MONOGRAPH

FENTANYL

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

- Fentanyl is a synthetic opioid analgesic that activates opioid receptors in the central and peripheral nervous systems to produce analgesia and sedation.[1]
- It is 70-100 times more potent as an analgesic than morphine but with minimal sedative activity. Fentanyl has a quicker onset and shorter duration of action than morphine, and is more haemodynamically stable due to lack of histamine release.[2, 3]
- Fentanyl is a High Risk Medicine and a Schedule 8 medication.

INDICATIONS AND RESTRICTIONS[2, 4]

Fentanyl is a Schedule 8 medicine.

- Moderate to severe acute pain and cancer pain
- Procedural pain and breakthrough pain
- Adjunct in epidural infusions
- Anaesthesia induction and maintenance

CONTRAINDICATIONS

- Hypersensitivity to Fentanyl or any component of the formulation.[2]
- Concomitant use (or use within 14 days) of monoamine oxidase inhibitors[1]

PRECAUTIONS

- Use with caution in non-intubated patients with[1, 2, 4]
  - Respiratory depression, severe obstructive airway disease, at risk of upper airway obstruction, asthma
  - Hypothyroidism, adrenocortical insufficiency, CNS depression – careful dose titration required.
  - Raised intracranial pressure, intracranial mass, head trauma – hypoventilation can cause carbon dioxide retention and raised CSF pressure.
  - Epilepsy, or at risk for seizure (e.g. head injury, metabolic disorders, CNS infections) – may increase risk of seizure.
  - Bradyarrhythmias – may be exacerbated.
- Hepatic impairment[4]
- Myasthenia gravis[5]
- Consider starting with a lower dose of fentanyl when using with another CNS depressant[1]
- Opioid induced constipation - monitor bowel function and chart regular prophylactic oral aperients for all patients receiving regular opioids (unless contraindicated).
  - Consider osmotic laxatives (first line). If ineffective/unsuitable consider stool softeners and/or stimulant laxatives.[6]
  - For PCC patients refer to bowel management in Enteral Nutrition in the Paediatric Critical Care Unit.
- Urinary retention – all patients on fentanyl infusion should have a urinary catheter inserted.

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- *Lozenges:* 200 microg, 400 microg, 600 microg
- *Ampoules:* 100 microg/2 mL, 500 microg/10 mL
- *Patch:* 12 microg/hour, 25 microg/hour, 50 microg/hour
- *Fentanyl Protocol syringes:* 50 microg/10mL (available in PACU only)
- Fentanyl 20 microg in sodium chloride 0.9% (2 mL) - available in NICU

- *Intranasal solution:* 450 microg/1.5 mL (available in DTU/HiTH for prescribing by rehabilitation physicians for botox patients only)
- *Pre-filled syringes (Baxter®)* for continuous infusion:
  - 300 microg/30 mL in sodium chloride 0.9%
  - 2500 microg/50 mL (NEAT)

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Dosing in Overweight and Obese Children: Dose adjustment may be required (refer to policy)

- Fentanyl is highly lipophilic and has a large volume of distribution. Consider higher initial doses and lower maintenance doses in obese patients.[7]

Renal impairment:

- Fentanyl has no active or toxic metabolites and may be used in renal impairment.[4]
- Transdermal patches – reduce dose in mild-moderate renal impairment and avoid use in severe renal impairment.[2]

Hepatic impairment:

- Use with caution. Reduce initial dose and titrate to clinical effect with careful monitoring, especially in severe hepatic disease.[2, 4]

Approximate equianalgesic potencies of various opioids[8]		
Opioid	**Parenteral**	**Oral**
Morphine	10 mg IM/IV/subcut	30 mg
Fentanyl	150 microg IM/IV/subcut	—
Hydromorphone	2 mg IM/IV/subcut	6 mg
Oxycodone	10 mg IV/subcut	20 mg
Tramadol	100 mg IM/IV	150 mg

Note: For opioid rotation in PCC refer to Analgesia and Sedation in PCC and for opioid conversions for weaning in PCC refer to Withdrawal Syndrome Management.

The doses below are within the standard reference range for each indication; however, the dose of fentanyl may need to be titrated according to the patient's clinical response.

Infusion and Patient Controlled Analgesia (PCA) on General Ward Areas

Refer to: Opioid Infusion Management in General Ward Areas and Intravenous Patient Controlled Analgesia (PCA)

- On general ward areas intravenous infusions and patient controlled analgesia must be prescribed by an anaesthetist or the Acute Pain Service.

