HOUSE OF LORDS

Preterm Birth Committee

Corrected oral evidence: Preterm birth

Monday 20 May 2024

3.50 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. 18 Heard in Public Questions 239 - 243

Witnesses

I: Professor Jonathan Benger, Chief Medical Officer and Interim Director of the Centre for Guidelines, NICE; Dr Clare Morgan, Director of Implementation and Partnerships, NICE.

Examination of witnesses

Professor Jonathan Benger and Dr Clare Morgan.

Q239 **The Chair:** Welcome. I thank you most sincerely for coming today to help us with this extremely important session. We have heard a lot of evidence related to guidelines and adherence to guidelines, so the session is extremely important for our report. Before we start, I would be grateful if you could introduce yourselves so that we can record your name and designation before we start the questions.

Professor Jonathan Benger: I am the chief medical officer and the interim director at the Centre for Guidelines at NICE. I am also professor of emergency care at the University of the West of England and a practising emergency and pre-hospital physician in Bristol.

Dr Clare Morgan: I am director of implementation and partnerships at NICE.

The Chair: Thank you. Thank you for coming today. I will ask Baroness Wyld to kick off the questions.

Q240 **Baroness Wyld:** Thank you, Lord Chair. Good afternoon. I want to open

the conversation by talking about the implementation of your guidelines. As Lord Patel said, we have taken a lot of evidence about the variation in implementation. Can you first comment on that and tell us, in your opinion, what we can do to reduce the variation? Within that, would you be able to tell us for the record how NICE monitors the way your guidelines might be adapted for regional or local means?

Professor Jonathan Benger: Before we begin, on behalf of NICE I want to thank you for the invitation and for giving us the opportunity to attend the committee and speak. We are very pleased and keen to help you address these important questions, including the question that you have just asked. Clare and I are likely to divide the questions between us. Since Clare is our director of impact and partnerships, and that question is specifically within her domain, I hope you will allow Clare to answer it.

Baroness Wyld: Of course. Please do.

The Chair: We treat all our witnesses equally.

Dr Clare Morgan: Thank you. Right. I will answer then. We work incredibly closely with partners as the guidelines and the guidance are developed, so that in theory our guidance hits the system through a lit runway and is optimally implemented in the system. But we know the reality of a complex and multidisciplinary healthcare system. It is not NICE's sole responsibility to make sure that uptake is happening. That is absolutely where we work in partnership with the CQC or NHS England, but that tends to be more where we know that we have poor uptake or unwarranted variation in uptake.

I joined NICE just over 12 months ago. We have been doing a lot of foundational work with partners in the last 12 months to understand how our guidance is being implemented, a specific case in point being the topic that we are talking about today. We are taking national datasets and trying to derive insight. We have used our quality standard statements that are aligned to areas where we know that we have challenges in uptake and that are priorities to the health and care system. We have equally looked at policy and strategy. We have been mapping against Core20PLUS5.

This year, we looked at access to antenatal care; for example, we looked at the 10-week booking appointment where we had a feeling that uptake was not as planned. With that insight, we have been able to derive that there is variation in 10-week booking appointments by provider of between 18% to 20%. We have split that down by the ethnicity and deprivation index and there is a 22% variation among black women. We have just started on work with the Race and Health Observatory to understand where some of the opportunities are for development of implementation toolkits, for decision support tools and for different kinds of tools that will enable better uptake. That is a very specific example.

We have written our guidance and we have used system intelligence and surveillance to understand where uptake has been poor. Over the last 12

months, we have focused on those priority areas. You also asked about local versus national variation.

Baroness Wyld: Regional.

Dr Clare Morgan: Yes. We write our guidance with that lit runway approach, understanding what the national issues are. We have committee membership that is multidisciplinary and understands what some of the implementation issues are.

Regarding the guidance that we are talking about today, we have seen that things are adopted differently in local providers. Where we have seen some of the biggest opportunity is working on a regional basis and working with ICBs to help them understand where they have poor variation and the opportunity to understand where that unwarranted variation is.

