis.

Three guidelines relevant to Q2 of this report considered prophylactic agents for the prevention of gonococcal or chlamydial ON, including erythromycin,[8,13] and antibiotic management of any neonatal infection with onset within 72 hours of birth.[12]

Five guidelines[8-11,14] relevant to Q3 of this report considered screening pregnant women for several STIs including chlamydia and gonorrhea,[8,11,14] chlamydia and gonorrhea alone,[9] or specifically gonorrhea.[10]

Outcomes

The outcomes of interest for the SR by Darling and McDonald were rates of chlamydial and gonococcal ON.[3] The main relevant outcomes considered in the included guidelines and associated SR were clinical effectiveness and harms of antibiotic prophylaxis for newborns,[12,13] infection transmission,[8,9] and maternal and fetal health outcomes in general.[9,11,14]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of SRs and guidelines are provided in Appendix 3.

Systematic Review

The included SR[3] demonstrated several methodological strengths, including the performance of a comprehensive literature search and duplicate study selection and data extraction. However, it was unclear whether an a priori protocol or design was used to guide its conduct, and a search for unpublished literature was not performed. An included study list with clearly described characteristics, as well as a list of excluded studies, was provided. The major methodological limitations affecting each included study were described and addressed in the review conclusions. An assessment of publication bias was planned; however, no results of this assessment were reported. Similarly, the methods of this SR also mentioned that tests for heterogeneity were performed, yet neither the results of statistical analyses nor a discussion of clinical heterogeneity were provided. It is therefore unclear whether it was appropriate to pool the data, particularly given the mixed study populations with varying risk levels (e.g., potentially different prevalence rates of chlamydia and gonorrhea in different countries, or studies with all newborns included versus newborns born to mothers with chlamydia infection). Finally, conflict of interest was not addressed for either the review authors or the individual included studies.

Evidence-Based Guidelines

Scope and Purpose

Most guidelines specifically described an overall objective, but the two recommendation statements produced by the USPSTF[9,13] lacked detail regarding the scope and rationale of the guidelines. In one guideline, the importance of identifying and treating ON was stated yet the recommendation is about prophylaxis,[13] and in the other set of recommendations regarding screening for chlamydia and gonorrhea, screening was not described in the introduction and only appeared in the evidence summaries and recommendations. The health questions addressed in the guidelines were evident in five publications[8,9,12-14] and were not specifically described in two guidelines.[10,11] In most cases, the target population was clearly described; however, the setting for use of the BASHH guideline[10] was stated but the target population within that setting was not defined.

Stakeholder Involvement

The two NICE guidelines[12,14] had clear involvement of the relevant professional groups in the guideline development process. In the five remaining guidelines, it was unclear whether a methodology expert was included in the guideline development group.[8-11,13] While this is part of the USPSTF guideline development policy, the working group composition specific to the two USPSTF guidelines in this report was not provided within the guidelines.[9,13] In all cases, it was either unclear whether the views and preferences of the target population were sought during guideline development,[8,9,11-14] or it was explicitly stated that this was not done.[10] Most guidelines clearly described the target users of the guideline; while the intended users of the USPSTF

guidelines can be reasonably inferred due to the content of the recommendation summary, they were not explicitly defined in the documents.[9,13]

Rigour of Development

Most included guidelines described a systematic literature search strategy; this was unclear for the ICSI guidelines, which indicated that a formal literature search was conducted by a medical librarian but did not describe the search strategy.[11] All but two guidelines[10,11] had clearly described criteria for selecting the evidence. The strengths and limitations of the selected evidence were generally presented well; however, they were not clearly reported in one USPSTF guideline[13] and were inconsistently applied to some evidence statements and not others in the BASHH guideline.[10] The methods for formulating the recommendations were unclear in two guidelines; the ICSI guideline[11] generally referred to using the literature to inform recommendations, and the CDC guideline[8] relied on discussion of the evidence, not otherwise described, to develop recommendations. Furthermore, explicit links between evidence and recommendations were inconsistently presented in this guideline (e.g., the references supporting the recommendations for use of erythromycin were unclear).[8] The health benefits and harms were clearly considered in formulating the recommendations for all but one of the guidelines.[10] The majority of guidelines included an external review process prior to publication[8-10,12-14] and three guidelines provided a procedure for updating the guideline after publication.[11,12,14]

Clarity of Presentation

All included guidelines had specific recommendations that were easily identifiable, and presented considerations for special populations and different options for management of the applicable condition.

Applicability

Considerations for implementation were not presented in three guidelines.[8,9,13] The two guidelines by NICE provided implementation recommendations, presented a variety of care pathways to organize the recommendations, and performed a cost-effectiveness analysis to consider resource use implications.[12,14] The ICSI guideline also presented facilitators and barriers to its implementation, along with an annotated table of recommendations according to the prenatal visit time point to which they apply.[11] The BASHH guideline clearly defined monitoring and auditing criteria.[10]

Editorial Independence

Most guidelines addressed conflicts of interest among members of the guideline development group;[8-12,14] however, only one guideline explicitly stated that the funding body did not influence guideline development.[11]

Summary of Findings

A detailed summary of study findings and recommendations is provided in Appendix 4.