PACU Protocol

See Intermittent Intravenous (IV) Opioid Analgesia in the Post Anaesthetic Care Unit (PACU)

Intranasal[3]

Children >1 year: 1.5 microg/kg via 1mL syringe with an atomiser attached.

Dose may be repeated once after 5 to 10 minutes if required. Usual maximum dose is 100 microg due to volume limitations.

Lozenge

To be prescribed on the advice of the Acute Pain Service (APS). Use with caution in opioid naïve patients due to the risk of respiratory depression.

Transmucosal (2-18 years and >15kg): 10-15 microg/kg (maximum 400 microg).[9, 10] Recommended to start with 200 microg lozenge on the first occasion.

Repeat dose once after 15 minutes if necessary.[2]

If more than 4 episodes of breakthrough pain daily, consider adjusting background analgesia.[2]

Epidural

Adjunct to local anaesthesia infusion: 0 – 2 microg/mL[11].

Refer to Epidural Infusion Management

Patch

To be prescribed on the advice of APS or Palliative care/Oncology. NOT for use in acute pain setting or in opioid naïve patients.

Contact APS for advice on opioid conversion and starting dose.

Oral 24 hour morphine (mg/day)[3]	Recommended fentanyl patch
30-59mg	12 microg/hr
60-134mg	25 microg/hr
135-224mg	50 microg/hr
225-314mg	75 microg/hr
315-404mg	100 microg/hr

> 2 years: Apply 1 patch every 72 hours[3]

Do **not** use patches for acute management of pain as patches take about 24-72 hours to reach steady blood level and maximum effect.[3]

CRITICAL CARE AREAS

See Analgesia and Sedation in Paediatric Critical Care (PCC) Guideline

Intravenous infusion (intubated & ventilated patients)

Higher doses may be required (e.g. in opioid-tolerant patients, patients on Extra Corporeal Membrane Oxygenation).

	<50kg	≥50kg
Loading dose (IV)	2-3 microg/kg[2]	100-150 microg[2]
Continuous IV infusion	1-10 microg/kg/hr[2]	25-200 microg/hr[2, 11]
Bolus dose for pain	1-2 microg/kg [2] Dose may be repeated after 5-10 minutes[3]	50-100 microg[2, 11] Dose may be repeated after 5-10 minutes[3]

Intravenous bolus (For procedural pain/sedation)

≥ 6 months: 0.5 – 2 microg/kg/dose (max 50 microg) IV initially. May repeat half the original dose every 3 to 5 minutes if necessary.[2]

Intravenous bolus (For intubation)

1 month – 17 years: 1 – 5 microg/kg IV given 1 to 3 minutes prior to intubation.[2]

REVERSAL OF OPIOID TOXICITY

See Opioid Infusion Management in General Wards

Naloxone: Birth (at term) – 18 years

	IV	Intranasal	IM
Excess sedation	2 microg/kg (max 100 microg)[3]	4 microg/kg (max 200 microg)	2 microg/kg (max 100 microg)[4]
Resuscitation	10 microg/kg (max 400microg)[3]	20 microg/kg (max 400 microg)[12]	10 microg/kg (max 400 microg)[4]
Dosing interval	1-2 minutes[5]	2-3 minutes[4]	15 minutes
	Max 5 doses.[4] Consider IV infusion if repeated doses required		

ADMINISTRATION

Infusion and PCA on General Ward Areas

Syringes should be ordered from Pharmacy Compounding Services (PCS) during business hours. Ward staff may make up syringes after hours or when needed urgently.

- Dilute 20 microg/kg (max 1000 microg) of fentanyl and make up to 50 mL with a compatible diluent.

Intranasal

- Use 100 microg/2 mL IV ampoules, where available, (except Day Treatment Unit (DTU) / Hospital in the Home [HiTH] where the intranasal formulation is available).
- Sit child at a 45-degree angle or with head to one side. Divide the dose between both nostrils and administer in 0.2 mL aliquots to maximise absorption and minimise sneezing.[4]
- If an atomiser is used, draw up an extra 0.1 mL to prime the atomiser prior to administration.[4]

Lozenge

- The fentanyl lozenge should be placed in the mouth and wiped against the cheek using the applicator until pain relief achieved. Let it dissolve over 15 minutes.[1, 4]
- Patient should be cognitively able to self-administer the dose.
- The lozenge should not be sucked or chewed. Immediately remove the lozenge if excessive opioid effects appear.[1]

