Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

OFFICIAL REPORT (Hansard)

Group B Streptococcus

8 February 2012

NORTHERN IRELAND ASSEMBLY

Committee for Health, Social Services and Public Safety

Group B Streptococcus

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Members present for all or part of the proceedings:
Ms Sue Ramsey (Chairperson)
Mr Jim Wells (Deputy Chairperson)
Ms Paula Bradley
Mr Mickey Brady
Mr Gordon Dunne
Mr Mark H Durkan
Ms Pam Lewis
Mr John McCallister
Mr Kieran McCarthy

Witnesses:

Dr Margaret Boyle	Department of Health, Social Services and Public Safety
Dr Michael McBride	Department of Health, Social Services and Public Safety

The Chairperson: I welcome Dr Michael McBride, who is no stranger to the Committee, and Dr Margaret Boyle, a senior medical officer, who is also no stranger to the Committee. Apologies from the Chairperson of the Committee, who has broken her foot. I am in a caretaker role, and I am not in a good mood.

Dr Michael McBride (Department of Health, Social Services and Public Safety): They say forewarned is forearmed.

The Chairperson: Given that you are no strangers to the Committee, and members have a lot of background material on group B strep (GBS) and have been here for some of the evidence sessions, I will hand over to you for your presentation. We will then take questions or comments from members.

Dr McBride: Thank you, Chair, and thank you, members. With your permission, we will make some introductory comments to take you through the short update paper that we provided for members.

As you are all aware, the National Screening Committee (NSC) review is well under way, and it is still anticipated that the review report will be available by the end of March 2012. The report and its recommendations will go out for a period of consultation. I understand that the National Screening Committee has been liaising with Group B Strep Support on the review, including inviting it to contribute any additional research evidence that it has not, as a committee, identified as part of its literature review and research. The National Screening Committee will then consider all the available

evidence and make recommendations to the Departments as regard its review of the literature and its understanding of the research.

We have guidance in place that dates back to 2003, which is being reviewed by the Royal College of Obstetricians and Gynaecologists (RCOG). My understanding is that the review is primarily around the prevention of early-onset group B strep and is due to be published in March 2012. I understand that that is still the timescale that is envisaged for the completion of that work.

We have undertaken additional actions in Northern Ireland. We are conducting an audit of women in labour against the 2003 RCOG guidelines, and that work is under way. It is being completed by the Guidelines and Audit Implementation Network (GAIN), and we expect the report to be completed by the end of this month. We will then share that report and its findings with the National Screening Committee to inform its analysis of the evidence and research.

There are three main strands to the audit. The first is the assessment of the management of individual women. We are looking at a sample of about 15%, and some 600 case notes will be reviewed with risk factors as assessed against the RCOG guidelines. The second strand involves the identification of newborns diagnosed with early-onset group B strep and a review of mothers' case notes for risk factors and management to align whether or not the management has been appropriate in those circumstances. The third element relates to the identification of stillbirths for whom group B strep was found to be the cause of death at post-mortem examination. Again, a review of the mothers' case notes for risk factors and management will be conducted in that cohort. The final element of the programme is an audit of the screening programme that was in place in Antrim Area Hospital until early 2011, which will be included as part of the work. All the findings on that will be shared with the National Screening Committee to inform its consideration of the evidence.

In respect of actions taken since colleagues last had the opportunity to meet the Committee, the Acting Chief Nursing Officer and I issued a letter to health professionals in September 2011 highlighting the clinical management of group B strep in pregnancy, primarily to ensure that those at risk are managed appropriately and that all pregnant women are made aware of group B strep. I want to make you aware that I have also communicated with Dr Eddie Rooney, the chief executive of the Public Health Agency (PHA), requesting that the agency undertake work to raise awareness of group B strep in pregnancy. A number of actions are being taken forward as a result of that. Pending the updated RCOG guidance, the Public Health Agency has issued the current RCOG patient information leaflet to trusts and GPs, requesting that health professionals use the leaflet when discussing group B strep with women. When the updated RCOG guidance has been received, an updated patient information leaflet will be made available and issued to trusts and GPs.

Another important element is the interim use of a group B strep reminder sticker, which has been produced by the Public Health Agency. It lists the categories of women who should be offered intravenous antibiotics, as outlined in the 2003 RCOG guidance. The Public Health Agency has issued the stickers to trusts, requesting that health professionals place them in the intranatal section of each pregnant woman's maternity handheld record. So a sticker will be placed in the record itself, as a reminder and prompt to health professionals of the appropriate management risk assessment to prevent early-onset group B strep in neonates. In due course, the sticker will be replaced by a page in the updated maternity handheld record, which will include the final recommendations from the ongoing work by the National Screening Committee and others.

As part of the work on raising awareness, an updated section that reflects current departmental policy and RCOG guidance has been drafted for inclusion in the revised 'Pregnancy Book', which will be available later this month. We have also ensured that information on group B strep is made available on the Public Health Agency and NI Direct websites with links to other relevant websites, including Group B Strep Support.

To raise awareness, we have organised a joint RCOG/Royal College of Midwives conference for 23 February 2012. The programme now includes a specific section on group B strep in pregnancy, which will be delivered by a consultant obstetrician in the Province, with input from a consultant neonatologist. It will be attended by obstetricians and midwives. It is a further effort to ensure that we increase and raise awareness of group B strep in pregnancy.

A range of work is under way at a national level across the UK and here in Northern Ireland. On co-ordination, I established a group B strep steering group to ensure that the various strands of work are co-ordinated and delivered in a timely manner. On 16 December, I chaired the group's first meeting. We have representatives from the Department, the Public Health Agency, including midwifery and public health. Membership of the group includes a chairperson of the Northern Ireland audit steering group, a neonatologist and John Jenkins, who will be known to some members.