What is the clinical effectiveness of erythromycin for newborn eye prophylaxis?

Gonococcal ON

Pooled data from one SR[3] showed that there was no significant difference in the risk of gonococcal ON between prophylaxis with erythromycin and prophylaxis with silver nitrate or povidone-iodine. One study included in this SR that compared erythromycin with no treatment did not observe any cases of gonococcal ON in either treatment group.

Chlamydial ON

There was no statistically significant difference in the risk of chlamydial ON between erythromycin and no treatment or povidone-iodine; data were not pooled as there was one study per comparison reported in the SR.[3] However, pooled data from four studies suggested that the risk of chlamydial ON was significantly lower in newborns who received prophylactic erythromycin compared with those who received silver nitrate.[3]

What are the evidence-based guidelines for newborn eye prophylaxis?

Three evidence-based guidelines produced by the CDC,[8] NICE,[12] and the USPSTF[13] were identified that provide recommendations for prophylaxis of newborn eyes against ON.

The CDC and the USPSTF recommend newborn eye prophylaxis for the prevention of gonococcal ON.[8,13] The CDC specifically recommends a single dose of 0.5% erythromycin for this intervention as well as for the prevention of chlamydial ON despite a reported lack of substantial evidence of effectiveness of erythromycin for chlamydial ON prevention.[8] As there was no explicit link between systematically reviewed evidence and the CDC recommendations regarding prophylaxis against gonococcal or chlamydial ON, the evidence base to support these recommendations is unclear. The USPSTF guideline does not address chlamydial ON or specify a preferred prophylactic agent, but the recommendation for prophylaxis against gonococcal ON was given an A grading, representing a high certainty of substantial net benefit. This was based on an update literature review that revealed no substantial new evidence of benefits or harms of prophylaxis for gonococcal ON with any prophylactic agent since the previous USPSTF recommendation statement from 2009, as well as a review of existing guidelines from other groups at the time of publication that all recommended neonatal eye prophylaxis.

However, NICE does not recommend routine antibiotic treatment, including prophylaxis for ON, for newborns without known risk factors or suspected infection.[12] This recommendation was based on a review of six RCTs, two of which evaluated the effectiveness of interventions for the prevention of ON that provided low to very low quality evidence.

What are the evidence-based guidelines for screening women for gonorrhea and chlamydia in pregnancy?

Five evidence-based guidelines produced by the CDC,[8] the USPSTF,[9] BASHH,[10] ICSI,[11] and NICE[14] were identified that provide recommendations for screening pregnant women for chlamydia and gonorrhea.

The USPSTF recommends that sexually active women under the age of 25, and older women at increased risk of infection, should be screened for gonorrhea and chlamydia.[9] It was designated

a grade B recommendation, reflecting a moderate-to-high certainty of benefit. This recommendation applies to all women, including pregnant women, although no studies of screening pregnant women were identified in the accompanying systematic review.[15] The CDC cited these USPSTF recommendations in their guidelines, and added that pregnant women who meet these age or risk group criteria should be retested for chlamydia and gonorrhea in their third trimester of pregnancy; however, the strength of the CDC recommendations was not rated and the evidence supporting this recommendation was not explicitly presented.[8] Based on evidence from a SR, ICSI similarly recommends screening all women at high risk of gonorrheal or chlamydial infection before or during pregnancy.[11] The ICSI guidelines also make a recommendation based on low quality evidence regarding chlamydia screening that pregnant women who continue to be at high risk of infection should be rescreened in their second trimester.[11]

The BASHH guidelines on gonorrhea testing do not comment on timing or frequency of screening, but recommend the use of nucleic acid amplification tests for screening asymptomatic individuals for gonorrhea.[10]

The NICE guideline does not recommend routine screening of pregnant women for chlamydia due to insufficient evidence of effectiveness, feasibility, and acceptability of this practice.[14] Instead, NICE recommends that pregnant women belonging to a high chlamydia prevalence group due to their age (younger than 25 years) should be informed of the National Health Service's National Chlamydia Screening Programme to pursue testing if applicable. Further research about chlamydia screening in the antenatal setting is noted as a key research recommendation. This guideline does not address gonorrhea screening.

Limitations

No studies regarding the clinical effectiveness of erythromycin for the prevention of ON published more recently than 2010 were identified for inclusion in this report, despite the lack of high quality evidence from few studies included in the SR from 2010.[3] Likewise, the quality of the evidence supporting recommendations regarding newborn eye prophylaxis and screening pregnant women for gonorrhea and chlamydia, when reported, was generally low. The CDC recommendations were the only identified guideline that provided a recommended regimen for erythromycin ointment, which is the topical antibiotic used for neonatal eye prophylaxis in Canada, and the evidence supporting this recommendation was unclear. The USPSTF recommendation which was given a rating representing a high certainty of substantial benefit was based on a review of several prophylactic agents; this level of benefit may not be generalizable to a Canadian setting in which erythromycin is the only treatment option.

