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DR FIONA MCQUAID (Orcid ID : 0000-0002-9599-5084)

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Antenatal vaccination against Group B streptococcus: Attitudes of pregnant women and healthcare professionals in the UK to participation in clinical trials and routine implementation

Running headline: Attitudes towards antenatal GBS vaccine

Fiona McQuaid¹, Christine Jones², Zoe Stevens¹, Gretchen Meddaugh¹, Catherine O'Sullivan², Beverly Donaldson³, Rhona Hughes⁴, Carolyn Ford⁴, Adam Finn⁵, Saul N Faust⁶, Diane Gbesemete⁶, Helen Bedford⁷, Stephen Hughes⁸, Anu Susan Varghese⁸, Paul T Heath² & Matthew D Snape¹

¹Oxford Vaccine Group, Department of Paediatrics, University of Oxford and the NIHR Oxford Biomedical Research Centre, Oxford, ²Paediatric Infectious Diseases Research Group & Vaccine Institute, Institute for Infection and Immunity, St Georges, University of London & St Georges University Hospitals NHS Foundation trust, London, ³Department of Paediatrics, Imperial College London, London, ⁴Simpson Centre for Reproductive Health, Royal Infirmary, Edinburgh, ⁵Bristol Children's Vaccine Centre, University Hospitals Bristol NHS Foundation Trust & University of Bristol, Bristol, ⁶Southampton NIHR Wellcome Trust Clinical Research Facility, University Hospital Southampton NHS Foundation Trust & Academic Unit of Clinical and Experimental Sciences, Faculty of Medicine and Institute for Life Sciences, University of Southampton, Southampton, ⁷Population, Policy and Practice Programme, UCL Great Ormond

Street Institute of Child Health, London, ⁸Department of Paediatric Allergy and Immunology,
Royal Manchester Children's Hospital, University of Manchester, Manchester, UK

Corresponding author

Fiona McQuaid

Centre for Immunity, Infection and Evolution, University of Edinburgh, Ashworth Laboratories
3 level 4, Kings Buildings, West Mains Road, Edinburgh, EH9 3JT, UK

Email: Fiona.mcquaid@ed.ac.uk

Conflicts of Interest

SNF, MDS, PTH and AF act as investigators for clinical trials conducted on behalf of their respective Universities and NHS Hospital Trusts sponsored by vaccine manufacturers and have participated in advisory boards but receive no personal payments from these activities (all monies being paid to their employing institutions). SNF and MDS have had travel and accommodation expenses paid by vaccine manufacturers to attend international conferences related to paediatric infectious disease. RH and PTH are co-authors of the RCOG green top guidelines 36 "Prevention of Early-onset Group B Streptococcal disease. The remaining authors have no potential conflicts of interest to declare.

Abstract

Introduction: Maternal vaccination is increasingly part of antenatal care in the UK and worldwide. Trials of Group B streptococcus (GBS) vaccines are ongoing. This study investigated the attitudes of pregnant women and healthcare professionals towards antenatal vaccination, both in routine care and a clinical trial setting. *Material and methods:* Survey of 269 pregnant women, 273 midwives/obstetricians and 97 neonatal doctors across seven sites in the UK assessing attitudes towards antenatal vaccinations, knowledge of GBS, a hypothetical GBS vaccine and participation in clinical vaccine trials. *Results:* Sixty-eight percent of pregnant women intended to receive a vaccine during their current pregnancy (183/269) and 43% (of all respondents, 115/269) reported they would be very/fairly likely to accept a vaccine against GBS despite only 29% (55/269) knowing what GBS was. This increased to 69% after additional information about GBS was provided. Twenty-four percent of pregnant women reported they would be likely to take part in a clinical trial of an unlicensed GBS vaccine. Fifty-nine percent of maternity professionals and 74% of neonatologists would be likely to recommend participation in a GBS vaccine trial to women, with the vast majority (>99%) willing to be involved in such a study. Incentives to take part cited by pregnant women included extra antenatal scans and the opportunity to be tested for GBS. *Conclusion:* Pregnant women and healthcare professionals were open to the idea of an antenatal GBS vaccine and involvement in clinical trials of such a vaccine. Education and support from midwives would be key to successful implementation.

