**Consultation on draft guideline – deadline for comments 5pm on 6 July 2021 email:** inducinglabourupdate@nice.org.uk

**Checklist for submitting comments**

- Use this comments form and submit it as a **Word document (not a PDF)**.
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include **document name, page number and line number** of the text each comment is about.
- Combine all comments from your organisation into 1 response form. **We cannot accept more than 1 response from each organisation**.
- **Do not** paste other tables into this table – type directly into the table.
- Ensure each comment stands alone; **do not** cross-refer within one comment to another comment.
- **Clearly mark any confidential information or other material that you do not wish to be made public. Also, ensure you state in your email to NICE that your submission includes confidential comments.**
- **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted.
- Spell out any abbreviations you use.
- For copyright reasons, **do not include attachments** such as research articles, letters, or leaflets. We return comments forms that have attachments without reading them. You may resubmit the form without attachments, but it must be received by the deadline.
- **We have not reviewed the evidence for the recommendations shaded in grey. Therefore, please do not submit comments relating to these recommendations as we cannot accept comments on them.**
- **We do not accept comments submitted after the deadline stated for close of consultation.**

You can see any guidance that we have produced on topics related to this guideline by checking NICE Pathways.

**Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.

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| | **Please read the checklist above before submitting comments. We cannot accept forms that are not filled in correctly.** |

**Inducing labour (update)**

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| | We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment.<br><br>In addition to your comments below on our guideline documents, we would like to hear your views on these questions. **Please include your answers to these questions with your comments in the table below.**<br>1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.<br>2. Would implementation of any of the draft recommendations have significant cost implications?<br>3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)<br>4. The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.<br>See Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting. |
| **Organisation name** (if you are responding as an individual rather than a registered stakeholder please specify). | AIMS (Association for Improvements in the Maternity Services) |
| **Disclosure** (please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry). | None |
| **Name of person completing form** | Debbie Chippington Derrick |

**Consultation on draft guideline – deadline for comments 5pm on 6 July 2021 email:** inducinglabourupdate@nice.org.uk

| **Comment number** | **Document** [e.g. guideline, evidence review A, B, C etc., methods, EIA] | **Page number** **'General'** for comments on whole document | **Line number** **'General'** for comments on whole document | **Comments**<br>• Insert each comment in a new row.<br>• Do not paste other tables into this table, because your comments could get lost – type directly into this table.<br>• Include section or recommendation number in this column. |
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| 1 | Guideline | General | | 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. |
| 2 | Guideline | General | | Discussions should include information about the quality of the evidence underlying each recommendation. |
| 3 | Guideline | General | | 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. Especially in cases where 'consider' has been used it ought to read 'consider offering'. |
| 4 | Guideline | General | | We feel it would be helpful to clarify that for all indications where induction is offered women should also be offered the option of a planned caesarean as well as expectant management |
| 5 | Guideline | General | | We would ask that the term 'prolonged pregnancy' be changed to read' longer pregnancy' or other similar term which does not imply the presence of pathology. |
| 6 | Guideline | general | | We are deeply concerned that in many places "the committee were aware that.." is used without reference to any research that would inform whether it would be appropriate to offer induction. We feel that the guideline should in all cases make clear what evidence, if any, there is to support the recommendation and the quality of that evidence. We are particularly concerned about recommendations based on race without any evidence to support the benefit of offering induction early on this basis. |
| 7 | Guideline | 1 | In Box | "We suggest checking whether the wording "and this should be taken to include people who do not identify as women but who have given birth" is acceptable to the a range of individuals and organisations in the LGBTQ+ community" |
| 8 | Guideline | 4 | 1 | The statement "People have the right to be involved in discussions and make informed decisions about their care" should more accurately say "People have the right to be given the information that they |

