AIMS For a better birth...

Influencing NICE guidelines – the stakeholder role

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What are NICE guidelines?

Among the roles of NICE (the National Institute for Health and Care Excellence) the best known is probably their production of guidelines to inform care. These are defined as "Evidence-based recommendations developed by independent committees, including professionals and lay members, and consulted on by stakeholders." In addition to this, it also publishes quality standards, technology appraisals that assess the clinical and cost effectiveness of new drugs or other types of treatment, and various other types of information and advice across the fields of health, public health and social care.

Guidelines are drafted by a Guideline Development Group (GDG). This is a multidisciplinary group which normally includes a mix of healthcare professionals, lay members including "at least two members who have experience or knowledge of patient and carer issues", and a number of technical support people such as an information specialist to identify relevant clinical research, a systematic reviewer to summarise the evidence, a health economist and a project manager.

Although NICE guidelines can be influential, hospitals are not obliged to follow them, and neither are they rules that individual maternity service users have to accept. They are a list of recommendations about the care that should be offered in different situations. These recommendations are intended to be "based on the best available evidence", but they can only be as good as the evidence that they use or is available.

What does NICE mean by 'the best available evidence'?

NICE has a process for reviewing evidence (Identifying the evidence: literature searching and evidence submission | Developing NICE guidelines: the manual)[1] which considers the type and quality of research. This means that if there is evidence from randomised controlled trials (RCTs), evidence from Observational studies is likely not to be considered. (For an explanation of the strengths and weaknesses of these two types of research see our Birth Information page Understanding quantitative research evidence.)[2] This process also means that "When there is little or no evidence, the committee may also use expert testimony, {or} make consensus recommendations using their knowledge and experience." In other words, sometimes a recommendation is just the opinion of a small group of people.

Details of the evidence considered and an assessment of its quality can be found in the 'Evidence Review' document relating to each recommendation. However, these are technical documents and may not be easy for an ordinary reader to understand. Usually the evidence is given a rating according to the 'GRADE' system (See What is GRADE? | BMJ Best Practice)[3] which is an assessment of the 'certainty' (from 'Very Low' to 'High') that the effect estimated by the research is similar to the true effect. You may wish to check out how often recommendations are made on the basis of 'low' or 'moderate' evidence.

Initially NICE made the level of the evidence behind a recommendation very clear, but this information is now not included with the recommendations, making it very difficult to quickly judge how robust a recommendation may be. Many stakeholders, including AIMS, objected to this change, stating how it would undermine informed decision making, but we were unsuccessful in persuading NICE to retain this information. Instead, their practice is to use standard wording which is intended to reflect the strength of a recommendation. For example 'offer/do not offer' will be used when the evidence is stronger, but 'consider' if there is "a closer balance between benefits and harms."

Sometimes there is an expandable box within a guideline to explain why a recommendation was made, which may be more informative.

Role of Stakeholders

Any 'registered stakeholder' can submit comments during the preparation of a new or updated guideline. Stakeholders can include national charities (like AIMS) who represent service users, patient or carers' organisations, organisations representing healthcare practitioners (such as the relevant Royal Colleges), providers and commissioners (such as NHS Trusts and Clinical Commissioning groups) and commercial companies with an interest in the topic. Note that there is currently no mechanism for individuals to become registered stakeholders, but many organisations, including AIMS, welcome input to their

submissions to NICE.

Stakeholders are invited to give comments:

1. On the scope of the guidance

The scope sets out what the guideline will and will not include, and the key clinical issues for the GDG to address. In the case of an existing guideline, the scope identifies which sections will be updated – normally those where there is thought to be new evidence to consider.

Once a draft scope has been prepared, it is made available on the NICE website, and registered stakeholders are invited to attend a workshop to discuss the key clinical issues. They are also able to submit written comments to suggest, for example, additional issues that they think should be included. All of these comments will be considered before the scope is finalised, though they won't always be accepted. Stakeholders are sent a written response, which is also published on the NICE website.

2. On the draft guidance

Once the GDG has reviewed the evidence and written a draft of the guidance this is made available on the NICE website. This means that anyone can review the draft, but only registered stakeholders are able to submit comments.

Comments from stakeholders are considered by NICE to be "a vital part of the quality-assurance and peer-review processes." In AIMS experience they are taken seriously, and can have a powerful influence on the wording of the final guidance. This means that the final guidance can differ substantially from the draft. All stakeholders receive a copy of all the comments made and the GDG's response to them, and this is subsequently published on the NICE website.

What AIMS tries to do as a stakeholder

AIMS is a registered stakeholder for guidelines relating to the maternity services and over the years has contributed comments to many of these, subject to having the volunteer time available. Our preferred method of working is for a group of volunteers to review the draft guideline and then get together to discuss their individual comments and agree on the wording of the AIMS submission.

Our submissions may include a variety of types of comments. We've illustrated these with some of our comments on the update to the Induction of Labour guideline, published in November 2021, together with the GDG's response to them. We submitted 65 comments, most of which were accepted. For a summary of the influence we were able to have see www.aims.org.uk/campaigning/item/nice-iol-comments.[4] The full set of stakeholder comments is here NICE comments table.[5]

Comments are more likely to be acted on if multiple stakeholders make the same point (though preferably not in identical words). For this reason we try to publish our comments on the AIMS website

before the end of the consultation period, in the hope we will be able to raise awareness of our concerns with draft recommendations, enabling others to comment on similar lines if they share our concerns.

