Process overview: development of NICE guidelines

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Developing NICE guidelines is a complex and involved procedure. This article provides an overview of the whole process from start to finish, including an inside view from a former NICE guideline committee chair.

NICE is an independent public body that provides evidence-based national guidance and recommendations made by independent committees on a wide range of topics related to health and social care in England. Its role is to improve outcomes for users of the NHS and other public health and social services.

The guidance takes several forms, including NICE guidelines, quality standards, technology appraisal guidance, and guidance on medical technologies, diagnostics and interventional procedures (see Table 1). These can be used by the NHS, local authorities, employers, voluntary groups and others involved in delivering care or promoting wellbeing, or those who access services as a user.

All health professionals and many members of the public know about NICE guidelines and many more are affected by them, but unless they are actively involved in their organisation, they might well be a bit vague about the whole process of developing them and their recommendations. Who chooses the topics? Who decides what questions to ask? Who makes the decisions and how do they decide on NICE recommendations? It’s a long story but here is an overview, with insights from a former guideline committee chair.

What do the guidelines cover?
As well as clinical guidelines, there are NICE guidelines on public health, social care, medicines practice and safe staffing. Topics extend from the prevention and management of specific conditions, health improvement and medicine management in different settings, to the provision of social care and support across different ages – and planning broader services to improve the health of communities. The NICE topic remit also includes the promotion of individualised and integrated care, for instance in recommending ways to manage transitions from children’s to adult services and from health to social care.

More about the guideline development process can be found in NICE’s process and methods document, Developing NICE Guidelines: The Manual, published in 2014. Figure 1, taken from this document, provides an overview of the whole process.

How does NICE choose guideline topics?
New topics for NICE guidelines, which are a key source for the development
of NICE quality standards, are usually chosen from a library of topics for quality standards then agreed with the relevant commissioning body. A NICE Topic Selection Oversight group considers the topics, according to certain criteria, then discusses those it has identified with NHS England, the Department of Health and Public Health England, who agree a prioritised list. The topics are then formally referred to NICE and scheduled into its guideline development plans.

At this stage, NICE commissions one of its specialist centres to become the guideline developer, which uses expert input from the royal medical colleges, professional bodies and patient/carer organisations to produce the guidelines. Guidelines relating to general chronic and acute conditions are referred to the National Guideline Centre. Other NICE-funded centres specialise in topics relating to cancer, mental health, and women’s and children’s health.

Who are stakeholders and what is scoping?

Once the guideline is commissioned, stakeholders register an interest. These are usually national organisations representing patients and carers, and/or healthcare professionals, companies that manufacture medicines or devices related to the guideline topic, researchers, health service providers and commissioners. Once identified, they are consulted throughout the process.

The developer, which might be a team within NICE or in an organisation contracted by NICE to develop the guidelines, is responsible for scoping the guideline. This is the first step in developing the guideline: setting out its boundaries; understanding the current context; identifying the population and key issues; defining the areas to be considered and those to be excluded; deciding what it intends to achieve. NICE then agrees it before putting it out for public consultation on the website, where anyone can contribute their views. The guideline committee is usually recruited once the scope has been finalised, although scope consultation and committee recruitment can run in tandem. NICE staff and contractors work closely with the committee throughout and carry out quality assurance to ensure the process is followed appropriately. They contribute to discussions but not to the development of recommendations during meetings and they do not hold voting rights.

An inside view

Professor Swaran Singh, head of division, mental health and wellbeing at the University of Warwick, also a consultant psychiatrist in Birmingham and a commissioner of the UK Equality and Human Rights Commission, was recruited in 2014 to chair a guideline committee responsible for developing the NICE guideline on transition from children’s to adults’ health or social care services. He was appointed at an early stage of the process and his experience is unusual in that he was involved in the development of the scope and helped to select the guidelines committee.

He says: “We first decided who are the stakeholders, who are the ones whose views are needed. The obvious ones are academics involved in research and clinicians, but NICE is very careful also to apply to people at the receiving end of services.” The final group of 12 to 15 people on his committee included a GP who was also a commissioner, people representing residential care, the criminal justice system, parents – and because of the nature of the topic – people with complex needs.

“The group is tasked with taking the broad idea and working out the fine details,” explains Professor Singh. “You have a fixed amount of resource and a time frame.”

Professor Singh points out that, although NICE has a hands-off approach and allows autonomy to the guidelines committee, it observes very closely. He says NICE had spotted him picking up emails during meetings and “given him feedback” about it. He realised that he should have switched his mobile phone off and paid full attention during discussions, and began to tell other committee members to do the same. He adds: “NICE doesn’t want you to say one thing or the other, they just want you to get it right.” That means listening to one another, and not sending tweets or picking up messages.

What is the guideline committee’s role?

Following public consultation, there are stakeholder meetings, where the feedback is used to refine the scope and convert it into a series of answerable questions. A team with expertise in systematic reviews and meta-analyses examines how the data will be included or excluded, to ensure the reliability and validity of the process. Professor Singh details the committee’s scrutiny of the evidence, where “question by question, step by step, you end up with a complete list of all the evidence available in the medical literature.” The committee then rigorously evaluates the quality of the evidence and economic analyses, and where they identify shortfalls, they work in partnership with experts experienced in the topic area to provide additional evidence.