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| | | | | need to make informed decisions about their care, and to have those decisions respected" to reflect the legal principle of autonomy (see www.birthrights.org.uk/factsheets/consenting-to-treatment/ ) |
| 9 | Guideline | 4 | 6 | It is not clear when the explanation should be taking place and we would suggest that this should be provided in early pregnancy, including information in a written or other accessible format. |
| 10 | | 4 | 10 | Suggest adding "discuss with the woman their preferences and priorities for their birth experience. Where induction of labour is chosen, consider how these wishes can be best facilitated in an obstetric setting, taking into account any staffing and equipment limitations". |
| 11 | Guideline | 4 | 11 | "their choice of place of birth may be limited, as they may need interventions" should say " ...may be recommended to have further interventions". |
| 12 | Guideline | 4 | 19 | 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. |
| 13 | Guideline | 4 | 19 | 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. |
| 14 | Guideline | 4 | 19 | Other information which should be given to women in early pregnancy includes the greater pain which they may experience from induction and the use of oxytocin compared with spontaneous labour, especially in the event of hyperstimulation, and the fact that they are more likely to require an epidural for pain relief. |
| 15 | Guideline | 5 | 3 | Section 1.1.3. Add that women should be informed about the number of vaginal examinations likely to be recommended, and the discomfort this may involve. |
| 16 | Guideline | 5 | 3 | Also add that they have the right to stop the induction process at any time. |
| 17 | Guideline | 5 | 3 | 1.1.3 We suggest including that women should be advised that low Bishop's score is linked to a higher chance of failed induction/unplanned caesarean, and that a baseline examination for cervical assessment be offered for those whose decision might be affected by the findings. |
| 18 | Guideline | 5 | 22 | We suggest adding the wording "Advise women that they are entitled to decline the offer of treatment such as induction of labour or caesarean birth, even when it would benefit their or their baby's health and..." ahead of "support the woman in whatever decision she makes". We also suggest adding the words "Do not attempt to coerce a woman into changing her decision, even if you disagree with it." |
| 19 | Guideline | 6 | 3 | We would ask that women be told the percentage or proportion of labours which will have started by 42 weeks, or even better to quantify by 40, 41, 42 and 43 weeks. |
| 20 | Guideline | 6 | 5 | We are please to see this amended wording recognising the need to take account of individual circumstances, but it would be even better to say "Discuss her individual circumstances and preferences and provide any information she requires to help her decide about options for birth, including:" |

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| 21 | Guideline | 6 | 12 | In order to make an informed decision women need to know what the actual increase in the risk of each adverse outcome would be, rather than just being told it 'increases' without knowing by how much. For example, they should be told the actual stillbirth rate per 1000 at 40, 41, 42 and 43 weeks of pregnancy. We would therefore like to see this wording amended to say<br>"Offer women information about the increase in actual risks beyond 40+0 weeks of:" |
| 22 | Guideline | 6 | 20 | The wording should be "Consider offering induction…"<br>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. We think that the recommendation ought at least to put greater emphasis on the need for an individualised assessment of risks, including socioeconomic factors and the woman's medical as well as obstetric history.<br>We note that although there are no RCTs to inform this recommendation, there is a recent UK cohort study of induction in older mothers (Knight et al 2017 Perinatal mortality associated with induction of labour versus expectant management in nulliparous women aged 35 years or over: An English national cohort study (plos.org). This found no difference in perinatal deaths with induction at 39 weeks, but a reduced rate with induction at 40 weeks compared to expectant management. Although such a study has limitations, given the lack of other evidence we suggest that the recommendation should read "Discuss with women... whether she wishes to bring forward the birth to between 39+0 and 40+0 weeks" |
| 23 | Guideline | 6 | 24 | The section "Take into account:<br>● the risk of complications<br>● the woman's preferences<br>● the woman's previous obstetric history"<br>should be replaced with wording which reflects the autonomy of the woman as the decision-maker and the need for tailored information e.g. "Support her decision-making by offering to discuss with her:<br>● the actual increase in the risk of complications in the light of her obstetric history, health status and socio-economic factors<br>● her preferences and other factors of importance in her decision-making". |
| 24 | Guideline | 7 | 16 | suggest "recognising the need to avoid pressuring the person towards intervention" etc |
| 25 | Guideline | 8 | 4 | This section needs to make clear that a woman could choose to continue expectant management beyond 37 weeks if she had not gone into labour by then. The GDG may wish to suggest a further discussion of the options at this point, either to accept induction or continue expectant management. |

