


## PROTOCOL

# Integrated Pulmonary Index during nurse-administered procedural sedation: Study protocol for a cluster-randomized trial

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## Abstract

**Aim:** To determine if smart alarm-guided treatment of respiratory depression using the Integrated Pulmonary Index is an effective way to implement capnography during nurse-administered sedation.

**Design:** Parallel cluster-randomized trial.

**Methods:** Nurses will be randomized to use capnography with or without the Integrated Pulmonary Index enabled. Capnography alarm performance will be compared between nurses using capnography alone or with the Integrated Pulmonary Index enabled. The target sample size is 400 adult patients scheduled for elective procedures with nurse-administered sedation. The primary outcome is the number of seconds in an alert condition state without an intervention being applied. Secondary outcomes are alarm burden, number of appropriate alarms, number of inappropriate alarms, total duration of alert conditions, choice of alarm settings and adverse sedation events. This study has been funded since April 2021.

**Discussion:** Implementing capnography into practice for respiratory monitoring during nurse-administered sedation is considered a high priority. The Integrated Pulmonary Index shows promise as a strategy to optimize the implementation of capnography for respiratory monitoring during nurse-administered sedation. If it is found in this study that using the Integrated Pulmonary Index improves the nursing management of physiologically abnormal states during nurse-administered sedation, it would provide the high-level evidence needed to support broader use of this 'smart alarm' strategy for respiratory monitoring in practice.

**Impact:** With advances in medical technology continuing to expand the indications for minimally invasive surgical techniques, the use of nurse-administered sedation during medical procedures is likely to expand in the future. The findings may be applied to other populations receiving nurse-administered sedation during medical procedures. Results from this study will help translate the usage of smart alarm-guided treatment of respiratory depression during procedural sedation.

**Trial registration:** NCT05068700.

## KEYWORDS

capnography, integrated pulmonary index, nursing, procedural and analgesia, sedation, sedation anaesthesia

## 1 | INTRODUCTION

Procedural sedation involves the administration of sedative and/or analgesic medications that allow patients to tolerate painful or uncomfortable diagnostic or therapeutic procedures. A specialist anaesthetist is not always required to manage sedation (Dobson et al., 2018). Nurse-administered sedation is used commonly internationally (Conway et al., 2014). Monitoring and responding to altered respiration are vital aspects of the nursing role when sedation is used during medical procedures without an anaesthesiologist present. In many departments, the standard-of-care is for nurses to assess respiratory function through clinical observations (respiratory rate, depth and effort) and oxygen saturation monitoring. However, the use of capnography is associated with a significantly increased likelihood of detecting respiratory depression than standard care (Waugh et al., 2011).

Implementing capnography into practice for respiratory monitoring during sedation is considered a high priority; the Canadian Anesthesiologists' Society's position statement recommends that capnography should be available wherever moderate or deep sedation is used (Dobson et al., 2018). The Academy of Medical Royal Colleges (UK) Standard and Guidance report on Safe Sedation Practice for Healthcare Procedures noted that whilst capnography is not a mandated practice, providers should consider implementing capnography as a long-term goal (Furniss & Sneyd, 2015). These recommendations are in place because sedated patients who are not monitored with capnography have frequent undetected, and therefore untreated, respiratory depression. Of note, though, these guidelines do not provide specific recommendations for how capnography should be implemented for nurse-administered sedation.

## 1.1 | Background

Results of a systematic review and meta-analysis of capnography for sedation showed that applying interventions to either stimulate breathing or restore airway patency after short periods of hypoventilation or apnea (10–30 s) improved patient safety by reducing the risk of hypoxemic events (RR 0.71; 95% CI = 0.56–0.91; Conway et al., 2016). Of concern, these interventions are not reliably implemented when capnography is being used in real-world practice though. In a study that measured capnography waveform abnormalities during nurse-administered sedation, abnormal ventilation patterns were frequently detected (Conway et al., 2019). In particular, 169 episodes of apnea that lasted longer than 30 s or more were observed in 48 of the 102 participants included in the sample (Conway et al., 2019). However, only 35 interventions were applied to stimulate breathing in response to these capnography waveform abnormalities (Conway et al., 2019). This failure to consistently initiate interventions, which have been proven to improve safety in the

randomized trial context, is indicative of suboptimal implementation of capnography into practice.

