Document Number #QH-GDL-415:2014

Safe paracetamol use

1. Purpose

This Guideline provides recommendations regarding best practice for the judicious, effective and safe use of paracetamol. It is to be used in conjunction with the relevant Product Information and any local specialist procedures.

2. Scope

This Guideline provides information for all employees, contractors and consultants within the Department of Health divisions, commercialised business units and Hospital and Health Services.

3. Related documents

Authorising Policy and Standard/s:

- Queensland Health List of Approved Medicines

Procedures, Guidelines and Protocols:

- National Inpatient Medication Chart Guidelines

4. Guideline

Background

Paracetamol (also known as acetaminophen) is a common and widely-used non-opioid analgesic. Its excellent safety in therapeutic doses sees it commonly used as the first-line analgesic for mild to moderate pain, particularly of soft tissue and musculoskeletal origin.

Safety

Paracetamol has a well established safety profile when used appropriately. In acute overdose, paracetamol can lead to severe and sometimes fatal hepatotoxicity. There have also been a number of cases of chronic ‘therapeutic’ overdoses (or iatrogenic overdoses).

Factors that may potentially increase the risk of paracetamol toxicity include:

Adults	Infants and children
• Prolonged fasting or dehydration • Chronic under-nutrition • Chronic, excessive alcohol use • Chronic use of anticonvulsants • Severe hepatic impairment • Elderly, frail patients	• Febrile illness • Younger age • Prolonged fasting, vomiting or dehydration • Chronic under-nutrition • Hepatic impairment • Prior paracetamol intake (e.g. in over-the-counter cough / cold preparations) • Use of adult rather than paediatric formulations, use of paediatric formulations designed for an older age group (e.g. siblings) or availability of multiple strengths of paediatric formulations

Prescribing

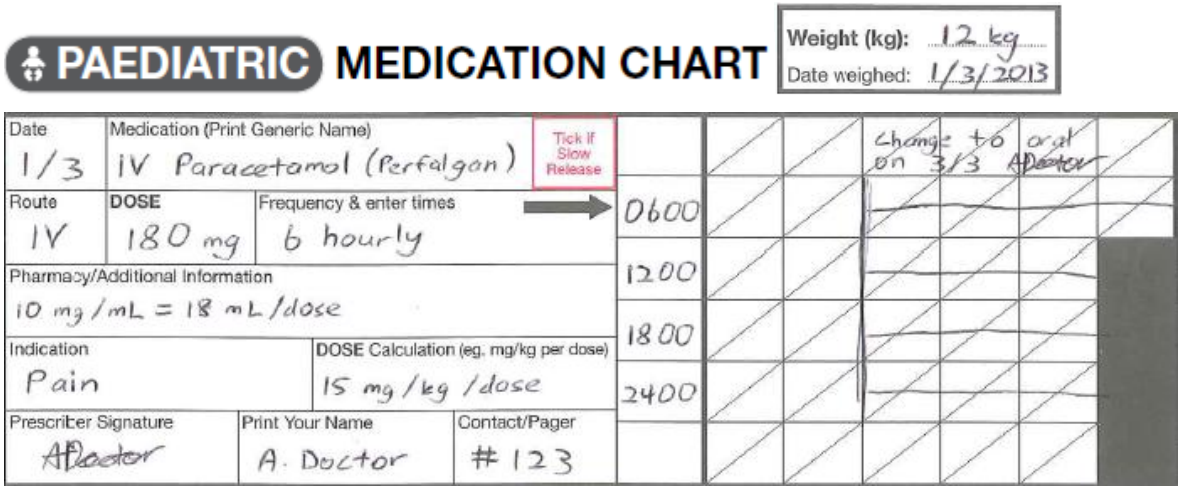
All authorised prescribers must order medicines for inpatients in accordance with legislative requirements as documented in the *Health (Drugs and Poisons) Regulation 1996*. In addition, prescriptions on the *National Inpatient Medication Chart* should comply with the requirements of the *National Inpatient Medication Chart* guidelines.