The generalizability of findings from the SR[3] to the Canadian population is uncertain, as the primary studies were conducted in several African countries, China, France, Mexico, and the United States, where the prevalence of chlamydia and gonorrhea may be different than in Canada. The benefit of routine prophylaxis can reasonably be expected to be different in areas of high prevalence compared with areas of low prevalence. Furthermore, data from all studies were pooled for each comparison without discussion of differing study populations, which potentially introduced confounding and limits confidence in the results.

Not all included guidelines considered cost-effectiveness or resource use during formulation of the recommendations, which may partially account for different recommendations between guideline development groups. Resource use and cost may be particularly important

considerations in clinical situations in which there is limited high-quality evidence of effectiveness.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Results from one SR[3] of low quality evidence suggested that there is no statistically significant advantage to using erythromycin over other prophylactic agents for the prevention of gonococcal ON, though erythromycin may be more effective than silver nitrate for the prevention of chlamydial ON. There was limited available evidence comparing prophylactic erythromycin to no treatment. These results were based on a total of eight studies for all treatment comparisons conducted in a variety of study populations and settings, and without additional reporting of heterogeneity; it was unclear whether it was appropriate to pool these data. Therefore, results should be interpreted with caution. Three evidence-based guidelines presented contrasting recommendations on this subject; the CDC[8] and the USPSTF[13] recommend universal newborn eye prophylaxis, while NICE[12] does not recommend routine prophylaxis for newborns who are not at increased risk or showing signs of infection. The evidence base supporting the CDC recommendation for newborn eye prophylaxis using erythromycin was not clear and the strength of the recommendations was not provided. The strongly positive USPSTF recommendation for prophylaxis was based on evidence of the effectiveness and guidelines for use of several prophylactic agents; therefore, it is unclear how much this recommendation was influenced by evidence regarding erythromycin in particular, or whether this recommendation would apply with the same level of certainty to clinical situations in which erythromycin is the only prophylactic option. Additional evidence from high quality studies, particularly comparing erythromycin with no treatment for the prevention of ON, would be required to formulate strong conclusions about clinical effectiveness of newborn eye prophylaxis with erythromycin and to support related recommendations. Furthermore, other factors not consistently addressed in these guidelines, such as the cost of universal prophylaxis and the potential for antibiotic resistance, may need to be considered for the development and implementation of recommendations.

Five evidence-based guidelines[8-11,14] were identified that provide recommendations regarding screening pregnant women for chlamydia and gonorrhea. Routine screening of pregnant women is not recommended by NICE,[14] and three guidelines from the United States recommend screening when women are at high risk of infection or belong to a high prevalence age group.[8,9,11] This contrasts with the CPS position statement recommendation that all pregnant women should be screened for gonorrhea and chlamydia.[2] However, the evidence-based guidelines produced by the CDC and the USPSTF recommend targeted maternal screening and also recommend universal newborn prophylaxis, suggesting that there may be increased need for or value of prenatal screening and subsequent treatment of pregnant women with confirmed gonorrheal and chlamydial infections if routine newborn eye prophylaxis was no longer recommended. Additional research examining the effectiveness of universal prenatal screening for gonorrhea and chlamydia, followed by treatment of confirmed cases, for the prevention of gonococcal and chlamydial ON in the absence of universal newborn eye prophylaxis would be required to demonstrate this relationship with greater certainty.

