AMA Queensland Feedback on QH Queensland Clinical Guideline: Induction of labour v0.02

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General Feedback

AMA Queensland strongly advocates for clinical guidelines that are evidence-based and consistent with best practice models of care. This is the only means of ensuring patient safety and optimal health outcomes. Clinical guidelines that are not based on rigorous science and represent vested interests only serve to place the community at risk and denigrate the reputation of the health profession generally.

AMA Queensland does not support key aspects of Queensland Clinical Guidelines' *Induction of labour* (v0.02) (the 'Guideline'). Reiterating the feedback provided on *Queensland Clinical Guidelines: Normal Birth v4* submitted to Queensland Health on 5 August 2022, AMA Queensland notes the Guideline fails to take a multidisciplinary approach, excluding obstetricians and obstetric treatment in vital aspects of clinical care.

Any induction of labour (IOL) requires obstetrician involvement as it is outside the scope of practice for midwives, who provide expert care in uncomplicated pregnancy and vaginal delivery. The Guideline's contemplation of home-based IOL is alarming, dangerous and contrary to established clinical protocols and must be immediately deleted.

The Guideline must also be amended to include respectful, neutral terminology and only those treatments which are substantiated by current, rigorous scientific evidence. Set out below are the key issues which AMA Queensland submits must be amended before the Guideline is finalised to ensure patient safety and best practice care.

Inappropriate Terminology

AMA Queensland reiterates its feedback provided on *Queensland Clinical Guidelines: Normal Birth v4* (the 'NB v4 Guideline') submitted to Queensland Health on 5 August 2022. AMA Queensland reiterates its request that neutral terminology be adopted throughout all clinical guidelines to ensure patient inclusiveness and best practice care. Inappropriate terminology included in the Guideline should be amended as per the table below.

Current Inappropriate Terminology	Replacement Neutral Terminology
Intervention	Treatment
Birthing	Birth
Women	Female patients
Mother	Mother and Birth-Parent, or Patient
Normal birth	Vaginal birth

Feedback by Section & Page Number

- Flow chart: 'Method of IOL', page 3
    - AMA Queensland is alarmed and disappointed that the Guideline continues the adversarial, exclusionary and anti-obstetrician and obstetric treatment approach taken by Queensland Clinical Guidelines (QCG) in its NB v4 Guideline. This only serves to place patients at risk and denigrate the reputation of midwives and the profession generally. It also calls into question the professionalism and integrity of the entire Guideline and its proponents.
    - AMA Queensland submits that all decisions for IOL must involve an obstetrician. It is out of scope for midwives or any other health practitioner to induce labour. To suggest otherwise is misleading and dangerous.
- Table 1: 'Clinical standards', page 11
    - AMA Queensland suggests the table include the reasons IOL is increasing across Australia. These include maternal request; advancing maternal age; comorbidities such as GDM, hypertension etc; and international literature that suggests IOL may be associated with a decrease in unexplained stillbirth at term.[1]
- Table 2: 'Timing of birth', page 12
    - AMA Queensland suggests inclusion of unexplained stillbirth in the risk associated with early-term birth.
- Table 3: 'Setting for cervical ripening', page 13
    - AMA Queensland is alarmed at the suggestion in the Guideline that IOL could be undertaken at home. IOL is an obstetric treatment and should only be undertaken in a clinical location where electronic fetal monitoring is available and action can be taken where abnormal monitoring is observed.
    - AMA Queensland submits there are no settings other than hospitals that are appropriate for IOL. We note:
        - the manufacturers of Cervidil (dinoprostone) explicitly state 'CERVIDIL should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities'; and that it is 'For Hospital Use Only -- CERVIDIL should be administered in a hospital setting with an obstetrical care facility';[2]
        - Pfizer Australia's Medical Information for Prostin E2 Vaginal (dinoprostone) states "PROSTIN E2 Vaginal Gel should only be used under the supervision of qualified medical personnel in obstetric units with facilities for fetal and maternal monitoring and operative delivery. It is recommended that during induction of labour with PROSTIN E2 Vaginal Gel that continuous monitoring of uterine activity and fetal heart rate be employed";[3]
        - the UK electronic medicines compendium states the following about the dosage and administration of Prostin E2 Vaginal Gel (dinoprostone) "Usage is restricted to qualified health care professionals and to hospitals and clinics with specialised obstetric units with facilities for continuous monitoring";[4] and

[1] See, for example: https://www.nejm.org/doi/full/10.1056/NEJMe1807747
[2] Cervidil, 'Full Prescribing Information' (revised Jan 2020), sections 2.2 and 5.1, available at: https://d2hu1op93domjx.cloudfront.net/wp-content/uploads/sites/12/2021/06/24085312/CERVIDIL-USPI-Clean-Rev.-01.2020.pdf.
[3] Available at: https://apps.medicines.org.au/files/pfpproeg.pdf.
[4] Available at: https://www.medicines.org.uk/emc/files/pil.1090.pdf.

