JBI Systematic Review Title Registration Form

Title: Efficacy and Safety of Intranasal Fentanyl in neonates: a Systematic Review

Centre: Aligning Health Needs and Evidence for Transformative Change (AH-NET-C): A JBI Centre of Exce

Primary Reviewer

Name: Helen McCord **Email:** hmccord@dal.ca

Question: In neonates undergoing painful procedures, how does the use of intranasal fentanyl, compared to the standard pain management protocol or placebo, affect the safety and efficacy in pain relief

PICO

Population: will focus on infants born both preterm and at term gestation until the age of 6 months corrected who have received fentanyl via IN route of administration as treatment for procedural pain. All studies documenting the usage of IN fentanyl in pediatric patients will be examined to ascertain whether any part of their study population comprised infants aged 6 months or younger. Infants will be excluded if simultaneously receiving fentanyl by other routes (e.g. intravenous).

Intervention: Intervention (quantitative - effectiveness)

Intranasal Fentanyl for procedural pain in hospitalized neonates

Comparator: Comparator (quantitative - effectiveness)

Standard pain management protocol or placebo

Outcome: Outcome (quantitative)

Safety and efficacy in pain relief.
Types of outcome measures:
Primary outcomes:
a) Safety:
Safety will be assessed through patients who received opioid reversal (naloxone), and the frequency of respiratory depression as an oxygen saturation < 85%, or apnea with or without intervention to recover, hypotension, chest wall rigidity, airway support, such as stimulation for respiratory depression or bag–mask ventilation. Occurrence of any of the following adverse events associated with IN fentanyl within 24 hrs of dosing will be recorded: death, hypotension, bradycardia, worsening respiratory status, and chest wall rigidity. Hypotension will be defined as the need for fluid bolus resuscitation or vasopressor therapy (dopamine, epinephrine, vasopressin); bradycardia as a documented HR < 100 beats per minute; worsening respiratory status as difficulty breathing requiring immediate intervention or escalating respiratory support;

Please **download**, **fill in**, **save** and **email** this form to: jbisynthesis@adelaide.edu.au