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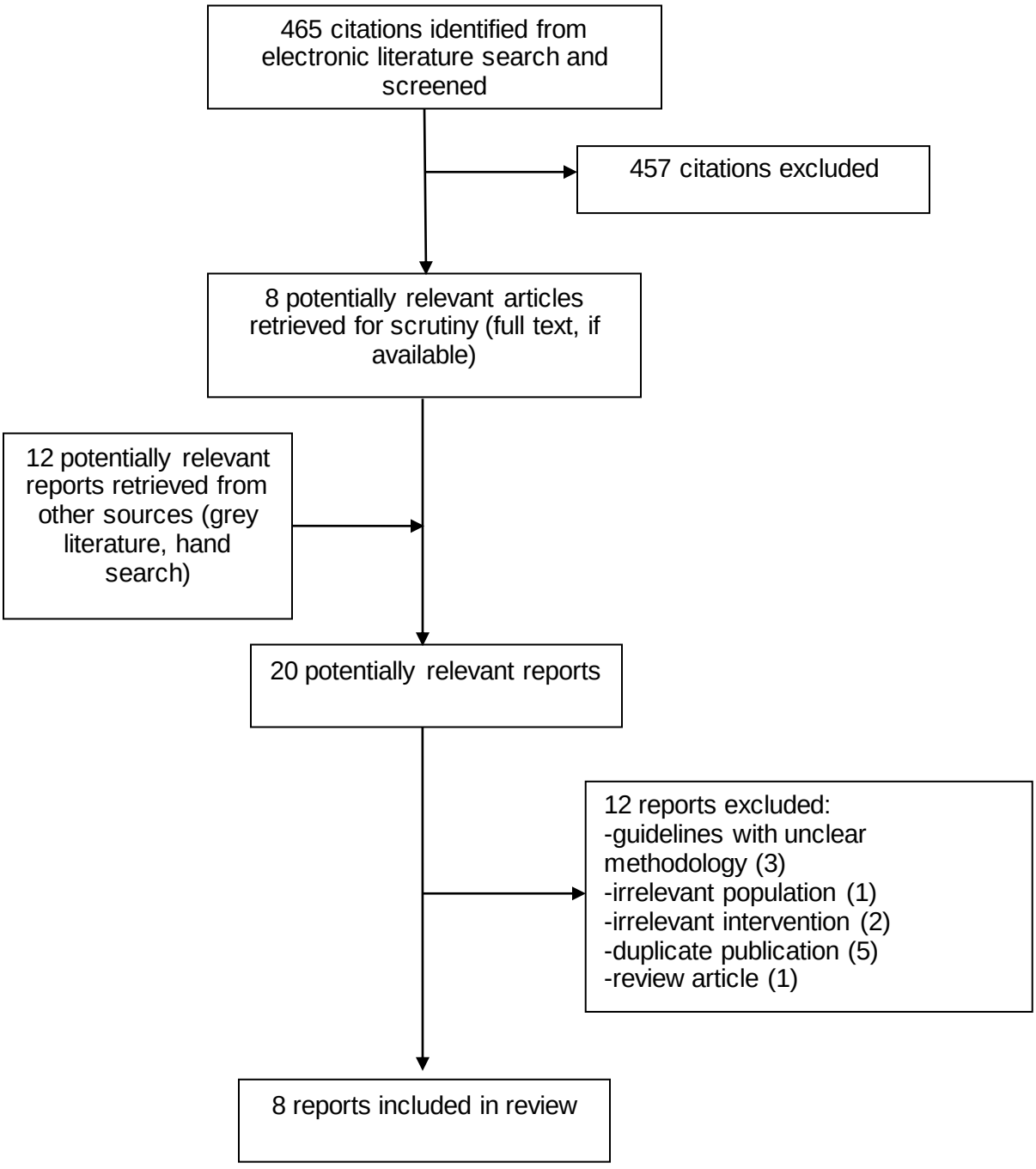
APPENDIX 1: SELECTION OF INCLUDED STUDIES



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses

Author, Publication Year, Country	Types and numbers of primary studies included	Population Characteristics	Intervention(s) & Comparator(s)	Clinical Outcomes, Length of Follow-Up
Darling and McDonald, 2010[3] Canada	8 primary studies included: 7 quasi-RCTs, 1 RCT	Newborns in hospital settings (n = 14,037; in 2 studies, all newborns born to mothers with chlamydia at time of birth, n = 290) Country setting: Mexico, Kenya, Zaire, China, France, United States	Erythromycin vs. silver nitrate (4 studies); tetracycline vs. silver nitrate (5 studies); povidone-iodine vs. silver nitrate (3 studies); povidone-iodine vs. erythromycin (1 study); povidone-iodine vs. chloramphenicol (1 study)	Chlamydial ON, gonococcal ON; Follow-up not reported or incomplete in most studies

DTA = diagnostic test accuracy; ON = ophthalmia neonatorum; RCT = randomized controlled trial.
[a] Systematic review to update the USPSTF Recommendations: Screening for Gonorrhea and Chlamydia.[9]

Table A2: Characteristics of Included Guidelines

Objectives			Methodology			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality Assessment**	**Recommendations development and Evaluation**	**Guideline Validation**
Guidelines for Newborn Eye Prophylaxis						
CDC, 2015[8]						
Intended users: physicians and HCPs in any health care setting serving persons at risk for STIs Target population: individuals with or at risk of STIs, including pregnant women	Treatment and counseling for STIs, prophylactic agents for ON	Microbiologic eradication of infection; alleviation of signs and symptoms; prevention of transmission and sequelae; cost-effectiveness; adverse events	Systematic review: search of electronic database for published and unpublished literature (date ranges NR); evidence summarized in tables	Informal discussion	Recommendations proposed for CDC consideration by a working group according to the USPSTF rating system, CDC prepared draft recommendations after review of existing guidelines from other groups	Review of draft recommendations by an independent panel of clinical experts
NICE, 2012[12]						
Intended users: HCPs involved in the care of pregnant women or newborns in any setting; policy and decision makers responsible for planning related health	Antibiotic management of early-onset (within 72 hours of birth) neonatal infection	Information and support provided to pregnant women and caregivers; maternal and fetal risk factors for early-onset neonatal infection; effectiveness of antibiotic prophylaxis	Systematic review: search of electronic databases for literature published as of the year 2000; evidence summarized in tables	GRADE	Informal consensus methods were used to agree to evidence statements and form recommendations. In areas where insufficient evidence was identified, evidence-based guidelines and consensus statements from other groups were considered. Formal consensus methods were used to evaluate clinical	External stakeholder review of the draft scope and guideline