The other piece of work that we have been doing is working closely with the CQC on the single assessment frameworks, because ultimately it is the CQC's responsibility to make sure that safe and quality services are in place. We are working with the guidance and the quality statements to think how we underpin some of the questions, perhaps where they have concerns about local uptake. We are trying to think more proactively about the opportunity for working regionally with ICBs to be able to understand where they have variation and where there are opportunities for improvement.

Baroness Wyld: Thank you. You have talked about who is responsible and the different players. In different ways, you have explained where you think points of responsibility lie, but for the record could you just join that up for me and tell me what you think best practice should look like? How can patients have confidence that this will be gripped, with all the moving parts that you talked about? Just tell me what that should look like.

Dr Clare Morgan: It is about working closely with partners pre-guidance publication and making sure that all the arm's-length bodies—NHS England, us and the CQC—are fully aware of any implementation issues. That is the triumvirate of how we are working.

Baroness Wyld: What about the different networks within the ICBs? What about maternity and fetal versus neonatal? How do you see the balance there?

Dr Clare Morgan: Jonathan might want to pick this up clinically. Certainly, as we publish guidance, we work closely with the national clinical directors and with the clinical networks as we roll it out. This is where we have been thinking about how we make sure that we are harnessing the regional clinical networks and the tools and information they need, as new or updated guidance or guidance where we know we have problems with variation is rolling out, so that there is a more proactive approach. Jonathan, do you want to add to that?

Professor Jonathan Benger: Clinically, this is a microcosm of a much larger problem, which is variation in the delivery of care and services across the country. I know that some members of the committee have a background in clinical practice and will be familiar with the fact that there is that variation, which may be driven by local services and local leaders in clinical practice. The challenge, of course, is that guidance is guidance, and most of the time individuals should follow guidance, but occasionally expert clinicians will deviate from guidance because they have the expertise to do so. The complexity is in understanding the right time to follow guidance and the right time to deviate from that guidance.

There is always a risk that people find reasons not to follow guidance, when probably the population as a whole would be served by mechanisms that encouraged greater uniformity of care delivery. It is a difficult area. There is a lot of variation around the country. As you move around the country, different systems will say, "We have a different system here. We have a different population. We need a slightly different approach". Senior clinicians in the field may say, "Well, we feel differently about some of these particular women in preterm birth". That is a difficult challenge. There is a role for professional leadership from colleges and others to assist. It is certainly not confined to preterm birth. I am sure that the committee is well aware that there is substantial variation in the implementation not only of NICE guidance but of guidance in the round.

Baroness Wyld: Yes, thank you.

The Chair: I am disappointed, in a way. I think what you said is correct, Professor Benger; there is variation of care in every specialty despite the guidelines that, if practised, would deliver the best outcomes. There is no point writing a guideline that will not deliver the best outcome, yet we tolerate the mess of variation in care because you said there are reasons. There are no reasons for tolerating mess, surely.

To take preterm birth, we heard over and over again that there is variation in the administration of steroids, which then ends up causing harm to the babies. We heard that the timing of cord clamping, which is scientifically proven, or, correctly put, cutting off the circulation from the placenta to the newborn, is critical in relation to the subsequent complications that arise and subsequent development, yet there is huge variation. You are saying that we cannot do much about it because it is local practice with independent practitioners. As an organisation that is responsible for driving guidelines, what is your role and what should you do? Should we give you more authority or should we say that you should be disbanded because you are not much use?

Professor Jonathan Benger: Those are the reasons people give as to why there is variation in practice. I am certainly not saying, to be absolutely clear, that they are necessarily justified or right, or appropriate reasons. For some of the examples that you have given, it is very clear that we should be standardising practice in those areas. To be clear, I feel very strongly that we should be standardising practice where there is good evidence; that is why I work for NICE, but NICE cannot do that

alone. We do not have a regulatory function to oblige providers to comply, neither do we have jurisdiction over clinicians and colleges. We have an important part to play. We are respected and trusted as independent arbiters of evidence.

