HOUSE OF LORDS

Preterm Birth Committee

Corrected oral evidence: Preterm birth

Monday 11 March 2024

4.40 pm

Watch the meeting

Members present: Lord Patel (The Chair); Baroness Blackstone; Baroness Cumberlege; Lord Hampton; Baroness Hughes of Stretford; Baroness Owen of Alderley Edge; Baroness Seccombe; Baroness Watkins of Tavistock; Lord Winston; Baroness Wyld.

Evidence Session No. 10 Heard in Public Questions 135 - 148

Witnesses

I: Professor Alexander Heazell, Professor of Obstetrics, University of Manchester; Dr Jenny Carter, Research Midwife, King's College London; Professor Neena Modi, Professor of Neonatal Medicine, Imperial College London.

Examination of witnesses

Professor Alexander Heazell, Dr Jenny Carter and Professor Neena Modi.

Q135 **The Chair:** Good afternoon. Thank you for coming today to help us. You are an important group, because we have a midwife, an obstetrician and a neonatologist to nail the issue of the consistency of care in obstetrics, midwifery and neonatology, which we can hear about from you. Can you introduce yourselves so that we get on record who you are and what you represent? As well as the main questions, my colleagues will have some supplementaries. We are now on broadcast, so we are being listened to by whoever in the world is interested in this session.

Professor Neena Modi: I am professor of neonatal medicine at Imperial College London and honorary consultant neonatologist at Chelsea and Westminster Hospital. I have held a number of professional leadership roles in my career, including as president of the Royal College of Paediatrics and Child Health, the Medical Women's Federation and, most recently, the British Medical Association. I have also led two relevant academic societies, the Neonatal Society and the Academic Paediatrics Association of Great Britain and Ireland. I am a fellow of the Academy of

Medical Sciences and the incoming president of the European Association of Perinatal Medicine.

Professor Alexander Heazell: I am professor of obstetrics at the University of Manchester and an honorary consultant obstetrician at Saint Mary's Hospital in Manchester. I am also the director of the Tommy's stillbirth research centre at the University of Manchester and the regional lead obstetrician for the north-west of England.

Dr Jenny Carter: I am a midwife by background. I have worked in women's health research for over 20 years. For the last 12 or so years, I have worked with Professor Andrew Shennan and his team at St Thomas' Hospital and King's College London. I am a founder member of the UK Preterm Clinical Network, and I set up and manage the UK Preterm Clinical Network Database. I was inspired to become a midwife because of the Winterton report and *Changing Childbirth*, the report of the group that Baroness Cumberlege chaired in 1993, so thank you for that.

The Chair: It obviously did a lot of good.

Q136 **Baroness Wyld:** Good afternoon to the witnesses. I will start the questioning on clinical guidance by asking about the Saving Babies' Lives care bundle and what you think the impact of version 2 has been on outcomes for preterm birth?

Moving on from that, what will be the impact of version 3? Can you talk about how it sits alongside the NICE guidelines and say whether you think that is working well in practice? Might there be a case for consolidation of guidance? I am looking at you, Professor Heazell. I know you have done a lot of evaluation of this, so perhaps we could start with you and then go to the other witnesses.

Professor Alexander Heazell: Thank you for the question. We are in the midst of evaluating the second iteration of the Saving Babies' Lives care bundle, using a mixture of nationally available data through the maternity services dataset and the neonatal research database, which Professor Modi leads. One challenge we have in that evaluation is disentangling the effect of Covid from the effect of what happened to women's outcomes during the same period. When there is a policy change or something is implemented, one challenge is that we are often trying to evaluate its effectiveness post hoc, so we are looking at changes over time. Up to 2020, there had been a fall in preterm birth rates from about 7.95% to about 7.4%, but there was a bounce back up in 2021, and we saw similar outcomes in neonatal death and stillbirth.

Admissions to the most severe neonatal intensive care units on the neonatal research database—the data that we are looking at—have shown a slight decline, although overall neonatal unit admissions are up. That shows that there may be a reduction in the most premature babies, who have the worst outcomes, but I would defer to Professor Modi to give us that data.