        - the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) does not support cervical ripening with prostaglandin outside the hospital setting. Its Induction of Labour Guidelines states 'Once the prostaglandin has been inserted, your baby will be monitored and you will need to stay in hospital'.[5]
    - There are also important and concerning medico-legal implications should IOL be conducted anywhere but hospitals. If Queensland Health and QCG intend to implement IOL in practices outside manufacturer and RANZCOG recommendations, they must clearly articulate this stance and fund the associated indemnity costs.
- Table 4: 'Risks and benefits of IOL', page 14
    - AMA Queensland suggests the following should be included in the cited 'Benefits' of IOL:
        - A decrease in perinatal death, NICU admissions and rates of cesarean section without an increase in rates of operative vaginal births.[6]
        - Improved outcomes for patients with comorbidities from delivering during business hours when the entire support team including other specialists such as haematology and renal medicine are available.
- Table 5: 'Outcomes for IOL versus expectant management at *term', page 15
    - AMA Queensland fully supports Table 5 and submits it should be provided to patients considering IOL.
    - In addition, AMA Queensland recommends it forms part of the patient consent process for accepting or declining IOL where recommended by an obstetrician.
- Table 8: 'Indications covered in other Queensland Clinical Guidelines', page 18
    - AMA Queensland submits the Cochrane Review should be included in Table 8 since it showed IOL was associated with decreased perinatal death, NICU admissions and rates of cesarean section without an increase in rates of operative vaginal births.[7]
- Table 11: 'Suspected fetal macrosomia', page 19
    - AMA Queensland does not support the inclusion of 'higher incidences of third and fourth degree perineal tears' as a 'Consideration' in Table 11.
    - The large United Kingdom trial, documented in the Ockenden Review, did not find IOL was associated with a higher incidence of third and fourth degree perineal tears.[8] As such, this 'Consideration' cannot be included because it is not supported by current scientific evidence.
- Table 12: 'Obstetric cholestasis', page 20
    - AMA Queensland submits the associated serum total bile acid levels in the 'Risk/Benefit' section of Table 12 should be amended to be consistent with the Key Recommendations of the Royal College of Obstetricians and Gynaecologists (RCOG) Green-Top Guidelines *Intrahepatic cholestasis of pregnancy* (June 2022), specifically:[9]

[5] RANZCOG, 'Induction of Labour Guideline' (July 2021), available at: https://ranzcog.edu.au/wp-content/uploads/2022/06/Induction-labour-pamphlet.pdf.
[6] The Cochrane Collaboration, 'Induction of labour at or beyond 37 weeks' gestation (Review) (2020), available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004945.pub5/epdf/abstract.
[7] The Cochrane Collaboration, 'Induction of labour at or beyond 37 weeks' gestation (Review) (2020), available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004945.pub5/epdf/abstract.
[8] Available at: https://www.gov.uk/government/publications/final-report-of-the-ockenden-review/ockenden-review-summary-of-findings-conclusions-and-essential-actions.
[9] Available at: https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17206.