We are in our 25th year this year. We have built a reputation on independence, transparency and rigour. The challenge that we have and that you have cut right to the heart of with your opening questions is that we have produced the best possible guidance, but it is not fully implemented in the system. We do our very best to work with systems, to prepare systems and to develop through our independent committees guidelines that we believe should be implemented, and we work with partners to implement those guidelines. It is a cause of great regret to me, my colleagues at NICE and, of course, to the very many women and their families who are affected that that guidance is not always followed.

We have a part to play, but we do not have sole responsibility for variation in the system or for implementation of our guidance. We would like to see an improved alliance, and potentially an improved framework that reduced variation and made NICE guidance much more readily and universally applied. You practised in obstetrics and you will be aware that there are strong challenges from professions, individuals and systems that have to be systematically addressed.

The Chair: By the way—a truly old piece of information—on 17 October 1997, I wrote the policy paper to establish the then National Institute for Clinical Excellence.

Professor Jonathan Benger: I am very grateful.

Baroness Watkins of Tavistock: I probably should declare an interest in that I was on a NICE appraisal committee for seven years, and I think that you and I worked together a bit in the South Western Ambulance Service NHS Foundation Trust some years ago.

Professor Jonathan Benger: That is correct.

Baroness Watkins of Tavistock: I want to come back to the issue about an improved alliance. Do you feel that NICE produces the best evidence-based practice guidelines? Do people in the service actually have time to read and utilise that information to change their practice?

Professor Jonathan Benger: It will come as no surprise to you that I think that NICE guidance is the best product possible. We have, as I said, built our reputation on independence, transparency and rigour. NICE is not just nationally but internationally respected. This committee has heard evidence from overseas where NICE guidance has been cited as important in guiding practice across the world.

The challenge that NICE has—you will have had experience of this from being on a committee—is that high quality is not quick. To do things well, and to be sure, takes time. To do the evidence searches, to consider the implications of that evidence and to complete robust economic health

analyses all takes time. The challenge is that people will say NICE is not fast enough, and I am happy to speak in more detail about what we are doing to address that.

The second part of your question—accessibility—is also important. We recognise that accessibility to NICE guidance needs to be improved, because we have excellent information but it is not always readily available for clinicians at the point of use. There is a very good example with clinical knowledge summaries in general practice, where NICE guidance has been taken and applied in a way that general practitioners use on a daily basis. That is effective, but if, for example, you were to ask if the NICE website could be improved and the usability of our guidance could be improved, of course it could.

Baroness Watkins of Tavistock: That would include in this particular domain.

Professor Jonathan Benger: It would certainly include this domain and in any domain.

Baroness Watkins of Tavistock: Thank you.

Professor Jonathan Benger: Clare, you are responsible for our publishing strategy, so do you want to say anything more about what we are doing with that?

Dr Clare Morgan: Yes, absolutely. The four pillars are "relevant", "timely", "usable" and "impactful"; and "usable" and "impactful" have been grouped together purposely because we cannot have impactful guidance that is taken up as best as it possibly can be if it is not usable. As Jonathan said, there is a real focus this year on making our recommendations more structured so that we can move to more of a content approach and think about our product. At the moment, we have static PDFs, in which, at the point of sitting in a consulting room with a person in front of you, trying to find things is sometimes a little tricky. Our strategy over the next 18 months is how we have structured, templated recommendations that we can start to centre around the use cases—why do people come to take NICE guidance?—and making sure that it is packaged in ways that are fit for purpose for that use at that time.

Baroness Watkins of Tavistock: Thank you.

Q241 **Baroness Owen of Alderley Edge:** My question is about how NICE ensures that the guidelines on preterm birth reflect the latest evidence. This committee has heard a bit about how the practice lags behind the evidence. One of the witnesses even said that it was three to five years. We are keen to find out how updating the guidance more regularly might improve the outcome for mothers at risk of preterm birth and for their babies.

Professor Jonathan Benger: It is certainly true to say, and I already alluded to the challenge, that sometimes NICE does not have a reputation

for speed; it is rather quality, transparency, independence and rigour. However, that has to change, because the pace of evidence is changing and the speed at which practice is changing is always increasing. I am not sure that I would say it is about more frequent updates; it is about the way that we approach the evidence.