You asked about the NICE guidelines. Looking qualitatively, one thing the care bundle is about is implementing what we have in our best practice guidance. The NICE guidelines tell us what we should do but not how to go about implementing that, while the care bundle is about operationalising what we have. The staff feel overwhelmingly positive about the preterm birth clinics: that they are allowing intervention to be tailored and delivered to the right women. That is echoed by service users. They identified some areas for improvement, particularly in making sure that choice of mode of delivery and things like that were still offered in preterm birth, but another encouraging thing is that service users reported particularly seeing a joined-up approach from the obstetric, neonatal and midwifery services, such that, when a baby is going to be born preterm, we are optimising babies better, which we hope improves outcomes.

Professor Neena Modi: Data are complicated, and we have not conducted an analysis of the Saving Babies' Lives care bundle yet. I can give you, if it would be of interest, a broad-brush picture of what has happened in the country over the last 10 years. This is an analysis that we have almost completed and will submit for publication soon, so I crave the Chair's indulgence. It is not finalised and has not yet been peer-reviewed, but I present it as it currently stands.

We have done an analysis of trends in England and Wales over the last 10 years using our national neonatal research database, and what they show is very interesting. First, over this 10-year period there has been no statistically significant change in extremely preterm and very preterm births. Very preterm births are babies born between 28 and 32 weeks' gestation, and extremely preterm are those below 28. There have been fluctuations, so depending on where you cut your data you might, for example, see a fluctuation from one year or one period of time to the next, but over the 10-year period there has been no change.

There is a lot of data here, so please stop me if I give too much. We also looked at changes in the delivery of some cardinal processes of care. This includes antenatal steroids, birth in a level 3 neonatal intensive care unit, birth by emergency caesarean section, and whether the baby was getting their own mother's milk at discharge. The delivery of these care processes has all improved over time, but unfortunately their delivery does not seem to have translated into improvements in outcomes. We also looked at a series of key outcomes: we examined bronchopulmonary dysplasia, retinopathy of prematurity and all the standard important preterm conditions, and there has been no statistically significant change over 10 years in most of those conditions.

I have to say that this is a broad-brush picture over the whole of England and Wales. We have also been looking at regional differences but have not looked specifically at the impact of the Saving Babies' Lives care bundle. As you would expect, there is variation by geographical region, by socioeconomic deprivation, by ethnicity and so forth. There is a lot more data there, but I will stop.

Dr Jenny Carter: Saving Babies' Lives version 2, with the introduction of element 5, was exciting for us working in preterm birth. It was the first time we had ever had guidance like it for the care of women and identifying those who should be seen. It has definitely helped to improve things, and I think version 3 will carry that on. We were particularly happy to see the introduction of the recommendation that midwives should be part of the multidisciplinary team. Most preterm clinics that I am aware of will also have a midwifery input, which is really important, because continuity of midwifery care is one of the very few interventions where there is a lot of evidence of it reducing preterm births.

The Chair: I am aware of that study, but can you give the figures and evidence so that it is on record?

Dr Jenny Carter: I do not have them at my fingertips at the moment, but there are a number of reviews—the Cochrane review and, I think, Sandall in 2016—and other studies since that have shown a reduction not just in preterm birth but in fetal loss. Because of Covid, unfortunately, a lot of initiatives to increase midwifery continuity of care have been shelved a bit at the moment because of staffing and stuff. I am not sure where we are on getting back to that, but I hope we will. It has improved, but it is difficult to know exactly in what way, because the data is quite poor. In neonatal services, the way the data is collected is much better and much more consistent, but on the pregnancy side of it I am afraid it is still not done very well.

Baroness Wyld: Would you say that you have not seen the better co-ordination that Professor Heazell pointed to?

Dr Jenny Carter: There has been an improvement in the services provided, but it is difficult to get a really good ongoing or concurrent picture because of the way trusts collect data. They all have different electronic records systems, and the maternity systems within those are even more different, so it is difficult to capture the ongoing data. We have a solution to that in our preterm clinical network database, but at the moment not all services are using it.

