Queensland Clinical Guidelines

Translating evidence into best clinical practice

Maternity and Neonatal **Clinical Guideline**

Supplement: Perinatal substance use: neonatal

Queensland Government

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1 Introduction

This document is a supplement to the Queensland Clinical Guideline Perinatal substance use: neonatal. It provides supplementary information regarding guideline development, makes summary recommendations, suggests measures to assist implementation and quality activities and summarises changes (if any) to the guideline since original publication. Refer to the guideline for abbreviations, acronyms, flow charts and acknowledgements.

1.1 Funding

The development of this guideline was funded by Queensland Health Healthcare Innovation and Research Branch. Consumer representatives were paid a standard fee. Other working party members participated on a voluntary basis.

1.2 Conflict of interest

Declarations of conflict of interest were sought from working party members as per the Queensland Clinical Guidelines *Conflict of Interest* statement. No conflict of interest was identified

1.3 Guideline review

Queensland clinical guidelines are reviewed every 5 years or earlier if significant new evidence emerges. Table 1 provides a summary of changes made to the guidelines since original publication.

Table 1. Summary of change

Publication date *Endorsed by:*	**Identifier**	**Summary of major change**
April 2016 *Statewide Maternity and Neonatal Clinical Network*	MN16.38-V1-R21	First publication Replaces Neonatal Abstinence Syndrome guideline (MN10.10-V4-R15)
February 2017	MN16.38-V2-R21	Appendix A amended Scores amended: • Sneezing > 3–4 in half hour score 1 • Nasal flaring score 2

2 Methodology

Queensland Clinical Guidelines (QCG) follows a rigorous process of guideline development. This process was endorsed by the Queensland Health Patient Safety and Quality Executive Committee in December 2009. The guidelines are best described as 'evidence informed consensus guidelines' and draw from the evidence base of existing national and international guidelines and the expert opinion of the working party.

2.1 Topic identification

The topic was identified as a priority by the Statewide Maternity and Neonatal Clinical Network at a forum in 2009.

2.2 Scope

The scope of the guideline was determined using the PICO Framework (Population, Intervention, Comparison, and Outcome) as outlined in Table 2.

Table 2. PICO Framework

PICO	
Population	Babies born to substance using women
Intervention	Clinical surveillance and management of babies after birth and during postnatal period
Comparison	n/a
Outcome	Early diagnosis of babies with NAS and others born to substance using women Best practice care of babies with NAS and others born to substance using women and their families

2.3 Clinical questions

The following clinical questions were generated to inform the guideline scope and purpose:

- What are the commonly used substances?
- How are babies with NAS identified?
- What best practice care can be provided to babies with NAS?
- What are the considerations when planning discharge of babies of substance using women?

2.4 Exclusions

The following exclusions were identified in the guideline scope:

- Fetal alcohol syndrome
- Drugs for analgesia for babies (e.g. undergoing surgery; Intensive care)

2.5 Search strategy

A search of the literature was conducted during July and August 2015. The QCG search strategy is an iterative process that is repeated and amended as guideline development evolves and the draft guideline is refined, additional areas of interest emerge, areas of contention requiring more extensive review are identified or new evidence is identified. All guidelines are developed using a basic search strategy. This involves both a formal and informal approach.

Table 3. Basic search strategy

Step		Consideration
1.	Review clinical guidelines developed by other reputable groups relevant to the clinical speciality	• This may include national and/or international guideline writers, professional organisations, government organisations, state based groups. • This assists the guideline writer to identify: o The scope and breadth of what others have found useful for clinicians and informs the scope and clinical question development o Identify resources commonly found in guidelines such as flowcharts, audit criteria and levels of evidence o Identify common search and key terms o Identify common and key references
2.	Undertake a foundation search using key search terms	• Construct a search using common search and key terms identified during Step 1 above • Search the following databases o PubMed o CINAHL o Medline o Cochrane Central Register of Controlled Trials o EBSCO o Embase • Studies published in English less than or equal to 5 years previous are reviewed in the first instance. Other years may be searched as are relevant to the topic • Save and document the search • Add other databases as relevant to the clinical area
3.	Develop search word list for each clinical question.	• This may require the development of clinical sub-questions beyond those identified in the initial scope. • Using the foundation search performed at Step 2 as the baseline search framework, refine the search using the specific terms developed for the clinical question • Save and document the search strategy undertaken for each clinical question
4.	Other search strategies	• Search the reference lists of reports and articles for additional studies • Access other sources for relevant literature o Known resource sites o Internet search engines o Relevant text books