Patch

- Apply ONE patch to clean, hair-free skin on the upper torso, flank or upper arm every 3 days.[4]
- The patch may be applied to the upper back for young children. Alternate site of application with every patch change.[11]
- Avoid exposure to external heat sources (e.g. hot packs) and do not apply straight after a hot bath/shower.[4]
- Patches should not be cut or manipulated.[3]

PCC

Ventilated patients

Use the following standardised concentrations:

Patient's Weight	Concentration	Notes
10 kg or less	300 microg in 30 mL sodium chloride 0.9% (10 microg/mL)	In a 3kg patient, 1 microg/kg/hr = 0.3 mL/hr
Above 10 kg	2500 microg in 50 mL (50 microg/mL)	In a 20kg patient, 1 microg/kg/hr = 0.4 mL/hr

- Patients 10kg or less may be prescribed the higher strength (2500 microg in 50mL) preparation to reduce fluid overload if clinically indicated, at the treating consultant's discretion.

Non-Ventilated Patients

- Dilute 20 microg/kg of fentanyl (max 1000 microg) and make up to 50 mL with a compatible diluent.

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: Glucose 5%, Sodium chloride 0.9%[13]

Compatible at Y-site: Glucose 10% (PIG), Potassium Chloride 20 mmol/L (PIG), Plasma-Lyte 148 (Fentanyl ≤10 microg/mL)[2, 13]

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs: Co-trimoxazole, dantrolene, diazoxide, gemtuzumab, hydroxocobalamin, pantoprazole, phenytoin[2]

MONITORING

General Monitoring for Intravenous Administration:

See Opioid Infusion Management in General Ward Areas and Intravenous Patient Controlled Analgesia (PCA).

- Pre-administration and ongoing pain assessment.
- Baseline and post dose heart rate, level of sedation, respiration rate, oxygen saturation and blood pressure.
- Continuous pulse oximetry.
- Withdrawal symptoms on discontinuation, especially if abrupt or after prolonged regular use (> 5 days). Refer to the WAT-1 form (MR859.80) and Withdrawal Syndrome Management.

Monitoring for epidural: Refer to Epidural Infusion Management

Monitoring for intranasal: Refer to PCH ED Guideline - Fentanyl (Intranasal)

PCC: Refer to Analgesia and Sedation in Paediatric Critical Care

ADVERSE EFFECTS[4]

Common: Nausea, vomiting, drowsiness, dyspepsia, dizziness, headache, orthostatic hypotension, itch, dry mouth, miosis, urinary retention, constipation (see precautions), rash, erythema (patch)

Infrequent: Respiratory depression, bronchospasm, confusion, hallucinations, delirium, agitation, mood changes, tremor, visual disturbances, urticaria, hypothermia, hypertension, bradycardia, biliary spasm, paralytic ileus, raised liver enzymes, myoclonus, chest wall rigidity (with rapid/high IV doses)

Rare: SIADH, anaphylaxis, seizure

STORAGE

Fentanyl is a Schedule 8 medication and must be stored as outlined in the Schedule 8 and Restricted Schedule 4 Medication Policy

Store below 25°C. Protect from light.[1]

DISPOSAL OF UNUSED PORTION OF MEDICATIONS

Unused portions of medications must be emptied into a Pharmaceutical Waste Container with denaturing chemicals. The disposal must be witnessed and documented by two authorised persons (registered nurse, doctor, or pharmacist).

See Schedule 8 and Restricted Schedule 4 Medication Policy

DISPOSAL OF FENTANYL PATCHES

Used fentanyl patches should be folded together so that the adhesive side of the patch sticks to itself, wrapped and disposed of into the non-return sharps container.[1]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Caution with concomitant use of serotonergic agents – monitor for serotonin syndrome.[1]

Please note: The information contained in this guideline is to assist with the preparation and administration of **Fentanyl**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures, and guidelines
List and hyperlink the titles of related CAHS/PCH/CAMHS/Community Health/Neonatology policy documents – use full titles in alphabetic order, one document per line
Schedule 8 and Restricted Schedule 4 Medication
Opioid Infusion Management in General Wards
Epidural Infusion Management
Intravenous Patient Controlled Analgesia (PCA)
Guidelines for Drug Dosing in Overweight and Obese Children 2 to 18 Years of Age
High Risk Medicines
Intermittent Intravenous (IV) Opioid Analgesia in the Post Anaesthetic Care Unit (PACU)

Related CAHS internal policies, procedures, and guidelines
Analgesia and Sedation in Paediatric Critical Care
Withdrawal Syndrome Management
PCH Emergency Department Guideline - Fentanyl (Intranasal)

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The Vancouver style referencing is as per CAHS Library and Information Service.

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