Q137 **Baroness Wyld:** When you started, you had quite a positive outlook: you said that the saving babies care packages have improved things. What main piece of evidence would you give to the committee on what improvement you are most pleased with?

Dr Jenny Carter: There have been surveys of hospital trusts asking whether they have preterm clinics and what services are provided in those clinics, but those surveys do not happen that often and we would want to see some ongoing monitoring so that we can constantly keep an eye on what everyone is doing, what the variation of care is and how we can identify gaps.

Baroness Watkins of Tavistock: My understanding is that directors of midwifery are now accountable, wherever possible, for delivering continuity of care in how they structure the use of their workforce. You

look as if you do not think that is happening.

Dr Jenny Carter: That is the aim, but in practical terms, with understaffing and everything, they have sort of put it on a back burner. It is not happening as much as it should be.

Q138 **Baroness Wyld:** There are a number of things in version 3 that one would obviously hope will improve outcomes a lot. How confident are you about the implementation?

Professor Alexander Heazell: On version 3, because implementation has been incentivised through a maternity incentive scheme, units are taking that up. I would just differentiate slightly between spontaneous and non-spontaneous preterm birth. We are obviously focusing on element 5 of the care bundle, which looks at spontaneous preterm birth, but through better management of diabetes, which is element 6 in version 3 of the care bundle, and trying to get fetal growth restriction and pre-eclampsia prevention, we anticipate that that should also reduce preterm birth but not the spontaneous preterm births, the iatrogenic preterm birth for complications of pregnancy.

The Chair: I am interested that you used the word "iatrogenic", which does not quite apply. It is disease-oriented in preterm.

Professor Alexander Heazell: Yes, disease-oriented. I meant provider-initiated birth rather than spontaneous pre-term birth.

The Chair: Dr Carter, what I was trying to emphasise about the role of midwives, which you rightly bring out, was that the Cochrane data, which I saw recently, clearly shows that continuity of care via midwife support brings in a reduction in primary preterm births of over 30%. It is quite impressive that continuity of care provided by a midwife will reduce the rate of preterm birth in people with no history of any complication. It is unfortunate that it is now not possible to provide it because of Covid, as you say, and because of a lack of staffing. Is that a point you would make?

Dr Jenny Carter: Yes, sadly, but we have been trying to do continuity of care for a very long time—since 1993.

Q139 **Baroness Hughes of Stretford:** Good afternoon. It is good to see you. Thank you for coming. We have heard quite a lot in various sessions, including today, about the variation—particularly, let us say, in England—in the implementation of current guidance not only on outcomes for the children, with inconsistency in interventions, but on mothers who look to be at risk, for one reason or another, of having a preterm birth.

We want to dig under the skin of this. It might be quite obvious to you. I do not know. We have heard some suggestions, but what would you say are the primary causes of that variation? People have mentioned staffing and standard things like that. How could the inconsistency be addressed? What is the trajectory? Are people focused on that and saying that they have to get better at it? Will the latest Saving Babies' Lives care bundle—

version 3—help to improve consistency? There are a number of sub-questions wrapped up there, for which I apologise. I will repeat any that you want me to.

Professor Alexander Heazell: I anticipate that ongoing iterations of the care bundle will improve consistency of care. Our evaluation of the first version of the care bundle showed, in relation to screening for fetal growth restriction, that providing the structure to enable individual NHS trusts to risk-stratify mums appropriately and to provide a specialist pattern of scans, for example, led to improvements in the number of scans provided and, consequently, in outcome.

So, by the same token, I would expect us to be able to see a change in the preterm birth clinics and how that is structured. In our own region, we now have specialist preterm birth clinics in all our individual provider trusts, and they have formed a network that has enabled us to undertake region-wide quality improvements initiatives. So instead of 19 NHS trusts doing something slightly differently, we can do them as a block, enabling providers to meet the needs of their individual clients but also providing the structures by which we can generate improvement.

One thing we learned from the first care bundle evaluation was that there is huge variation in the clinical guidelines that individual providers use. One problem with providers is that we take best practice from NICE or from the care bundle that individual providers might adapt for their own local context. Sometimes there is a temptation to water it down and say, "I can't provide that preterm birth clinic, because I don't have the resource, so I won't write that into our clinical guidance". We have to say, "This is what best practice is. How do we facilitate that in our maternity service?"

