Queensland Clinical Guidelines

Translating evidence into best clinical practice

Maternity and Neonatal Clinical Guideline

Guideline supplement: Neonatal medicines



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1 Introduction

This document is a supplement to the Queensland Clinical Guideline (QCG) *Name of GL: Change in Advanced Document Properties.* 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 Healthcare Improvement Unit, Queensland Health. 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 <u>Conflict of Interest</u> statement. No conflict of interest was identified.

1.3 Summary of changes

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
August 2019 Queensland Neonatal Services Advisory Group	MN19.54-V1-R24	First publication

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 neonatal clinicians in 2018.

2.2 Scope

The scope of the guideline was determined using the following framework.

Table 2. Sco	pe framework
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Scope framewo	Scope framework		
Population Infants			
Purpose	Develop standard monographs for neonatal medicine use in Queensland		
Outcome	 Support: Safe neonatal medicine administration Standardised practice in neonatal medicine administration The potential to reduce medicine medication errors 		
Exclusions	 Administration via infusion devices not specified in the monograph Development of library guard rails and other software for device infusion Medications not included in the initial monograph review Drug pharmacokinetics Detailed mechanism of action and pharmacodynamics Brand availability/preference of the medicine monograph Comprehensive information of alternative how supplied dosage forms, and strengths associated with the medicine monograph 		

2.3 Clinical questions

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

- What are the safety considerations when using a neonatal medicine monograph?
- What domains should be included in the neonatal medicine monograph?

2.4 Search strategy

A search of the literature was conducted during October to November 2018. The QCG search strategy is an iterative process that is repeated and amended as guideline development occurs (e.g. if 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: The scope and breadth of what others have found useful for clinicians and informs the scope and clinical question development Identify resources commonly found in guidelines such as flowcharts, audit criteria and levels of evidence Identify common search and key terms 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 PubMed CINAHL Medline Cochrane Central Register of Controlled Trials EBSCO 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 Known resource sites Internet search engines Relevant text books 		

2.4.1 Keywords

The following keywords were used in the basic search strategy: medication, medication safety, neonatal medication, medication error, medication management, medication administration, parenteral access, umbilical artery access.

Other keywords may have been used for specific aspects of the guideline.

2.5 Consultation

Major consultative and development processes occurred between January and June 2019. These are outlined in Table 4.

Process Activity	
Clinical lead	The nominated Clinical Leads were 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 in September 2018 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 Each monograph is review by the working party

Table 4. I	Major	guideline	development proc	esses
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2.6 Endorsement

The guideline was endorsed by the:

- Queensland Clinical Guidelines Steering Committee in August 2019
- Statewide Neonatal Services Advisory Group in August 2019

2.7 Publication

The guideline and guideline supplement were published on the QCG website in August 2019 The guideline can be cited as:

Queensland Clinical Guidelines. Neonatal medicines. Guideline No. MN19.54-V1-R24. Queensland Health. 2019. Available from: <u>http://www.health.qld.gov.au/qcg</u>.

The guideline supplement can be cited as:

Queensland Clinical Guidelines. Supplement: Neonatal medicines. Guideline No. MN19.54-V1-R24. Queensland Health. 2019. Available from: http://www.health.qld.gov.au/qcg.

3 Evidence base

There is limited high level evidence about the use of neonatal medicines. It is common to find variations between reputable reference sources for dosages, administration techniques compatibilities/incompatibilities and side effects. It is also common to find widely varying practices and opinions among neonatal clinicians.

3.1.1 Overarching principles

Information in the NeoMedQ monographs:

- Preferentially references:
 - o Primary sources of recognised reliability/accuracy
 - Neonatal specific content
 - o Current information (date of development/most recent review can be identified)
 - o Practices consistent with expert Queensland clinician opinion
- Is presented in a manner that enables identification of areas of uncertainty or those requiring clinical judgement on an individual basis

Table 5. Grade levels of evidence

Grade Levels of evidence			
1++	1++ Evidence obtained from high quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias.		
1+	1+ Evidence obtained from well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.		
1	Evidence obtained from meta-analyses, systematic reviews or RCTs, or RCTs with a high risk of bias.		
2++ Evidence obtained from high quality systematic reviews of case-control or cohort studies <i>or</i> high quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal.			
2+ Evidence obtained from well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that th relationship is causal.			
 Evidence obtained from case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal. 			
3	Evidence obtained from non-analytic studies, e.g. case reports, case series.		
4	Expert opinion.		