AIMS has volunteers who have been involved in providing stakeholder feedback for many years, and also some who have been involved with guideline development as members of GDG. This experience has enabled AIMS to provide feedback which is constructive and based on the way that NICE Guidelines are developed. We actively work with new volunteers to help them understand NICE processes and to be able to put together constructive feedback. We review draft guidelines to make sure they reflect the evidence and support informed decision making. We explain carefully why we feel the recommendation is problematic. Often we will make suggested wording changes that better reflect the evidence. We will also suggest wording that makes it clear that treatments and interventions are an offer, and it's up to the individual whether to accept or decline the offer. We have had many cases where our carefully considered suggested wording change, or something similar, actually appears in final guidance.

Comments to make language supportive of autonomy and informed decision-making

AIMS Comment: We are pleased to see that the Guideline Development Group has taken some care in their language to make it clear that it is the woman who is the decision-maker, but unfortunately this has not been done throughout. We would ask that all wording is reviewed to recognise the principle of autonomy and make clear that the carer's role is to provide the information to support the individual's informed decision making, NOT to make the decision for them.

GDG response: We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline.

Wording in the final guideline: "recognise that women can decide to proceed with, delay, decline or stop an induction. Respect the woman's decision, even if healthcare professionals disagree with it, and do not allow personal views to influence the care they are given. Record the woman's decision in her notes."

Requests for fuller information provided including statistics, actual risks and quality of evidence

AIMS comment: We feel that in any discussion of 'risks' women should be told what the actual risk is in different circumstances rather simply that something 'increases' the risk. Without this information they cannot make an informed decision. Baseline risks should be given for comparison, and risks should be stated in a consistent format as the actual rather than the relative risk.

GDG response: We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.

(These tables are in Appendix A[6] which includes the important comments that "this should not be taken

as definitive evidence based on the limitations of the included studies" and "the absolute risk remains low.")

Comments questioning recommendations that are not evidence based

The draft guideline recommended offering early induction purely on the basis of race, age, BMI or conception through IVF – a recommendation which was not only discriminatory but also likely to impact a substantial number of people without any evidence of benefit. Many people objected vociferously to this on grounds of racism. AIMS took a more measured and we hoped more effective tone, focusing on the lack of evidence to support the recommendation.

AIMS comment: We are concerned that the recommendation to consider induction from 39 weeks for women at a higher risk of complications is not evidence-based and could lead to large numbers of women having unwanted inductions purely because they fall into one of these 'higher risk' categories.

GDG Response: Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.

Wording in the final guideline: "Be aware that, according to the 2020 MBRRACE-UK report on perinatal mortality, women from some minority ethnic backgrounds or who live in deprived areas have an increased risk of stillbirth and may benefit from closer monitoring and additional support." Note that they have also quietly removed any mention of age, BMI or IVF as indications for induction!

Comments requesting that wording is clarified

In the original draft, the recommendations for information to be explained to women included "some methods of induction can cause the uterus to contract too frequently, called hyperstimulation, and that these too-frequent contractions can lead to changes in fetal heart rate and result in concerns about fetal wellbeing." We felt that this underplayed the potential risk to the baby's wellbeing, and that it was unhelpful to say "some methods" without explaining which ones might have this effect.

AIMS comment: We would like to see the wording "concerns about fetal wellbeing" strengthened to make it clear that hyperstimulation can cause actual fetal compromise and in some cases the need for an unplanned caesarean. It is not clear whether 'some methods' includes the use of an oxytocin drip, and we feel that the methods which have this potential effect should be stated.

GDG Response: We have amended the wording of this recommendation to state that hyperstimulation can lead to changes in fetal heart rate and result in fetal compromise {and} to make it clear that this just refers to pharmacological methods of induction (which would include oxytocin).

Wording in the final guideline: "pharmacological methods of induction can cause hyperstimulation – this is when the uterus contracts too frequently or contractions last too long, which can lead to changes in

fetal heart rate and result in fetal compromise."

Get involved

If you are a member of a relevant organisation you might want to encourage them to become a registered stakeholder for any new guidelines or updates that are of interest to you. The more stakeholder organisations that comment, the more likely the GDG is to listen.

Alternatively, anyone - whether or not you are an AIMS volunteer or member – is welcome to help us review draft guidelines and compile our submission. Please check our members newsletter or join our mailing list here www.aims.org.uk/join-us to hear about these or other opportunities to get involved, or contact enquiries@aims.org.uk to let us know you are interested in getting involved.

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[1]NICE (2014 - updated 2022) Identifying the evidence: literature searching and evidence submission | Developing NICE guidelines: the manual. www.nice.org.uk/process/pmg20/chapter/identifying-the-evidence-literature-searching-and-evidence-submission

[2]AIMS, Higson N. (2020) Understanding quantitative research evidence www.aims.org.uk/information/item/quantitative-research

[3] BMJ Siemieniuk R., Guyatt G. (No date) BMJ Best Practice-Evidence-based medicine (EBM) toolkit-Learn EBM-What is GRADE? bestpractice.bmj.com/info/toolkit/learn-ebm/what-is-grade/

[4] AIMS (2021) NICE Inducing Labour Guideline - Consultation on Draft July 2021 www.aims.org.uk/campaigning/item/nice-iol-comments

[5] NICE (2021) Inducing labour (update)Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021 www.nice.org.uk/guidance/ng207/documents/guidance-consultation-comments-and-response

[6] NICE (2021) Appendix A: Risks associated with different induction of labour timing strategies www.nice.org.uk/guidance/ng207/resources/appendices-a-b-and-c-10883967373/chapter/Appendix-A-Risks-associated-with-different-induction-of-labour-timing-strategies