Q140 **Baroness Hughes of Stretford:** That seems quite important. I had not anticipated that providers would be able to rewrite the guidance to some extent. That could explain some of the variation.

Leaving that point aside, in relation to a trust or even a unit, who has the accountability for trying to pursue best practice and for monitoring the level of performance against the guidelines?

Professor Alexander Heazell: I can answer that from an obstetric point of view. Ultimately, the clinical director of the unit and the director of midwifery are responsible for the clinical output of that unit and have to report to their board. Each unit will also report to its ICB and local maternity and neonatal system. I cannot speak for other regions because I do not know how they structure it, but we have a regional dashboard that reports all our preterm birth rates. So as regional lead obstetrician for the north-west of England I can see all our units, and we can see where we have outliers and changes in trends. So the system is able, and should be able, to see these patterns.

Then we have the specific optimisation work, which Professor Modi might be able to comment on, such as making sure that when a baby is born

preterm it is born in the right place. Again, we have a work package whereby the region sees that at our improvement meetings.

Professor Neena Modi: I completely agree with everything that Professor Heazell said. I will add a couple of points. Inappropriate variation is not advisable, but not all variation is bad. I absolutely agree that guidelines are guidelines, and a practitioner should feel able to modify those guidelines depending on the requirements of the particular patient in front of them. So not all variation is necessarily bad. The challenge, therefore, is to work out what variation we should want to eliminate and what degree of variation is acceptable.

The second important point is that the application of a care bundle or a guideline may not be wise if it is not well rooted in strong evidence, because if your guideline is based on a consensus view and not on evidence, that consensus view may be imposing on every patient what will ultimately turn out to be a poor practice. We have very good evidence to show that inappropriate understanding of the nature of guidelines is in some quarters turning out to be an impediment to the conduct of research that is trying to identify the evidence of best practice.

My third and final point is about consistency. You can have something like antenatal steroids, which are very well evidenced to improve outcomes. However, the World Health Organization hit on a tricky problem when it tried to implement this globally, including in low and middle-income countries. Several billion pounds and two very large international studies later it was forced to retract its original advice and modify its original guidance quite substantially, because it found that implementation that worked in one setting was not appropriate for another setting.

So there are some important caveats about the nature of guidelines and the extent to which you can assume that they will necessarily deliver what we all hope they will deliver.

Q141 **Baroness Hughes of Stretford:** Can you give any examples of guidelines from NICE or the care bundle that you think are based more on consensus and groupthink as opposed to being strongly evidence-based? It seems to me that if you start saying that not all guidelines are good things and that some might not be very strong, you are kind of pulling the rug from under everybody. I am quite concerned about that.

Professor Neena Modi: There are certainly a number of guidelines in existence in every speciality in the NHS—and, indeed, around the world—that are based on consensus opinion. Of course, we have not only local and national guidelines but international ones, and these guidelines may not necessarily be in accordance with each other.

One example of an area where you very often come across consensus-based as opposed to evidence-based guidelines is in my own research field of preterm nutrition. It is incredibly important, because every baby has to be fed, but there is a very scant evidence base to guide this. So in

the interests of trying to bring about some consistency in care, we very often see the use of consensus-based guidelines.

The Chair: But, focusing on England on Wales and not on any international low-income countries, the point that Baroness Hughes is making has to be correct: that any guidance that is based on sound evidence, such as antenatal preterm steroids, has to be followed in the United Kingdom and has to be in the guidelines. That is not a consensus view. That is an evidence-based, researched view.

Professor Neena Modi: I absolutely agree with you. Antenatal steroids and their use in this country are a very good example. There is extremely strong evidence that they are effective and that everyone should be doing it. That is why its use has been audited for quite some time and why, as a community of practitioners, we are very pleased to see that antenatal steroid coverage has gone up steadily over the years.

Having said that, I repeat my earlier point that it is disappointing that this is not translated into an improvement in morbidity-free survival in preterm babies. We do not understand the reasons for that.