There are probably three parts. The first is how we conduct surveillance and identify new evidence, and make sure that we immediately become aware of practice-changing evidence and prioritise it to update our guidance. We have recently introduced a new concept in NICE, which is our topic suites and the faculties that support them. One of our four suites is maternal and reproductive health. The purpose of that suite is to draw together expertise from across the field to identify new emerging trends, high-quality research and other areas where NICE should be responding.

With our new prioritisation board, which I can also talk about if you are interested, we have the opportunity to be quicker at identifying the evidence. Once the evidence is identified, we need to be quicker at incorporating it into guidance.

One of the key steps forward with the new suite design is that we are starting to take a modular approach. Historically, we tended to update whole guidance, and that could take three years, by which time practice would have moved on, so we are taking a more modular approach and updating guidance much more quickly. Our current target is to update within six months of prioritisation of new evidence so that we can get information to practitioners quickly so that they are aware of the best care. That modular approach allows us to be swifter than would otherwise be the case.

A good example would be the recent update that we have made on twin and triplet birth in relation to progesterone following cervical scanning. I think the committee heard in February that we were consulting. We published the update last month. As I say, we now have a new target to work to in terms of speed. The tricky bit with speed is that we have to be sure that we do not compromise on quality and rigour, because that is the foundation of the work that we do. We must maintain trust but we must get faster.

The other challenge in relation to doing a modular update is that there is a risk that the guideline itself starts to become incoherent. If you update one part of a guideline, you often have to update another part of the guideline and another guideline and another part of a guideline. We have more than 3,000 current guidance products in circulation today. It is a common criticism that NICE guidance is not fully aligned, so we are working through methods to address that. It is going to be a problem; modular updates have a challenge in ensuring that we are fully aligned across all our guidance products.

Baroness Owen of Alderley Edge: On that note, can we ask why the 2022 surveillance report on NICE guideline NG25, which noted the

updates to delayed cord clamping and the use of the QUiPP app, was not taken forward?

Professor Jonathan Benger: A surveillance review was conducted in 2022, as you say, and two areas were picked up: the timing of cord clamping and the identification of preterm labour in women with intact membranes. That was commissioned in December 2022. In May 2023, I took over as the interim director of the Centre for Guidelines. It was clear at that time that our portfolio was too large and it was impossible to complete our current commitments within our resources, so I undertook a reprioritisation exercise. At that point, work on that particular update was paused, and I will explain why.

We had, in fact, already picked up the first part, in relation to the timing of cord clamping. During 2022, we were also running an update in relation to antenatal corticosteroids, but in the consultation the British Association of Perinatal Medicine pointed out that our guidance in relation to cord clamping was out of date, inaccurate and potentially a safety issue for women and babies, which Lord Patel has already referred to. We take safety extremely seriously in NICE, so we had already updated our guidance to indicate that cord clamping should occur at least 60 seconds after delivery and that one should not milk the cord. That element had already been covered. The evidence reviews need to be updated, but we can come back to that. The recommendation is now correct.

The second part refers to the QUiPP app that you described. We are aware that NHS England was recommending the QUiPP app as part of the Saving Babies' Lives Care Bundle version 3. Given that a reputable partner organisation was now strongly recommending that and we knew that it was being used in practice, we felt that there was less urgency for us to proceed with that update. However, our women's and reproductive health suite leads have further updated that paper and resubmitted it for further consideration. We may come back to look at the identification or diagnosis of preterm labour with intact membranes. It is a difficult area, though. I can discuss it in a little more detail if the Chair is willing.

The Chair: Go ahead.

Professor Jonathan Benger: This is an important consideration for the committee. The QUiPP app is recommended by NHS England and it is in widespread use. If we were to look at it as NICE, we would not look at the app in isolation; we would look at the identification or diagnosis of preterm labour in women with interact membranes across the board. We would look at the QUiPP app, as well as any other app that might be available, and other diagnostic tests—fibronectin, cervical scanning and so on. We would look at it in detail and to a high standard, and we would look at it from the view of cost effectiveness.

