# Hamilton Acute Pain Service Safety Study

## *Using Root Cause Analysis to Reduce the Incidence of Adverse Events*

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## ABSTRACT

**Background:** Although intravenous patient-controlled analgesia opioids and epidural analgesia offer improved analgesia for postoperative patients treated on an acute pain service, these modalities also expose patients to some risk of serious morbidity and even mortality. Root cause analysis, a process for identifying the causal factor(s) that underlie an adverse event, has the potential to identify and address system issues and thereby decrease the chance of recurrence of these complications.

**Methods:** This study was designed to compare the incidence of adverse events on an acute pain service in three hospitals, before and after the introduction of a formal root cause analysis process. The "before" cohort included all patients with pain from February 2002 to July 2007. The "after" cohort included all patients with pain from January 2009 to December 2009.

**Results:** A total of 35,384 patients were tracked over the 7 yr of this study. The after cohort showed significant reductions in the overall event rate (1.47 *vs.* 2.35% or 1 in 68 *vs.* 1 in 42, the rate of respiratory depression (0.41 *vs.* 0.71%), the rate of severe hypotension (0.78 *vs.* 1.34%), and the rate of patient-controlled analgesia pump programming errors (0.0 *vs.* 0.08%). Associated with these results, the incidence of severe pain increased from 6.5 to 10.5%. To achieve these results, 26 unique recommendations were made of which 23 being completed, 1 in progress, and 2 not completed.

**Conclusions:** Formal root cause analysis was associated with an improvement in the safety of patients on a pain service. The process was effective in giving credibility to recommendations, but addressing all the action plans proved difficult with available resources. **(Anesthesiology 2014; 120:97-109)**

During the 1980s, the introduction of patient-controlled analgesia (PCA) and epidural analgesia combined with the desire to manage postoperative pain more effectively lead to the introduction of acute pain services (APSs).[1] These services are organized in a number of ways, but the common theme is to have a clinical team (that includes anesthesiologists and acute pain nurses) that round on patients with acute pain and manages their analgesia requirements, which includes writing and modifying the medication orders, and side-effect management. In most countries, PCA and epidural analgesia have become the foundation of postoperative analgesia.[2]

Although effective at improving pain control, safety concerns have been raised regarding the analgesia modalities used on APSs. The opioids used in both PCA and epidural analgesia are sedating, with potential for progression to respiratory depression, respiratory and cardiac arrest, and even death. Severe hypotension is another complication of both PCA and epidural analgesia. Beyond the opioid side

### What We Already Know about This Topic

- Acute postoperative pain treatment, including intravenous and epidural opioids, can result in severe morbidity

### What This Article Tells Us That Is New

- Comparing data from more than 35,000 postoperative patients before and after a root cause analysis–led intervention showed a reduction by 1/3 in major adverse events, accompanied by an increase by 1/3 in the incidence of severe pain

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**Table 1.** APS Adverse Events That Were Tracked and Their Definitions

| Adverse Event | Definition |
|---|---|
| Cardiac arrest | Sudden loss of cardiac function in the patient presenting without a pulse |
| Death | Patient unable to be resuscitated at the time of presentation |
| Epidural abscess | Abscess formation in the epidural space of the spine |
| Epidural hematoma | Bleeding into the epidural space of the spine |
| Inappropriate anticoagulation | Patient with indwelling epidural systemically anticoagulated without contacting the APS |
| Medication error | An error involving the wrong drug, dose, frequency, or route of administration |
| Pain pump (PCA or epidural) malfunction | The pump did not deliver the medication as programmed |
| Pain pump (PCA or epidural) programming error | Problem with the pump setup or programming was different from the physician's order |
| Prolonged or high motor block | Patient unable to move their feet or knees secondary to an excessive epidural block |
| Respiratory depression | RR <10 or patient required naloxone for resuscitation |
| Severe hypotension | Systolic blood pressure ≤80 mmHg |
| Uncontrolled severe pain | Pain score ≥6 on two consecutive assessments |

APS = acute pain service; PCA = patient-controlled analgesia; RR = respiratory rate.

effects, epidural analgesia can also result in prolonged or progressive motor block and rarely spinal hematoma or spinal abscess. The incidence of these complications has been reported to be relatively low, approximately 1% or less and varies depending on the precise definition used and the analgesia modality.[3–6]

The three APSs (McMaster University Medical Centre, Henderson General, and Hamilton General, Hamilton, Ontario, Canada) at Hamilton Health Sciences (HHS) began an acute pain database project for the purpose of clinical documentation, quality assurance, and research in February 2002.* Until 2006, adverse events (AEs) were discussed informally during the monthly HHS APS meetings in an effort to address safety issues. In this forum, it was seen that many of the safety issues and potential solutions raised were not further investigated or followed-up. Consequently, the AEs persisted, and similar issues were raised from meeting to meeting.

The root cause analysis (RCA) approach, advocated by the U.S. Veteran Affairs National Center for Patient Safety (Ann Arbor, Michigan), is a process to deal with AEs from a systems level.†[7] This process is not an accountability or blaming system but rather a learning system with the focus on determining: (1) what happened, (2) why it happened, and (3) what is necessary to prevent similar incidents from happening in the future. The Canadian Patient Safety Institute (Ottawa, Ontario, Canada) was established in 2003 with the goal of collaborating with health professionals and organizations to build a safer healthcare system. The Canadian Patient Safety Institute developed a framework for RCA which was adapted from the National Center for Patient Safety approach.‡

Although the RCA process seemed a promising and a logical solution to our persistent problem with AEs on the APS, there was insufficient evidence to demonstrate that it would be effective. The Hamilton Acute Pain Safety Study was a prospective before–after cohort study that evaluated the effectiveness of formal RCA on the incidence of AEs amongst patients on an APS.