Dr Jenny Carter: I can give an example by looking at element 5 of Saving Babies' Lives. One relatively recently identified risk factor for spontaneous preterm birth is a previous in-labour or full dilatation caesarean section. We have not yet got to the point where we have a randomised control trial that shows that, so NICE would not be interested in considering it because it does not consider any evidence below RCTs. But there is increasing evidence that this is a major risk factor for some women—not all. Obviously, there are lots of women who have full dilatation caesarean sections in the second stage of labour who do not go on to lose their babies, but we are doing lots of research and looking at MRI scans and all sorts of other things to try to identify the women who do need to come into those clinics.

So there is evidence, and it is growing, not enough to satisfy NICE but enough to satisfy enough experts in the field to say, "We want this in the Saving Babies' Lives care bundle as a recommendation that these women should have some sort of review by preterm specialists". Some people might not agree with that, but most of the preterm experts do.

The Chair: That is always the problem with the observational studies that you describe, as opposed to properly conducted randomised studies. At what stage of labour was there a cervical full dilatation? Was it 8 centimetres or whatever higher level of dilatation of the cervix, and what kind of caesarean section was done? People are taught to do lower-segment caesarean sections as low as they can. That runs the risk of incising the cervix that was dilated quite far on, and not making an incision on the uterus, and that would raise the incidence of cervical damage and therefore preterm labour.

So it is a long way to go from an observational study to recommending something, because there are several stages where the damage could

have been done. You are quite right that we need evidence, because otherwise you will increase the caesarean section rates.

Dr Jenny Carter: We do not want to do that. At the same time, the women who have this problem have it really early—

The Chair: This needs to be investigated. I get that point.

Dr Jenny Carter: —and they will often lose two babies at about 20 weeks before they come to us. It is awful, so we really want to reduce that.

The Chair: I agree with that.

Q142 **Baroness Blackstone:** I must begin by declaring an interest, as I am lay chairman of the RCOG's trust. I would like to follow up on some things that have already been said to ask, perhaps starting with Professor Modi, what the integrated care boards and other regional organisations, for that matter, should do to take action to increase the consistency of what is happening in their own areas?

Professor Neena Modi: We have very good national data for neonatal outcomes. This is held in the National Neonatal Research Database that my group manages, so we have the wherewithal in this country to monitor outcomes very carefully indeed. I would like to separate out the delivery of processes from the delivery of outcomes. We can monitor processes too, but what we are really all after is improving outcomes for our patients.

With technological advances, we are in a position in this country, although we are not doing it yet, to examine our outcomes across the country, and not just in a small area, because you need large sets of data to have sufficient statistical and mathematical robustness to identify genuine changes. We have national data, so we could do that.

Integrated care boards need to work in tandem, not just in their own patch, because any individual integrated care board is unlikely to have the statistical power to detect meaningful changes. But they could do that if they were doing it in a concerted and integrated way in collaboration with all the other care boards. This calls for national co-ordination, and we are unique among countries in the world in having the ability to do this, and we can do it in increasingly sophisticated ways. I probably did not mention this earlier, but variation in outcomes may be due to variations in the nature of the patient—case mix. But again, with sophisticated approaches to handling big datasets we can adjust for differences in case mix, so we can get an idea of comparing apples with apples and not comparing apples with pears. As I say, this is within our grasp.

Q143 **Baroness Blackstone:** Should they get reasonable access to national data that would help them better understand why these inconsistencies exist and the ways of approaching and dealing with them? Is that data easily accessible and available?

Professor Neena Modi: Yes, it is all about data management and streamlining data flows. Prior to Covid, we were in close discussion with what was then NHS Digital about streamlining data flows out of electronic patient record systems and creating automated algorithms to quality assure and curate the data. I have to emphasise that it is really important that data are quality assured, because data that are simply sucked out of an electronic patient record system are what can loosely be called—forgive the language—dirty data. They need to be curated and quality assured, but with modern approaches to data handling you can automate many of the quality assurance algorithms and do so quite rapidly. I am afraid that those discussions fell by the wayside during Covid, but we look forward to picking up on them again. I repeat that this is within our grasp as a country and it would be incredibly impactful to patient care to be able to have high-quality, good, analytics delivered back to the providers of care at timely intervals.