Table A2: Characteristics of Included Guidelines						
Objectives			**Methodology**			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality Assessment**	**Recommendations development and Evaluation**	**Guideline Validation**
care services Target population: pregnant women and caregivers with babies at risk of, or with suspected or confirmed, early-onset neonatal infection		offered to pregnant women at or shortly before the expected time of labour and birth, or routinely to babies after birth (all babies or those with identified risk factors); investigations before starting antibiotics in the baby; optimal duration of antibiotic treatment; cost-effectiveness of investigations, antibiotic regimens, and care settings			care and research recommendations. Research recommendations were prioritized using a modified nominal group technique.	
USPSTF, 2011[13]						
Intended users: HCPs in family practice, infectious diseases, pediatrics, and	Ocular topical prophylaxis for gonococcal ON within 24 hours of birth	Clinical benefits and harms of prophylactic treatment; incidence of gonococcal ON;	Systematic review: searches of electronic databases (Jan 1, 1995 to Mar	Expert consensus and USPSTF rating system	Consensus recommendations developed based on review of the evidence and strength of recommendations	Comparison with guidelines from other groups, internal and external clinical expert

Table A2: Characteristics of Included Guidelines

Objectives			Methodology			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality Assessment**	**Recommendations development and Evaluation**	**Guideline Validation**
preventive medicine Target population: all newborns		morbidity (i.e., scarring, ocular perforation, and blindness)	1, 2009), hand searches of published literature; duplicate study selection		determined according to the USPSTF rating system	and stakeholder review of guideline
Guidelines for Screening Pregnant Women for Gonorrhea and Chlamydia						
USPSTF, 2014[9]						
Intended users: HCPs in family practice, internal medicine, obstetrics and gynecology, pediatrics, and preventive medicine Target population: all sexually active adolescents and adults, including pregnant women	Screening for chlamydia and gonorrhea	For men and non-pregnant women, including adolescents: complications of infection and transmission or acquisition of disease, identification of persons with gonorrhea or chlamydia, DTA, harms of screening For pregnant women: maternal complications, adverse pregnancy and infant outcomes, transmission or	Systematic review:[15] searches of electronic databases (Jan 1, 2004 to May or June 2014), hand searches of published literature; duplicate study selection; evidence summarized in tables	Quality of the body of evidence for each review question assessed in duplicate using USPSTF methods	Consensus recommendations developed based on review of the evidence and strength of recommendations determined according to the USPSTF rating system	Comparison with guidelines from other groups, internal and external clinical expert and stakeholder review of guideline

Table A2: Characteristics of Included Guidelines						
Objectives			**Methodology**			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality Assessment**	**Recommendations development and Evaluation**	**Guideline Validation**
		acquisition of disease in pregnant women, harms of screening				
BASHH, 2012[10]						
Intended users: HCPs in specialist sexual health clinics and settings where gonorrhea testing occurs Target population: individuals in the United Kingdom with or at risk for gonorrhea, including pregnant women	Screening and diagnostic tests (NAATs, bacterial culture, intracellular microscopy); sampling methods and sites; confirmatory testing of positive NAATs from extragenital sites and low prevalence populations; testing in groups with varying risk levels and clinical or social considerations; frequency of repeat testing in asymptomatic patients; post-treatment	DTA outcomes (sensitivity, specificity, positive predictive value); prevalence of gonorrhea; re-infection rate	Systematic review: searches of electronic databases (Jan 2006 to Dec 2010), hand searches of published literature	Weighting according to a rating scheme provided in the guideline document (levels Ia to IV)	Recommendations developed by expert consensus among a multidisciplinary writing committee; recommendations graded according to provided rating scheme (A, B, or C)	Internal peer review and external stakeholder review

Table A2: Characteristics of Included Guidelines						
Objectives			Methodology			
Intended users/ Target population	Intervention and Practice Considered	Major Outcomes Considered	Evidence collection, Selection and Synthesis	Evidence Quality Assessment	Recommendations development and Evaluation	Guideline Validation
	reassessment					
ICSI, 2012[11]						
Intended users: HCPs providing prenatal care in an outpatient or clinic-based setting Target population: all women who are pregnant or considering pregnancy	Screening and risk assessment strategies (including for STIs), counselling and education interventions, immunizations and chemoprophylaxis	Cost-effectiveness of prenatal care; sensitivity and specificity of screening maneuvers; maternal and fetal health outcomes	Systematic review: searches of electronic databases (Jan 2009 through Jan 2012); evidence summarized in tables	Modified GRADE rating system (ICSI GRADE) applied to individual evidence statements (high, moderate, and low quality evidence); conclusions regarding the body of evidence for a particular topic graded according to a provided rating scheme (grades I, II, III)	Recommendations developed by expert consensus among a multidisciplinary work group; strength of recommendations NR	Internal peer review
NICE, 2008[14a]						
Intended users: clinicians providing antenatal care, those	Providing information to women; provision and organization of care; lifestyle	Benefits and harms of lifestyle considerations; effectiveness of symptom	Systematic review: searches of electronic databases (up	Weighted according to a provided rating scheme (level 1a to 4)	Recommendations developed through informal consensus; formal consensus methods (modified Delphi techniques	Internal and external peer review; external stakeholder review