A further recent evaluation of the implementation of capnography during endoscopy and colonoscopy with nurse-administered sedation also indicated suboptimal initiation of interventions to treat sedation-induced respiratory depression. Adverse events (defined as a composite of oxygen desaturation below 90% and procedural interruption due to hemodynamic or respiratory instability) occurred in 8.2% of the pre-implementation cohort ( $n = 501$ ) and 11.2% of the post-implementation ( $n = 465$ ) cohort (Barnett et al., 2016). The difference in adverse events between these groups was not statistically significant after adjustment for confounding ( $p = .30$ ; Barnett et al., 2016). These results from evaluations of how capnography is currently being used for nurse-administered sedation underscores the fact that successfully implementing this technology into practice for nurse-administered sedation is not as simple as having the technology available for use and providing education to nurses about how to interpret capnography waveforms. As the current strategies for implementing capnography into practice for nurse-administered sedation have not been effective, there is a need to test alternatives.

## 1.2 | Optimizing the implementation of capnography

The processing of information from the multiple concurrent data sources required for respiratory monitoring with capnography during sedation is both time-consuming and cognitively demanding (Potter et al., 2005). This arises from the need to first examine parameters individually and then integrate the information from each to form an assessment. Physiological monitoring can be optimized by incorporating the Bayesian nature of clinical decision-making to create integrated 'smart alarm' systems, where the focus is shifted from threshold-based alarms for individual physiological parameters to automated integration of data from several sources (Chopra & McMahon, 2014). The Integrated Pulmonary Index is a 'smart alarm' that shows promise as a tool to assist the implementation of capnography for sedation (Ronen et al., 2016). It is a mathematically derived index of physiological parameters related to the assessment of respiratory function (end-tidal carbon dioxide, oxygen saturation, respiration rate and heart rate) based on a fuzzy-logic inference model (Ronen et al., 2016). It simplifies the interpretation of continuous oxygenation and ventilation monitoring by assigning clinical responses for given Integrated Pulmonary Index scores (Ronen et al., 2016). A clinical validation study demonstrated that at an index score of four, where intervention is recommended, the sensitivity and specificity for detection of a clinically significant event are over 90% (Ronen et al., 2016). A summary of this commercially available tool, which can be enabled

as a feature of the Medtronic (Minneapolis, USA) capnography monitoring devices, can be found in Table 1.

The Integrated Pulmonary Index shows promise as a strategy to optimize the implementation of capnography for respiratory monitoring during nurse-administered sedation. In this regard, it should be noted that although it is accepted that capnography monitoring is a sensitive tool for identifying deviations from physiologically normal ventilation patterns during sedation, proving that using this technology reduces severe adverse events and consequently improves patient safety is much more difficult. However, the burden of proof is often lowered when patient safety is the primary concern (Cook, 2016). An illustrative case for this point is pulse oximetry, which even in a randomized trial of 20,000 patients was not able to demonstrate that this technology improved clinical outcomes during anaesthesia for surgery (Moller et al., 1993). Therefore, consistent with precedents set for the uptake of interventions to improve patient safety in anaesthesia, we contend that demonstrating that smart alarm-guided treatment of respiratory depression using the Integrated Pulmonary Index during nurse-administered sedation exerts its intended effect may provide sufficient evidence to support broader uptake of this strategy. The Integrated Pulmonary Index is intended to reduce the cognitive burden of synthesizing multiple sources of physiological monitoring input and hence lowering the threshold for triggering intervention by clinicians to support respiration. This study will determine if using the Integrated Pulmonary Index during nurse-administered sedation achieves the desired effect of lowering the threshold for triggering intervention by directly measuring the time taken for nurses to respond to capnography monitor alarms.

## 2 | THE STUDY

### 2.1 | Aim

To determine if smart alarm-guided treatment of respiratory depression using the Integrated Pulmonary Index is an effective way to implement capnography during nurse-administered sedation.