We have also considered how best to engage with families. To that effect, I have had a meeting with the chief executive of the Patient and Client Council to discuss the best and most appropriate way to take that forward. At this point, I want to add that I very much appreciate the efforts that families have made in identifying gaps in current awareness of group B strep. I am mindful that it will have been a difficult experience for them. It is important that we learn from their experience and seek to reflect it in our ongoing work.

A number of issues were raised in the Committee's communication, which I will now seek to address. A specific question has been asked about the role of Dr Paul Fogarty in providing policy advice to the Department on group B strep screening. I want to confirm for Committee members that Dr Fogarty has no role in providing policy advice to the Department on screening for group B strep in pregnancy. We asked him to attend the Health Committee's evidence session on 14 September 2011 because he is an office bearer in the RCOG. Indeed, it was our view that he may have had detailed information about the development of revised guidance on the prevention of early-onset group B strep in neonates, which would have assisted Committee members. That was the only capacity in which he attended the Committee that day.

We were also asked to provide specific comments on the evidence that was given to the Committee at our previous meeting. Colleagues Liz Mitchell and Margaret Boyle were present. We have provided comments on points that were raised by Group B Strep Support with regard to the specific evidence that was given at that time. Certainly, we are very happy to go over them with the Committee and expand on them if necessary. However, you will note that analysis and interpretation of the research is being undertaken by the National Screening Committee. That work is at a fairly advanced stage. You will also note that the version that you currently have, Chairperson, does not contain a response from Dr Fogarty. We have now received his response to those specific questions. We will forward that to you immediately after the meeting.

That concludes our update on the work that has been ongoing since our previous update session with the Committee. Clearly, a lot of work is going on not only at national level but at Northern Ireland level on raising awareness and on audit issues, the latter of which we hope will inform the National Screening Committee's consideration of all the evidence. I am certainly happy to take any questions or comments, and I am happy to reattend at a later stage and give further evidence to the Committee. In the next number of months, some key and vital dates are coming up, with the initial report on the consultation being published towards the end of March. That may be a key time when members may wish to hear from us again.

The Chairperson: Thank you. Do you want to add anything, Dr Boyle?

Dr Margaret Boyle (Department of Health, Social Services and Public Safety): I have nothing to add at the moment unless members have questions.

The Chairperson: Thanks for your presentation. It is important that the Department is doing as much as possible to raise awareness of group B strep. Nobody can criticise that. I want to make a couple of points before I open the discussion to members. They can indicate to me that they want to ask questions.

Dr McBride, when was the response received from Dr Fogarty? You said that you would make it available to the Committee this afternoon.

Dr McBride: I will defer to Dr Boyle who has been co-ordinating the response.

Dr Margaret Boyle: I have been trying to contact him, and I know that he had been out of the country. I have got comments back from him. I have not got it fully signed off from him, but I have certainly asked him for comments. I know that there are still one or two gaps, but I would expect to get those either today or tomorrow. However, it may be that there are no further comments to be made.

The Chairperson: I appreciate that he has been out of the country. However, it would have been useful to have received it before this meeting. We have just agreed to send a letter to Dr Fogarty with our own questions, and we will do that. However, if we could get the information that you are talking about before the close of this meeting —

Dr Margaret Boyle: I will send up what we currently have.

The Chairperson: If we have as much information as possible, we can come to a collective decision on our next steps. As regards Dr Fogarty, do you feel comfortable with the fact that women who go privately are offered the screening, while those in the health service are not? That does not sit comfortably with me.

Dr McBride: I cannot comment on an individual's private practice. If standards are evidence-based, they should apply in all settings, whether that is in the health service or in private practice. I agree with the Chair's comments that standards are standards are standards, evidence is evidence is evidence, and in my view, those should apply equally, irrespective of where the practice is performed.

The Chairperson: A core principle of the health service is that it is free at the point of delivery. A core principle is the need for treatment not the ability to pay. I cannot understand how somebody who goes privately is able to access, in whatever field, a bit more that somebody in the health service, especially when the person is coming to the Committee to say that technically it is not needed but it is offered privately.

Dr McBride: I genuinely have no knowledge or details personally on any consultant's private practice, so I cannot comment on the specifics. In general terms, there are aspects of care that are available to individuals who pay privately that may not necessarily be available in the health service, but that does not necessarily mean that those aspects of care that they wish to pay for privately should be available in the health service. There are a range of other treatments and interventions that are available in private practice that are not currently available or, indeed, recommended for use in the health service.

The Chairperson: It is on Dr Fogarty's website. We will give you a copy of the letter when he responds to us. However, with regard to the group B strep steering group, someone who chairs it could make a recommendation that people who go privately can access something beyond the steering group's recommendations. Maybe I have got that wrong in my head.

Dr McBride: Just to be clear: Dr Fogarty does not have a role in the work being undertaken by the National Screening Committee. The National Screening Committee is considering all the evidence and has been liaising with Group B Strep Support to ensure that it has analysed comprehensively all the available evidence. It is on the basis of the recommendations and conclusions of the National Screening Committee that advice will be provided to the Departments. Departments and Ministers will ultimately have to make a decision based on that advice.

The RCOG guidance is just that: guidance. It is a clinical utility to help professionals working in that field, but Royal College guidance is not necessarily endorsed by Departments.

The Chairperson: You talked about organising a conference for consultants and midwives. Will he have a role in that?