2.5.1 Keywords

The following keywords were used in the basic search strategy. Other keywords may have been used for specific aspects of the guideline:

Neonatal, baby, infant, substance use, drug use/abuse, withdrawal, neonatal abstinence syndrome, alcohol, tobacco, illicit.

2.6 Consultation

Major consultative and development processes occurred between November and December 2015. These are outlined in Table 4.

Table 4. Major guideline development processes

Process	Activity
Clinical lead	• The nominated Clinical Lead was approved by QCG Steering Committee
Consumer participation	• Consumer participation was invited from a range of consumer focused organisations who had previously accepted an invitation for on-going involvement with QCG
Working party	• An EOI for working party membership was distributed via email to Queensland clinicians and stakeholders (~1000) in November 2015 • The working party was recruited from responses received • Working party members who participated in the working party consultation processes are acknowledged in the guideline • Working party consultation occurred in a virtual group via email
Statewide consultation	• Consultation was invited from Queensland clinicians and stakeholders (~1000) during November 2015 to December 2015 • Feedback was received primarily via email • All feedback was compiled and provided to the clinical lead and working party members for review and comment

2.7 Endorsement

The guideline was endorsed by the:

- Queensland Clinical Guidelines Steering Committee in March 2016
- Statewide Maternity and Neonatal Clinical Network [Queensland] in March 2016

2.8 Publication

The guideline and guideline supplement were published on the QCG website in April 2016.
The guideline can be cited as:

> Queensland Clinical Guidelines Perinatal substance use: neonatal. Guideline No. MN16.38-V2-R21. Queensland Health. 2016 Available from: http://www.health.qld.gov.au/qcg

The guideline supplement can be cited as:

> Queensland Clinical Guidelines. Supplement: Perinatal substance use: neonatal Guideline No. MN16.38-V2-R21. Queensland Health. 2016. Available from: http://www.health.qld.gov.au/qcg

3 Levels of evidence

The levels of evidence identified in the National Health and Medical Research Council (NHMRC) levels of evidence and grades for recommendations for developers of guidelines (2009), and the Canadian Paediatric Society were used to inform the summary recommendations. Levels of evidence are outlined in Table 5 and Table 6. Canadian Paediatric Society. Summary recommendations are outlined in Table 7.

Note that the 'consensus' definition* in Table 5. NHMRC is different from that proposed by the NHMRC and instead relates to forms of evidence not identified in the NHMRC's level of evidence and/or the clinical experience of the guideline's clinical lead and working party.

Table 5. NHMRC

NHMRC: Levels of evidence[1]	
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial**.**
III-1	Evidence obtained from well-designed pseudo randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies including systematic review of such studies with concurrent controls and allocation not randomised (cohort studies), case control studies or interrupted time series with a control group**.**
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.
Consensus*	Opinions based on respected authorities, descriptive studies or reports of expert committees or clinical experience of the working party.

Table 6. Canadian Paediatric Society

Canadian Paediatric Society Fetus and Newborn Committee[2]			
Level of evidence		**Strength of recommendations**	
I	Evidence obtained from at least one properly randomized controlled trial	A	There is good evidence to recommend the clinical preventive action
II-1	Evidence from well-designed controlled trials without randomization	B	There is fair evidence to recommend the clinical preventive action
II-2	Evidence from well–designed cohort (prospective or retrospective) or case–control studies, preferably from more than one centre or research group	C	The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
II-3	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D	There is fair evidence to recommend against the clinical preventive action
		E	There is good evidence to recommend against the clinical preventive action
III	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees	F	There is insufficient evidence to make a recommendation; however, other factors may influence decision-making

3.1 Summary recommendations

Summary recommendations and levels of evidence are outlined in Table 7.