### 2.2 | Objectives

The primary objective of the study is to determine if the time between the onset of a capnography monitor alarm and initiation of

an intervention is reduced when the Integrated Pulmonary Index is enabled during nurse-administered sedation.

The secondary objectives of the study are to investigate the effect of the Integrated Pulmonary Index on the:

- Total Alarm burden.
- Number of appropriate alarms.
- Number of inappropriate alarms.
- Total duration of alert conditions.
- Choice of alarm settings.
- Number and severity of adverse sedation events.

## 2.3 | Design and methods

A hybrid effectiveness-implementation design (Curran et al., 2012) will be used for this study, incorporating a parallel cluster-randomized trial (Hemming et al., 2014). Capnography monitoring will be implemented as standard practice for all patients undergoing procedures with nurse-administered sedation in the four departments participating in the study, as per recommendations for procedural sedation in Canada (Dobson et al., 2018). Nurses working in the four departments will be invited to choose to participate in the randomized controlled trial component of the study. If they choose to participate, they will be randomized to use capnography either with or without the integrated pulmonary index (IPI) enabled. This type of implementation design, where health care providers 'opt-in' to be randomized to a specific condition has been used successfully before in the discipline of anaesthesia. Boet and colleagues conducted a study to determine the effect of audit and feedback on rates of postoperative hypothermia. In this study, individual anaesthesiologists at one institution were randomized to have their practice audited and receive feedback or not (Boet et al., 2018).

There will be establishment (2 months) and stability (4 months) phases where the implementation of capnography (with or without IPI enabled) into practice commences and is optimized through an audit and feedback process. Data collection for the primary outcome will be undertaken during the evaluation period. This design was chosen for two main reasons. First, it allows for the establishment phase, which will provide the time required for the research team to meaningfully engage with staff at each department and recruit nurses to participate in the randomized controlled trial component of the study. Second, the stability period will involve sustained engagement with clinicians in the department, regardless of assignment, to optimize the implementation of capnography monitoring (with or without the IPI enabled) into practice using a facilitated audit and feedback process (Figure 1).

Procedural and reporting elements will adhere to CONSORT guidelines as well as guidance for the process evaluation of complex interventions from the Medical Research Council (Hemming et al., 2018; Moore et al., 2015). This design was deemed the most suitable for our study considering that there is already evidence in support of using capnography for sedation (Hemming et al., 2015).

TABLE 1 Integrated pulmonary index

IPI	Patient status
10	Normal
8–9	In normal range
7	Close to normal range; requires attention
5–6	Requires attention and may require intervention
3–4	Requires intervention
1–2	Requires immediate intervention

