

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department**Appendix 1A: Patient and sedation characteristics to be examined for association with the occurrence of respiratory adverse events**

Patient Characteristics	Further Description/Categories
Age	Age, in years AND as a categorical variable < 2 years/≥ 2years
Sex	male/female
BMI	Weight (kg)/height(m ²)
ASA classification	I/II/III/IV/V
Fasting status for solids	yes/no (according to ASA guidelines) AND as a continuous variable in minutes prior to the sedation?
Fasting status for clear liquids	yes/no (according to ASA guidelines) AND as a continuous variable in minutes prior to the sedation?
Pre-oxygenation	yes/no
Pre-procedural opioids	yes/no AND as a continuous variable in minutes prior to sedation
Underlying health risks	Stridor when awake/history of sleep apnea/history of snoring/large tongue/micrognathia/pre-existing neurologic impairment
Current respiratory illness	Upper respiratory tract infection/active asthma
Sedation medication	Ketamine/Ketamine+midazolam/Ketamine+Fentanyl/Propofol/Propofol+opioid/Propofol+ketamine
Total dose of sedation medication	In mg/kg/min duration of the procedure
Initial dose of sedation medication	Ketamine: low < 1.5mg/kg, usual ≥ 1.5mg/kg, high ≥ 2.0mg/kg Propofol: low < 1.0mg/kg, usual ≥ 1.0 mg/kg, high ≥ 2.0mg/kg * exclude children receiving combination ketamine+propofol
Patient behaviour prior to sedation	Calm vs not calm
Sedation medication	Ketamine/Ketamine+midazolam/Ketamine+Fentanyl/Propofol/Propofol+opioid/Propofol+ketamine
Total dose of sedation medication	In mg/kg/min duration of the procedure
Duration of the procedure	Start of physiologic recovery-start of sedation, in minutes

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

Procedure	orthopedic reudction/laceration repair/foreign body removal/cardioversion or defibrillation/chest tube insertion/dressing change/I+D abscess/inguinal hernia reduction/joint aspiration/LP/paraphimosis reduction/rectal prolapse reduction/testicular torsion/throracentesis/other
-----------	---

Appendix 1B: Patient and sedation characteristics to be examined for association with the occurrence of vomiting

Patient Characteristics	Further Description/Categories
Age	Age, in years AND as a categorical variable < 2 years/≥ 2years
Sex	male/female
BMI	Weight (kg)/height(m ²)
ASA classification	I/II/III/IV/V
Fasting status for solids	yes/no (according to ASA guidelines) AND as a continuous variable in minutes prior to the sedation?
Fasting status for liquids	yes/no (according to ASA guidelines) AND as a continuous variable in minutes prior to the sedation?
Pre-procedural opioids	yes/no AND as a continuous variable in minutes prior to sedation
Underlying health risks	Gastroesophageal reflux/chronic constipation/vomiting illness
Pre-procedural anti-emetics	yes/no
Sedation medication	Ketamine/Ketamine+midazolam/Ketamine+Fentanyl/Propofol/Propofol+opioid/Propofol+ketamine
Total dose of sedation medication	In mg per kg
Duration of the procedure	Start of physiologic recovery-start of sedation, in minutes
Procedure	Fracture reduction/dislocation reduction/laceration repair/foreign body removal/cardioversion or defibrillation/chest tube insertion/dressing change/I+D abscess/inguinal hernia reduction/joint aspiration/LP/paraphimosis reduction/rectal prolapse reduction/testicular torsion/throracentesis/other

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department**Appendix 1C: System characteristics to be examined for association with the occurrence of any adverse event**

Patient Characteristics	Further Description/Categories
Personnel involved in sedation as a fraction of a full complement	Four separate individuals performing the following functions will be considered a full complement: a) recording vital signs b) administer medications +/- monitor vital signs c) monitor airway d) perform procedure. Fractions of this complement will be examined for an association with adverse events
Number of physicians per sedation	Sum of MD (staff, resident, fellow) in health care personnel involved in sedation

*Factors significant at the two-sided $p < 0.10$ level on univariate analysis will be considered for inclusion in the multivariate model. When variables are highly correlated, the less clinically relevant ones will be omitted.

