

BMJ Open The design of a multicentre Canadian surveillance study of sedation safety in the paediatric emergency department

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ABSTRACT

Introduction: Procedural sedation and analgesia have become standard practice in paediatric emergency departments worldwide. Although generally regarded as safe, serious adverse events such as bradycardia, asystole, pulmonary aspiration, permanent neurological injury and death have been reported, but their incidence is unknown due to the infrequency of their occurrence and lack of surveillance of sedation safety. To improve our understanding of the safety, comparative effectiveness and variation in care in paediatric procedural sedation, we are establishing a multicentre patient registry with the goal of conducting regular and ongoing surveillance for adverse events in procedural sedation.

Methods: This multicentre, prospective cohort study is enrolling patients under 18 years of age from six paediatric emergency departments across Canada. Data collection is fully integrated into clinical care and is performed electronically in real time by the healthcare professionals caring for the patient. The primary outcome is the proportion of patients who experience a serious adverse event as a result of their sedation. Secondary outcomes include the proportion of patients who experience an adverse event that could lead to a serious adverse event, proportion of patients who receive a significant intervention in response to an adverse event, proportion of patients who experience a successful sedation, and proportion of patients who experience a paradoxical reaction to sedation. There is no predetermined end date for data collection.

Ethics and dissemination: Ethics approval has been obtained from participating sites. Results will be disseminated using a multifaceted knowledge translation strategy by presenting at international conferences, publication in peer-reviewed journals, and through established networks.

INTRODUCTION

Procedural sedation and analgesia have become standard practice in paediatric

Strengths and limitations of this study

- This will be the first multicentre study to estimate the risk of serious adverse events in paediatric emergency department procedural sedation.
- This study uses a novel data collection method that is integrated into clinical care, eliminating duplicate documentation, and increasing efficiency and data quality by utilising built-in error checking and other smart functions.
- All participating sites are tertiary care paediatric emergency departments, thus, findings may not be directly generalisable to general emergency department (ED) settings or other procedural sedation settings outside of the operating room.

emergency departments worldwide. Each year, thousands of North American children receive emergency department (ED) procedural sedation, and the number is rapidly increasing as emergency department (ED) experience and expertise has grown.^{1 2}

Although procedural sedation performed outside the operating room is generally regarded as safe, serious adverse events have been known to occur.^{3–8} Bradycardia, asystole, pulmonary aspiration, permanent neurological impairment, and death have been reported, but their incidence is unknown due to the infrequency of their occurrence and lack of consistent surveillance of safety of sedation.^{4 5 7 8} These serious adverse outcomes have not been reported in paediatric ED procedural sedation, though they are understood to be preceded by more commonly occurring events, such as oxygen desaturation, vomiting, apnoea and laryngospasm. The occurrence rates for these events have been reported to be between 2% and 26% based on small, single centre ED cohorts.^{9–19} Unfortunately,

these studies have sample sizes that are too small to reliably determine the comparative safety of different sedation modalities for both minor and major adverse events. Moreover, aggregation of results from these studies has been difficult as they have used varied terminology and definitions to describe the same adverse events and outcomes.

To improve our understanding of the safety, comparative effectiveness and variation in care of paediatric ED procedural sedation, we have established a multicentre patient registry that is fully integrated with clinical documentation of patients undergoing procedural sedation in participating Canadian paediatric EDs. This sustainable design uses methodology that results in prospectively collected, consistently complete data, without the use of research personnel for patient recruitment or data collection. As such, this system allows for ongoing data collection and surveillance of adverse events and rescue interventions.

OBJECTIVES

The objective of our multicentre prospective cohort study is to establish a surveillance system for adverse events in procedural sedation in six paediatric EDs across Canada by implementing a standardised electronic data collection system that is fully integrated within clinical care.

METHODS

Study design

This is an ongoing multicentre prospective cohort study. We are enrolling all consenting patients undergoing procedural sedation in six Canadian paediatric EDs. Data collection began in July 2010 in a staged rollout across sites with the most recent site being added in June 2013. There is no predetermined end date for data collection. The parents of patients who experience an adverse event, and 15% of enrolled patients at each site who do not experience an adverse event, will be contacted by telephone 1–2 weeks following ED discharge to determine their child's state of physical and psychological health after receiving procedural sedation in the ED.

Study setting

The study is taking place in the EDs of 6 of the 12 tertiary care children's hospitals in Canada. Participating sites are: IWK Health Centre (Halifax, Nova Scotia), Montreal Children's Hospital (Montreal, Quebec), Children's Hospital of Eastern Ontario (Ottawa, Ontario), The Hospital for Sick Children (Toronto, Ontario), Stollery Children's Hospital (Edmonton, Alberta) and Alberta Children's Hospital (Calgary, Alberta). All sites are members of Pediatric Emergency Research Canada (PERC), a national collaborative research network of 15 Canadian paediatric EDs.^{20–22} The sites have a combined annual ED census of approximately 350 000 patient visits and cumulatively perform parenteral sedation for an estimated 3500 children each year.