Keywords

Group B streptococcus, antenatal vaccine, pregnancy, attitudes, healthcare professionals, pregnant women, clinical trials

Abbreviations

GBS- Group B streptococcus

Key Message

Both pregnant women and healthcare professionals were open to the idea of an antenatal Group B streptococcus vaccine and involvement in clinical trials of such a vaccine. Education and support from midwives would be key to successful implementation.

Introduction

Immunisation of pregnant women to protect both themselves and/or their infants is increasingly part of routine care both in the UK and worldwide. Current UK recommendations state that all pregnant women should receive a pertussis-containing vaccine from 16 to 32 weeks gestation and the influenza vaccine during the influenza season, at any stage of gestation (1, 2). There is evidence that these antenatal vaccines are both safe, and effective at preventing disease both in the mother and the infant (3-7).

Around 60-75% of UK pregnant women received the pertussis vaccine in 2016 (8), with a marked increase between winter 2015 and 2016 (8). However, uptake rates for influenza remain sub-optimal with recent figures showing that only 43% of eligible pregnant women received the influenza vaccine in 2016 (9); thus a significant proportion of pregnant women and their babies remain susceptible to potentially fatal, yet preventable, diseases.

Antenatal immunisation also offers the potential to target additional major neonatal pathogens including Group B streptococcus (GBS), the leading cause of sepsis and meningitis in infants under the age of 3 months (10, 11). There was around 850 cases (0.95/1000 live births) of culture-proven confirmed GBS cases in the UK and Republic of Ireland in the 13 months from April 2014 resulting in 53 deaths (personal communication, unpublished data C. O'Sullivan), substantially more than the 14 deaths from neonatal pertussis infections in the 2012 pertussis outbreak that prompted the current maternal immunisation strategy (12). Strategies for the prevention of neonatal GBS infection include the risk-based intrapartum antibiotic approach currently used in the UK (13), or a universal swab-based screening programme used in the USA, Canada, much of Europe and parts of Australia (14, 15). Neither strategy impacts on GBS disease beyond the first week of life, and both have the potential to miss cases or contribute to the overuse of antibiotics. An antenatal vaccine against GBS is therefore desirable and clinical trials of candidate GBS vaccines involving over 500 pregnant women have been conducted (16) or are ongoing (17).

The aim of this study was to investigate the attitudes of pregnant women and the healthcare professionals involved in their care, towards antenatal vaccination, GBS disease and the prospect of a GBS vaccine. Secondary aims included identifying factors affecting vaccine uptake and

exploring attitudes towards participating in clinical trials of an antenatal GBS vaccine, and how these could be addressed to optimise uptake in a routine setting and in recruitment for clinical trials.

Material and methods

Self-completed paper questionnaires in English were distributed to 356 pregnant women, 407 maternity professionals (defined as practising midwives or doctors working in obstetric practice) and 118 neonatal doctors across seven NHS trusts in the UK. The sites were Oxford University Hospitals NHS Foundation Trust, NHS Lothian in Edinburgh, Imperial College Healthcare NHS Trust and St George's University Hospitals NHS Foundation Trust in London, University Hospital Southampton NHS Foundation Trust, University Hospitals Bristol NHS Foundation Trust and Central Manchester University Hospitals and NHS Foundation Trust. Pregnant women were recruited from October 2014 until June 2015, and healthcare professionals from October 2014 until July 2015.

Three different questionnaires were developed for each of the groups of interest (Supporting Information Appendix S1). Inclusion criteria were that the respondent should be over 18, be able to read and write English and be either pregnant or working as a midwife (including community midwives), obstetric doctor or neonatal doctor at one of the study sites.