To reduce potential for adverse events, the following additional information should be included on all prescriptions for paracetamol:

- Weight (this is especially important for children, frail elderly patients and adults less than 50 kilograms with eating disorders or chronic disease).
- The generic medication name ‘paracetamol’. Prescriptions for IV paracetamol should be written as the generic name ‘IV paracetamol’ **and** the brand name (e.g. Perfalgan®, Paracetamol Actavis®) to emphasise route of administration, intended formulation and prevent inadvertent administration of oral formulations via the IV route.
- Dose of paracetamol (total dose in milligrams). Dose must be appropriate for the indication, risk factors, route of administration, age and **ideal body weight*** **(for obese patients)**. For children, frail elderly patients and adults less than 50 kilograms with eating disorders or chronic disease, qualify dose in mg/kg/dose.
- Maximum duration of therapy or interval for review of ongoing therapy.

* Ideal body weight for **adults** can be calculated using online calculators such as the Medication Dosing Calculators available on QHEPS http://medicationdosingcalculators.health.qld.gov.au or the eTG ideal body weight calculator.
Ideal body weight for **children** can be approximated using growth charts accessible at http://www.apeg.org.au/clinicalresourceslinks/growthgrowthcharts/tabid/101/default.aspx

When prescribing any liquid medication (including intravenous paracetamol solution for infusion), the dose in milligrams must always be specified. Where the intended volume for administration is to be documented, this must be in addition to the milligram dose. See example below for a two year old child weighing 12 kilograms, unable to take paracetamol by the oral or nasogastric route, and for whom rectal paracetamol is not suitable:



PAEDIATRIC MEDICATION CHART

Weight (kg): 12 kg
Date weighed: 1/3/2013

Date	Medication (Print Generic Name)	Tick if Slow Release			
1/3	IV Paracetamol (Perfalgan)		0600		Change to oral on 3/3 ADoctor
Route	DOSE	Frequency & enter times	1200		
IV	180 mg	6 hourly	1800		
Pharmacy/Additional Information			2400		
10 mg/mL = 18 mL/dose					
Indication	DOSE Calculation (eg. mg/kg per dose)				
Pain	15 mg/kg/dose				
Prescriber Signature	Print Your Name	Contact/Pager			
ADoctor	A. Doctor	#123			

Recommended dose

There is limited evidence supporting dose reduction in patients with risk factors that may potentially increase the risk of paracetamol toxicity. However, incidents involving paracetamol toxicity in patients with risk factors warrant conservative dosing in this at risk group.

Adults and children 12 years and above		
No risk factors	0.5 – 1 g every four to six hours, up to a maximum of 4 g in 24 hours	Review at 48 hours (IV paracetamol review at 24 hours)
One or more risk factors (see **Safety**) and actual weight greater than or equal to 50 kg	0.5 – 1 g every four to six hours, up to a maximum of 3 g in 24 hours	Review at 48 hours (IV paracetamol review at 24 hours) If treatment to continue beyond 48 hours, consider monitoring LFTs and INR IV paracetamol should be converted to oral paracetamol within 48 hours
One or more risk factors (see **Safety**) and actual weight less than 50 kg	15 mg/kg/dose every four to six hours up to a maximum of four doses in 24 hours	
Severe hepatic impairment and actual weight greater than or equal to 50 kg	0.5 – 1 g every four to six hours, up to a maximum of 2 g in 24 hours	
Severe hepatic impairment and actual weight less than 50 kg	15 mg/kg/dose every four to six hours up to a maximum of three doses in 24 hours	

Infants and children 3 months to 11 years*		
No risk factors	15 mg/kg/dose (do not exceed 1 g per dose) every four to six hours up to a maximum of 60 mg/kg in 24 hours (do not exceed 4 g in 24 hours)	Review at 48 hours (IV paracetamol review at 24 hours) If treatment to continue beyond 48 hours, consider reducing dose
One or more risk factors (see **Safety**)	15 mg/kg/dose (do not exceed 1 g per dose) every four to six hours up to a maximum of 45 mg/kg in 24 hours (do not exceed 3 g in 24 hours)	Review at 48 hours (IV paracetamol review at 24 hours) If treatment to continue beyond 48 hours, consider monitoring LFTs and INR IV paracetamol should be converted to oral paracetamol within 48 hours

* The doses listed in this table **do not** reflect the Product Information for paracetamol solution for intravenous infusion. However, the upper limit of these doses has been used safely at the Royal Children's Hospital, Queensland and is supported by the New South Wales Therapeutic Advisory Group.