Inclusion criteria

1. Age less than 18 years.
2. Patients undergoing ED procedural sedation for painful procedures.

Exclusion criteria

1. Patients receiving only anxiolytic medications.
2. Patients receiving only analgesic medications.
3. Patients receiving a combination of oral, inhaled and/or intranasal medications *without* any intravenous medications for procedural sedation and analgesia.
4. Insurmountable language barrier that prevents informed consent and follow-up by telephone

Outcome measures

Primary outcome measure

The primary outcome is the proportion of patients who experience a serious adverse event as a result of their sedation. Serious adverse events are apnoea, laryngospasm, hypotension, bradycardia, complete airway obstruction, clinically apparent pulmonary aspiration, permanent neurological injury and death, as defined by the Quebec Guidelines.^{23 24}

Secondary outcome measures

1. Proportion of patients who experience an adverse event that could lead to a serious adverse event. These events are: oxygen desaturation, partial airway obstruction and vomiting, as defined by the Quebec Guidelines.^{23 24}
2. Proportion of patients who receive a significant intervention in response to an adverse event. Significant interventions are: bag-mask ventilation, tracheal intubation, administration of vasoactive medications, administration of neuromuscular blockade agents and chest compressions.
3. Proportion of patients who experience any adverse event as a result of their sedation. Adverse events are defined by the Quebec Guidelines.^{23 24}
4. Proportion of patients who experience a successful sedation, as defined by the Quebec Guidelines.^{23 24}
5. Proportion of patients who experience a paradoxical reaction to sedation, as defined by the Quebec Guidelines.^{23 24}
6. Duration of the sedation, defined as the time from the administration of the first sedation medication to the end of physiologic recovery.
7. Proportion of patients undergoing ketamine sedation who have preprocedural agitation (agitated and responds to comforting, or, agitated and does not respond to comforting).
8. Proportion of patients who experience age-inappropriate recovery reactions (crying, agitation, delirium, dysphoria, nightmares or hallucinations) as specified by the Quebec Guidelines.^{23 24}
9. Patient characteristics that may be associated with respiratory adverse events and vomiting and system-level characteristics that may be associated with any

adverse event. These characteristics are further defined and described in the online supplementary appendix 1A–C.

10. The proportion of children experiencing maladaptive behaviours following their ED discharge, as reported by a summary score on the modified Post-hospital Behaviour Questionnaire (PHBQ).^{25–27} On the PHBQ, behaviours that increase after a procedure are scored positively, behaviours that decrease are scored negatively, and behaviours that do not change are given a score of 0. Summary scores can range from –54 to +54. A positive score indicates a maladaptive behaviour change.
11. The proportion of children who experience vomiting in the first 48 h following ED discharge.

Overview of data collection

Electronic data collection tool

A unique electronic procedural sedation form (Microsoft InfoPath) has been created for each site that aesthetically resembles their paper sedation record (Red Engine, Edmonton, Alberta, Canada). The unique form contains all data elements required for the study as well as information that is captured on their paper sedation record. This eliminates the need for duplicate documentation. Radio buttons, check boxes and dropdown menus have been employed, and functions are automated, where possible, to increase efficiency and data quality. Free text is only permitted for details of medications administered and descriptions of procedures performed if not found in the dropdown menus. Built-in data validation will ensure complete datasets for each patient. Errors in data input and blank fields (including consent questions) are flagged by the programme and corrected by the user at the time of documentation. The electronic sedation forms reside on tablet computers housed on mobile carts which are securely stored in a convenient, accessible area in each ED. The tablet computers are used exclusively for this purpose.

Definitions

Standardised definitions for sedation terminology (pre-sedation state, efficacy of sedation), time intervals and adverse events have been used according to the Quebec Guidelines.^{23 24}

Study documentation

Study documentation includes patient demographic characteristics, preprocedure assessment and interventions, medication choice, behaviour information, adverse event review and recovery information. Where applicable, free text variables can be inputted by the user in imperial or metric units, but are automatically converted and stored in metric units by the programme. All times are stored in relation to the start of the sedation (time of first sedation medication) which is stored as ‘time zero’. Events prior to the sedation are stored as negative minutes, and events following the sedation are stored as

positive minutes. Details about each data field to be collected and the electronic format for each variable can be found in the online supplementary appendix 2.