The questionnaires were developed after reviewing the literature, using data collected from an online survey of over one thousand women of child bearing age (18), and in-depth qualitative work with pregnant women, parents with experience of GBS and maternity professionals (19). Prior to the national survey, the questionnaires were piloted amongst the interview and focus group participants and adapted based on their feedback.

Questionnaires were distributed by study staff in antenatal clinic waiting rooms, antenatal classes, multi-professional meetings, staff rooms and via email. Participation was voluntary, the questionnaires were confidential, anonymous and no personal identifying information was collected. Respondents were asked to tick a box at the beginning of the questionnaire to indicate that they understood their answers would be used as part of a research study. Respondents were also given a sealed envelope with the GBS additional information sheet (Supporting Information Appendix S2) which they were instructed to open at a specified point.

Statistical analyses

Questionnaires were returned to a single site (Oxford) and data entered into the OpenClinica database before being exported to the Microsoft Excel software program for analysis. Statistical analyses were conducted with Graphpad Prism software (GraphPad, La Jolla, USA) using Chi-square and Fisher's exact tests. Not all questions were fully completed by every respondent, however, unless otherwise stated, the percentages stated are of all responses with those who did not complete the question recorded as missing data. For the ranking questions, data were included even if the respondents only ranked some of the options. However if the respondent only ticked, rather than numbered, boxes, this were recorded as "uninterpretable" and counted as missing data.

Ethical approval

The study was approved by the NRES Committee South Central- Hampshire A ethics committee reference 13/SC/0619. The study was funded by a grant from the charity Meningitis Now.

Results

A total of 356 pregnant women, 407 maternity professionals and 118 neonatal doctors were approached to take part in the study and 300 (84.3%), 306 (75.2%) and 101 (85.6%) completed the questionnaire, respectively. Of these, 31 pregnant women, 33 maternity professionals and 4 neonatal doctors were excluded from the final analysis as they had not ticked the 'permission' box, leaving 269 pregnant women, 273 maternity professionals and 97 neonatal doctors.

The age of the pregnant women ranged from eighteen to forty-six years and ethnicity was well matched for the UK population (20). Further demographic details for all groups are shown in Tables 1 and 2.

Seventy-seven percent (208/269) of the pregnant women recollected being offered at least one vaccination during their current pregnancy (Table 1) and 68% (of all respondents, 182/269) indicated that they had received or intended to receive a vaccination during this pregnancy, 19.7% (53/269) did not intend to have any vaccinations and 11.2% (30/269) were undecided. Vaccination details for the healthcare professionals are shown in Table 1. When pregnant women were asked to rank the relative importance of the potential benefits of antenatal vaccination, the highest ranking was protecting their baby from a rare but serious condition,

while protecting self or others was less important (figure 1). Major concerns about receiving antenatal vaccination were that it might cause harm to the baby and specifically that it may cause a miscarriage (figure 2). Factors influencing whether the maternity professionals would recommend a vaccine in pregnancy also highlighted the perceived importance of preventing serious conditions as 24.2% (66) ranked this as the most important consideration. The existence of a national recommendation was also key with 32.2% (88) of maternity professionals stating this was the factor which would be most influential.

Pregnant women reported receiving information about antenatal immunisation from their midwife, obstetrician or general practitioner (187, 69.5%), via leaflets (132, 49.1%) or their own independent research (46, 17%, multiple answers permitted). However, 18% (49) reported they had received no information about antenatal vaccination; these women were significantly less likely to have had, or to intend to have, any antenatal vaccines than those who had received information (table 2).

Forty-six percent (124) stated that the most important source of information would be their midwife, with general practitioners and obstetricians being the next most highly-ranked sources and the media being least popular. Those who had a discussion with their midwife, general practitioner or obstetrician (as opposed to only a leaflet/own research) were more likely to have/to intend to have, a vaccine (table 2). Ninety-four percent (258) of maternity professionals agreed that information about vaccination in pregnancy was most appropriately delivered by midwives.