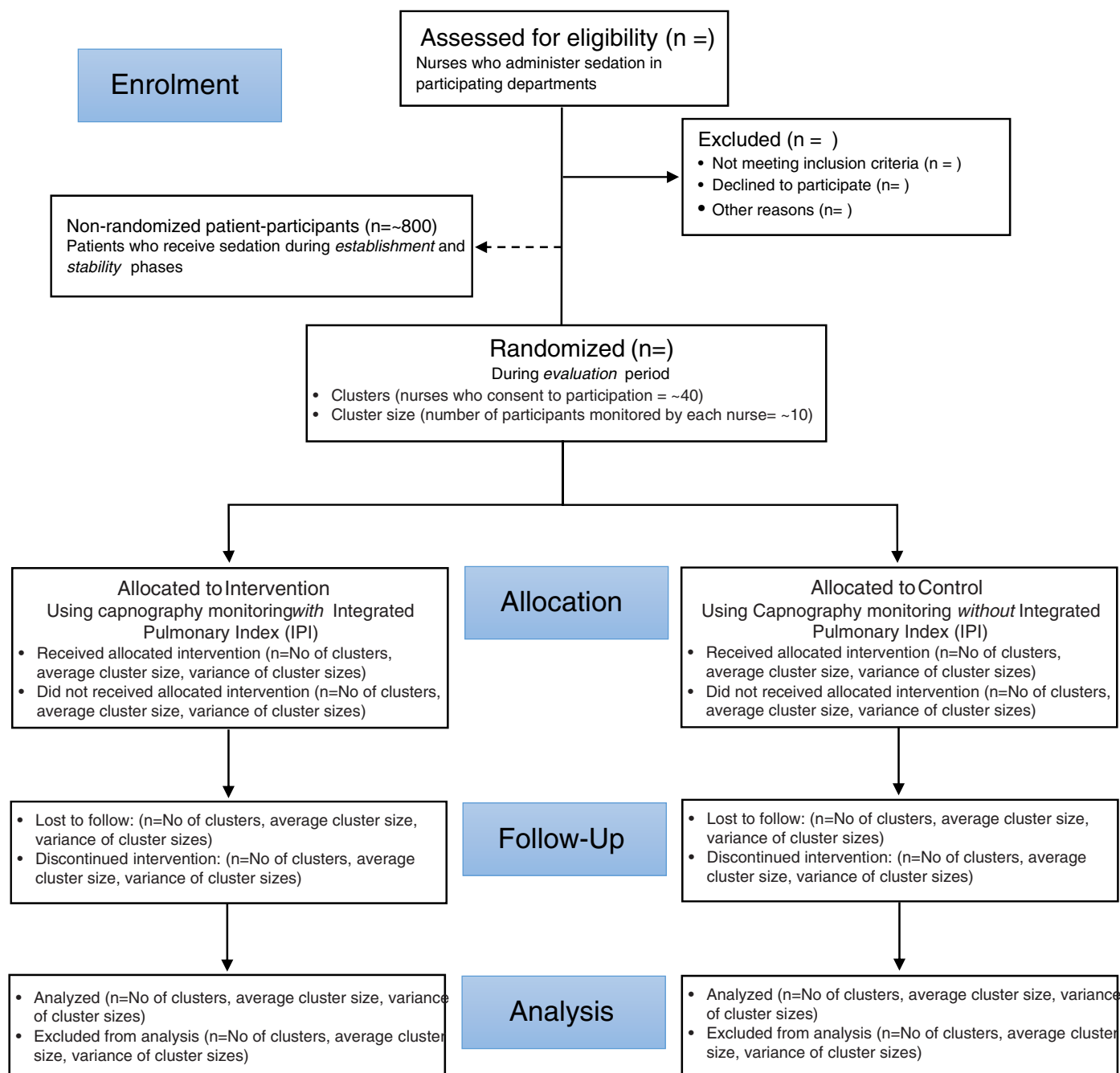


FIGURE 1 CONSORT diagram

## 2.4 | Trial registration

This study is registered as a primary clinical trial at [ClinicalTrials.gov](https://clinicaltrials.gov) (ID: NCT05068700).

## 2.5 | Setting and participants

Participants will be enrolled from four cardiac catheterization and interventional radiology departments at a network of academic hospitals in a large metropolitan region in North America. Each of these sites has been selected on the basis that procedures are performed with nurse-administered sedation.

### 2.5.1 | Inclusion criteria

#### 2.5.2 | Nurses

All nurses who administer and monitor sedation in the departments will be eligible to participate.

#### 2.5.3 | Patients

Due to the hybrid effectiveness-implementation design to be used, all adult patients who are scheduled to undergo elective procedures with sedation administered by the nursing staff will be eligible for inclusion in the study.

## 2.5.4 | Exclusion criteria

### *Patients*

Patients will be excluded from the study if a preference against the presence of a research assistant observer during their procedure is expressed.

## 2.6 | Sample size and randomization

### 2.6.1 | Sample size calculation

We estimate that approximately 1200 patients in total will be included through the whole study. This comprises approximately 800 patients included in the 'establishment' and 'stability' phases as a component of the audit and feedback process and approximately 400 patients included during the evaluation period for assessment of the primary outcome. This target of 400 patient-participants in the evaluation period is a function of the number of nurses who comprise the clusters (i.e. the unit of randomization---estimated to be 40) and the cluster size (i.e. the number of participants monitored by each randomized nurse included in the study---estimated to be 10). Cluster-randomized trial sample size calculation software was used to determine the sample size required for the primary outcome (Hemming et al., 2020). Assuming a type I error rate of 5%, an intra-cluster correlation (ICC) of 0.02 and accounting for 40 nurse participants being randomized to use capnography with or without IPI enabled, a cluster size of approximately 10 patient-participants would achieve >80% power to detect a standardized effect size of 0.3 (equating to a total sample size of 400) for the primary outcome. The cluster size is the number of procedures that are observed by the RA during the evaluation period. The sample size calculation takes the duration of the study into account. If fewer nurses are randomized, the cluster size needs to increase to achieve 80% power. A cluster size of 20 procedures would be required if 20 nurses choose to participate.