Table 7. Summary recommendations

Recommendation		Grading of evidence
1	Perform a breastfeeding risk benefit analysis on an individual basis (e.g. Methadone use is not a contraindication to breast feeding)	**Consensus***
2	Avoid unnecessary separation of the baby from their mother	**Consensus***
3	Monitor all babies at risk of NAS and use a validated tool (e.g. Finnegan Tool) to assess signs of withdrawal	**III-2***
4	Initiate pharmacological treatment of infants with NAS due to opioids when the Finnegan score averages eight or more on three consecutive scores or 12 or more on two consecutive scores when assessed by an experienced scorer	**III-1***
5	Babies with exposure to SSRIs require observation for at least three days	**Grade A#**
6	Observe babies born to benzodiazepine-dependent women for 1 week in hospital before discharge, and provide an outpatient review weekly during the first month of life	**IV***

*NHMRC levels of evidence
#Canadian Paediatric Society levels of evidence

4 Implementation

This guideline is applicable to all Queensland public and private maternity facilities. It can be downloaded in Portable Document Format (PDF) from www.health.qld.gov.au/qcg

4.1 Guideline resources

The following guideline components are provided on the website as separate resources:

- Flowchart: Perinatal substance use: neonatal Management of neonatal abstinence syndrome
- Flowchart: Perinatal substance use: neonatal Morphine schedule
- Flowchart: Perinatal substance use: neonatal Phenobarbitone schedule
- Appendix A Finnegan neonatal abstinence severity score
- Appendix F Management of babies born to Hepatitis C infected woman
- Education resource: Perinatal substance use: neonatal
- Knowledge assessment: Perinatal substance use: neonatal
- Auditing resources: Perinatal substance use: neonatal
- Parent information brochure: Neonatal abstinence syndrome

4.2 Suggested resources

During the development process stakeholders identified additional resources with potential to complement and enhance guideline implementation and application. The following resources have not been sourced or developed by QCG but are suggested as complimentary to the guideline:

- Inter-observer reliability and intra-observer reliability testing tools
- Auditing resources: Perinatal substance use: neonatal

4.3 Implementation measures

Suggested activities to assist implementation of the guideline are outlined below.

4.3.1 QCG measures

- Notify Chief Executive Officer and relevant stakeholders
- Monitor emerging new evidence to ensure guideline reflects contemporaneous practice
- Capture user feedback
- Record and manage change requests
- Review guideline in 2021

4.3.2 Hospital and Health Service measures

Initiate, promote and support local systems and processes to integrate the guideline into clinical practice, including:

- Hospital and Health Service (HHS) Executive endorse the guidelines and their use in the HHS and communicate this to staff
- Promote the introduction of the guideline to relevant health care professionals
- Support education and training opportunities relevant to the guideline and service capabilities
- Align clinical care with guideline recommendations
- Undertake relevant implementation activities as outlined in the *Guideline implementation checklist* available at www.health.qld.gov.au/qcg

4.4 Quality measures

Auditing of guideline recommendations and content assists with identifying quality of care issues and provides evidence of compliance with the National Safety and Quality Health Service (NSQHS)Standards[3]. Suggested audit and quality measures are identified in Table 8. NSQHS Standard 1.

Table 8. NSQHS Standard 1

NSQHS Standard 1: Governance for Safety and Quality in Health Service Organisations	
Clinical Practice: Care provided by the clinical workforce is guided by current best practice	
Criterion 1.7:	**Actions required:**
Developing and/or applying clinical guidelines or pathways that are supported by the best available evidence	1.7.1 Agreed and documented clinical guidelines and/or pathways are available to the clinical workforce
	1.7.2 The use of agreed clinical guidelines by the clinical workforce is monitored

The following clinical quality measures are suggested:

Table 9. Clinical quality measures

No	Audit criteria	Guideline Section
1.	Use of validated scoring tool for neonates with NAS	2.5 Assessment of withdrawal
2.	Inter-observer reliability of use of Finnegan scoring tool	2.5 Assessment of withdrawal
3.	Occasions of neonate/maternal separation	4.2 Pharmacological care
4.	Number of neonates with NAS due to opioids commenced on pharmacological treatment when the Finnegan score averages eight or more on three consecutive scores or 12 or more on two consecutive scores when assessed by an experienced scorer	4.2 Pharmacological care
5.	Individual risk benefit analysis regarding breast feeding undertaken on individual basis	5.1 Breastfeeding
6.	Lengths of stay of neonates of substance using women appropriate for substance used	6 Discharge

4.5 Areas for future research

During development the following areas where identified as having limited or poor quality evidence to inform clinical decision making. Further research in these areas may be useful

- Nil identified

4.6 Safety and quality

Implementation of this guideline provides evidence of compliance with the NSQHS and Australian Council on Healthcare Standards (ACHS) EQuIPNational accreditation programs[3,4]

Table 10. NSQHS/EQuIPNational Criteria

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
Standard 1: Governance for Safety and Quality in Health Service Organisations		
Clinical practice 1.7 Developing and/or applying clinical guidelines or pathways that are supported by the best available evidence	1.7.1 Agreed and documented clinical guidelines and/or pathways are available to the clinical workforce	☑ Queensland Clinical Guidelines is funded by Queensland Health to develop clinical guidelines relevant to the service line to guide safe patient care across Queensland ☑ The guideline provides evidence-based and best practice recommendations for care ☑ The guideline is endorsed for use in Queensland Health facilities. ☑ A desktop icon is available on every Queensland Health computer desktop to provide quick and easy access to the guideline
Performance and skills management 1.12 Ensuring that systems are in place for ongoing safety and quality education and training	1.12.1 The clinical and relevant non-clinical workforce have access to ongoing safety and quality education and training for identified professional and personal development	☑ The guideline has accompanying educational resources to support ongoing safety and quality education for identified professional and personal development. The resources are freely available on the internet http://www.health.qld.gov.au/qcg
Standard 2: Partnering with Consumers		
Consumer partnership in designing care 2.5 Partnering with consumers and/or carers to design the way care is delivered to better meet patient needs and preferences	2.5.1 Consumers and/or carers participate in the design and redesign of health services	☑ Consumer consultation was sought and obtained during the development of the guideline. Refer to the acknowledgement section of the guideline for details
Standard 9: Recognising clinical deterioration and escalating care		
Establishing recognition and response systems 9.1 Developing, implementing and regularly reviewing the effectiveness of governance arrangements and the policies, procedures and/or protocols that are consistent with the requirements of the National Consensus Statement.	9.1.2 Policies, procedures and/or protocols for the organisation are implemented in areas such as: • Measurement and documentation of observations • Escalation of care • Establishment of a rapid response system • Communication about clinical deterioration	☑ The guideline is consistent with National Consensus statement recommendations ☑ The guideline recommends the use of the Maternity Early Warning Tool. The tool is consistent with principles of recognising clinical deterioration and escalating care

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
EQuIPNational		
Standard 12 Provision of care		
Criterion 1: Assessment and care planning 12.1 Ensuring assessment is comprehensive and based upon current professional standards and evidence based practice	12.1.1 Guidelines are available and accessible by staff to assess physical, spiritual, cultural, physiological and social health promotion needs	☑ Assessment and care appropriate to the cohort of patients is identified in the guideline ☑ The guideline is based on the best available evidence

References

1. National Health and Medical Research Council. NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. 2009; Canberra:Commonwealth of Australia.

2. Jefferies A, Canadian Paediatric Society Fetus and Newborn Committee. Selective Serotonin Reuptake Inhibitors in pregnancy and infant outcomes. Position Statement. 2014.

3. Australian Commission on Safety and Quality in Healthcare. National Safety and Quality Health Service Standards. 2012 [cited 2014, October 14]. Available from: http://www.safetyandquality.gov.au/.

4. The Australian Council on Healthcare Standards. EQuIPNational Guidelines. 2012 [cited 2014 October 20]. Available from: http://www.achs.org.au/programs-services/.