Neither age nor having other children appeared to significantly affect the decision to have an antenatal vaccination, although White British respondents were significantly more likely to have had/to intend to have vaccination than those identifying themselves as Black or White Other, the majority of whom were from elsewhere in Europe (table 2).

Both maternity professionals and pregnant women considered 21-30 weeks' gestation to be the most acceptable time in pregnancy for vaccination (pregnant women: 21.2% (57), maternity professionals: 40.7% (111)). Themes emerging from the free text answers for both groups included a perception that this was a "safer" time as the baby was more developed and there was less risk of miscarriage.

Knowledge about GBS amongst pregnant women was low with 70% (189) reporting that they didn't know what it was (figure 3). Almost all the maternity professionals (269, 98.5%) and neonatal doctors (96, 99%) had some clinical experience of GBS, with similar percentages in

both groups reporting they had had discussions with women about GBS (pre or post-natal) or prescribed/administered antibiotics for GBS. Most (94.8%, 92) of neonatal doctors had experience of caring for a baby with GBS infection compared to 61.5% (168) of maternity professionals. Preferred preventive strategies for GBS also varied between the healthcare professional groups with universal screening of all pregnant women preferred by maternity professionals (116, 42.5%, more than one response permitted) and vaccination by the neonatal doctors (48, 49.5%). Only 32.2% (88) and 24.7% (24) respectively felt the current UK risk based approach was most appropriate.

Before and after reading a leaflet with information about GBS, all respondents were asked how likely they would be to either have (pregnant women), recommend (maternity professionals) or support (neonatal doctors) a GBS vaccine. Prior to reading the information, 42.8% (115) of pregnant women stated they would be very/fairly likely to receive the vaccine, which rose to 68.4% (184) after reading the information (figure 4a). The shift was less dramatic for maternity professionals (figure 4b) and there was virtually no change for neonatal doctors (figure 4c).

Respondents were asked whether they would accept, recommend or support a GBS vaccine according to different numbers of previous vaccine recipients in clinical trials (figure 5). The percentage of pregnant women willing to accept the vaccine increased from 30% to 60% as the hypothetical number of previous recipients increased from 1,000 to 10,000. The most frequently cited period of required follow up for adverse outcomes before maternity professionals or neonatal doctors would recommend the vaccine was 5 years (133 (48.7%) and 55 (56.7%), respectively).

After reading additional information about the current trial status of GBS vaccines, 23.8% (64) of pregnant women stated that they would be very or fairly likely to take part in a clinical trial of a GBS vaccine. This was not significantly affected by age, parity, or ethnicity. The most frequently preferred mode of recruitment was to be invited by their own midwife (49.8%, 134). Internet adverts, for example, on parent forums or emails from the study team were not popular. When the concept of a randomised control trial was explained (i.e. that they may or may not receive the active vaccine and would not be able to choose), the majority of women (177, 65.8%) felt this would not affect their decision to take part, however 4.5% (12) would be more likely to take part as there was a chance they would not get the vaccine (but still receive the benefits of being in the trial) and 12.6% (34) would be less likely to take part as they would want a guarantee of receiving the vaccine.

Healthcare professionals were generally supportive of GBS vaccine trials with 59.3% (162) of maternity professionals and 74.2% (72) of neonatal doctors very or fairly likely to recommend a pregnant woman to take part in a trial. Almost all (>99%) wanted to be involved in some capacity if their hospital was taking part in a GBS trial, with 78% (213) of maternity professionals willing to discuss the trial, 42% (113) to take consent, and 30.5% (82) to administer the vaccine. Neonatal doctors were also keen to be involved with 46.4% (45) willing to be part of the study team and 41.2% (40) to take consent.

Among the pregnant women, strong motivators which would make respondents more likely to take part in a clinical trial included having extra scans, being tested themselves for GBS carriage, their baby having regular check-ups for several years and having extra antenatal appointments (Figure 6).

“I think it's great that a vaccine is being tried and tested to develop into something which can save lives and limit effects of GBS.”

Pregnant woman SP032

“For me to take part in the trial, I would need time to think about it, real info on the possible risks and benefits to myself, my baby and others. All discussed with my midwife, so it is face to face.”