I do not know what our independent committee would say, but there are two things that they might say: they might recommend the QUiPP app, in which case we have, effectively, repeated what NHS England has already decided; or they might not recommend the QUiPP app, which would

cause additional confusion in the system because then NHS England would be saying one thing and NICE would be saying a different thing. This touches on the challenge of multiple guideline producers working in the guideline space. I am wary of producing guidance in the same spaces as other reputable guidance-producing organisations because either we end up with slightly different products, in which case it is confusing and we have to justify why they are slightly different, or we end up with identical products, in which case we have not necessarily used taxpayers' money in NICE in the most efficient way.

I know that this committee has looked hard at the complexity of guidelines in this space. In general, we have been successful in working with our partners, particularly the Royal College of Obstetricians and Gynaecologists as well as others. We are pretty good at avoiding overlap, but there are some areas of overlap and some areas of contradiction, and we are currently looking at ways of managing that.

Our foremost concern is not that we are aligned with other people's guidelines but that we are aligned with the evidence. We have to go where the research tells us to go and we have to make guidance, through our independent committees, on the basis of the science in front of us. We are, of course, aware of other guideline organisations. We work with them; our committee members and our staff are aware of them, and we do our best. We can allow the evidence reviews and guidelines of other organisations to inform our guidance. We have recently adopted methodologies effectively to incorporate elements or adapt elements of other recommendations into our guidance providing that they meet our standards for evidence.

It is a challenging space, and we have to be careful about how we approach that. We wish to avoid confusion and we wish to have clarity, but NICE is founded on absolute rigour and following the evidence, and ensuring that any practitioner can trust us for our independence and that this is the best evidence available at the time.

The Chair: Professor Benger, it was never in doubt in my mind, and I am sure the others, that guidelines produced by NICE are the ultimate authority, based on absolute evidence available as to how practice should be conducted by clinicians on the basis that that guideline, if followed, based on the scientific evidence available at the time, will deliver the best outcome. Compromising that by any other guidelines gives the public—it is the public whom we should keep in mind—the impression that practice can vary and that that variation will not cause harm. But it will.

The public do not know about guidelines, so the first issue is how the public find out that NICE guidelines are the most up-to-date authoritative guidelines. It should be made quite clear that any other guidelines produced by any other organisation are irrelevant unless they improve NICE guidelines, with the authority of NICE. While we are members of this committee, we are also parliamentarians and therefore interested in issues related to healthcare in policy issues.

Professor Jonathan Benger: It is not possible for NICE to produce a guideline on everything, unfortunately. As I say, we have more than 3,000 guidance products in circulation at the moment. Evidence moves quickly and practice expands. There are new medicines and new technologies. We do a lot of work in health and digital technologies. Given our finite budget and the need to update and keep our guidance up to date, we will never be able to meet the demand for guidance. There are elements of jurisdiction to consider. Our jurisdiction is, effectively, England and Wales, but other organisations may take a view for the United Kingdom.

The Chair: I am aware of SIGN in Scotland.

Professor Jonathan Benger: Yes, and it is a very reputable organisation. The WHO writes guidelines—

The Chair: But it is older than you.

Professor Jonathan Benger: Indeed it is, a fact it has reminded me of on occasion. It does not have the resources that NICE has, neither does it have NICE's international reputation. I have a great deal of respect for other guideline producers. I have a great deal of respect for the royal colleges, which produce very high-quality guidance for their members. They have a slightly different focus. NICE is founded on cost effectiveness, so our focus is on cost effectiveness. Most clinical guidelines made by colleges do not consider cost effectiveness in the way that we do.

The Chair: Does your cost effectiveness compromise on quality outcomes?

Professor Jonathan Benger: We have a dual purpose, which is to get the best care to patients fast and to ensure value for the taxpayer. Our methodologies are long established as to what value for the taxpayer means. It is most obvious probably in medicines. Of course, the committee will be aware of many high-profile discussions where NICE has not recommended a medicine as cost effective. There are several in the press at the moment. It also applies to all our guidance products, including our guidelines.

