Dear Andrew

Re: Scottish Parliament Public Petition PE1505 on Awareness of Strep B in Pregnancy and Infants

Thank you for your letter of 28 March 2014 with regards to the following question from the Scottish Parliament Public Petitions Committee —

- What are the potential “harms” from screening for Group B Streptococcus, and what data or evidence is there on the incidence of “harms” resulting from screening for Group B Streptococcus?

The UK National Screening Committee (UK NSC) chaired by the Deputy Chief Medical Officer for England, advises Ministers and the NHS in the four UK countries about all aspects of screening and supports implementation of screening programmes. Using research evidence, pilot programmes and economic evaluation, it assesses the evidence for programmes against a set of internationally recognised criteria covering the condition, the test, the treatment options and the effectiveness and acceptability of the screening programme. Assessing programmes in this way is intended to ensure that they do more good than harm at a reasonable cost.

At its meeting on 13th November 2012 the UK NSC recommended that screening for GBS carriage at 35 -37 weeks of pregnancy should not be offered, this is because:

- Currently available screening tests cannot distinguish between women whose babies would be affected and those which would not. As a result about 140,000 low risk pregnant women would be offered antibiotics in labour
following a positive screening test result. The overwhelming majority of these women would have a healthy baby without screening and treatment.

- There are concerns about resistance to some antibiotics used to prevent early onset GBS, the long term effects on the newborn and the potential for anaphylactic reactions in labour.
- The majority of babies who die from early onset GBS are premature and are, sadly, born too early to be helped by screening.
- It is estimated that screening may prevent 5 – 7 deaths to early onset GBS per year out of a total of about 40. Between 17,000 – 25,000 women would need to receive intravenous antibiotics in labour to prevent 1 infant death.
- It has been estimated that up to 49,000 women carrying GBS at 35-37 weeks of pregnancy may no longer be GBS carriers when receiving treatment during labour. Studies of the test suggest that between 13% and 40% of screen positive women will no longer be carriers at the point of delivery.
- Concerns about the impact on maternity services, increasing the medicalisation of labour, and limiting the options for home births and births in midwife led units.

According to the only enhanced surveillance GBS in the UK, published in 2004 by the British Paediatric Surveillance Unit (BPSU), the prevalence of early onset GBS (EOGBS) in the UK is 0.48/1000 and lowest (0.21/1000) in Scotland. Although comparisons are not always robust, this incidence of EOGBS is similar to recently reported rates of infection, after screening, in the USA (0.21/1000). The BPSU will revisit the UK prevalence of EOGBS with a new study, beginning in April 2014.

The decision not to offer screening for GBS was primarily taken because there was no clear demonstration of benefit above the current recommended EOGBS prevention strategy outlined in the guidelines produced by the Royal College of Obstetricians and Gynaecologists (RCOG) and National Institute for Health and Care Excellence (NICE). The harms of a screening programme were noted to be poorly understood however there was emerging evidence, specifically on antibiotic use, that the UKNSC considered in its decision.

One of the fundamental limitations of the screening programme is the high number of women who would be treated with antibiotics unnecessarily. Aside from the unwarranted medicalization of labour, the use of antibiotics to such a degree was not in agreement with the current movement to limit their use to clinical scenarios where they are required.

One of the reasons why antibiotics are being used in such a way is because of increasing concern about resistance. Although there have been no confirmed cases of penicillin-resistant GBS isolates in the United Kingdom to date[i], there have been reports from the Far East and United States describing the emergence of clinical GBS isolates with reduced susceptibility to penicillin[ii][iii][iv][v].

Clindamycin is the alternative first-line agent for penicillin-allergic patients. Levels of both clindamycin and erythromycin-resistant GBS isolates increased in the period 1991-2010, with resistance to erythromycin increasing markedly from 2.5% in 1991 to 15% in 2010[vi]. The high level of clindamycin resistance has severe implications
for treatment options for penicillin-allergic patients, in particular where treatment is
given empirically.

As well as increasing concerns about resistance, antibiotic use is also known to
cause allergic reactions in a minority of pregnant women. In an audit undertaken in
Northern Ireland, 5 cases were reported in 2011 and 2012. The severity of cases of
allergic reaction and anaphylaxis is variable but it can be fatal.

As with all UK NSC screening policies, the evidence on GBS screening is reviewed
every 3 years (next review being Spring 2015). We would encourage all interested
stakeholders to comment on the consultation documents that will be available during
this process. Furthermore, it is understood that PHE is working together with the
Department of Health, the RCOG and the National Institute for Health Research
Heath Technology Assessment (NIHR HTA) on a number of areas:

- PHE are establishing enhanced surveillance of infant disease in 2014 in
  partnership with the British Paediatric Surveillance Unit and national public
  health bodies across the UK and Ireland to assess disease incidence,
  associated mortality and frequency of established risk factors. PHE will
  monitor developments on GBS vaccines and undertake a grant-funded study
to assess the potential impact of a maternal immunisation programme. They
  are also seeking research funding to identify any genetic differences in GBS
  carriage strains compared to those causing infant disease as a means to
develop a more specific screening test.

- The RCOG in partnership with the London School of Hygiene and Tropical
  Medicine have appointed a clinical research fellow to carry out an audit across
  the UK. It aims to provide feedback and advice to all participating trusts about
  how they can further improve their adherence to the RCOG’s guideline on the
  prevention of neonatal group B streptococcus disease.

- The NIHR HTA programme is seeking to commission a study to provide
evidence on whether intrapartum testing in some groups at high risk enables
more timely identification of women with GBS carriage so as to target
antibiotic use. A study of this type would focus on pregnant women at high
risk of having an affected baby, with reference to the risk factors identified in
the guidance from the RCOG.

Yours sincerely,

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