Re: Moore DL and MacDonald NE. Preventing ophthalmia neonatorum. Paediatr Child Health 2015;20(2):93-96.

To the Editor;

We read with concern the Canadian Paediatric Society (CPS) position statement "Preventing ophthalmia neonatorum" (1).

We are concerned it fails to adequately review the evidence regarding the efficacy of ocular prophylaxis and the risks posed by its cessation, while overstating the risks of its continuation.

Regarding efficacy, the statement relies on a meta-analysis by Darling and McDonald (2), which is summarized as showing that evidence "regarding the efficacy of prophylactic agents used to prevent gonococcal and chlamydial conjunctivitis was not of high quality". We are concerned this inadequately reflects the study's findings. Darling and McDonald find that the lack of evidence is due to a lack of adequate statistical power related to low prevalence of maternal gonorrhoea. They note that it would be unethical to randomize newborns at risk to receive no prophylaxis because prophylaxis is generally regarded as being highly effective. In relation to chlamydial conjunctivitis, the statement argues that "ocular prophylaxis is not effective", but Darling and McDonald find that "overall, these data suggest that prophylactic agents lead to some reduction in the risk of chlamydial conjunctivitis".

The CPS statement also states that screening is more effective. Evidence of this is not presented. There are multiple sources of potential for failure including risks posed by false-positives, false-negatives, nonengagement with prenatal care, nonengagement with follow-up, antimicrobial resistance and medication side effects. Given evidence that in Canada socially vulnerable groups engage less with prenatal care (3), we are concerned that screening, being heavily reliant on prenatal care, will expose children of parents in vulnerable groups to disproportionate risk. Comparative studies are required.

The CPS statement argues that gonoccocal ophthalmia neonatorum (ON) is rare, and points to regions where prophylaxis has stopped as an argument for cessation in Canada. While gonoccocal ON is rare, there is also evidence that ON is underreported and subject to cyclical fluctuations in incidence (4,5). There is also evidence from Sweden, Florida and Denmark that ON incidence has increased since cessation of prophylaxis (6).

The CPS statement states that irritation caused by prophylaxis has been perceived by parents as "interfering with mother-infant bonding". This risk is overstated. The paper referred to, in fact found that "even though silver nitrate alters eye openness, and even though these mothers noticed this, it did not alter their baby-focused attention nor did it prevent their pleasure and excitement during this initial social encounter" (7).

It is noteworthy that silver nitrate is the most irritant of ocular prophylaxis options and is no longer available. Other than chemical conjunctivitis, the most commonly used prophylactic agents (povidone-iodine, tetracycline and erythromycin) are not associated with significant side effects (8,9). The United States Preventative Services Task Force reviewed the evidence in this area, and concluded that there is convincing evidence that prophylaxis is not associated with serious harm (10).

We urge the CPS to reconsider this position statement. We urge a retraction of its recommendation to abandon, and advocate against mandatory prophylaxis until the safety and efficacy of alternative protocols are known. We urge consultation with the Canadian Association of Pediatric Ophthalmology and Strabismus in developing a new position statement.

Dr C Mulholland and Dr J Gardiner (President);
on behalf of the Canadian Association of
Pediatric Ophthalmology and Strabismus

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The author responds;

Drs Mulholland and Gardiner express concern about the Canadian Paediatric Society (CPS) position on the prevention of neonatal ophthalmia, which advocates for discontinuation of mandatory ocular prophylaxis (1).

Whenever a preventive measure is recommended, the potential risks and benefits must be assessed carefully, as such measures are predominately directed at those who are healthy. The vast majority of neonates born in Canada are not at risk for ophthalmia neonatorum (ON). Hence prophylaxis must show very strong benefit and minimal risk within the context of care options to be acceptable.

An important point that the authors do not mention is that in Canada at present, the only option for ocular prophylaxis is erythromycin ointment. Regarding the efficacy of ocular prophylaxis, Darling and McDonald concluded that while it appears that prophylaxis does reduce the risk of gonococcal ON (GON) and chlamydia ON (CON), all agents have significant failure rates (2). While these failure rates may have been acceptable in the pre-antibiotic era, when there was no option for treatment, today we have options that, based on the efficacy of screening and treatment, are expected to be more effective. Erythromycin failures with GON were demonstrated even in the era when gonococci were susceptible, and efficacy against CON is questionable (3-6). The evidence of benefit of erythromycin prophylaxis today is not strong.

The authors suggest that in countries where ocular prophylaxis has been discontinued, rates of ON have increased. While the review article cited (7) implies this, the studies referred to in that article do not support the statement (8). In Denmark, between 1984 to 1988, there was no increase in GON after prophylaxis was discontinued. CON was most frequent, but data are presented only for the period after prophylaxis was discontinued (9). The paper from the United Kingdom suggesting low reporting rates did not show any recent increase in ON. The infection rates reported were calculated from all hospital admissions for ON and dacryocystitis, without information on microbial etiology (10). The report from Sweden describes an increase in overall gonorrhoea rates in 1997 to 1998, but does not mention ON or gonorrhoea in pregnancy (11). There are no recent data reporting increases in rates of ON in these countries. Prophylaxis was not discontinued in Florida; the increase in GON between 1984 to 1988 may have been related to the introduction of erythromycin for ocular propylaxis (12).

With regard to the perception of eye irrritation interfering with mother-infant bonding, the letter authors are correct; the citation in our article is incorrect. It should have been an earlier study by the same authors (13), who mentioned this potential concern and subsequently did the study cited in our article, which in fact did not show intereference (14). While there is no evidence that bonding is affected, concern about this, as well as about pain and discomfort for their newborns may result in parental anxiety. Chemical conjunctivitis, while rare with erythromycin, does occur (3,15), and manipulation of the eyelids of the newborn could potentially have an adverse effect if not performed carefully. Another potential risk is induction of erythromycin resistance in the newborn's flora. The monetary cost of a preventive measure that may not work must also be considered.

The letter authors are concerned about vulnerable groups with inadequate or no prenatal care. For these, screening of the mother and baby at delivery, and treatment if indicated, are essential, as noted in the recommendations in the CPS position statement. Babies born to mothers with no or inadequate prenatal care are at high risk for acquisition of other infections and, in addition, have risks unrelated to infection. Appropriate care includes ensuring close follow-up for the baby and the mother. Ocular prophylaxis does not address the needs of the mother. Perhaps one of the greatest dangers of possibly ineffective ocular prophylaxis is the induction of a false sense of security among health care providers.

Finally, the letter authors raised the concerned that the CPS position is out of sync with that in the United States. While the United States has not yet shifted practice, despite changes in resistance and decades of evidence from several European countries noted above, this may reflect, in part, that in the United States, there are still pockets of women who do not receive prenatal care at all, and follow-up also may be lacking. In contrast, in Canada, and in the European countries noted, this is distinctly uncommon. Of note, this is a topic the American Academy of Pediatrics is planning to review, which may well lead to changes in their recommendations.

The CPS statement had input from its Community Paediatrics and the Fetus and Newborn Committees, as well as from the Society of Obstetricians and Gynaecologists of Canada and the Public Health Agency of Canada's Canadian STI Expert Working Group, and reflects a broad range of expertise.

While ocular prophylaxis with erythromycin has a low rate of adverse effects, continued universal use of a likely ineffective measure is not justified. This is a very different era from that when silver nitrate was introduced, or even when gonococci were universally senstive to macrolides. In summary, ocular prophylaxis of ON no longer meets the benefit risk balance required for a prophylactic measure.

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