Q242 **Lord Hampton:** Quite a lot of my question has been dealt with quite well by Professor Benger. You talked about harnessing regional clinical networks to make a more linked approach. You talked about approved alliances. You talked about mechanisms to encourage greater uniformity. We were looking at other bodies and how you ensure guidelines, and you talked about avoiding overlap, aligning with the evidence and adapting methodology. But specifically about preterm birth, what can you do better? As Lord Patel said, we tolerate the mess of variations in clinical care. What can be done, without talking about methodologies too much, in layman's language?

Professor Jonathan Benger: We need to continue to collaborate more effectively across the space that we work in. A lot of the challenge is to

get the best out of the system as a whole. Sometimes, colleges produce guidance because they feel that there is a gap or that NICE has not covered something correctly. Sometimes they get frustrated and feel that we are not quick enough, and they want to produce something quickly.

We have recently employed a new consultant clinical adviser in NICE directly, Mary Ann Lumsden. She is a consultant obstetrician and gynaecologist who has been helpful in supporting our women's and reproductive health suite. She has previously worked very closely with the Royal College of Obstetricians and Gynaecologists and has been involved in European guideline development, which is helping us to forge links in that space. There are, of course, many other important and reputable guideline producers. We have talked about SIGN. There is the British Association of Perinatal Medicine. There is a wide range of excellent individuals and clinicians, all of whom want to do the best thing.

We recently retired our former accreditation process. Last week, our executive team agreed a new approach to collaboration where we will be looking to work more effectively with other reputable guideline producers to ensure that we have a menu of options to pick from so that we avoid duplication, and we support and work with other guidance producers but do not undermine the core principles of NICE and do not stray away from the fundamental values that have made NICE world leading, which Lord Patel very kindly complimented us on earlier.

The reality is that it is all about negotiating with the space, identifying where the expertise is and working to avoid duplication, overlap and confusion in the system. I have a huge amount of respect for the clinicians, colleges and other associations who are working in this space. We are all trying to do the same thing. This committee has clearly highlighted where we could do better. We could always do better. I am sure your recommendations will help us to do better. It is a complex space. The RCOG has retired guidance. It retired its guidance on tocolytics. It retired its guidance on antenatal steroids when we published our guidance. Those are good examples of working. That inevitably has to be the way forward.

Lord Hampton: You talked about recruiting somebody who has helped you. Would there be a case for secondments across the different bodies?

Professor Jonathan Benger: Possibly. When I joined NICE a year and a half ago, the first thing I did was found a clinical director in NICE because I felt that the clinical leadership needed to be improved, particularly the relevance of NICE to the system. NICE has to focus on the challenges of the system because they are so consuming and prominent at the moment. I work in an emergency department in Bristol every week. I am very familiar with the challenges that we have in the system. I want NICE to be more clinically led and clinically focused on challenges. Mary Ann's appointment is a good example. We have also just appointed two general practitioners to our staff to support that, but we have a limited budget, and we use that budget wisely.

The Chair: What is your budget, by the way?

Professor Jonathan Benger: That is a good question.

Dr Clare Morgan: It is £57 million grant in aid, and then we have approximately £11 million in terms of income through our technology appraisals.

Lord Winston: Sorry, how much was that?

Professor Jonathan Benger: Lord Winston, we were just getting our story straight. Seventy million popped into my head, and Clare has confirmed that it is around £70 million. Most of that is grant in aid, but we also raise funds from our health and life science partners. I would be very happy, Lord Patel, to arrange submission of a more detailed breakdown from our accounts, which are just in the process of being published.

The Chair: That will help. Thank you indeed.

Q243 **Baroness Hughes of Stretford:** I want to pick up the points that Lord Patel was making earlier about the multiplicity of guidelines in this area. I understand what you are saying about royal colleges and similar bodies producing their guidelines. Given your pre-eminence in terms of the authority that is imbued in the guidelines produced by NICE, how is it that the NHS produced the Saving Babies' Lives Care Bundle and the guidance associated with that, drawing, I understand, from your guidelines but differing in some respects? How does it happen that the NHS produces another set of guidelines alongside those of NICE? Is the difference explained by your focus as well on cost effectiveness? Would the bundle be focused only on maximising outcomes, whereas you would temper some of your guidelines because of the cost element?