Pregnant woman OP030

Concerns expressed in the free text section centred on any risk to the baby, particularly of miscarriage,

“Risk of miscarriage or other health complications for the baby *in utero* and beyond. I would be more likely to take part in research concerning my health alone and not that of an unborn child, who has no choice.”

Pregnant woman SP003

The potential, unknown, long-term side effects were also a concern and that some women disliked the thought of being a “guinea pig”.

In a similar way, maternity professionals and neonatal doctors were concerned about the potential risks to both mother and baby, though the prospect of litigation if things went wrong ranked as the third highest concern and extra workload was also a potential issue.

Discussion

This study provides important new insights on the attitudes of pregnant women and healthcare professionals towards antenatal vaccination and clinical vaccine trials involving pregnant women in the UK. Other attitudinal studies have been conducted mainly in the USA (21), or have focused on single vaccines (22) and few have assessed the views of healthcare professionals (23), or considered clinical trial participation.

Our findings suggest that provision of information is key to encourage antenatal vaccine uptake. However a significant number of women reported they had not been offered information and fears persist about the perceived risk of miscarriage or harm to the baby. Similar concerns have been highlighted in other studies exploring attitudes to maternal immunisation, among different populations such as in the USA and Australia (21, 22, 24). Our data suggest that emphasising the protection for the baby and the potential severity of the infections, rather than benefit for mother or protection from a common illness could be more effective at promoting vaccine uptake. This may partly explain the difference in uptake between the pertussis and influenza vaccines as pertussis is primarily presented as protecting the baby while influenza vaccine programmes are primarily designed to protect the pregnant women herself, despite evidence that they can also improve the health of babies (3). Differences in the perception of the severity of pertussis and influenza for mother and infant have been reported elsewhere, with influenza generally not regarded as serious by any group (25). However other factors, such as the different gestation at which these vaccines are recommended, may also play a part.

It is vital that healthcare professionals are aware of the evidence regarding the safety of antenatal vaccination, in particular that there appear to be no increased risks and that there may be additional benefits (3, 6, 7, 26), such as improved birthweight. Providing a short, written information sheet can be very effective as demonstrated by the 26% increase in pregnant women likely to accept a GBS vaccine after reading the information sheet, although for the women surveyed here, discussion with a healthcare professional significantly increased the likelihood of acceptance compared to written information alone. As well as having knowledge, maternity professionals need training about how best to communicate key information to all pregnant women. Shortly after the introduction of the antenatal influenza vaccine, Ishola et al found that only 26% of London midwives felt well prepared to advise women about the influenza vaccine (27). Evidently this is an important area for development. The specific concern about

miscarriage, now of particular relevance to both the influenza and pertussis vaccines which may be given early in pregnancy, should be actively addressed and reassurance given.

The low level of awareness among pregnant women about GBS is consistent with other UK studies (18) and is perhaps unsurprising in the UK context where screening for GBS is not routine (13). However this could have important implications for the uptake of a future GBS vaccine and our data suggest that implementation will need to be accompanied by an intensive education campaign for both pregnant women and maternity professionals. One other study in the USA, exploring the attitudes of pregnant women towards a hypothetical GBS vaccine, reported a higher potential acceptance rate of 79% (28) although it is important to note that this was in the context of a routine GBS screening programme.