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| | | | | Alternatively the wording could be amended to "the options of expectant management until **at least** 37+0 weeks…" |
| 26 | Guideline | 8 | 5 | Replace the words "When making a shared decision" with "Provide information about the following factors to enable her to make an informed decision:" |
| 27 | Guideline | 8 | 7 | This should specify the need to offer information about actual risks e.g rates of sepsis per 1000 women/babies after preterm prelabour rupture of the membranes with immediate induction or expectant management till 37 weeks. |
| 28 | Guideline | 8 | 21 | Since women have the right to decline induction even if it is 24 hours since prelabour rupture of the membrane it is incorrect to recommend that the only choices to be offered are<br>● "induction of labour as soon as possible or<br>● expectant management for up to 24 hours"<br>This section should therefore say:<br>● induction of labour as soon as possible or<br>● induction after 24 hours or<br>● expectant management<br>and "Discuss the risks and benefits of all three options…"<br><br>We would also ask that the guideline makes it clear that women have the right to decline 'expectant management' and just to wait for spontaneous labour to start without any form of surveillance or monitoring, but also that there is very limited evidence about what is offered in the package of care referred to as 'expectant management. |
| 29 | Guideline | 9 | 10-12 | In order to make an informed decision women need to know what the actual increase is in the risk of these adverse outcomes with induction. |
| 30 | Guideline | 9 | 17 | Rather than "If delivery is indicated" suggest "if there are reasons for the baby to be born early…" |
| 31 | Guideline | 9 | 23 | "may benefit" rather than "would benefit" |
| 32 | Guideline | 10 | 9 | We would request that delivery is change to birth in this sentence |
| 33 | Guideline | 10 | 23 | This should recommend giving actual figures for how common shoulder dystocia is in cases of fetal macrosomia, and by how much induction may reduce the risk, as well as by how much it increases the risk of tears, to enable women to make an informed decision. |
| 34 | Guideline | 12 | 7 | We would like clarity around why the recommendation is to wait 36-48 hours after mifepristone as parents may not want to wait so long. |
| 35 | Guideline | 13 | 3 | Needs to include something about when a sweep might not be possible or advisable |

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| 36 | Guideline | 13 | 5 | This should recommend that women are given actual figures for the likelihood of going into labour with or without a membrane sweep to enable them to judge the potential benefit of having this. |
| 37 | Guideline | 13 | 10 | Replace “Obtain consent from the woman before carrying out membrane sweeping.” with “Do not carry out a membrane sweep unless you have obtained the woman’s informed consent.” Some women might decline it! |
| 38 | Guideline | 13 | 14 | What is the justification for offering a membrane sweep at 39 weeks? (This conflicts with membrane sweep discussion later in the document.) As far as we know there is no evidence to support membrane sweep <40 weeks and Avdiyocski (2019) suggests an increased risk of pre-labour rupture of membranes with early membrane sweep: this doesn't seem to have been considered. |
| 39 | Guideline | 13 | 16 | Should say ‘consider offering’ not ‘consider, although we feel “discuss” would be better.<br>What is meant by “additional membrane sweeping if labour does not start spontaneously”? What is the evidence for this? This probably needs to either specify a gestation or an elapsed time after the first sweep at which to discuss the timing of further sweeps (if the evidence supports this). |
| 40 | Guideline | 13 | 19 | A vaginal examination to assess the Bishop’s score and any method of induction are also things to be offered. It would be better to say “Explain to women that a vaginal examination to assess the readiness of the cervix (recorded as the Bishop score) will be offered as this will help her to decide which method of induction to use first.” |
| 41 | Guideline | 14 | 2 | Women should be told the actual risks of hyperstimulation with both dinoprostone and misoprostol |
| 42 | Guideline | 14 | 10 | The preceding section says that induction will be stopped should hyperstimulation occur but not what might happen then. This section therefore needs an additional comment about what women should be told about what their options would be in that situation. |
| 43 | Guideline | 14 | 11/17/23 | Suggest recommendation 1.3.9, 1.3.10 and 1.3.11 are combined. This needs to include a recommendation to discuss the risks and benefits of both prostaglandins and mechanical methods, including the risk of hyperstimulation and the chances of success, and support the woman’s decision about which to try. |
| 44 | Guideline | 15 | 1 | This implies that amniotomy and intravenous oxytocin infusion should be offered together, but women may prefer to try these sequentially. It would be better to say “offer induction of labour with amniotomy, followed by the offer of an intravenous oxytocin infusion if active labour does not start within an agreed individualised timeframe.” |
| 45 | Guideline | 16 | 22 | Pleased to see this recommendation |
| 46 | Guideline | 17 | 3 | Offer to reassess... |
| 47 | Guideline | 17 | 6 | Offer to carry out... |
| 48 | Guideline | 17 | 18 | Discuss the option of… in the light of the woman’s medical and obstetric history |
| 49 | Guideline | 18 | 14 | Pleased to see unsuccessful used here |