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department**Appendix 2: Detailed description of all data fields to be collected and their corresponding electronic format**

1. Patient demographics: age (free text in months \leq 24 months, then years+months), sex (drop down menu: M,F), weight (free text), and height (free text).

2. Risk assessment: American Society of Anesthesiology (ASA) classification (radio button: I, II, III, IV, V), NPO date (drop down calendar with default to “today” but any date can be chosen) and time (free text) for liquids and solids, current medications (radio buttons: no current medications, antibiotics, asthma medication, seizure medications, ADHD medications, other with a free text box), underlying health risks (radio buttons: no underlying health risks, stridor when awake, history of sleep apnea, history of snoring, large tongue, micrognathia, facial dysmorphism, other airway risk factor with free text box, gastroesophageal reflux, chronic constipation, vomiting illness, pre-existing neurologic impairment, cardiac disease, history of prematurity, other underlying health risk with free text box), current upper respiratory infection (radio button: yes, no), and active asthma as defined by bronchodilator use in the previous 48 hours (radio button: yes, no).

3. Pre-procedure information: procedure performed (drop down menu: fracture reduction, dislocation reduction, laceration repair, foreign body removal, cardioversion or defibrillation, chest tube insertion, dressing change, abscess incision and drainage, inguinal hernia reduction, joint aspiration, lumbar puncture, paraphimosis reduction, rectal prolapsed reduction, testicular torsion, thoracentesis, other), anatomic location of procedure, if procedure performed was fracture reduction (drop down menu: ankle, femur, fibula, foot, hand, humerus, nose, radius, radius and ulna, supracondylar, tibia, tibia and fibula, ulna, other with free text box), dislocation reduction (drop down menu: ankle, elbow, foot and toes, hand and fingers, hip, knee, patella, shoulder, wrist, other with free text box), laceration repair (drop down menu: face and mouth, eye+/-lid, vulva or perineum, scrotum, nailbed, other with free text box), foreign body removal (drop down menu: ear, eye, foot, genitourinary, hand, head and neck, lower limb not foot, nose, pharynx, trachea, upper limb not hand, other with free text box), pre-oxygenation (radio button: yes/no), pre-procedural pain medications (radio button: yes, no; if yes, drop down menu: acetaminophen, codeine, dilaudid, fentanyl ibuprofen, meperidine, morphine, ketorolac, other medication with free text box; after selecting a medication, the user is prompted to enter the dose (free text), units (drop down menu: mg, mcg), route (drop down menu: IV, IM, PO, PR), and time (“now” button that records current time with ability to edit and input free text), other medications pre-procedure (radio button: yes, no; if yes, drop down menu: gravol, Benadryl, ondansetron, midazolam, other medication with free text box; after selecting a medication, the user is prompted to enter the dose (free text), units (drop down menu: mg, mcg), route (drop down menu: IV, IM, PO, PR), and time (“now” button that records current time with ability to edit and input free text).).

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

4. Intra-procedure information: supplemental oxygen during the procedure (radio button: yes, no), health care personnel present during the procedure (4 drop down menus: staff MD, resident or fellow, nurse, respiratory therapist, nurse practitioner, other personnel with free text box), the role each health care personnel performed (radio buttons, can select more than one: airway monitoring, vital signs recording, vital signs monitoring, administration of sedation medications, perform procedure), sedation medications administered (drop down menu: atropine, chloral hydrate, etomidate, fentanyl, glycopyrolate, ketamine, midazolam, nitrous oxide, pentobarbital, propofol, other medication with free text box), for each medication chosen the user is prompted to input the dose (free text), units (drop down menu: mg, mcg), route (drop down menu: IV, IM, PO, PR), and time (“now” button that records current time with ability to edit and input free text).