3.2 Summary recommendations

Summary recommendations and levels of evidence are outlined in Table 5.

Table 6. Summary recommendations

Re	commendation	Grading of evidence
1	Follow the Australian National Quality and Safety Standards for medication safety	Expert opinion

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:

- Education resource: Neonatal medicines
- Knowledge assessment: Neonatal medicines

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:

- Local protocols/work instruction for use and management of medication administration devices
- Parent information about commonly used neonatal medicines

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

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 <u>www.health.qld.gov.au/qcg</u>

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)Standards¹ [Refer to Table 7. NSQHS Standard 1]. Suggested audit and quality measures are identified in Table 8. Clinical quality measures.

Table 7. NSQHS Standard 1

NSQHS Standard 1: Clinical governance		
Clinical performance and effectiveness		
Criterion 1.27:	Actions required:	
Evidence based care	a. Provide clinicians with ready access to best-practice guidelines, integrated care pathways, clinical pathways and decision support tools relevant to their clinical practice	
	b. Support clinicians to use the best available evidence, including relevant clinical care standards developed by the Australian Commission on Safety and Quality in Health Care	

The following clinical quality measures are suggested:

Table 8. Clinical quality measures

No	Audit criteria	Guideline Section
1.	 In what proportion of infant medication records are the following components 100% complete Patient identification Prescriber details Weight documentation Adverse drug reactions detailed (if any) Medication history is available Pharmaceutic review documented at least once 	Section 3
2.	 In what proportion of infant medication records is the medication prescription appropriately completed for the patient in terms of: Dose, frequency, route Start and stop dates Signatures indicating administration completed Discrepancies in medication administration are documented and notated 	Section 3 Section 4

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.

• Safety data about the administration of neonatal medicines via the umbilical artery catheter

4.6 Safety and quality

Implementation of this guideline provides evidence of compliance with the National Safety and Quality Health Service Standards and Australian Council on Healthcare Standards (ACHS) Evaluation and Quality Improvement Program (EQuIP) National accreditation programs.^{1,2}

Table 9. NSQHS/EQuIPNational Criteria

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
NSQHS Standard 1: Clinical governan	ce	
Patient safety and quality systems Safety and quality systems are integrated with governance processes to enable organisations to actively manage and improve the safety and quality of health care for patients.	Diversity and high risk groups 1.15 The health service organisation: a. Identifies the diversity of the consumers using its services b. Identifies groups of patients using its services who are at higher risk of harm c. Incorporates information on the diversity of its consumers and higher-risk groups into the planning and delivery of care	 Assessment and care appropriate to the cohort of patients is identified in the guideline High risk groups are identified in the guideline The guideline is based on the best available evidence
Clinical performance and effectiveness The workforce has the right qualifications, skills and supervision to provide safe, high-quality health care to patients.	Evidence based care 1.27 The health service organisation has processes that: a. Provide clinicians with ready access to best-practice guidelines, integrated care pathways, clinical pathways and decision support tools relevant to their clinical practice b. Support clinicians to use the best available evidence, including relevant clinical care standards developed by the Australian Commission on Safety and Quality in Health Care	 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 management 1.22 The health service organisation has valid and reliable performance review processes that: a. Require members of the workforce to regularly take part in a review of their performance b. Identify needs for training and development in safety and quality c. Incorporate information on training requirements into the organisation's training system	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 <u>http://www.health.qld.gov.au/qcg</u>
Patient safety and quality systems Safety and quality systems are integrated with governance processes to enable organisations to actively manage and improve the safety and quality of health care for patients.	Policies and procedures 1.7 The health service organisation uses a risk management approach to: a. Set out, review, and maintain the currency and effectiveness of, policies, procedures and protocols b. Monitor and take action to improve adherence to policies, procedures and protocols c. Review compliance with legislation, regulation and jurisdictional requirements	 QCG has established processes to review and maintain all guidelines and associated resources Change requests are managed to ensure currency of published guidelines Implementation tools and checklist are provided to assist with adherence to guidelines Suggested audit criteria are provided in guideline supplement The guidelines comply with legislation, regulation and jurisdictional requirements