Neonates and infants less than 3 months
Seek specialist advice

Administration

- **Check both regular and PRN sections of the National Inpatient Medication Chart (NIMC), as well as any additional charts to ensure that there are no duplicate paracetamol orders. Duplicate paracetamol orders should be cancelled or the prescriber contacted for clarification.**
- Check the timing of previous paracetamol doses, including the stat dosing section on the front of the NIMC, to ensure that the dose intended to be administered is within the dosing interval prescribed in the order.
- Check for combination products that contain paracetamol (e.g. 'cold and flu' preparations, 'strong pain' preparations (e.g. paracetamol with codeine such as Panadeine®, paracetamol with tramadol such as Zaldiar®)).
- Query unfamiliar products with a pharmacist or product reference (e.g. MIMS) to ascertain whether or not the product contains paracetamol.

Monitoring

- All paracetamol orders should be reviewed at 48 hours, except IV paracetamol orders which should be reviewed at 24 hours.
- Where risk factors are present and treatment is to continue beyond 48 hours, monitoring of liver function tests (LFTs), including International Normalised Ratio (INR), is recommended.

Practice points

- Take a full history and assess for potential risk factors for toxicity prior to initiation of paracetamol treatment. Identify if and when any products containing paracetamol have been ingested, both prescribed and over-the-counter.
- Recognise and treat any suspected cases of paracetamol hepatotoxicity without delay according to local protocols. Advice on suspected poisoning with paracetamol is available from the Poisons Information Centre on 131126.
- Consider limiting the number of paracetamol-containing preparations available in the facility.

5. References and suggested reading

1. Therapeutic Guidelines: Analgesic (accessed 28/01/2014) – Paracetamol https://online-tg-org-au.cknservices.dotsec.com/ip/
2. Paracetamol Use: A Position Statement of the NSW Therapeutic Advisory Group Inc, December 2008 http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/position-statements/paracetamol-use-dec-2008.pdf
3. Intravenous Paracetamol Use: Addendum to the 2008 ‘Paracetamol Use’ Position Statement of the NSW Therapeutic Advisory Group Inc, December 2012 http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/position-statements/paracetamol-iv-addendum-dec-2012.pdf

6. Review

This Guideline is due for review on: 1 May 2017

Date of Last Review: N/A

Supersedes: N/A

7. Business Area Contact

Medicines Regulation and Quality

medicationsafety@health.qld.gov.au

8. Approval and Implementation

Policy Custodian:

Dr Sue Ballantyne

Director, Medicines Regulation and Quality

Responsible Executive Team Member:

Dr Jeannette Young

Chief Health Officer

Approving Officer:

Dr Sue Ballantyne

Director, Medicines Regulation and Quality

Approval date: **28 January 2014**

Effective from: **1 May 2014**

Version Control

Version	Date	Prepared by	Comments
1	16/04/2014	Justin Lee	Initiating document

Disclaimer

This guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach.

Information in this guideline is current at time of publication.

The Department of Health, Queensland Government does not accept liability to any person for loss or damage incurred as a result of reliance upon the material contained in this guideline.

Clinical material offered in this guideline does not replace or remove clinical judgement or the professional care and duty necessary for each specific patient case.

Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This guideline does not address all elements of standard practice and assumes that individual clinicians have the responsibility to:

- Discuss care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary.
- Advise consumers of their choice and ensure informed consent is obtained.
- Provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct.
- Apply standard precautions and additional precautions as necessary, when delivering care.
- Document all care in accordance with mandatory and local requirements.

Safe Paracetamol Use guideline

Published by the State of Queensland (Queensland Health), May, 2014

For further information contact Medication Safety Officer, Medicines Regulation and Quality, Locked Bag 21, Fortitude Valley BC Qld 4006, email MedicationSafety@health.qld.gov.au.
For permissions beyond the scope of this licence contact: Intellectual Property Officer, Department of Health, GPO Box 48, Brisbane Qld 4001, email ip_officer@health.qld.gov.au, phone (07) 3328 9862.