Professor Jonathan Benger: The first thing to say is that NICE generally does not recommend care bundles, and the reason for that is that care bundles are complex interventions with multiple parts. If a care bundle of six components improves outcomes, we do not know which component, or components, of that care bundle is responsible. In fact, care bundling is more common within the system where delivery is being focused on.

Baroness Hughes of Stretford: Delivery as in?

Professor Jonathan Benger: As in achieving changes in practice.

Baroness Hughes of Stretford: Right. Not a baby.

Professor Jonathan Benger: Apologies. I should say "where implementation is key". That is a very important distinction, is it not? Clare may want to speak a bit more about it. It is an implementation science idea. You say, "We're going to follow this bundle of care. There are six things you have to do". It helps people to remember and comply with best practice. People take evidence-based interventions and then

they bundle them and offer them to the system as a way of implementing them, and it supports people in doing so. The Sepsis Six is another one where we have a particular series of things that we do for somebody with sepsis; some of those are evidence based and some of them less so.

NICE is most effective in making evidence-based guidance for the management of patients at the interface of care. I know that this committee has heard some evidence that NICE only pays attention to randomised trials. That is not true. We prefer randomised trials because of their high degree of scientific validity, but we recognise a wide range of other evidence. We adhere to the MRC framework for complex interventions. We have a real-world evidence framework that is published and that we use for other evidence sources.

When we move down the evidence hierarchy towards expert consensus and there is no good science, that is where professional societies can be helpful, because that is where the expertise is. It is often what drives implementation science and care bundling. We have done the same with the OASI bundle at delivery as well, where the RCOG recommended the bundle, with support from NHS England. We found it difficult because, while the whole bundle may be effective, we do not know which components of it are effective. In a bundle for care that is effective, there is always a risk that some is effective and some is ineffective or even harmful, but you would not know because it is all packaged up in a group. It does not fit particularly well with NICE's approach to methodology, but it fits very well with implementation science. Bundling care really helps clinicians and it generally drives compliance with NICE guidance and other professional standards for delivery.

Clare, do you want to say something about bundling?

Dr Clare Morgan: Not a huge amount. We worked closely with NHS England at the time. It is the dual approach of how we make sure that, where we can, we include all the quality of the guidance and practicality about how we get started and the key things that people need to pay due attention to. That is the real challenge that we have in the very complex challenge system that we have of how we factor in the quality and the rigour that we stand for while making sure that we get started. That is why the partnership with NHS England is so important.

Baroness Hughes of Stretford: That is very helpful, thank you. Finally, you would say in relation to those two examples, the care bundle and your own guidance, that some of the practices that NICE recommends are included in the care bundle because you have evidence to support their efficacy, but some of the elements in the care bundle are not recommended by NICE specifically because you do not have the evidence base. Is that a fair summary?

Professor Jonathan Benger: Yes. I would need to look at the detail of the Saving Babies' Lives Care Bundle, because I do not have it immediately to hand. If you permit it, I will ask the team to review that and see how that care bundle shapes up to our evidence-based

recommendations. It is an important question, and I would like to make sure that you get a 100% factually accurate answer.

Baroness Cumberlege: I was thinking about the report. I read another report that I was party to quite recently and looked at the recommendations that we made. We have to be very careful with this report to ensure that everything that we recommend is based on evidence. It is not a wish list. It is something that we have seen and it works and has proved successful. It is a question of drilling down to ensure that what we recommend is something that we know works well and we have seen it work, and it may well be in other areas from health.

There is another thing that I want to mention on the guidelines. Guidelines have to be very clear. They have to be doable. Again, they are not a wish list. They are something that we really want to see put into practice to produce the good evidence that we may have seen in other places, and influence the outcomes for good, for better and for best. I would like to think a bit about that, and perhaps you wise people may want to think a bit about it as well.