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
NSQHS Standard 2: Partnering with Consumers		
Health literacy Health service organisations communicate with consumers in a way that supports effective partnerships.	Communication that supports effective partnerships 2.8 The health service organisation uses communication mechanisms that are tailored to the diversity of the consumers who use its services and, where relevant, the diversity of the local community 2.9 Where information for patients, carers, families and consumers about health and health services is developed internally, the organisation involves consumers in its development and review 2.10 The health service organisation supports clinicians to communicate with patients, carers, families and consumers about health and health care so that: a. Information is provided in a way that meets the needs of patients, carers, families and consumers b. Information provided is easy to understand and use c. The clinical needs of patients are addressed while they are in the health service organisation d. Information needs for ongoing care are provided on discharge	 Consumer consultation was sought and obtained during the development of the guideline. Refer to the acknowledgement section of the guideline for details Consumer information is developed to align with the guideline and included consumer involvement during development and review The consumer information was developed using plain English and with attention to literacy and ease of reading needs of the consumer
Partnering with consumers in organisational design and governance Consumers are partners in the design and governance of the organisation.	 Partnerships in healthcare governance planning, design, measurement and evaluation 2.11 The health service organisation: a. Involves consumers in partnerships in the governance of, and to design, measure and evaluate, health care b. Has processes so that the consumers involved in these partnerships reflect the diversity of consumers who use the service or, where relevant, the diversity of the local community 2.14 The health service organisation works in partnership with consumers to incorporate their views and experiences into training and education for the workforce 	 Consumers are members of guideline working parties The guideline is based on the best available evidence The guidelines and consumer information are endorsed by the QCG and Queensland Statewide Maternity and Neonatal Clinical Network Steering Committees which includes consumer membership
NSQHS Standard 4: Medication safety		
Clinical governance and quality improvement to support medication management Organisation-wide systems are used to support and promote safety for procuring, supplying, storing, compounding, manufacturing, prescribing, dispensing, administering and monitoring the effects of medicines	 Integrating clinical governance 4.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for medication management b. Managing risks associated with medication management c. Identifying training requirements for medication management 	The guideline provides current evidence based recommendations about medication

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
NSQHS Standard 5: Comprehensive care		
Clinical governance and quality improvement to support comprehensive care Systems are in place to support clinicians to deliver comprehensive care	Integrating clinical governance 5.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for comprehensive care b. Managing risks associated with comprehensive care c. Identifying training requirements to deliver comprehensive care Partnering with consumers 5.3 Clinicians use organisational processes from the Partnering with Consumers Standard when providing comprehensive care to: a. Actively involve patients in their own care b. Meet the patient's information needs c. Share decision-making	 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 <u>http://www.health.qld.gov.au/qcg</u> The guideline provides evidence-based and best practice recommendations for care Consumer information is developed for the guideline
NSQHS Standard 6: Communicating for		
Clinical governance and quality improvement to support effective communication Systems are in place for effective and coordinated communication that supports the delivery of continuous and safe care for patients.	 Integrating clinical governance 6.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures to support effective clinical communication b. Managing risks associated with clinical communication c. Identifying training requirements for effective and coordinated clinical communication Partnering with consumers 6.3 Clinicians use organisational processes from the Partnering with Consumers Standard to effectively communicate with patients, carers and families during high-risk situations to: a. Actively involve patients in their own care b. Meet the patient's information needs c. Share decision-making Organisational processes to support effective communications processes to support effective communications when: a. Identification and procedure matching should occur b. All or part of a patient's care is transferred within the organisation, between multidisciplinary teams, between clinicians or between organisations; and on discharge c. Critical information about a patient's care, including information on risks, emerges or changes 	 Requirements for effective clinical communication by clinicians are identified The guideline provides evidence-based and best practice recommendations for communication between clinicians The guideline provides evidence-based and best practice recommendations for communication with patients, carers and families The guideline provides evidence-based and best practice recommendations for communication with patients, carers and families The guideline provides evidence-based and best practice recommendations for discharge planning and follow –up care