Q144 **Baroness Blackstone:** Can I come back to something you mentioned earlier, Professor Modi, but perhaps ask your two colleagues to comment on it? You said that there was a very disappointing result from some research that has been done, which shows that although the guidance has led to great improvements in the processes, the actual outcomes do not seem to be budging or getting any better. Why might this be? There must be some hypothesis at least about what is preventing an improvement in outcomes given that the processes have all been adopted.

Professor Alexander Heazell: There can be a variety of reasons for changes between what you see in a clinical trial and what you see in the real world. It is very important that we have the quality of data that Professor Modi has alluded to. Are those changes that we saw happen in a clinical trial and would expect to see in the real world actually happening?

There is a whole variety of reasons why that may be. First, it may be that the clinical trials are carried out rigorously on a specific group of patients, and then you use that technique or that drug in the dirty, real world and that benefit may not translate. Secondly, the way the intervention was being delivered may have differed in the real world. There is compelling data about the benefits of delayed umbilical cord clamping on preterm babies, for example, yet it has taken such a long time for that to get into clinical practice. We still see that there is a debate: should we clamp the cord after a minute, after two minutes? Even there, there will be individual variation in what we are doing. That sometimes accounts for it.

Sometimes it is simply a matter of statistical power. For some of the rarer, most severe outcomes, even with a national database you may sometimes need time to accrue enough cases to see whether there is a reduction in things like neonatal death, because overall survival rates, even for extremely preterm babies, are very much better than they were. The difference between 92% survival and 90% survival requires quite large numbers to determine.

Dr Jenny Carter: I very much agree with Professor Modi that we have the potential with the NHS and NHS data to look at this on a national rather than regional scale. I wish that the maternity and pregnancy side of the data was as good as the neonatal stuff. We have the potential to do it, but at the moment each trust has control over the procurement of its IT systems, electronic records and budgets for that, which to be honest just seems totally potty to me and to everyone I speak to who works in this. We talk about trying to access data that is joined up nationally, but even within one trust pregnant women's care and hospital records are not always accessible by their GP and community midwives. I think there should be top-down procurement for the NHS completely, so that everyone uses the same system. That would really help.

Alex talked about the differences between RCTs and getting evidence into the world. This is a massive problem that has been going on for ever. It is nice to see that there is now more implementation science along with research, so that when you are evaluating interventions you are looking not just at outcomes but at how they are being implemented and what the differences are to make sure that they can be implemented in all local contexts.

Professor Alexander Heazell: We cannot emphasise strongly enough the value of the neonatal research database and the fact that we do not have the same thing in maternity services. We are trying to establish a maternity services dataset, which, as Professor Modi said, is the electronic patient record—just putting stuff into a bigger dataset. The problem is that if that is not cleaned, curated and looked after, it is not of the same quality.

Our intention, when we did the initial evaluation of the Saving Babies' Lives care bundle version 2, was that we would use the maternity services dataset to evaluate it, but we realised that we just could not do it; the quality of data in the system was simply not good enough. We cannot make huge policy decisions based on poor-quality data. That needs to be addressed by both sides. It is great that the neonatal research database is there, but we need the other side of it from the mums. They need to be married together and of equal quality.

Baroness Blackstone: So you would see dealing with that as a high priority matter.

Professor Alexander Heazell: I cannot overstate that. Until we have good-quality data that we can trust, we will just go round in circles. One of the challenges we face when we go to individual providers and say, "We're a little concerned that you're an outlier", is that I can guarantee that the first thing that is said is, "It's the data". We need to be able to say, "No, it isn't. Let's move on".

Q145 **Baroness Blackstone:** Moving from this big national question, I gather that a slightly different care bundle has been introduced in the south-west. It is presumably some kind of pilot, but I know nothing about it. Would you like to see something like it introduced in other places? Has it

been evaluated adequately to consider distributing it more widely and using it in other regions?