Table A2: Characteristics of Included Guidelines						
Objectives			**Methodology**			
Intended users/ Target population	**Intervention and Practice Considered**	**Major Outcomes Considered**	**Evidence collection, Selection and Synthesis**	**Evidence Quality Assessment**	**Recommendations development and Evaluation**	**Guideline Validation**
responsible for commissioning and planning maternity services Target population: healthy women with an uncomplicated singleton pregnancy	considerations (e.g., supplementation, alcohol consumption); maternal and infant screening strategies; clinical examination of pregnant women; management of pregnancy symptoms; fetal monitoring	management interventions; DTA of screening tests; cost-effectiveness of screening programs; maternal and fetal health outcomes	to June 2007); evidence summarized in tables		or nominal group technique) were employed if required (e.g. grading recommendations or agreeing audit criteria). Recommendations from the 2003 guideline were graded according to the level of evidence upon which they were based (Grade A, B, C, D, or Good Practice Point). Recommendations developed for this 2008 guideline update were not graded.	

BASHH = British Association of Sexual Health and HIV; CDC = Centers for Disease Control and Prevention; DTA = diagnostic test accuracy; GRADE= Grading of Recommendations Assessment, Development and Evaluation; HCP = health care provider; ICSI = Institute for Clinical Systems Improvement; NAAT= nucleic acid amplification test; NICE = The National Institute for Health and Care Excellence; NR = not reported; ON = ophthalmia neonatorum; STI = sexually transmitted infection; USPSTF = United States Preventive Services Task Force.

[a] The guideline was originally published in 2008 but reviewed in 2014 and no changes were made to this section of the guideline at that time. The guideline was moved onto the static list in 2014.

APPENDIX 3: Critical Appraisal of Included Publications

Table A3: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR[6]

Strengths	Limitations
Darling and McDonald, 2010[3]	
• Study selection, assessment of methodological quality, and data extraction performed independently by two reviewers • Comprehensive search of multiple databases performed • List of included and excluded studies provided • Characteristics of included studies clearly described • Areas of substantial methodological weakness were reported for each study • Scientific quality of the included studies was addressed in the conclusions	• No a priori design provided • Unpublished literature was not solicited for inclusion • Methods indicate that tests for heterogeneity were performed but no discussion of clinical or statistical heterogeneity was provided in the results section • Methods indicate that an assessment of publication bias was planned but results not reported • Conflict of interest not addressed for review authors or individual studies

[a] Systematic review to update the USPSTF Recommendations: Screening for Gonorrhea and Chlamydia.[9]

Table A4: Strengths and Limitations of Guidelines using AGREE II′

Item	Guideline						
	CDC, 2015[8]	USPSTF, 2014[9]	BASHH, 2012[10]	ICSI, 2012[11]	NICE, 2012[12]	USPSTF, 2011[13]	NICE, 2008[14]
Domain 1: Scope and Purpose							
1. The overall objective(s) of the guideline is (are) specifically described.	✓	X	✓	✓	✓	X	✓
2. The health question(s) covered by the guideline is (are) specifically described.	✓	✓	X	X	✓	✓	✓
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	✓	✓	X	✓	✓	✓	✓
Domain 2: Stakeholder Involvement							
4. The guideline development group includes individuals from all relevant professional groups.	X	X	X	X	✓	X	✓
5. The views and preferences of the target population (patients, public, etc.) have been sought.	X	X	X	X	X	X	X
6. The target users of the guideline are clearly defined.	✓	X	✓	✓	✓	X	✓
Domain 3: Rigour of Development							
7. Systematic methods were used to search for evidence.	✓	✓	✓	X	✓	✓	✓
8. The criteria for selecting the evidence are clearly described.	✓	✓	X	X	✓	✓	✓
9. The strengths and limitations of the body of evidence are clearly described.	✓	✓	X	✓	✓	X	✓
10. The methods for formulating the recommendations are clearly described.	X	✓	X	X	✓	✓	✓
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	✓	✓	X	✓	✓	✓	✓
12. There is an explicit link between the recommendations and the supporting evidence.	X	✓	X	✓	✓	✓	✓

Table A4: Strengths and Limitations of Guidelines using AGREE II′

Item	Guideline						
	CDC, 2015[8]	USPSTF, 2014[9]	BASHH, 2012[10]	ICSI, 2012[11]	NICE, 2012[12]	USPSTF, 2011[13]	NICE, 2008[14]
13. The guideline has been externally reviewed by experts prior to its publication.	✓	✓	✓	X	✓	✓	✓
14. A procedure for updating the guideline is provided.	X	X	X	✓	✓	X	✓
Domain 4: Clarity of Presentation							
15. The recommendations are specific and unambiguous.	✓	✓	✓	✓	✓	✓	✓
16. The different options for management of the condition or health issue are clearly presented.	✓	✓	✓	✓	✓	✓	✓
17. Key recommendations are easily identifiable.	✓	✓	✓	✓	✓	✓	✓
Domain 5: Applicability							
18. The guideline describes facilitators and barriers to its application.	X	X	X	✓	✓	X	✓
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	X	X	X	✓	✓	X	✓
20. The potential resource implications of applying the recommendations have been considered.	X	X	X	X	✓	X	✓
21. The guideline presents monitoring and/or auditing criteria.	X	X	✓	X	X	X	X
Domain 6: Editorial Independence							
22. The views of the funding body have not influenced the content of the guideline.	X	X	X	✓	X	X	X
23. Competing interests of guideline development group members have been recorded and addressed.	✓	✓	✓	✓	✓	X	✓