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance
NSQHS Standard 6: Communicating for	or safety (continued)	
Communication of critical information Systems to effectively communicate critical information and risks when they emerge or change are used to ensure safe patient care.	 Communicating critical information 6.9 Clinicians and multidisciplinary teams use clinical communication processes to effectively communicate critical information, alerts and risks, in a timely way, when they emerge or change to: a. Clinicians who can make decisions about care b. Patients, carers and families, in accordance with the wishes of the patient 6.10 The health service organisation ensures that there are communication processes for patients, carers and families to directly communicate critical information and risks about care to clinicians 	 Requirements for effective clinical communication of critical information are identified Requirements for escalation of care are identified
Correct identification and procedure matching Systems to maintain the identity of the patient are used to ensure that the patient receives the care intended for them.	 Correct identification and procedure matching 6.5 The health service organisation: a. Defines approved identifiers for patients according to best-practice guidelines b. Requires at least three approved identifiers on registration and admission; when care, medication, therapy and other services are provided; and when clinical handover, transfer or discharge documentation is generated 	Requirements for safe and for correct patient identification are identified
Communicating at clinical handover Processes for structured clinical handover are used to effectively communicate about the health care of patients.	Clinical handover 6.7 The health service organisation, in collaboration with clinicians, defines the: a. Minimum information content to be communicated at clinical handover, based on best-practice guidelines b. Risks relevant to the service context and the particular needs of patients, carers and families c. Clinicians who are involved in the clinical handover 6.8 Clinicians use structured clinical handover processes that include: a. Preparing and scheduling clinical handover b. Having the relevant information at clinical handover c. Organising relevant clinicians and others to participate in clinical handover d. Being aware of the patient's goals and preferences e. Supporting patients, carers and families to be involved in clinical handover, in accordance with the wishes of the patient f. Ensuring that clinical handover results in the transfer of responsibility and accountability for care	The guideline acknowledges the need for local protocols to support transfer of information, professional responsibility and accountability for some or all aspects of care

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NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance	
NSQHS Standard 7: Blood management			
Clinical governance and quality improvement to support blood management Organisation-wide governance and quality improvement systems are used to ensure safe and high-quality care of patients' own blood, and to ensure that blood product requirements are met.	Integrating clinical governance 7.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for blood management b. Managing risks associated with blood management c. Identifying training requirements for blood management	The guideline provides evidence-based and best practice recommendations for use of blood products	
Prescribing and clinical use of blood and blood products The clinical use of blood and blood products is appropriate, and strategies are used to reduce the risks associated with transfusion.	 Optimising and conserving patients' own blood 7.4 Clinicians use the blood and blood products processes to manage the need for, and minimise the inappropriate use of, blood and blood products by: a. Optimising patients' own red cell mass, haemoglobin and iron stores b. Identifying and managing patients with, or at risk of, bleeding c. Determining the clinical need for blood and blood products, and related risks Prescribing and administering blood and blood products 7.6 The health service organisation supports clinicians to prescribe and administer blood and blood products appropriately, in accordance with national guidelines and national criteria 	 The guideline provides evidence-based and best practice recommendations for use of blood products The guideline is consistent with recommendations of national guidelines 	

NSQHS/EQuIPNational Criteria	Actions required	☑ Evidence of compliance	
NSQHS Standard 8: Recognising and responding to acute deterioration			
Clinical governance and quality improvement to support recognition and response systems Organisation-wide systems are used to support and promote detection and recognition of acute deterioration, and the response to patients whose condition acutely deteriorates.	 Integrating clinical governance 8.1 Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for recognising and responding to acute deterioration b. Managing risks associated with recognising and responding to acute deterioration c. Identifying training requirements for recognising and responding to acute deterioration Partnering with consumers 8.3 Clinicians use organisational processes from the Partnering with Consumers Standard when recognising and responding to acute deterioration to: a. Actively involve patients in their own care b. Meet the patient's information needs c. Share decision-making Recognising acute deterioration that require clinicians to detect acute physiological deterioration that require clinicians to: a. Document individualised vital sign monitoring plans b. Monitor patients as required by their individualised monitoring plan c. Graphically document and track changes in agreed observations to detect acute deterioration over time, as appropriate for the patient 	 ☑ The guideline is consistent with National Consensus statements recommendations ☑ The guideline recommends use of tools consistent with the principles of recognising and responding to clinical deterioration ☑ Consumer information is developed for the guideline 	
EQuIP 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 	

5 References

1. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards [Internet]. 2017 [cited 2018 January 08]. Available from: http://www.safetyandquality.gov.au.

2. The Australian Council on Healthcare Standards. EQuIPNational. [Internet]. 2016; (cited 2018 January 08). Available from: <u>http://www.achs.org.au</u>.