The data regarding pregnant women's potential involvement in a clinical trial are novel and are of practical relevance for those designing and recruiting to studies of antenatal vaccines including not only those against GBS but also other major pathogens such as Respiratory Syncytial Virus. Encouragingly, almost a quarter of pregnant women would consider taking part in a hypothetical GBS clinical trial and healthcare professionals were also supportive in that they would be willing to provide significant practical help to the study teams. The involvement of the patient's own clinician is particularly important in optimising participation (29), although our previous qualitative work has suggested that some maternity professionals may be very ambivalent about clinical vaccine trials (19). It is reassuring that these were not the views of this more representative sample of UK maternity professionals and suggests that recruiting local staff to be part of the study team could be key to success. While maternity professionals have the most contact with pregnant women, neonatal doctors could also prove to be a valuable resource as a group which strongly supports antenatal vaccination and could be involved in long-term postnatal follow up, an important motivator for the pregnant women. Contrary to the usual emphasis on minimising the number of visits to cause as little inconvenience as possible in many standard vaccine studies, it seems that offering additional time, scans and appointments could improve the likelihood of pregnant women participating, while incentives such as vouchers or money would have little effect on recruitment. A previous study of mostly non-pregnant women had indicated that those with children might be more likely to take part in a clinical vaccine trial (30), although the differences here were not significant. In the same study among non-pregnant women, 32% of respondents indicated they would be very/fairly likely to take part (18) compared to 23.8% of the pregnant women surveyed here. However, for women who are

pregnant, the scenario of engaging in a vaccine study while pregnant is closer to their current situation and the results shown here are more likely to reflect reality.

There are a number of limitations to this study to be acknowledged. Only respondents who could read and write English were included, thus we excluded important groups who are likely to have particular challenges in accessing information and the vaccines themselves. Future work should make special efforts to reach this under-represented population. While the ethnic background of our sample was proportionally representative of the UK population, there were relatively few respondents from ethnic minorities and ethnicity is known to influence attitudes towards healthcare and vaccination (21, 22). Similarly, there should be caution in extrapolating these data to populations where screening for GBS is routine in whom background knowledge of GBS among pregnant women may be greater. Though a high proportion of those approached (75-85%) agreed to take part in the study, no data were collected on those who declined to participate and although a broad range of ages, gestations and parity were included, we cannot rule out responder bias. Only vaccine trials and real life implementation will confirm whether the interventions suggested by these data are able increase vaccine uptake.

Antenatal vaccination is an important tool with increasing potential to reduce both maternal and neonatal mortality and morbidity, if it can be delivered effectively. In keeping with previous studies, these data show that both pregnant women and the healthcare professionals do have concerns about the use of vaccination in pregnancy, but encouragingly many are open to the concept of novel vaccines and willing to participate in research to bring these forward. Education of both pregnant women and those caring for them is key to both improve uptake of current and future vaccines and help optimise recruitment for clinical trials to further reduce the burden of neonatal disease both in the UK and worldwide.

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Supporting Information legends

Appendix S1: Survey questions for pregnant women, maternity professionals and neonatal doctors.

Appendix S2: GBS fact sheet.

Table and figure legends

Table 1 Participant demographic details (percentages rounded to one decimal place).

Table 2 Had/intend to have antenatal vaccination according to whether information received and ethnicity.

Figure 1: Pregnant women, perceived benefits of antenatal vaccination. 1 = most important, 7 = least important (n= number of respondents giving that rank to any statement).

Figure 2: Pregnant women, concerns about antenatal vaccines. 1= greatest concern, 10 = least (n= number of respondents giving that rank to any statement).

Figure 3: Pregnant women, “Have you heard of group B streptococcus (sometimes called Group B strep or GBS)?” Of the 22 (8%) women who reported being directly affected by GBS, 2 indicated having a previous child with GBS infection, 11 a positive GBS swab in this or a previous pregnancy, 6 knew a friend/family who had a child with GBS infection, 1 reported that she had had GBS, 1 that a friend had been told her recurrent miscarriages could be due to GBS and another did not specify.

Figure 4: a) Pregnant women, b) maternity professionals and c) neonatal doctors, likelihood of receiving/recommending/supporting an antenatal vaccination against GBS before and after reading information sheet.

Figure 5: Number of pregnant women who would have to have had the vaccine before each group would consider receiving, recommending or supporting a GBS vaccine.

Figure 6: Pregnant women, motivators to take part in a GBS vaccine trial. 1 = most preferred, 9 = least preferred. (n= number of respondents giving that rank to any statement). 20% (54) stated that nothing would make them more likely to take part.