Study procedures

Training and introduction to electronic documentation

Prior to study initiation, all sites used paper sedation records. The PI (MB) and/or the project technology coordinator (Gabino Travassos) conducted formal small group and one-on-one training sessions for site champions and end users at each site. The site champions completed training of all end users before the site-specific ‘go-live’ date. *Phase I* of training consisted of (1) demonstration of the electronic form by the trainer to the end user either one-on-one or in a small group, (2) end user completion of three sample cases using the electronic documentation form while being directly observed by the trainer. Completion of this step was required by 80% of end users prior to the go-live date. During *Phase II* (2 weeks duration, following the go-live date), site champions and/or research assistants were called in for all sedations taking place in the ED (24 h a day, 7 days a week) to support the team with the electronic documentation for all sedations (‘at elbow’ training). During *Phase III* (6 weeks duration following the end of Phase II), the site champions/research assistants were available on an on-call basis to help the ED team with any problems or questions encountered during the electronic documentation (by telephone and in person on a case-by-case basis). Buy-in was elicited from nursing and medical leadership prior to initiation of the study. Sites have been encouraged to remove all paper sedation records from the ED to maximise the use of the electronic sedation documentation form.

Procedure for data collection in the ED

When a decision is made that a patient requires ED procedural sedation, the healthcare team member caring for the patient opens the electronic sedation record on the tablet computer and begins documentation. The tablet computer remains with the patient for the duration of their ED stay, as the electronic form is used to document all sedation care, from the preprocedural assessment to recovery and discharge. All documentation is completed by the health professional caring for the patient (physician, nurse, respiratory therapist), minimising the need for research personnel to sustain the study. Informed written consent and/or assent for collection of study information and transmission of de-identified records to a central database is also obtained by the healthcare professional in accordance with the specific requirements dictated by each site’s Research Ethics Board (details below). If a patient/parent does not consent to participation, the sedation is still documented electronically, but the programme logic prevents study information from being saved to the tablet database. At ED discharge, a site-specific sedation paper record is printed from the electronic form which

becomes the official record of care provided to the patient. The printed document is identical to the site-specific sedation record and does not contain any of the extra information collected for study purposes. After printing, the user is asked to submit the form to an encrypted database residing on the tablet computer, saving only information collected for study purposes and discarding all site-specific clinical information. All data fields must be complete and correctly formatted in order for the form to be submitted to the database.

Data transmission

Research personnel at each site complete a data transfer process, at minimum, on a weekly basis. This manually initiated but automated process transfers records from the tablet computers to a private local network drive and will simultaneously transfer these records in de-identified form to a central database (Clinical Research Informatics Core (CRIC), University of Alberta, Edmonton, Canada). Once the transfer of data to the central database is successful, the records are automatically deleted from the tablet database.

Patient follow-up

The parents of all patients who experience an adverse event as well as a random sample of 15% of patients who were sedated at each site and who did not experience an adverse event are contacted by telephone within 1 week of their ED discharge. The weekly list of telephone follow-ups for each site is automatically generated by the central database (CRIC) and sent by email to the site coordinator and physician site lead. Parents are asked about their child's occurrence of maladaptive behaviours following the ED sedation using the PHBQ (modified), as well as additional questions about the occurrence of vomiting. These questions can be found in online supplementary appendix 3. Phone calls are conducted by trained, experienced research assistants and coordinators. Three attempts are made to contact the family at varied times of the day. Data is recorded on a standardised paper data collection form.

Estimation of missed, eligible patients

To estimate the proportion of procedural sedation cases not captured at each site, surveillance for missed cases is performed during the 3rd week of each month. We will extrapolate these numbers to generate overall compliance/consent rates. Since this study will enrol patients for a period of years, daily surveillance for missed patients was thought too onerous for the sites to maintain over the long term. To minimise sampling bias, we monitor all shift times during the 7 days of surveillance. The site coordinator performs a review to identify children who were sedated during this 7-day period but are not registered in the database. Methods to identify missed patients vary by site. Daily hand searching of ED charts, pharmacy record queries and electronic medication dispensing system queries are used depending on

site opinion of the most reliable method at their institution. A medical record review is performed on all missed patients, and an electronic data collection form is used to document the following patient information (1) age, (2) sex, (3) sedation medication received and (4) adverse events experienced.

Data analysis

Patient, sedation and system-level characteristics, overall and by site, will be summarised using descriptive statistics. Discrete variables will be summarised using frequency and percentage. Continuous variables will be summarised using mean, SD, median, IQR and range, as appropriate.

The primary analysis will use logistic regression to compute OR, by medication, of a serious adverse event, adjusting for key potential confounders: age, body mass index (<25, ≥25), use of preprocedural opioids, nil per os (NPO) ≥6 h for solids, NPO ≥2 h for liquids, presence of an underlying health risk, personnel present (represented as a fraction of 4 possible personnel) and site. ORs will be reported together with 95% CIs. Two-sided p values less than 0.05 will be considered statistically significant.