Dr McBride: It is available to obstetricians and midwives. The obstetrician who is presenting is Dr Robin Ashe, and the neonatologist is Dr Stan Craig. I would be surprised if Dr Fogarty, given his interest in obstetrics and gynaecology, were not attending that. However, I do not know —

The Chairperson: There will not be a formal role.

Dr McBride: No.

Dr Margaret Boyle: As Dr McBride said, Dr Ashe and Dr Stan Craig will cover the two areas on the obstetric and the newborn side of the programme.

Mr McCarthy: Thanks very much for your presentation. You answered a number of my questions, namely about the reports and when they will be published. That will happen towards the end of March, which is good. Will the NSC review be put out to consultation throughout the UK, including Northern Ireland?

Dr Margaret Boyle: Yes. When the NSC produces a review document on any screening programme, it goes onto its website and is available to anyone who wants to comment. It is not a full public consultation, but it is a consultation for professional bodies, organisations, voluntary groups — in fact, anyone who can send in comments. It is usually on the website for about six weeks.

Dr McBride: If it would be helpful, we can certainly bring it to members' attention when it appears on the National Screening Committee's website.

Mr McCarthy: I pay tribute to the excellent work done by Group B Strep Support. I find it annoying that it has taken so much activity by that group to bring this matter to the forefront. It is a pity that it has taken the loss of babies and the resultant stress for so many families to get us to this point. At our previous evidence session on the matter, I raised the issue of producing leaflets. Mr McBride, you said that that is in hand, which is very welcome. Will, or did, Group B Strep Support have any input into those leaflets?

Dr Margaret Boyle: The leaflet that has been issued to the service is the information leaflet produced by the Royal College of Obstetricians and Gynaecologists. There is also general information on group B strep on the Public Health Agency and NI Direct websites. Those have links to various websites, including the BabyCentre and the Group B Strep Support websites, where people can get further information.

Mr McCarthy: Do you accept the good work that Group B Strep Support has done to bring us to this point? This is new. Those people came to our Committee in dire straits; they had lost babies.

Dr McBride: Group B Strep Support is a well-established and highly regarded support group. From memory, I think that it was established in 1998. It is important that we recognise the fact that such groups play an essential and vital role in seeking to raise awareness and the profile of issues that may not necessarily demand the profile that they rightly require. As I said in my introduction, I commend the efforts of local families here in Northern Ireland. Our written response to comments made by Group B Strep Support last time say that those families have shown initiative. It cannot have been easy and, indeed, must have been extremely painful. However, they certainly identified gaps. As I stated earlier in my update, we are moving to identify those gaps, particularly around raising awareness more generally among pregnant women and health professionals. That is vital work, and Group B Strep Support has played an important role.

Mr McCarthy: A letter from Group B Strep Support to the Committee outlines a number of misunderstandings. I will speak only about the first misunderstanding. Will you explain why the Department disagrees with Group B Strep Support and feels:

"The sensitive (Enriched Culture Medium) test for group B Strep is unreliable and misses lots of carriers."

That is only one of a number of misunderstandings.

Dr McBride: Margaret might want to comment as well, but this is a very complex area. There is a range of significant bodies of research evidence. It is vital that we have an opportunity, and allow the National Screening Committee an opportunity, to look at all aspects of the evidence base for screening, the benefits of screening in countries that have moved to screening, the usefulness of different tests and the risk benefit analysis of introducing screening to advise on the effectiveness of screening and the intervention. If this issue were straightforward and not complex, with respect, we

would not be having this discussion. It is probably best to leave that detailed analysis to the work of the National Screening Committee, which will then make its recommendations based on a completely independent review of the evidence and advise Departments. In due course, Departments and Ministers will make decisions. However, I appreciate that the issue is detailed and complex and that there is a range of views and interpretations of the research. As you will find with any research, it is open to interpretation.

Dr Margaret Boyle: I will add a little to that. How the test performs and the evidence around it will be looked at as part of the whole research. At our last meeting, we heard that research papers are coming out of America, France and Italy about the test to look at the effectiveness of the screening. Those places are finding that about 60% of the babies who were infected with group B strep had been born to mothers who were previously screened and shown to be negative. So that raised issues about the reliability of a negative result and how you could depend on that. There are also issues with how well the test is taken, because vaginal and rectal swabs have to be taken and in, I think, the Italy study, the rectal swab was not always taken. There can also be issues with the transport of a test, and there has been guidance from America following some of the findings about such transport. None of those issues is insurmountable if you were to have a screening programme, but they need to be looked at in the totality, because if screening were in place and you suddenly found that 60% of babies affected were being born to mothers with negative results, that raises questions. So we need to look at the totality of the evidence and at the test, particularly at the reliability of a negative result.

Dr McBride: I will not get into the detail because it is complex, and the National Screening Committee will look at all elements of the issue. I know the quality of its work, and I know that it will carry out an exhaustive review of all the literature and research and make recommendations. When there are uncertainties about what the evidence is telling us, the NSC will indicate the need for further research. When it last looked at the issue in 2008, there was insufficient evidence to make a recommendation. That situation may have changed, because there has clearly been further work and research since that time. However, it is complex, and interpretation of research findings can differ, even among individuals who read the same paper.

The Chairperson: A number of members want to ask questions, and others can come back in if we have time at the end.

Mr Durkan: I welcome Michael and Margaret. I hate to focus on an individual, but we have mentioned Dr Fogarty already and the question of the stage at which he changed his mind on group B strep, presuming that he did so after hearing the evidence at this Committee. That would be great and could be down to the arguments of Group B Strep Support and the Committee. However, it would be more worrying if he had been providing those services prior to the Committee meeting, in which case he would have deliberately misled the Committee. I do not know what can be done about that.