        - *Advise women with isolated ICP and a singleton pregnancy that the risk of stillbirth only increases above population rate once their serum bile acid concentration is 100 micromol/L or more.*
        - *In women with peak bile acids 19–39 micromol/L (mild ICP) and no other risk factors, advise them that the risk of stillbirth is similar to the background risk. Consider options of planned birth by 40 weeks' gestation or ongoing antenatal care according to national guidance.*
        - *In women with peak bile acids 40–99 micromol/L (moderate ICP) and no other risk factors, advise them that the known risk of stillbirth is similar to the background risk until 38–39 weeks' gestation. Consider planned birth at 38–39 weeks' gestation.*
        - *In women with peak bile acids 100 micromol/L or more (severe ICP), advise them that the risk of stillbirth is higher than the background risk. Consider planned birth at 35–36 weeks' gestation. [Grade A]*
    - AMA Queensland submits IOL should be considered in cases of obstetric cholestasis from 36 weeks, not 37 as included in Table 12. This is supported by current scientific evidence in publications including Up to Date which also recommends clinical evaluation by an obstetrician.[10]
    - AMA Queensland also submits the Guideline should not remove the opportunity for individualisation of health care in favour of strict, protocol-driven processes. Best practice models are evidence-based and, after patient safety, prioritise individual patient choice.
    - In addition, there have been a number of medico-legal cases where the key issue was the appropriateness of the gestational age at which patients with cholestasis were given IOL. It is important that the Guideline does not add to the current uncertainty by imposing an arbitrary 37-week gestational age which is not currently supported by the science.
- Table 13: 'Advance maternal age', page 20
    - Most obstetric documents define 'advanced maternal age' as 35 years or older. AMA Queensland requests an explanation as to why the Guideline differs and recommends 40 years or older.
    - AMA Queensland submits the Guideline's recommendation of 40 years or older is not based on the current scientific evidence and it should be amended to state 35 years or older.
- Table 15: 'Other fetal concerns', page 21
    - AMA Queensland submits the 'expert practitioner' referred to under the 'Recommendation' section of Table 15 is an obstetrician and should be specifically identified as an obstetrician.
    - Further, it is the role of obstetricians to consult with physicians and neonatologists or other experts as deemed clinically necessary. This should also be included in Table 12.
- Table 16: 'Maternal request', page 21
    - AMA Queensland submits that the 'Recommendation' section in Table 16 must include reference to clinical practice standards that an obstetrician must assess the suitability for IOL.

[10] Available at: https://www.wolterskluwer.com/en/solutions/uptodate/uptodate.

- Table 18: 'Membrane sweeping', page 22
    - AMA Queensland submits that the inclusion of serial membrane sweeping every 2 days is a very invasive treatment and specific patient consent must be obtained if this is to be included in the final guideline.
- Table 21: 'Balloon catheter considerations', page 24
    - AMA Queensland advises that patient acceptability data for balloon induction appears to be less favourable than for other cervical ripening methods which should be noted in the Guideline.
    - Under the 'Risk' section of Table 21 must be included reference to patient acceptability. Again, AMA Queensland reiterates its statement that best practice models are evidence-based and, after patient safety, prioritise individual patient choice.
- Table 22: 'Dinoprostone', page 25
    - Under 'Contraindication' in Table 22, AMA Queensland suggests a definition should be included for 'Grand multiparity'. The number of patients having large numbers of children is decreasing and traditional definitions may no longer be valid.
    - Further, if any induction method is undertaken in a grand multiparity with an unfavourable cervix, there are safety advantages with balloon or Cervidil over Prostin gel due to the ease of removal.
- Table 23: 'Artificial rupture of membranes', page 26
    - AMA Queensland notes the MBS score for treatments has increased from previous versions of the Guideline. The MBS score for favourable cervix under 'Indication' in Table 23 is listed as '7 or more', however, previous guidelines used to state ARM could be undertaken at MBS 6.
    - AMA Queensland requests an explanation for this increase from MBS 6 to MBS 7 including the supporting scientific evidence.
- Table 26: 'Unsuccessful IOL', page 27
    - AMA Queensland submits that under 'Context' in Table 26 a further 'Consideration' should be added to include the circumstance where the patient requests cessation of IOL and a cesarean section.
- Appendix D: Oxytocin regimen administration, 'Oxytocin regimen', page 36:
    - AMA Queensland submits the table on page 36 should be replaced with the table on the following page.
    - In addition, AMA Queensland submits the table and related parts of the Guideline are amended to ensure an obstetrician must be consulted before any syntocinon is commenced, and that the patient must have an additional obstetric review if the rate is to be increased above 20 milliunits.

Infusion: oxytocin (30 International units in 500 mL) 1 milliunit/minute is equal to 1 mL/hour Obstetrician consultation required	
Time after starting (minutes)	**Dose (milliunit/minute)**
0	1
30	2
60	4
90	8
120	12
150	16
180	20
Prior to exceeding 20 milliunit/minute: Obstetrician review required	
210	24
240	28
270	32