### *Randomization*

Nurses who choose to participate in the randomized controlled trial component of the study will be allocated randomly to intervention (IPI enabled) and control (IPI disabled) groups. A stratified (by department) randomized sequence will be generated using the redcapAPI package in R and uploaded to REDCap™. The RA will retrieve the allocation for each consecutive nurse who chooses to participate from REDCap™ during the establishment phase. Randomization will occur during the 'establishment' period of the study.

## 2.7 | Intervention

### 2.7.1 | Sedation management and monitoring

#### *Medication*

There will be no restrictions on sedation dosing for this study. It is typical for a bolus dose of 25–50 µg of fentanyl followed by 1–2 mg

of midazolam to be administered approximately 2–5 min prior to procedure commencement. Further doses of 1 mg midazolam and 25 µg fentanyl are usually administered at the discretion of the proceduralist to maintain sedation.

#### *Supplemental oxygen*

Supplemental oxygen is routinely applied for patients unless contraindicated by preexisting conditions, such as severe chronic obstructive pulmonary disease. The oxygen flow rate will be adjusted as per direction from the proceduralist.

#### *Physiological monitoring*

As part of usual practice in these departments, all patients receive all aspects of standard physiological monitoring including electrocardiography for heart rate and rhythm, noninvasive blood pressure measurements taken at regular 5–10 min intervals (or more frequently if deemed required by nursing or medical staff) and continuous pulse oximetry. Assessments of respiratory rate and depth, as well as level of consciousness, are taken at regular intervals.

Additionally in this study, the standalone Capnostream 35p monitor (Medtronic) will be used. It displays a capnography waveform as well as end-tidal CO<sub>2</sub> and respiratory rate. A nasal cannula or facemask that allows oral and nasal sampling of exhaled air as well as the delivery of supplemental oxygen will be used (Medtronic). The nasal cannula or facemask will be connected to the capnography monitoring device (Capnostream 35P, Medtronic). Nurses who choose to participate in the randomized controlled trial component of this hybrid effectiveness-implementation study, will be randomized to use capnography with or without the Integrated Pulmonary Index enabled. The IPI is a feature, which can be enabled in the Capnostream 35p devices. Nurses who are *not* participating in the randomized controlled trial component of the study will use capnography with or without the IPI feature enabled, at their own discretion. The Capnostream 35p monitor also collects SpO<sub>2</sub> and heart rate measurements via pulse oximetry using a finger probe.

### 2.7.2 | Establishment period

The establishment and stability periods will be guided by recommendations for improving the quality of clinical alarms from The Society for Critical Care Medicine Alarm and Alert Fatigue Task Force (Winters et al., 2018). During the establishment period specifically, each department will be provided with two Capnostream 35p monitors so that capnography monitoring can become part of routine practice for nurse-administered sedation. At this time, the research team will assist with providing education to nursing staff for capnography monitoring and the Integrated Pulmonary Index. The principal investigator will provide an overview of the Capnostream 35p device and how to use it, including the functionality of the Integrated Pulmonary Index. All nursing staff will be provided with printed information about how to access a standardized education program designed by Medtronic, which is certified for accreditation with the American Nurses Credentialing Centre and American Association

for Respiratory Care (<https://www.medtronic.com/covidien/en-us/clinical-education/catalog/healthstream-capnography-standard-of-care-for-procedural-sedation-monitoring.html>). Specifically, in this course nurses will have access to education material covering topics including how to detect common capnographic waveform abnormalities, which indicate sedation-induced alveolar hypoventilation, and implement an appropriate intervention if indicated according to the alert conditions.