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| 50 | Guideline | 19 | 9 | **Multiple concerns with this paragraph;** 1) CTG is listed in the "prevention" of complications section - this is not a preventative measure, but we presume is intended to expedite detection of fetal compromise in the event of significant cord compression. We suggest "take the following precautions to predict the likelihood of cord prolapse and expedite diagnosis of fetal compromise in such an event" 2) The paragraph appears to imply that the woman should remain attached to CTG for the duration of her (potentially prolonged) antenatal stay - we suggest this is inappropriate and impractical. It would be better to recommend that CTG only be offered if there has been rupture of membranes in order to detect suspected fetal compromise at this point, leading to the offer of examination and diagnosis. 3) We suggest that when a woman is considered to be at higher risk of cord prolapse, this should be specifically discussed, along with the potential implications including the possible need for an urgent caesarean. |
| 51 | Guideline | 20 | 28 | Disappointing that membrane sweeping is seen as an adjunct rather than a method of IOL. It is implied further up the document that this is the beginning of the sequential IOL process. Given that there are recommendations to start at 39+0 to offer "additional" membrane sweeps (potentially over and over), it would be good to see this reconsidered. It is, after all, an intervention, and not a benign one. All references to the offer of membrane sweeps must be accompanied by an assessment of the evidence. |
| 52 | Guideline | 20 | 22 | It is a very likely to be the case that labour will start naturally given time! Need to talk about within a timeframe acceptable to the woman. |
| 53 | Guideline | 21 | 13 | We note with interest several reviews of the evidence quoted within this guideline and would suggest that there are limitations and ongoing areas of uncertainty which would justify further research, in particular with regard to recommendations on the timing of birth. Indeed, it seems to us to be the case that the changes to the recommendations included in this draft ARE NOT underpinned by clear evidence and have the potential, given what we know about the implementation context, to do significant harm.<br>We would welcome further research into maternal satisfaction with IOL and more holistic effects over time on the family unit associated with different birth experiences. |
| 54 | Guideline | 24 | 16 | We question why, given that you state "there was not enough evidence to identify the optimal timing of induction more precisely" between 41 and 42 weeks you decided to recommend "offer induction of labour at 41+0 weeks, to take place then or as soon as possible afterwards." rather than " between 41+0 and 42+0 weeks" as in the previous version.<br>We are concerned that this recommendation is based entirely on the SWEPIS study which was stopped early and changed the primary outcome and is therefore not reliable evidence on which to base a recommendation with the potential to affect so many women and babies. We also note that the SWEPIS study found a much higher incidence of perinatal deaths than any previous trial, or than the |

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| | | | | authors anticipated in designing the sample. This also casts doubt on whether these findings would have occurred had the trial continued as originally planned. |
| 55 | Guideline | 25 | 4 | There can be little doubt that these recommendations 'are likely to' rather than 'may' increase the number of women who are offered induction.<br>We note that there is no discussion of the impact this may have on mental wellbeing, or the long-term health impact of induced labour on both women and babies. |
| 56 | Guideline | 28 | 22 | Given the discussion here that there is evidence for mechanical methods such as balloon catheters being effective at promoting vaginal birth within 24 hours without an increased risk of hyperstimulation, we question why pharmacological methods are presented as the first choice, and mechanical methods described only as an option to consider if 'pharmacological methods are not suitable' or the **mother prefers it.** |
| 57 | Guideline | 29 | 12 | This should say "Induced labour may be recommended in circumstances where it appears that the benefits outweigh the risks for mother and baby of continuing a pregnancy…" |
| 58 | Algorithm | | | suggest change "obtain consent" to, "request/check consent" |
| 59 | Algorithm | | All stages | Rather than 'before making decisions' this should say 'before they make their decisions' to clarify that it is women who are the decision-makers. |
| 60 | Algorithm | | Bishop score 6 or less | Replace 'Consider' with 'Offer the option of' for both oral misoprostol and mechanical methods |
| 61 | Algorithm | | Bishop score more than 6 | As above - why ARM and IV oxytocin together rather than waiting a while after ARM? |
| 62 | Algorithm | | cord prolapse | as above re continuous CTG - offer or consider - logically, no way ctg can have any predictive role here - not going to prolapse with intact membranes, and ctg is always offered following rupture of membranes in IOL for this reason<br>('To reduce the likelihood of cord prolapse:" - CTG doesn't reduce risk…) |
| 63 | Evidence review D (4) | 9 | 4 | seems to imply women with IUD and unscarred uterus don't also need one-to-one care |
| 64 | Evidence review D (4) | 10 | 29 | committee decided not to recommend mifepristone…. should this read "at the higher dose of 600mg"? |

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| 65 | Equality impact assessment | | 3.4 | IOL does make things more difficult for women with complex social factors/ unsupported. Longer stays, transport costs for birth supporters, childcare concerns etc |

Insert extra rows as needed

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