Secondary analyses

For the outcomes of (1) an adverse event that could lead to a serious adverse event, (2) a significant intervention being performed in response to an adverse event, (3) any adverse event, (4) successful sedation and (5) paradoxical reaction to sedation, similar analyses to the primary analysis will be performed. The same variables as for the primary analysis will be adjusted for in each of these analyses.

The distribution of duration of sedation will be examined, and if necessary, transformed to achieve approximate normality. Linear regression will be used to examine the relationship between the duration of sedation, procedure type, patient characteristics and occurrence of an adverse event. Length of stay in the ED will be analysed similarly. Residuals will be examined to ensure goodness of fit.

Sedation practices and outcomes in children under 2 years of age will be compared with children aged 2 years and older. For discrete variables, comparisons will be made using Pearson's χ^2 test or Fisher's exact test, as appropriate. For continuous variables, comparisons will be made using a Student t test or the Wilcoxon test, as appropriate.

The association between preprocedural agitation and adverse events, interventions and outcomes for patients undergoing ketamine sedation will be examined using logistic regression or linear regression as appropriate. Patient characteristics (age, weight, sex), patient state on recovery (age appropriate/age inappropriate), occurrence of adverse events, length of procedure (measured from start of sedation until start of physiological recovery in minutes), total dose of sedation medication administered

(in mg/kg), route of administration (intravenous/intramuscular), and length of stay will be examined in children with and without preprocedural agitation.

The proportion of children experiencing vomiting and maladaptive behaviours, as reported by a summary score on the modified PHBQ^{25–27} will be explored overall and by medication administered. Analysis will be conducted separately for the four most common medication combinations, and will be adjusted for important covariates (age, sex, type of procedure, length of procedure (minutes), occurrence of an emergence reaction).

ETHICS AND DISSEMINATION

Ethical considerations

There is minimal risk to patients involved in this study, as it is purely observational and will not interfere with patient care. Risks exist in the realm of privacy of data. Identifying patient information (name, medical record number) will be stored in study records in the tablet database. The following steps have been taken to ensure maximal privacy for all records stored on these computers: (1) the tablet database is encrypted making it difficult to easily access information (2) there is restricted access to these computers with a user authentication process (3) all files are deleted from the tablet database once the central data transfer process is complete (performed at minimum, once per week). We estimate that a maximum of five records will be contained in a tablet database at anytime. No further identifying information will be contained in the database. Date of birth is stored as age and all times and dates are recorded as minutes prior to or following the sedation. These study processes have been approved by the privacy commissioner at all participating sites.

Research Ethics Board approval has been obtained from all participating sites. The informed consent process varies by site as approved by each individual Research Ethics Board. The Montreal Children's Hospital, The Hospital for Sick Children, Children's Hospital of Eastern Ontario and the IWK Health Centre only enrol patients after written informed consent has been obtained from parents or legal guardians. Assent is also obtained at these sites from participants over 7 years old. Stollery Children's Hospital and Alberta Children's Hospital enrol patients if verbal consent is given by the parent or legal guardian. Consent is obtained for the possibility of receiving a follow-up telephone call within 1 week of ED discharge.

Knowledge translation

A multifaceted knowledge translation strategy will be used. We will disseminate the results of this study at international conferences, in manuscripts in peer-reviewed journals, and to a broad range of stakeholders using the PERC and TREKK (TRanslating Emergency Knowledge for Kids) networks. TREKK is a unique partnership, and knowledge exchange between 36 general EDs across

Canada and 12 PERC sites. The annual PERC and TREKK meetings and internal communication structures of these organisations will allow knowledge gained in this study to be widely and rapidly disseminated.

This cohort will represent the largest known ED procedural sedation cohort allowing us to explore predictors (patient, sedation and system factors) leading to the safest sedations for children. To further ensure distribution of study results and best sedation practices, the principal investigator will work with PERC and TREKK sites to create multidisciplinary improvement teams within each institution in order to develop systematic improvements in sedation care and patient outcomes.

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Contributors MB, GJ and DWJ created the study concept. MB, MGR and DWJ led the design and selected outcome measures. MB wrote the first draft of the manuscript with contributions from DWJ, MGR, KJF, SA, ASD, AD, CMMcT, SB and NB. MB, DWJ, MGR, KJF, SA, ASD, AD, CMMcT, SB and NB provided critical review and have given final approval of the submitted manuscript.

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Competing interests None declared.

Ethics approval Ethics approval has been obtained from the institutional research ethics boards at all six participating sites. Specifically, the IWK Health Center, Halifax (1003634), Montreal Children's Hospital, Montreal (PED-07-027), Children's Hospital of Eastern Ontario, Ottawa (#09/15X), The Hospital for Sick Children (1000024842), Stollery Children's Hospital, Edmonton (Pro00003165), Alberta Children's Hospital, Calgary (E-21351).

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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

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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
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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)).

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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

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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: _____

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“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

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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

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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

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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

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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