“So at the end of this long – maybe a year-long – process, you end up with: ‘What is the evidence for each of the questions that we have asked? And what is the strength of that evidence?’ Once we have all the evidence, we have to decide how we turn this into a list of recommendations.’”

The guideline committee breaks into smaller groups and takes each block of evidence. Professor Singh observes: “When you meet up, you find where you are contradicting yourself, then you have to go back and say, ‘Hang on, how did we...
get to this conclusion? ’ You find redundancies, duplications, contradictions and you resolve all of them. It’s very interesting to learn at that point the precision with which those recommendations are written. There is a clear action focus. It’s not a vague ‘good things must be done’, it’s very specific: ‘This should be done. This is the person who should do it and this is how it should be done.’ Very precise language is used: if something has statutory power, the word used is ‘must’; for robust evidence, it says you ‘should’; for weak evidence, it is ‘consider’. From reading the sentence you should be able to tell the strength of the evidence behind it.” At the end of that stage, the draft recommendations go to an editor with scientific writing experience, who then attends the meetings to hear the committee’s deliberations.

Once the guideline committee agrees the draft guidelines, registered stakeholders are consulted and an independent guideline review panel scrutinises the draft to ensure that stakeholder comments have been taken into account and responded to appropriately.

The final set of guidance returns to the committee for one last examination and once the committee is satisfied, it submit it to NICE. Professor Singh remarks: “They will either approve or come back with another set of questions and you have to go back, look at the evidence and just find every single thing. I think it is an astonishingly detailed and thorough process.”

“The final three things the committee has to do are: 1. Make a set of research recommendations on the basis of what we have found – what we don’t know and need to know; 2. Draw up an implementation plan – not when and how it will be implemented, that will be for local servicers – we have to say what it will look like; 3. Finally, we must say when it should be reviewed – sometimes after three, sometimes five years, it’s different for different topics.”

The National Guideline Centre produces the final guideline after it has been updated and stakeholder comments are included. NICE then formally approves the final guidance and issues it to the NHS. Guidelines are published
on the NICE website (www.NICE.org.uk) alongside summarised evidence and resources to help users implement them.

Professor Singh says: “When I talk to my colleagues across Europe or north America, they envy the fact that we have something like NICE. I know that NICE gets a lot of bad press because it has to make tough decisions. I started agnostic but now I feel that NICE is a very, very good process. The strength is that, at every single step, the process is transparent, open to scrutiny and flexible to accommodate any need. It is done in a very iterative, thoughtful manner.”

His own stint on the guideline committee finished, after almost two years, in February 2016. Does he have advice for anyone considering joining the NICE process? Yes: “Go for it, it’s a great learning experience and it contributes to one’s own personal development.” He continues: “While there’s a lot of consensus, there’s a lot of disagreement. By the end of the process, you are like family – you have bickered but you are all on the same side. We are all learning about ourselves and each other, about the process. We sometimes have two-day meetings – it’s very intense, they’re hard work – but I’m very, very glad I did it. I now see NICE in a completely different way.”

References
1. National Institute for Health and Care Excellence. Developing NICE guidelines: the manual. PMG20. October 2014. Available from: https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview. NICE guidance is prepared for the NHS in England, and is subject to regular review and may be updated or withdrawn. NICE has not checked the use of its content in this article to confirm that it accurately reflects the NICE publication from which it is taken.

Declaration of interests
None to declare

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POEMs

Metformin appears to be at least as effective as insulin for treatment of gestational diabetes

Clinical question: What are the short-term and long-term risks and benefits of metformin therapy compared with insulin therapy for glucose disorders in pregnancy?

Bottom line: The results of this systematic review and meta-analysis show that metformin is at least as effective as insulin in the management of gestational diabetes and type 2 diabetes during pregnancy. Most women would certainly rather take a pill than receive daily injections. (LOE=1a–)


Study design: Meta-analysis (randomised controlled trials). Funding source: Self-funded or unfunded. Setting: Various (meta-analysis).

Synopsis: These investigators thoroughly searched multiple databases including MEDLINE, EMBASE, BIOSIS, and the Cochrane Database, as well as bibliographies of pertinent publications. Eligible studies included English language-only randomised trials that compared metformin with insulin during pregnancy in women with gestational diabetes or type 2 diabetes. Two reviewers independently assessed individual trials for study inclusion and methodological quality using a standard quality-scoring tool. Discrepancies were resolved by consensus agreement with a third reviewer. Sixteen trials met eligibility requirements and quantitative data were available from 14 of them – 11 included women with gestational diabetes (n=2062) and three included women with type 2 diabetes (n=103). The overall quality of the studies was moderate; a lack of masking of the assessors was the most common flaw. Overall, there was no difference between metformin and insulin in the rate of preterm delivery or perinatal mortality, but metformin did significantly lower the risks of neonatal hypoglycaemia, large-for-gestational-age babies, and neonatal intensive care unit admission. Compared with insulin, metformin also significantly reduced the risk of pregnancy-induced hypertension, but had no effect on the rate of pre-eclampsia. There were no significant group differences in the rate of congenital malformations, shoulder dystocia, clavicular fracture, hyperbilirubinaemia, respiratory distress syndrome, APGAR scores, glycaemic control or Caesarean delivery. Total maternal weight gain during pregnancy was significantly lower in women who received metformin compared with women who received insulin. Finally, one study of long-term infant outcomes showed no differences in motor, social or linguistic development at 18 months of age. The authors did not perform any specific analyses for publication bias or heterogeneity.

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