The Chairperson: Before you go down that road, we have put forward a series of questions, and once we get the answers, we will be able to come to a conclusion. We need to make sure we do not make any accusations prior to getting that information.

Mr Durkan: I am not; I am asking questions.

The Chairperson: I am just trying to protect you.

Mr Durkan: I welcome the ongoing work of the Department and its collaboration with Group B Strep Support and awareness group. I am glad of the independent review and look forward to the NSC's findings. I hope that it moves forward and is based solely on a medical decision rather than a cost decision because, regrettably, we have had an acute public reminder from the recent incidents in neonatal wards about the fragility and preciousness of babies' lives. So it is vital that we push on this issue.

The Chairperson: Is there a question?

Mr Durkan: Can we? *[Laughter.]*

The Chairperson: I knew that you were coming to a question, and I stopped you. We will leave it there, and perhaps Dr McBride can give us some more information on the points that you have raised later.

Mr Wells: It worries me, Dr McBride, that we took evidence on 14 September 2011 from eminent experts, including Dr Fogarty, only to find, apparently, that Dr Fogarty was so convinced by the strength of our arguments that he is doing exactly what we asked him that he should do. He is now offering tests to expectant mothers privately. That worries me, and we need to get to the bottom of that. Equally, however, during that evidence session, in which Dr Fogarty played a very strong part, we were told, first, that the test was not accurate. Yet Jane Plumb, who wrote to us on 9 November 2011, indicated that her organisation believes that the test is 90% accurate. We have dealt with that already. We were also told that even if you tested all women and the test was accurate, and then administered antibiotics, you would create an even greater danger, because the antibiotics could cause a reaction in the expectant mother, which is more dangerous than the chances of the child being born. However, Jane Plumb's letter states:

"The risk of fatal anaphylaxis in Mum is estimated to be less than 1 in 1·8 million, compared with a risk of fatal early onset GBS infection in babies born to mums carrying GBS … of around 1 in 3,000."

There is a world of a difference between one in 1·8 million and one in 3,000. If we had not had the benefit of the expert evidence presented by Jane Plumb, we would not have been able to contradict the figures that we were given. Now, someone is wrong. My children are long grown up, but if my wife was of childbearing age, and I was given the choice of taking a risk of between one in 1·8 million and one in 3,000, particularly when I know that my wife has never had any reaction to penicillin for other conditions, I know which one I would choose.

I know that you do not want to get into the statistics, but they are at such variance to the information that was given to us in September 2011 that it makes me wonder who is right and who is wrong.

Dr McBride: Thank you for your question, Jim. I am very conscious that Dr Fogerty is not here, and I am very mindful of the Chair's comments. I am not here to speak on Dr Fogarty's behalf; indeed, he will respond, and we will forward his comments to the Committee in due course. This is a complex area, and your question shows that a range of factors needs to be weighed up and considered. Clearly, one of those will be around the effectiveness of a particular test to screen for a particular condition.

There are other issues, to which Margaret referred earlier: the acceptability of that screening test; the effectiveness, then, of the intervention in preventing the problem; and some of the potentially beneficial consequences and associated risks. You outlined some of the risks of anaphylaxis associated with the use of IV penicillin. I note that the Hansard record of 14 September 2011 reported the discussions around the problems associated with antibiotic resistance. There is a complexity and a wealth of issues that need to be considered in the round. That is why all Departments have expert advisory groups that are set up for the purpose of looking independently at all the science, research and evidence, weighing those up against internationally agreed criteria around screening, and providing advice to Departments on the benefit of any particular screening programme.

The National Screening Committee has an ongoing programme of looking at new screening programmes, as it has in this case. I wrote to the NSC to ask it to prioritise that work, given, as Kieran mentioned, the profile that families had raised.

That was due for review, but I asked for it to be brought forward and prioritised. The committee has an ongoing review programme that not only looks at potential new screening programmes — one recent example is the introduction of the screening programme for abdominal aortic aneurysm that it recommended on the basis of analysis of the evidence — but reviews, on an ongoing basis, existing screening programmes in terms of any changes.

It is complex, and, again, with respect, I am not certain that it would be a very productive use of your time to get into the detail of that evidence session at this stage. The National Screening Committee will look at and weigh up all those considerations when it makes its recommendations in due course. I can assure you of that because I am aware of the quality of the work. Margaret, you may want to add something on the specifics.

Dr Margaret Boyle: We all practise medicine on the basis of the best evidence available, and we will welcome the outcome of the National Screening Committee's review because that will, hopefully, give us a direction.

To come back to your more specific point about screening; first, as we said, there are some issues with the test, which the National Screening Committee will look at in more detail, and the evidence around that. Secondly, as I think you are all aware, about 25% of people will carry group B strep organisms, so 25% of pregnant women will carry those organisms. With national screening, it is always about balancing the benefits of anything against the harms that it might create. You have 7,000 women, all of whom will be given antibiotics. Around 12 babies a year will be born affected. We know that, even when women who have been screened or who have risk factors are given antibiotics, their babies can still develop the infection. Therefore, we will not eliminate it, but, obviously, it is about trying to reduce it to a minimum, as far as possible.

When taking a course of antibiotics, there is the potential for side effects and complications and, as was mentioned, anaphylaxis. I think that we would all say that death is a very uncommon event. There was one in Northern Ireland about three years ago, so we are very clear that it does occur. There are also issues around the baby in utero, in the womb. The baby can, as it is being delivered, be exposed to the antibiotics. We do not know if there are potential risks to those unborn babies. A study from about three years ago, the Oracle study, looked at antibiotics given to mothers just before they went into labour. The study followed up on those babies for seven or eight years and found that a significant number had developed cerebral palsy. We are not saying that that is exactly the same situation, because, in most cases of group B strep, women would be given penicillin. In that case, a different antibiotic was involved. However, what is highlighted is that we do not know the long-term potential risk for the babies of those 7,000 women — I say "potential risk" because we do not know if it is definitely there.