### 2.7.3 | Stability period

The goal of the stability period is to optimize the alarm conditions set for the Capnostream 35p devices prior to the evaluation period. This will involve an audit and feedback process for nurses choosing to participate in the randomized controlled trial component of the study. The audit and feedback process will evaluate the performance characteristics of the alerts triggered by the Capnostream 35p monitor (with or without IPI enabled depending on randomization). Alert performance characteristics to be audited include:

- Alarm burden (total number of alarms triggered by the Capnostream 35p).
- Number of appropriate alarms (defined as an alarm that triggered an intervention).
- Number of inappropriate alarms (defined as alarms that were triggered but manually dismissed by silencing the alarm).
- Duration of alert conditions (defined as the total time that an alert condition was active).

A Research Assistant will be present during procedures to observe and record the type of interventions implemented in response to capnography monitor alarms, as well as the time that the intervention was observed.

The feedback of data collected during the audits for nurses who choose to participate in the randomized controlled trial will take an aggregated summary form per department. It will further delineate alarm performance characteristics depending on whether or not the IPI was enabled. The feedback will be presented on a webpage created for each department so that it can be updated approximately weekly as new audits are performed. The link to the webpage will be provided to nurses at the time of randomization. Access to the webpage will be restricted to users through an email address with an organizational domain. The webpage will contain tabulated and other visual summaries of the audit data to highlight alarm performance characteristics, such as the number and duration of appropriate and inappropriate alarms, total alarms. In addition to the webpage, the Principal Investigator and/or Research Assistant will present summary findings from the audits at departmental meetings at least once per month to facilitate discussion amongst staff as to the appropriateness of current alarm settings and if changes are indicated.

This is an implementation study, employing an audit and feedback process to assist departmental staff to optimize capnography

alarm settings (with or without the IPI enabled). The alarm conditions set for the Capnostream 35p monitor can be revised at any time throughout the study period at the discretion of the nurses based on insights from this audit of performance characteristics.

### 2.7.4 | Evaluation period

Alarm performance for the Capnostream 35p monitor, now optimized for each capnography monitoring condition (with or without the IPI enabled) through the establishment and stability periods, will be compared between nurses randomized to use capnography alone or with the Integrated Pulmonary Index enabled.

### 2.7.5 | Procedures

#### *Participant selection and enrolment*

Due to the hybrid effectiveness-implementation design to be used, all patients undergoing procedures in the departments included in this study will receive capnography monitoring. We anticipate that approximately 1200 patients will undergo procedures with capnography monitoring across the departments during the study overall. The target sample size for the evaluation period is 400 patient-participants.

In the 'evaluation' period specifically, a Research Assistant will observe procedures being performed with nurses who have chosen to participate in the randomized controlled trial component of the study until the target sample size is reached. The Research Assistant will be blinded to allocation status, as this is essential for studies that use clustered randomized trial designs to reduce the risk of selection bias.

### 2.8 | Data collection

This study involves routinely collected clinical data and direct observation of nursing responses to capnography monitor alarms. During all phases ('establishment,' 'stability' and 'evaluation'), we will retrospectively retrieve data recorded on the Capnostream 35p monitors using the USB port. Specifically, the 'Real-time Full Continuous Transfer' report will be downloaded. This report contains the real-time CO<sub>2</sub> waveform plus real-time values of parameters (EtCO<sub>2</sub>, SpO<sub>2</sub>, pulse rate, respiratory rate and IPI) with 1-s resolution by repeating numerical values for every 50ms along with the waveform. Other fields include the patient type (adult), report generation date and time, alarm occurrences, equipment advisory messages (eg. waveform not available, battery low, etc) and events entered into the monitor by a clinician (medication administrations etc).