Baroness Blackstone: You said earlier, Professor Benger, that there are occasionally cases where your guidelines are, in fact, ignored or rejected, and sometimes that may be acceptable—sometimes less so, presumably. Can you give us any illustrations of where that has happened in the area that this Select Committee is concerned with?

Professor Jonathan Benger: I am not sure that "rejected" is quite the word I would use; "not implemented" certainly, and not implemented in the way that we would hope or intend.

Dr Clare Morgan: It is, as you said before, Jonathan, about clinical decisions. On a bigger scale, when we are updating or publishing new guidance, we look to understand where there may be challenges in implementation, whether from a financial perspective, a service perspective, a workforce perspective or a skills gap, and then work with partners to understand the scale or risk of non-implementation. That is a key part.

When we were publishing the guidance in 2015, the three areas that came out were on cervical measurement and the skills and resources to be able to do that. Reading through, that is still an issue that we need to keep an eye on, and I would urge the committee to do that too. It comes back to the implementation of the QUiPP app. There is a risk that if part of the QUiPP app, on the assessment of cervical measurement, is not done and they go purely on fibronectin measurement, that adds an additional risk factor.

The Chair: Fibronectin is a much more definitive test, but cervical length measurement is not.

Dr Clare Morgan: It was recommended, and the QUiPP app uses both in its determination. In terms of the guideline, there were three areas, and

the QUiPP app was not considered. The second was about fetal fibronectin and the routine implementation of that, as well as the variation in practice of tocolysis. When we publish, we look at those areas and we work with the royal colleges to make sure that those risk areas are considered from the outset to minimise the level of risk of uptake. Jonathan, do you want to add anything?

Professor Jonathan Benger: You are of course correct, Lord Patel, but as Clare says, the QUiPP app is based on history—cervical length and fibronectin—but not all systems can provide 24-hour fibronectin or cervical length measurements. Another area where we have noticed that there have been broad challenges is NG72, which is the follow-up of children and young people following preterm birth.

The Chair: That reminds me. I am glad you brought that up, because the evidence we heard showed that your guidelines about neurodevelopmental assessment at four years have been followed in only 7% of cases. That is implementation of only 7% for an important guideline on assessment of a preterm baby at four years for its subsequent management in terms of education.

Professor Jonathan Benger: I think we all share the same concerns. The overwhelming feedback that I understand the team has received on that relates to resources to provide follow-up and those services. Commissioners balance priorities, and, sadly, that particular service does not appear to be widely delivered—sorry, implemented—in the NHS at the moment.

Dr Clare Morgan: That is the feedback that we have had in terms of service provision, service capability and regional and local variation.

The Chair: We talked a lot about implementation, and in our earlier evidence session it was brought out that there were very few studies done in the area of implementation science. Would you agree?

Dr Clare Morgan: The NIHR funded the applied research collaborations—the ARCs—for exactly that purpose, and has refunded. In the research and implementation science space, there is an infrastructure to be able to assess that. I know that you have been having conversations about research funding prioritisation. It is how we align some of that and how we use that data and evidence to make sure that we are. The infrastructure is there, but are we prioritising that?

The Chair: Professor Benger and Dr Morgan, thank you for coming today. We have been challenging because our evidence is strong that much harm is being done to mothers and babies because of people not adhering to science-based, properly produced guidelines by NICE, and that is a bit of a concern to us. I am sorry if we have been challenging, but your evidence has been most helpful. Thank you both very much.

Professor Jonathan Benger: It is a concern to us too, Lord Patel. We share your concerns. The opportunity to speak to the committee—

The Chair: What do you think we should recommend?

Professor Jonathan Benger: I would not presume to offer an opinion on that, Lord Patel.

The Chair: The director of NICE does not have a—

Professor Jonathan Benger: Lord Patel, in this committee you have heard a lot more evidence than I have. I obviously want to see NICE continue to be a core part of the system. We have built an unparalleled national and international reputation over 25 years. We want to build on that over the next 25 and continue to be the leading producers of evidence-based guidelines globally.

The Chair: Thank you both very much for coming today. We appreciate it.