Professor Neena Modi: The PERIPrem care bundle is a large number of interventions—it may be six, if not more—wrapped up into a single bundle. It has not been fully evaluated yet, and it is really important that any quality improvement programme is properly evaluated and that, at the outset, there is a published peer-reviewed plan for its evaluation prior to scale-up. That is because, as I said earlier, we all hope that care bundles that bring together individual components that usually have been shown to be beneficial will work if you pull them together and deliver them across the population. However, as we have also said, that is not always the case for a multiplicity of reasons, some of which we understand and some of which we do not.

We owe it to the considered use of public funds to ensure that any quality improvement programme is evaluated rigorously and meticulously before we attempt to scale it up. Again, we have great opportunities in this country, because we could do some very careful and methodologically rigorous evaluations of quality improvements, but I have to say that I have rarely seen that done. It would be nice to see change for the future, and that should be the requirement for very careful evaluation of QI programmes prior to national scale-up. Otherwise, we risk wasting time and money. Even more so, we risk being slightly disingenuous or dishonest with our patients, because we are implying that something is absolutely going to work when, in fact, we really do not know whether it will or not.

Q146 **Baroness Blackstone:** From what you are saying, it is not the right time to extend this. Can you tell the committee who does these evaluations? It would help to know what system exists to evaluate something like this.

Professor Neena Modi: There is no uniform system for evaluating it. It is up to individuals to make a case. I suggest that we are going wrong as a nation here and it should be an absolute requirement—we owe it to the diligent use of public funds—to ensure that, prior to scale-up, there is a proper evaluation of any new implementation.

Baroness Blackstone: So it is another big priority.

Professor Neena Modi: Funding for research.

Q147 **The Chair:** We have now heard several times about evidence-based practices that would bring about better outcomes. At the same time, we hear that this is not universally done in the way it should be. I take your point, Professor Heazell, that the outcomes of clinical trials do not match the actual outcome levels when they are rolled out in practice—but not always. The efficacy rate falls, but not dramatically. It ought to show the good outcomes that the trial demonstrated. We have heard this in relation to cord clamping, antenatal steroids, surfactants and magnesium sulphate, so tell me how you would solve it. How would you make sure that the evidence that exists is put into practice?

Professor Neena Modi: That is the $1 million question. Shall I have a go? The nature of evidence changes and new evidence emerges, and we are not well set up to be fleet of foot and flexible—

The Chair: Professor Modi, you are confusing the issue. The clinical evidence is clear that you are to do XYZ to deliver the best outcome, but it is not implemented universally. Therefore, you get a variation of care.

Professor Neena Modi: Could I split that into two sections? The evidence may be clear at a moment in time. For example, Alex talked about cord clamping. A few years ago, we talked about delayed cord clamping, waiting for a minute at least, but we are now talking about perhaps delaying longer and physiological cord clamping. That is what I meant by "the evidence changes". While you are persuading practitioners to delay cord clamping, along comes another set of evidence that says, "Actually, don't wait just a minute. Wait a bit longer". This can be very confusing for many practitioners, who say, "Those terrible researchers keep changing their minds and keep saying that the evidence is changing. We can't keep up, so we're just not going to do anything".

We need to be able to convince our colleagues at this moment in time that it is quite clear we should, for example, be delaying cord clamping for at least a minute, and possibly longer, but we also need to disseminate a view among practitioners that the nature of evidence may change. We should have a learning healthcare system that enables us to adapt much more rapidly than we have done previously to evidence as it emerges.

The other point to make is that the strength of evidence can be very variable. Take the PERIPrem care bundle, for example. Some of the elements in it have a strong evidence base for them. For other elements, the evidence base is much weaker. So it is not surprising that many practitioners say, "We're going to do elements A, B and C of the PERIPrem care bundle", or any care bundle, "but not X, Y and Z, because the evidence base for those is not so strong". I hope that goes some way to answering your question.

The Chair: It is an answer but not convincing. There are certain things that I would say but cannot say here because we are on the record and there are implications if I say certain things, but if the evidence is clear that something may lead to harm if not practised, that has a lot of consequences. That is all that I can say at the moment, but I think you get the message.