During the 'stability' and 'evaluation' periods, a Research Assistant will be present during procedures to observe and record the type of interventions used, as well as the time that it was



observed. The Research Assistant will provide the nurse participant with a brief script to notify the patient about the identity and reason for their presence during the procedure. The Research Assistant will exit the procedure room if the patient expresses a preference against the presence of an observer. A data collection tool has been designed for this purpose, which will be accessed using an iPad. The times will be synced with the capnography monitoring device (Capnostream 35p). The research assistant will press an 'event' button on the Capnostream 35p at the same time as pressing a button on the data collection tool. This will provide a timestamp of the event on both devices. Data will be downloaded from the data collection tool to a comma separated value (CSV) formatted file at the end of procedures and uploaded to the research team's secure storage. Data in the CSV files will include only the participant's research ID number, the type of intervention that was performed and the time that the intervention was observed, as well as the timestamp to synchronize times from the Capnostream 35p. No personal health information will be stored on the CSV files.

During the 'stability' and 'evaluation' periods, standard demographic and clinical characteristics will be collected by a Research Assistant. Procedural characteristics (type and duration) and sedation characteristics (medication type and dosages) will be collected for the purposes of the audit and feedback process in the 'stability' periods and for the purposes of describing the participant characteristics in the evaluation period. The Research Assistant will complete the tracking and reporting outcomes of procedural sedation (TROOPS) tool at the end of the procedures (Roback et al., 2018). This data will be entered electronically at point-of-care into a REDCap database. No identifiable information will be collected or included in REDCap.

## 2.9 | Outcomes

The selection of outcomes was informed by recommendations from The Society for Critical Care Medicine Alarm and Alert Fatigue Task Force (Winters et al., 2018). The outcomes have been selected to assess differences between groups about the standardized alert fatigue metrics suggested by this task force. Outcomes are measured from the time between first sedative medication administration to the end of the procedure.

### 2.9.1 | Primary

Number of seconds in an alert condition state without an intervention being applied.

Higher values of the primary outcome will result from either a problem state that should have triggered an intervention but did not or an 'inappropriate' alert (i.e. an alert that was not important enough to warrant immediate intervention).

### 2.9.2 | Secondary

- Alarm burden (total number of Medtronic Capnostream 35p monitor alarms).
- Number of appropriate alarms (defined as an alarm that triggered an intervention).
- Number of inappropriate alarms (defined as alarms that were triggered but manually dismissed by silencing the alarm).
- Total duration of alert conditions (defined as the total time that an alert condition was active inclusive of the time to an intervention and the time until the alert conditions are resolved).
- TROOPS adverse sedation events.

The tracking and reporting outcomes of procedural sedation (TROOPS) tool was developed using a consensus process by a society for procedural sedation (Roback et al., 2018). The tool can be used to track adverse events related to sedation performed in any location by multidisciplinary sedation providers. The standardized nomenclature for sedation-related adverse events that is provided by this specific tool is noted as having the potential to facilitate the identification of sedation practices with the safest outcomes and allowing comparison of sedation research and subsequent systematic reviews and meta-analyses. Utilization of this tool for a safety outcome of this study is, therefore, most appropriate. Completion of the tool involves identification and description of the adverse event, the intervention, the outcome and classification of the overall severity of the adverse event (Roback et al., 2018).

- Area under the curve of oxygen desaturation

This composite measure comprises the incidence, depth and duration of an oxygen desaturation event. The area under the curve of oxygen desaturation can be calculated by taking the difference between a threshold (we will use SpO<sub>2</sub> 90% as the threshold) and actual oxygen saturation (SpO<sub>2</sub>) summed every second during which oxygen saturation was below the nominated threshold).

### 2.10 | Statistical analysis

As several patients will not experience any alert conditions, we expect the primary outcome to exhibit a bimodal, skewed distribution with a spike at zero. It has been recommended that it is more relevant for clinical outcomes with this characteristic, to model the median (or another appropriate percentile) that is closer to the major distribution mode (Myles et al., 2017).

The analysis will be performed on an intention-to-treat basis. Participants included in the intention-to-treat analysis will be those who were selected to be observed by the RA in the evaluation phase and then underwent a procedure *with* sedation. Patients who do not receive sedation during their procedure for any reason will not be included (i.e. those who receive opioid analgesia without a concomitant

sedative agent will not be included). For the primary outcome, the total number of seconds from initiation of an alarm to implementation of intervention will be compared between the capnography and Integrated Pulmonary Index groups using a linear-mixed model, adjusted for clustering, with the nurse and site included as random intercepts and time as a fixed effect for each of the two steps, as is the recommended practice for a stepped wedge design (the staggered C-RCT can be considered a special type of stepped wedge design; Hemming et al., 2015). Secondary outcome measures of continuous data will be analysed in a similar fashion and binary outcome variables will be analysed with binary logistic regression.