✓ = yes; BASHH = British Association of Sexual Health and HIV; CDC = Centers for Disease Control and Prevention; GRADE = Grading of Recommendations Assessment, Development and Evaluation; ICSI = Institute for Clinical Systems Improvement; NICE = The National Institute for Health and Care Excellence; USPSTF = United States Preventive Services Task Force; X = no or unclear.

APPENDIX 4: Main Study Findings and Author's Conclusions

Table A5: Summary of Findings of Included Systematic Reviews

Main Study Findings	Author's Conclusions
Darling and McDonald, 2010[3]	
Erythromycin vs. no prophylaxis • No cases of gonococcal ON observed in any treatment group (erythromycin, silver nitrate, tetracycline, no treatment) in one study with a no treatment comparator that evaluated this outcome (n = 4544) • RR of chlamydial ON = 0.93 (95% CI 0.48 to 1.79; 1 study, n = 2306) Erythromycin vs. silver nitrate • RR of gonococcal ON = 2.54 (95% CI 0.92 to 6.98; 2 studies, n = 10,004) • RR of chlamydial ON = 0.71 (95% CI 0.52 to 0.97; 4 studies, n = 4514) Povidone-iodine vs. erythromycin • RR of gonococcal ON = 0.85 (95% CI 0.35 to 2.03; 1 study, n = 2188) • RR of chlamydial ON = 0.74 (95% CI 0.54 to 1.03; 1 study, n = 2188)	• Evidence of limited quantity and quality from randomized and quasi-randomized studies suggests that there is no significant difference in clinical efficacy between erythromycin and other prophylactic agents or no treatment for the prevention of gonococcal ON, while erythromycin may be more effective than silver nitrate for the prevention of chlamydial ON. • Universal newborn eye prophylaxis may be beneficial in areas with high prevalence of maternal gonorrhea and chlamydia. • While additional large, high-quality trials would increase accuracy and precision of effect size estimates, the cost to conduct these trials may outweigh the benefits in low-prevalence settings. • North American laws requiring universal neonatal prophylaxis for ON should be revisited due to evidence of limited benefit of this practice in low-prevalence settings.

CI = confidence interval; NAAT = nucleic acid amplification test; ON = ophthalmia neonatorum; PID = pelvic inflammatory disease; RR = relative risk.
[a] Systematic review to update the USPSTF Recommendations: Screening for Gonorrhea and Chlamydia.[9]

Table A6: Summary of Recommendations in Included Guidelines	
Findings and Recommendations	**Grade/Strength of Recommendation**
Guidelines for Newborn Eye Prophylaxis	
CDC, 2015[8]	
• A single dose of prophylactic erythromycin (0.5%) applied to each eye at as soon as possible after delivery is recommended for the prevention of gonococcal ON • If erythromycin ointment is not available, a single dose of ceftriaxone 25–50 mg/kg IV or IM, not to exceed 125 mg can be administered to newborns at risk for gonococcal ON (born to mothers at risk of gonorrhea or who did not receive prenatal care) • *"Although the efficacy of neonatal ocular prophylaxis with erythromycin ophthalmic ointments to prevent chlamydia ophthalmia is not clear, ocular prophylaxis with these agents prevents gonococcal ophthalmia and therefore should be administered."* Chlamydial Infections Among Neonates, page 58	• NR
NICE, 2012[12]	
• *"Do not routinely give antibiotic treatment to babies without risk factors for infection or clinical indicators or laboratory evidence of possible infection."*[a]	• NR
USPSTF, 2011[13]	
• *"The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum."*	• A (Definition: The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Suggestion for practice: Offer or provide this service.)
Guidelines for Screening Pregnant Women for Gonorrhea and Chlamydia	
CDC, 2015[8]	
• Endorsed USPSTF recommendations for screening pregnant women aged 24 years or younger and aged 25 or older at increased risk for chlamydia and gonorrhea.[9] • Women under age 25 or at risk[b] should be retested for chlamydia during the third trimester of pregnancy	• NR
USPSTF, 2014[9]	
• *"The USPSTF recommends screening for chlamydia in sexually active females aged 24 years or younger and in older women who are at increased risk for infection."*[b] • *"The USPSTF recommends screening for gonorrhea in sexually active females aged 24 years or younger and in older women who are at increased risk for infection."*[b]	• Both recommendations: B (Definition: The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. Suggestion for practice: Offer or provide this service.)
BASHH, 2012[10]	
• *"NAATs are the test of choice for testing asymptomatic individuals for urethral or*	• NR