Another thing is the effect on the general population. We are all well aware of the issues around antibiotic resistance, infections in hospitals, the widespread use of antibiotics and the impact that that can have on resistance of organisms. So, again, the widespread use of antibiotics could have other effects on the wider population somewhere down the line.

As Dr McBride said, it is really about the National Screening Committee taking all the evidence in the round and trying to come to a firm conclusion based on evidence. It is about balancing the potential harm with the benefit that would accrue. Certainly, with screening, it is always about wanting to do more good than harm, but we know that there are always side effects.

Mr Wells: It would have helped if you had told us in September that the chance of having an anaphylactic reaction is one in 1.8 million. I remember it being said that there was a risk of it happening, and people said, "Oh, that is serious". We have had one death in Northern Ireland in three years, and that is highly regrettable, but, based on the stats and those odds, the chances are that it is highly unlikely that it will happen again for many, many years. If those stats are right, one of the major arguments thrown up against routinely administering antibiotics really does not stand up.

I had never heard of strep B until Jillian Boyd and Group B Strep Support came to see us. I had never heard of pseudomonas until about a month ago. As a result of all the publicity, has there been a change among expectant mothers? Are they questioning the midwives and the gynaecologists about this? Are they asking for the test? Is there a greater interest in this among expectant mothers? Has there been concern, or has it not registered with the general female population who are expecting children?

Dr Margaret Boyle: I do not have any detailed information around that. Certainly, nothing has been brought to our attention by the obstetricians and midwives. That is not to say that it is not happening, but it is not being raised with us.

Mr Wells: So there has not been a rise in demand for the test?

Dr Margaret Boyle: Not that we have been told. That is not the same as saying it has not happened.

Mr Wells: Have there been any further instances of children dying from strep B since the Committee last discussed this in September?

Dr Margaret Boyle: Again, we have not been told that there have been. However, it might only be following a post-mortem that that confirmation is made. Stillbirths and deaths in the newborn are part of the audit that we are currently doing and we are hoping that that will include data from 2011 as well. That information will become available then.

Mr Wells: I expect that had it happened, you probably would have heard about it.

Dr Margaret Boyle: I imagine we would have, yes.

The Chairperson: On the point that the Deputy Chairperson has made, it would be good if we could get any recent information.

Dr Margaret Boyle: I am certainly happy to follow that up.

Dr McBride: Jim, this is far from straightforward. If it were straightforward, we would not be here, we would not be having this discussion and we would not have the National Screening Committee looking at all the evidence. I wish it were straightforward. There are finely balanced judgements here, and it is vital that, in weighing up the evidence, we approach this in a planned, thoughtful and considered way. It is important that any advice that is provided by the National Screening Committee and any decision that is subsequently reached by Departments are based on the evidence of what is to the greatest benefit of mothers and babies. I have no idea what the National Screening Committee will conclude. It is a very complex area and it is vital that we present that to you as openly and clearly as possible, in terms of what we know and what we do not know; what is known and what is not known. There will be gaps in the current evidence and, as Kieran highlighted earlier, there will clearly be differences in interpretation of the research, such that it is. It is not straightforward, and I would not want to create the impression that this is straightforward or, indeed, that anyone in the Department or anywhere else has concluded or formed a view. We will be advised by the most robust analysis of the evidence that can be undertaken, and Departments will make decisions based on that.

The Chairperson: Dr McBride, you said that it is not straightforward and that the Department will look at all that information. Two things struck me in the course of this presentation and discussion. You are well aware that this Committee comes at things with a mature view, but, in a flippant way, can I ask you: why is Dr Fogarty not here? My other question is about the screening that you said was taking place in Antrim Area Hospital until 2011: why did it stop?

Dr McBride: I will deal with your first question, and Margaret can fill in the detail. That was an initiative that was put in place in Antrim Area Hospital; it was not something that was endorsed by the Department. Margaret can give you the details of that particular piece of work.

In relation to Dr Fogarty, just to reiterate, Chair, the Department invited Dr Fogarty as an office bearer for the RCOG in the expectation that it would be helpful to this Committee, given that the RCOG was reviewing its 2003 guidance and Dr Fogarty may have been in a position to advise the Committee on the timescale for that work or how it was progressing. That was his sole purpose for being here, and he attended at the Department's request to assist the Committee in its consideration of and deliberations on the evidence. He attended at the Department's request. He has no formal role —

The Chairperson: He did not seem to help the Department.

Dr McBride: Sorry?

The Chairperson: He did not seem to help the Department. He gave us more questions.

Dr McBride: He has no formal role in advising the Department.

The Chairperson: Did you ask him to come back here today?

Dr McBride: No. As far as I am aware, he was not invited to the Committee meeting today. I have no doubt that, had he been invited, he may have chosen —

The Chairperson: Did the Department ask him to come along today?

Dr McBride: No, we did not ask him to come along today, nor was I aware that an invitation had been extended to him.

The Chairperson: We did not invite him the first time; the Department brought him along.

Dr McBride: I am not certain of the point that you are making, Chair.

The Chairperson: Why did you not bring him along today as part of your delegation?

Dr McBride: We are here specifically to answer the request for the Department to come along. He was invited last time to advise specifically on the issue of the RCOG guidance.

The Chairperson: OK. There is the issue of Antrim Area Hospital.