4. Patient behavior: patient behavior prior to the sedation (drop down menu: calm, agitated but responds to comforting, agitated and does not respond to comforting), patient state upon recovery (drop down menu: age appropriate, crying- inconsolable, agitation, delirium, dysphoria, nightmares, hallucinations), interventions performed in response to unpleasant recovery (radio buttons: physical restraint, administration of medication, require additional personnel to care for patient, delayed discharge), unpleasant recall of the procedure (drop down menu: yes, no, too young to question, not questioned).

5. Adverse event review: radio buttons, able to select more than one (unless no adverse events was chosen): no adverse events, oxygen desaturation, central apnea, partial airway obstruction, complete airway obstruction, laryngospasm, clinically apparent pulmonary aspiration, vomiting, bradycardia, hypotension, seizure, myoclonus, muscle rigidity, paradoxical response to sedation, permanent neurologic injury, death, other with free text box. If any adverse event was selected, the user is taken to another window with further documentation of the adverse event according to the appendix of the Quebec Guidelines.

6. Recovery information: use of reversal agents (radio buttons: yes, no; if yes, drop down menu: naloxone, flumazenil, other medication with free text box; for each medication chosen, the user is prompted to input the dose (free text), route (drop down menu: IV, IM, PO, PR), and time (“now” button that records current time with ability to edit and input free text), if reversal agents are used, the user is asked a) indication for use (drop down menu: over sedation, apnea, agitation, itching, shorten recovery time, other reason with free text box), pain medications during recovery (radio button: yes, no; if yes, same drop down menu as in pre-procedural pain medications), vomiting during recovery (radio buttons: yes, no), if yes the user is asked a) if the patient was alert at the time (radio button: yes,no), b) if anti-emetic medication was administered (radio button: yes, no; if yes, drop down menu: gravol, ondansetron, other medication with free text box; for each medication chosen, the user is prompted to enter the dose (free text), unit (mg, mcg), route (IV, IM, PO, PR) and time (“now” button to record current time with ability to edit and enter free text), criteria for successful sedation (radio buttons: patient experienced a sedation-related adverse event leading to the abandonment of the procedure, patient experienced

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

a permanent complication, patient had an unplanned admission to hospital or prolonged ED observation as a result of the sedation, patient actively resisted the procedure or required physical restraint to complete the procedure).

7. *Time intervals*: Start of sedation (time of administration of first sedation medication), end of sedation (time procedure is complete; “now” button to record current time with ability to edit and enter free text), start of recovery (same as end of sedation), end of physiologic recovery (time patient returns to physiologic baseline; “now” button to record current time with ability to edit and enter free text), end of recovery (time patient is discharged; “now” button to record current time with ability to edit and enter free text).

Appendix 3: Post-Hospital Behavior Questionnaire**Pre-Procedure Information**

“Were you in the room when the actual procedure was being performed?”

Yes No

“Has your child ever had a procedure under sedation in the emergency department before?”

Yes No

If so, “what type of procedure(s)?” _____

“Has your child ever stayed in the hospital overnight?”

Yes No If so, “What for?” _____

Post-Procedure Information

“Did your child vomit (throw up) after leaving the emergency department?”

Yes No

If yes, “When?” Day of discharge

Day after discharge

2 days after discharge

Other _____

“Did your child stay home from school/kindergarten after leaving the emergency department?”

Yes No N/A If yes, “For how many days?” _____

“Did you or another parent stay home from work to care for your child after leaving the emergency department?”