Professor Neena Modi: To finish, I would agree. There is evidence where that is very clear and, in those areas, I would certainly agree with you.

Professor Alexander Heazell: One of the challenges is the difference between research and quality improvement. Where we have the research evidence, we need to be able to instigate strategies. With the best will in the world, as Professor Modi said, some of the evidence behind PERIPrem

is really good, such as on delayed cord clamping. We need to ensure that that information makes it all the way down to the people on the ground. There is no point me writing a letter to the director of midwifery saying, "You should definitely tell me that your unit is doing lots of delayed cord clamping", because I will then get a letter back saying, "Yes, we're all doing it". We need to make sure that it is disseminated effectively.

The Chair: Wait a minute. We are talking here about the delivery of very vulnerable babies. At the point of delivery, that baby is vulnerable and its chances could be improved by doing simple evidence-based procedures. I as an obstetrician would say that a very senior person, whether a neonatologist or a consultant obstetrician, should be there to make sure that it is implemented.

Professor Alexander Heazell: I do not disagree. We want to make sure that the people on the front line are doing this, but there is only a point in having a senior obstetrician or whoever there to make sure that the right thing happens if that person is educated and going to do the right thing. It is about making sure, as Professor Modi said, that we have a learning healthcare system that ensures the best changes are implemented on the front line. We are not as fleet of foot in doing that as we could be.

Dr Jenny Carter: I have worked in research like this for 20 years. It is the hardest thing. I have seen so many things where we have shown that something works, but getting it into practice is much harder than producing the evidence that it is good.

Going back to the implementation side of this, it is essential that when we try to introduce something new we have that alongside the implementation to try to understand what things are holding it up. It defies belief. I do not know why we cannot suddenly make these things happen. It is so hard.

Q148 **Lord Winston:** This is a trivial question, but perhaps Alex could supply the answer. With regard to cord clamping, is there a difference in practice between somebody doing a caesarean section with a premature baby and somebody delivering a premature baby vaginally, because different kinds of staff tend to do those procedures?

Professor Alexander Heazell: That is a very good question. In my professional experience, the answer is probably not, because it is now integrated into our training. A couple of years ago, I would almost certainly have said yes.

The Chair: In what way?

Professor Alexander Heazell: A couple of years ago, I would have said that midwives attending a vaginal birth were less likely to clamp it as fast as an obstetrician doing a caesarean section. Now, we have had it drummed into us very effectively that we have to be more patient with a caesarean section.

The Chair: Is the language used part of the problem? The evidence is about not cutting off the circulation from the placenta to the baby. When we talk about cord clamping, we talk about cutting off that circulation, but what we are actually talking about is restitution of the blood from the placenta to the baby and whether you are cutting it off too soon when that has problems. Even with a caesarean section—I am surprised that an obstetrician would do that knowing the evidence—you cut off the blood supply from the placenta to the baby.

Professor Alexander Heazell: The evidence originated in neonatology and it has taken a while. One thing that has the potential to help is the development of local maternity and neonatal systems. Having maternity and neonatal is critical. There is no point in having our neonatologists realise that we are clamping a cord too soon and it taking n years—where n is a big number—for them to tell the obstetricians and midwives to alter what they are doing.

I have now practised for 24 years, and I would say that we are slowly drifting together. Before, as an obstetrician I always used to go to the neonatal unit to see all the babies I had delivered preterm. My colleagues in the neonatal unit were frequently surprised to see me. They would say, "What are you doing here?" It has changed the view, and we have to have a view that this is about mums and babies.

Lord Winston: It has been quite a long-standing problem.

Professor Alexander Heazell: I would argue that it has, yes. It is something that we can address very easily.

Dr Jenny Carter: It is improving.

Professor Alexander Heazell: Yes, it is improving.

The Chair: I am long in the tooth, but I used to do the same. Anyway, you have been most helpful. I am sorry that the discussion went the way of trying to challenge you a bit, but it was to try to extract more information that will help us, and it has. I am also sorry that we have overshot on the timing a bit, but this session was important because you represent different backgrounds and professions. You have been extremely helpful. Thank you.