Dr Margaret Boyle: Antrim Area Hospital provided screening for some time. The screening programme was introduced by one of the paediatricians there and was in place for a number of years. It was subsequently reviewed by the obstetricians and paediatricians, who found that it had not been effective in identifying or preventing group B strep. That is perhaps not surprising, because the nature of the screening programme was that women were screened and swabbed for group B strep when they came to the hospital in labour. In other countries, a woman is swabbed at about 35 to 37 weeks of pregnancy. Often, the result was not back prior to those women delivering their babies. If it was back, staff looked at it in the context of any other risk factors that she might have had, such as premature labour, high temperature, etc. A decision would then be taken on the use of antibiotics. We were aware of that and, as part of the wider audit, we asked Antrim Area Hospital to look specifically at its practice and the screening programme that was in place at the time. That will be part of the wider audit, so perhaps we should wait and see what that shows. However, the decision to stop screening was taken by the hospital itself, having looked at the impact that it had over the years. The hospital felt that it had not had any significant role in reducing the level of group B strep.

Dr McBride: The important point is that we have that information. It is important that we use it to inform the consideration of the evidence and the work that the National Screening Committee is undertaking. We seek to include that to ensure that we in Northern Ireland can contribute to the consideration of all the available evidence.

Mr McCallister: Thanks, Chair. You were not long back in the Committee before taking over. Yours was a fairly rapid rise. *[Laughter.]*

I know that Jim is not a gambling man, but the stats that he gave show that there is a considerable difference in risk. In fairness to Dr Fogarty, when he was here, he very much made the case that this should be evidence-based. Whether or not he provided a service privately is a different matter. When this goes to the screening committee, will it also look at cost and benefit? Will it look at absolutely everything to do with this and make a decision based on that?

Dr Margaret Boyle: First, when you look at a test or screening for a particular condition, you look at whether it is feasible and at all the benefits and harms, etc. If the evidence points very much towards that being something that is good and useful to do, has a health gain and is a benefit, that is the advice that the committee would give. It would be after that that it would start to look at the costs involved. There may be occasions when you could screen and find something, but the cost of doing that would be totally prohibitive. In using the word "prohibitive", I know that there is a thing called quality-adjusted life years that tends to be used. There is a figure for that, above which you would say that it is a very cost-effective thing to do. It is about whether the evidence supports the introduction of a screening programme. If the evidence is there, that would indicate that that is the right thing to do. That is when you would start to look at the costs involved. However, there is no point in looking at

costs if you do not know that it is a useful thing to do, and, obviously, the costs have to consider potential benefits as well as harms. Those are all included in the equation.

Mr McCallister: Have you handed over to the screening committee some of the evidence of the experience in Northern Ireland in an impartial way, or have you been trying to say what you think might work? Did you just hand over the evidence and say, "Look at this. Here are our experiences."? Did you highlight some of the things that you mentioned, for example, the screening trial in Antrim and the downsides of that over the time that it was done? Maybe it was not the optimum time to be doing that.

Dr Margaret Boyle: At this point, we have not handed anything over to the screening committee. We are hoping that the ongoing audit might help to inform the screening committee when it evaluates the evidence and comes to conclusions. I am sure that it will be looking at information and audits from elsewhere in the UK, but it is also about the wider published evidence, which is much more rigorous in terms of how the research is conducted. However, that would certainly be personal experience —

Mr McCallister: So the screening committee will look at stuff from around the world to see where things can be pulled in and to establish the issues around it, the timing, what type of test to use and the difficulties around that. I suppose the difficulty for us — Michael touched on this earlier — is that, when this goes wrong, the consequences for the family are heartbreaking.

Dr McBride: Absolutely.

Mr McCallister: Many of us here have a family, and we could clearly see that the experience was just devastating for the groups who presented evidence to us.

So, at the minute, the process is entirely with the screening committee and your only real input was to ask it to bring forward the evaluation?

Dr McBride: You raise a very important point. To clarify; the Department's mind is completely and absolutely open on this. We want to be informed by the evidence and the research, which clearly determines what the right thing to do is. The National Screening Committee will look at all that evidence. The Department does not have a position on this, other than the fact that it will, as it does with all its screening programmes, continue to take advice on existing screening programmes from the National Screening Committee, which will look at the evidence on an ongoing basis as part of its reviews and will move to implement new screening programmes, subject to the Department's consideration and, ultimately, the Minister's decision — if, indeed, the committee recommends a new screening programme. However, there is absolutely no situation where the Department will be conveying a view to the National Screening Committee around the appropriateness or otherwise of a particular screening programme, other than to say, as I have said in a communication to the chair of the screening committee, "This is a priority; please bring forward your planned review."

Mr McCallister: You are writing in that capacity in response to the discussion that the Committee had with Group B Strep Support and saying that we need to look at the matter, make sure that we are absolutely right about it and see whether new evidence has come to light.

Dr McBride: Absolutely. If there is new evidence and the National Screening Committee identifies that, and if Group B Strep Support has identified other evidence that the National Screening Committee has not identified as yet, it is important that that is flagged up and that there is an absolutely and completely open, transparent and full assessment of all the available evidence. It is in all our interests to make sure that the right recommendations are made based on the best evidence that we have.

Mr McCallister: If the outcome is that the screening committee recommends screening, presumably we could put it in place fairly quickly?

Dr McBride: Obviously, there would be a process. The National Screening Committee will make recommendations to the UK Health Departments. Ministers will need to consider those recommendations, and there is then a process of considering how they might be implemented and what infrastructure and additional training would be required — if, indeed, that is the recommendation

— and what additional resources might be required. There would have to be a process to consider any recommendation, no matter what is recommended. The screening committee will make recommendations, whether it is to introduce a screening programme or not to introduce a screening programme or to introduce something short of that. I honestly do not know what the recommendation will be, John, but what I would hope for is, as Margaret said, a clear direction from the committee's work on looking at the available evidence.