### 2.10.1 | Process evaluation

A descriptive analysis of alarm performance during the 'establishment' and 'stability' phases will also be undertaken to evaluate how changes in alarm settings arising from the implementation process impacted alarm burden over time. We will calculate the alarm burden in terms of total number of alarms triggered and alarm duration for sites with and without the IPI enabled in each phase.

### 2.11 | Ethical considerations

The hospital Research Ethics Board (REB) approved the trial (REB 21-5249). This study involves only routinely collected clinical data and direct observation of nursing responses to capnography monitor alarms. As such, consent from patients will not be sought. The Tri-Council Policy Statement requires a study to fulfil conditions for waiver of consent, including that the alteration to consent requirement is necessary to address the research question. The integration of capnography monitoring with or without the IPI enabled is planned to be optimized in this implementation study through an audit and feedback process. As such, it will be impossible for individual patients to provide consent for participation in this study prior to the initiation of implementation and optimization of capnography into nurses routine care of sedated patients. A data monitoring committee will not be used for this study because capnography is a recommended monitoring strategy and devices used in the study have regulatory approval for their use during procedural sedation. Dissemination plans include publication in an academic journal and presentation to healthcare professionals at nursing and multidisciplinary conferences related to procedural sedation or anaesthesia. At the time of publication, the data and code required to reproduce results from the statistical analyses will be made available from a publicly accessible repository.

## 3 | DISCUSSION

Analyses of closed malpractice claims reported that severe adverse events caused by respiratory depression during procedural sedation were catastrophic (e.g. hypoxic brain injuries causing permanent

disability or death) and preventable with better monitoring of ventilation (Robbertze et al., 2006). The main outcome of this study will be the identification of an evidence-based strategy for how to implement better practice ventilation monitoring for nurse-administered sedation. With advances in medical technology continuing to expand the indications for minimally invasive surgical techniques, the use of nurse-administered sedation during medical procedures is likely to expand in the future. Results could be translated to the numerous other populations that receive nurse-administered sedation during medical procedures, such as people undergoing diagnostic and interventional gastrointestinal endoscopy, bronchoscopy and radiology procedures. Insights into the sustainability and possibilities for scaling up the use of smart alarm-guided treatment of respiratory depression during procedural sedation to be gained from our study will assist this translation. A further outcome of this research is the production of cost-savings for health services resulting from the implementation of capnography. A cost-effectiveness analysis of capnography for sedation during gastrointestinal endoscopy identified that adoption of this technology was associated with a 68% chance of producing cost-savings due to a reduction in the significant costs associated with treating severe adverse events (Saunders et al., 2016).

### 3.1 | Limitation

Due to the pragmatic implementation design and given the need for clinicians to use information derived from capnography measurements, blinding personnel to allocation assignment is not feasible. Although moderate sedation is targeted as per hospital policy for nurse-administered sedation in the departments at which the study will be undertaken, actual sedation depth will not be objectively measured, primarily because a sufficiently accurate instrument does not exist for this context (Conway & Sutherland, 2016). Instead, total doses of sedation used will be measured as an alternative to determining the generalizability of results to other settings where similar types and doses of sedative and analgesic medications are used for nurse-administered sedation.

### 3.2 | Conclusion

The Integrated Pulmonary Index is intended to reduce the cognitive burden of synthesizing multiple sources of physiological monitoring input and hence lowering the threshold for triggering intervention by clinicians to support respiration. This study will determine if using the Integrated Pulmonary Index during nurse-administered sedation achieves this desired effect of lowering the threshold for triggering intervention by directly measuring the time taken for nurses to respond to capnography monitor alarms.

### CONFLICT OF INTEREST

The authors have no conflict of interest to declare. The funder of this study has no role in study design, data collection, analysis,




interpretation of data, writing the reports and decision to submit the report for publication.

## PEER REVIEW

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