Table A6: Summary of Recommendations in Included Guidelines	
Findings and Recommendations	**Grade/Strength of Recommendation**
endocervical infection with Neisseria gonorrhoeae."	
ICSI, 2012[11]	
• Based on evidence from a systematic review, *"All women found to be at high risk for sexually transmitted diseases should be screened for Neisseria gonorrhoeae and Chlamydia trachomatis at a preconception visit or during pregnancy."* • Based on low quality evidence, *"The optimal frequency of screening has not been determined, but due to concerns about reinfection, an additional test in the second trimester is recommended for those at continued risk of acquiring chlamydia."*	• NR
NICE, 2008[14a]	
• *"At the booking appointment, healthcare professionals should inform pregnant women younger than 25 years about the high prevalence of chlamydia infection in their age group, and give details of their local National Chlamydia Screening Programme (www.chlamydiascreening.nhs.uk)."* • *"Chlamydia screening should not be offered as part of routine antenatal care."*	• NR

BASHH = British Association of Sexual Health and HIV; CDC = Centers for Disease Control and Prevention; ICSI = Institute for Clinical Systems Improvement; IM = intramuscular; IV = intravenous; kg = kilogram; mg = milligram; NAAT = nucleic acid amplification test; NICE = The National Institute for Health and Care Excellence; NR = not reported; ON = ophthalmia neonatorum; USPSTF = United States Preventive Services Task Force.

[a] This recommendation was based on a review of six RCTs, two of which evaluated interventions for the prevention of ON; both studies provided low quality evidence.

[b] Risk factors other than age include: "new or multiple sex partners, a sex partner with concurrent partners, or a sex partner with a sexually transmitted infection (STI); inconsistent condom use among persons who are not in mutually monogamous relationships; previous or concurrent STI; and exchanging sex for money or drugs."[9]

APPENDIX 5: Additional References of Potential Interest

Guidelines with Unclear Methodology

Newborn Eye Prophylaxis

Perinatal Services BC guideline: newborn eye prophylaxis and prevention of ophthalmia neonatorum [Internet]. Vancouver: Perinatal Services; 2015 Dec. [cited 2016 May 2]. Available from: http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Newborn/NewbornEyeProphylaxis.pdf

Newborn: prophylaxis with erythromycin eye ointment [Internet]. Winnipeg (MB): Winnipeg Regional Health Authority; 2014 May. [cited 2016 May 2]. (Practice guideline). Available from: http://www.wrha.mb.ca/extranet/eipt/files/EIPT-028-001.pdf

Management and treatment of specific infections: gonococcal infections. In: Canadian guidelines on sexually transmitted infections [Internet]. Ottawa: Public Health Agency of Canada; 2013 Jul [cited 2016 May 2]. Section 5. Available from: http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-ldcits/section-5-6-eng.php
See: Table 12: Neonates born to women with untreated gonorrhea; Table 13: Ophthalmia neonatorum

Management and treatment of specific infections: chlamydial infections. In: Canadian guidelines on sexually transmitted infections [Internet]. Ottawa: Public Health Agency of Canada; 2013 Jul [cited 2016 May 2]. Section 5. Available from: http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-ldcits/section-5-2-eng.php
See: Table 4: Children

Alberta treatment guidelines for sexually transmitted infections (STI) in adolescents and adults 2012 [Internet]. Edmonton (AB): Alberta Government; 2012 Dec. [cited 2016 May 2]. Available from: http://www.health.alberta.ca/documents/STI-Treatment-Guidelines-2012.pdf
Note: Adapted from the Canadian Guidelines on Sexually Transmitted Infections produced by the Public Health Agency of Canada

Chlamydia trachomatis infections [Internet]. Edmonton (AB): Alberta Health; 2012 Jul. [cited 2016 May 2]. (Public health notifiable disease management guidelines). Available from: http://www.health.alberta.ca/documents/Guidelines-Chlamydia-Trachomatis-2012.pdf
See: Pediatric Cases, page 9

Gonococcal infections [Internet]. Edmonton (AB): Alberta Health; 2012 Jul. [cited 2016 May 2]. (Public health notifiable disease management guidelines). Available from: http://www.health.alberta.ca/documents/Guidelines-Gonococcal-Infections-2012.pdf
See: Pediatric Cases, page 9

Screening Pregnant Women for Gonorrhea and Chlamydia

Management and treatment of specific infections: chlamydial infections. In: Canadian guidelines on sexually transmitted infections [Internet]. Ottawa: Public Health Agency of Canada; 2013 Jul [cited 2016 May 2]. Section 5. Available from: http://www.phac-aspc.gc.ca/std-mts/sti-its/cgsti-ldcits/section-5-2-eng.php

See: Section on Prevention and Control

Maternity care pathway [Internet]. Vancouver: BC Perinatal Health Program; 2010 Feb. [cited 2016 May 2]. (BCPHP Obstetric guideline 19). Available from: http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/Maternal/MaternityCarePathway.pdf
See: "Chlamydia screening" and "Gonorrhea screening", page 10