Ms Lewis: Thank you, Michael and Margaret, for attending today. I welcome the awareness-raising measures that have been put in place. From memory — Chair, you were not at the meeting — I do not think that any of the mothers of all ages of children who were there that day had ever heard of group B strep. We are glad to hear of the measures that have been put in place. I really look forward to the NSC review. I am very glad to hear that the Department has an open mind on that because, given the previous session, I think that it is fair to say that that is not the impression that we were getting from that meeting. To be perfectly honest, it seemed to be particularly weighted one way.

You mentioned the screening in Antrim Area Hospital. I think that I might have been responsible for raising that; a GP advised me that he thought that it was routine, and we then asked the question. What is the name of the paediatrician who introduced the screening at Antrim?

Dr Margaret Boyle: I think that it was John Jenkins, but I would have to seek clarification.

The Chairperson: We will see whether he gets an award. Earlier, we went through the awards to consultants.

Mr Durkan: The other one did.

Ms Lewis: Obviously, we Health Committee members are by no means medical experts. Maybe some are more expert than others, but I am certainly not. From what we have heard, the evidence appears to be there. We await confirmation of that, but it seems that screening would be a common-sense approach. As a mother, I know what way I would have chosen had I been given a choice and had I known the risk involved.

Mr Dunne: I welcome the panel this afternoon. Most of my points have been covered. We all appreciate that you have increased awareness among patients and expectant mums, and you have gone through various ways of doing that. Do you have any way of exploring whether that work is being carried out? Obviously, you have issued guidance at your level, but is there an assurance that it is happening and that people are being informed?

Dr Margaret Boyle: Yes. As Michael said earlier, he wrote to Eddie Rooney, who is the chief executive of the Health Promotion Agency, to ask him to take forward work around that. We have had written confirmation from the agency that it has issued the RCOG information leaflet to the hospitals, trusts and GPs. It said that it will issue another one when the new RCOG guidance comes out. We are aware that the section on group B strep in the 'The Pregnancy Book' has been updated and has been incorporated into the new edition. That book is given to every woman who is pregnant, and the new edition is out this month. As we said, the sticker has also been produced. It goes into the intrapartum section of the woman's handheld notes. It is an alert to the health professionals to tick whether the woman has any of the listed risk factors. Obviously, if she does, they need to consider antibiotics. That is very much an interim or temporary measure until the next update of the handheld records, at which point it will be a full page. Again, the information about group B strep is already on the Public Health Agency website and the NI Direct website. Those things have all happened.

Mr Dunne: So it is all part of managing the risk. You mentioned the sticker. I take it that that is part of the process of how you manage the risk? At the moment, patients are monitored on an ongoing basis. It is about where the risk is identified. Obviously, you or your professionals have identified expectant mums who are at risk. Are they tested when the risk is identified?

Dr Margaret Boyle: They are automatically given intravenous antibiotics in labour. That is part of the Royal College guidance; if a woman goes into preterm labour, before 35 or 37 weeks, she should

automatically be given antibiotics intravenously. That group of women is particularly at risk of having babies with group B strep.

Mr Dunne: It is important that you are managing the risk in certain areas.

Dr Margaret Boyle: That is something that has been in place for many years. Obstetricians and midwives assess the mums. They will consider giving antibiotics in situations where a mum goes into premature labour, has had a previous baby affected by GBS, has a prolonged rupture of her membrane, for over 18 hours, has a high temperature during labour or has had a swab or urine test taken during pregnancy for another reason and group B strep happened to be found. A risk-management programme is in place. That has been the basis of the 2003 college guidance. It is not as though we are not doing anything. We are. The whole risk-management process has been in place. Certainly, the college reckons that, by managing that number, we are probably identifying 60% to 70% of the women who might be at risk of having an affected baby.

Dr McBride: You raise a vital point. It is one thing to say that we have guidance and the prompt of a sticker on the chart. It is another to follow and adhere to that guidance on an individual basis, time after time after time. The audit is, basically, about seeking assurances that that is occurring, and, if it is not, taking action to ensure that it does occur. Obviously, the other element of that is raising awareness in the interim while we conduct the audit and see its findings.

Mr Dunne: So that is how you are managing the risk, as opposed to doing full screening.

Dr Margaret Boyle: Yes.

Mr Dunne: The argument now is whether or not we do full screening. Is that what we are moving towards, or will this continue to be managed on a risk basis?

Dr Margaret Boyle: The question of screening has always been raised. I appreciate that maybe not everyone has heard of group B strep before, but it has certainly been on the agenda of the National Screening Committee for many years. Back in 2003, it looked at the evidence around this and came to the conclusion that there was insufficient evidence to support a screening programme. The committee reviewed the evidence again back in 2008 and came to the same conclusion. However, there is always new information and new evidence being published, which is partly why the committee has a three-year rolling programme to try to look at all the screening conditions that it has reviewed, if new evidence comes round. In fact, if any important evidence comes out, it will review a programme quicker than that. This was part of its programme of reviews, but, as the Chief Medical Officer said, he asked for it to be prioritised and done more quickly. It was always on the agenda for this year, but it was about getting it further up the agenda.