Yes No N/A If yes, “For how many days?” _____

“If you had to rate how much pain your child was in (on the day of discharge / on the day after discharge / 2 days after discharge) on a scale from 1 to 10 where 1= No pain and 10 = the worst possible pain, how would you rate your child's pain?":

1 2 3 4 5 6 7 8 9 10

Day of discharge: _____ Day after discharge: _____ 2 days after discharge: _____

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department**Post Hospital Behavior Questionnaire**

“Each of the following questions asks about your child’s behavior since leaving the emergency department. For each question, think about how much your child does the described behavior and choose the best answer from “much less than before,” “less than before,” “same as before,” “more than before,” or “much more than before.” Some questions may not apply to your child, or may not seem age- appropriate as this question tool is being used for patients of all ages. If the question does not apply to your child, choose “same as before.” For example, if a question asks “Does your child ride a bicycle?” and your child does not know how to ride a bicycle, choose “same as before.” “

1. Does your child make a fuss about going to bed at night?

- much less than before
- less than before
- same as before
- more than before
- much more than before

2. Does your child make a fuss about eating?

- much less than before
- less than before
- same as before
- more than before
- much more than before

3. Does your child spend time just sitting or lying and doing nothing?

- much less than before
- less than before
- same as before
- more than before
- much more than before

4. Does your child need an object of comfort (like a pacifier or blanket)?

- much less than before
- less than before
- same as before
- more than before
- much more than before

5. Does your child seem to be afraid of leaving the house with you?

- much less than before
- less than before
- same as before
- more than before
- much more than before

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

6. Is your child uninterested in what goes on around him (or her)?

- much less than before
- less than before
- same as before
- more than before
- much more than before

7. Does your child wet the bed at night?

- much less than before
- less than before
- same as before
- more than before
- much more than before

8. Does your child bite his (or her) finger nails?

- much less than before
- less than before
- same as before
- more than before
- much more than before

9. Does your child get upset when you leave him (or her) alone for a few minutes?

- much less than before
- less than before
- same as before
- more than before
- much more than before

10. Does your child need a lot of help doing things?

- much less than before
- less than before
- same as before
- more than before
- much more than before

11. Is it difficult to get your child interested in doing things (like playing games, with toys, and so on?)

- much less than before
- less than before
- same as before
- more than before
- much more than before

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

12. Does your child seem to avoid or be afraid of new things?

- much less than before
- less than before
- same as before
- more than before
- much more than before

13. Does your child have difficulty making up his (or her) mind?

- much less than before
- less than before
- same as before
- more than before
- much more than before

14. Does your child have temper tantrums?

- much less than before
- less than before
- same as before
- more than before
- much more than before

15. Is it difficult to get your child to talk to you?

- much less than before
- less than before
- same as before
- more than before
- much more than before

16. Does your child seem to get upset when someone mentions doctors or hospitals?

- much less than before
- less than before
- same as before
- more than before
- much more than before

17. Does your child follow you everywhere around the house?

- much less than before
- less than before
- same as before
- more than before
- much more than before

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

18. Does your child spend time trying to get or hold your attention?

- much less than before
- less than before
- same as before
- more than before
- much more than before

19. Is your child afraid of the dark?

- much less than before
- less than before
- same as before
- more than before
- much more than before

20. Does your child have bad dreams at night or wake up and cry?

- much less than before
- less than before
- same as before
- more than before
- much more than before

21. Is your child irregular in his (or her) bowel movements?

- much less than before
- less than before
- same as before
- more than before
- much more than before

22. Does your child have trouble getting to sleep at night?

- much less than before
- less than before
- same as before
- more than before
- much more than before

23. Does your child seem to be shy or afraid around strangers?

- much less than before
- less than before
- same as before
- more than before
- much more than before

Development of a multi-centre surveillance system for sedation safety in the pediatric emergency department

24. Does your child have a poor appetite?

- much less than before
- less than before
- same as before
- more than before
- much more than before

25. Does your child tend to disobey you?

- much less than before
- less than before
- same as before
- more than before
- much more than before

26. Does your child demonstrate aggressive behaviour (like breaking things)?

- much less than before
- less than before
- same as before
- more than before
- much more than before

27. Does your child suck his (or her) fingers or thumbs?

- much less than before
- less than before
- same as before
- more than before
- much more than before