Dr McBride: It also raises a legitimate question in the public's mind. There is the same body of evidence, and everybody should be looking at the same body of evidence, yet different countries have taken different approaches. There is a question as to why that is the case. It is complex. It is complicated. Everyone should be looking at the same body of evidence. When you look at that evidence, you have to ask the question: why have certain countries made the decisions that they have and other countries made a different decision? Up until the time of the previous review in 2008, the National Screening Committee was saying that there was insufficient evidence for it to give a clear direction on this. As I said, we do not know what the latest review will determine or, indeed, how much more evidence there is or how much more evidence is required for the committee to give a clear direction on this issue.

Mr Brady: Thank you very much for your presentation. My question follows on from what Jim and Pam said. I had never heard of strep B, but, interestingly enough, on a personal note, my daughter-in-law was expecting just after the time when we got the evidence. Having met Group B Strep Support and listened to the evidence, I broached the subject with her. She tested positive but had not realised the implications of what was involved. She was given antibiotics during labour and, thankfully, has had a nice, healthy baby. However, that was not offered as a routine thing.

If I had not brought up the issue and we had not discussed it, she would not have been aware of it. Jim talked about the statistics, and there is a huge difference between one in 1·8 million and one in 3,000. It was her second baby. Are there any statistics about someone who did not test positive for group B strep during the pregnancy of a first baby but does test positive in a second pregnancy? If a woman gets through one birth and everything is OK, perhaps there is an assumption in the public's mind that there will be no problem with the second pregnancy. However, she tested positive with the second baby and was able to get the test simply because she asked for it and discussed it with the obstetricians.

In my view, the Committee has done something positive. The issue would not arise if women were screened routinely. Women could have three or four children, and it might happen only with the fourth or fifth pregnancy.

Dr Margaret Boyle: Even if a woman is screened between weeks 35 and 37 of her pregnancy, the organism may not even be present when it comes to the delivery. It is a transient organism that colonises, and 25% of us will carry it. It can be here now and may not be here next week because of its transient nature, and there is no way to predict that. If a woman has it during one pregnancy, it does not mean that she will have it during the next pregnancy, and vice versa.

Mr Brady: You mentioned costs earlier. How big a factor is that in certain hospitals or trusts? Sometimes, that question has to be asked. If Antrim Area Hospital was doing the screening and stopped, was that decision taken on medical or on cost grounds? I am not being facetious when I ask that question.

Dr Margaret Boyle: It is a very relevant and important question.

Mr Brady: Perhaps it needs to be investigated.

Dr Margaret Boyle: My understanding is that it was a clinical decision between the lead obstetrician and the lead pediatrician or neonatologist for the hospital.

Mr Brady: You talked about anaphylaxis or anaphylactic shock. In the current day and age, it would be assumed that the majority of people will have had some experience of antibiotics such as penicillin or ampicillin. People can get anaphylaxis from nut allergies, and so on, but it would be assumed that women of childbearing age would, for whatever reason, have some previous experience of antibiotics and the risk of allergy would be known.

Dr Margaret Boyle: You are right; an awful lot of people will know whether they are allergic. However, some may not know.

Mr Brady: As Jim said, there was, unfortunately, one case in three years. In statistical terms, however, it is a minimal risk.

Ms P Bradley: I want to pick up where Mickey left off. At the beginning of the meeting, we were rather negative, but there have been many positives in the past few months. What Mickey told us about is very positive and had a happy ending. The update in 'The Pregnancy Book', the stickers on the medical notes and the higher priority for the review is good and positive news, and we have to look at it positively. It is not all negative. The worst part is yet to come: when the evidence comes back and decisions have to be made, many more questions will be asked.

We need to say well done to the people who wrote to the Committee initially and asked for the issue to be highlighted. It shows how much work the Committee does and how it pushes issues forward and scrutinises them. I welcome everything that you have said today, and I look forward to your next visit, because that is when hard decisions will need to be made.

The Chairperson: Thank you, Paula. I said at the start that it is important that we raise awareness, especially of group B strep.

Ms P Bradley: This is doing that, which is good.

The Chairperson: We are the conduit between our constituents in the community and the Department. Although it might come across as though we are battling, what we are trying to do is to get to the bottom of the issues. Some comments that were made at the previous evidence session did not sit well. We need to try to get as much information as possible out to expectant mothers and families and, indeed, to people who might decide to have children in the future.

We asked you a number of questions, and you have agreed to provide some other information in evidence to the Committee. I would appreciate if we could get that as quickly as possible. On behalf of the Committee, I thank you both for coming up today. I have a few other questions, but I will hold them for a while until we receive the information that you will provide. Thank you for coming.

Dr McBride: Thank you. You mentioned that you might give me an opportunity to make a few closing comments. First, I thank the Committee for its attention and for the time that you have given us today.

Dr Fogarty and Dr Craig, who attended the previous evidence session, are health professionals. They are not departmental officials and are not necessarily familiar with the workings of Health Committees or their scrutiny process. They attended at our request to assist the Committee. If there are any issues with the evidence that was given, how it was given or its preparation, I accept responsibility for that on behalf of the Department.

We are all committed to doing the right thing, whether as parents, elected representatives, Committee members or professionals working in this area. As Margaret said, we are also very mindful of the fact that any screening programme has the potential to bring about significant benefit, and many screening programmes do that. However, in considering the introduction of screening programmes, we also have to consider the potential for harm. We are all committed to ensuring that we do the right thing based on the best available evidence.

I am very happy to appear before the Committee in due course. I agree with Paula's final comments that decisions will need to be taken. Hopefully, we will get a clear direction in the National Screening Committee's recommendations for us to consider and for the Department to advise the Minister on in due course.

The Chairperson: Thank you. It is useful to get as much information as possible when it is available. Once again, on behalf of the Committee, I thank Dr McBride and Dr Boyle for appearing at the Committee and for updating us.