## Materials and Methods

### Design

After research ethics approval (by the HHS Research Ethics Board, Hamilton, Ontario, Canada), this study was conducted at three tertiary care hospitals in Hamilton, Ontario, Canada. The study sites included: McMaster University Medical Centre, Hamilton General Hospital, and the Henderson General Hospital. The study was designed as a prospective cohort study that compared the incidence of AEs (table 1) before and after the introduction of a formal RCA process.

### Patient Population

The "before" cohort included all patients enrolled into the APS from February 2002 to July 2007 (before the introduction of a formal RCA process), the "study cohort" included all patients enrolled into the APS from August 2007 to December 2008 (during the active formal RCA process), and the "after" cohort included all patients enrolled from January 2009 to December 2009 (after the RCAs were complete and the recommendations were sent out). The before cohort of patients may have low estimates of AEs as this is a group of historical controls where data were collected before the implementation of the RCA intervention.

* Canadian Pain Society. Acute Pain Database Project at McMaster University in Hamilton. Available at: http://www.canadianpainsociety.ca/pdf/news-fall-2004.pdf. Accessed December 9, 2010.

† Canadian Patient Safety Institute. A systems approach, Safer Healthcare Now. Available at: http://www.saferhealthcarenow.ca/EN/events/PreviousEvents/Documents/National%20Learning%20Series%201%20(2005)/Patient%20Safety%20A%20Systems%20Approach.pdf. Accessed December 9, 2010.

‡ Canadian Patient Safety Institute. Canadian RCA framework. Available at: http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF. Accessed December 9, 2010.

**Table 2.** RCA Process

| Step | Description |
|---|---|
| ***WHAT* happened?** | |
| Identification of adverse events | The APS nurses identified events while on daily rounds. |
| Adverse events tagged for RCA | The most severe events that were more likely to recur were considered for RCA by the study PI and research coordinator. |
| Gather information | The research coordinator investigated the AEs flagged for RCA. This included a detailed chart review and discussions with the nursing staff, ward manager, patient, and their family. |
| Initial understanding | Once the initial investigation was completed, a timeline table (date/time, item, information source) was created with the key sequence of events. |
| RCA team | The team was multidisciplinary and included: study PI and APS Director (Dr. Paul), surgeon, research coordinator, pharmacist, nurse educator, APS nurses, hospital administrator (Director or VP), risk management consultant, ward manager, and nurse (from the unit where the event occurred). |
| RCA meeting | The RCA team met in a single meeting that lasted 2 to 3 h. |
| Additional information | The timeline was reviewed and was modified to include any additional information that was identified at the meeting. |
| Timeline and final understanding | The timeline was finalized once all the information was gathered. |
| ***WHY* did it happen?** | |
| Determination of contributing factors and root causes | The triage and triggering questions from the CPSI RCA framework were used to ensure the team considered all the relevant contributing factors. Causal factors were recorded by having team members place sticky notes on a Fishbone diagram that included the following categories: communication, training, fatigue/scheduling, policies/procedures, and barriers. |
| Formulation of causal statements | A cause–effect diagram was then constructed where the initial event was traced down to its root causes. After the meeting, the study team reviewed the results and formulated formal causal statements. |
| **How do we *PREVENT* it from happening again?** | |
| Development of action plans | The final part of the meeting was spent brainstorming for potential solutions to the issues raised. Action plans were developed after a literature review. Every effort was made to make the plans strong and evidence based whereby the recommendations would eliminate or at least control similar future events. |
| Plan implementation | The RCA details with the event description, timeline, cause–effect diagram, and recommendations were entered into an online reporting system. This system was used to generate and distribute a summary report to the team members. For each recommendation, a single person (a follow-up designate) was identified to consider the proposed recommendation and follow up with a resolution: completed, under consideration, or not to be completed. Reminder emails were sent every 2 weeks until a resolution was recorded. |
| Measurement of outcomes | To evaluate the effectiveness of each recommendation, the incidence rate for all events was measured both before and after the implementation of the RCA process. |

AE = adverse event; APS = acute pain service; CPSI = Canadian Patient Safety Institute; PI = principal investigator; RCA = root cause analysis; VP = vice president.

## Intervention

At the request of the investigative team, the Chief Executive Officer of HHS circulated a memorandum throughout the hospital administration describing the study and requesting the staff to do their best to respond to recommendations arising from the study. The study team (and 40 other hospital staff) underwent a full-day workshop on the RCA process which was run by the Canadian Patient Safety Institute. In addition, a member of the study team (Dr. Musson) with a background in medicine and social psychology (with specific experience in human factors and team performance analysis) attended the first three RCAs to guide the team in focusing on the system as opposed to just on the medicine and physiology when attributing root causes to AEs.

During the study period, 112 events occurred and 10 of them, which were considered severe and likely to recur, were flagged for RCA. The study team followed the Canadian Patient Safety Institute RCA Framework to identify root causes for these events and to develop action plans to prevent them from recurring, table 2. An online AE reporting system was developed to record the results of these investigations and to manage the follow-up of the resulting recommendations.

## Outcomes

The primary outcome for the study is the difference in AE rates before and after the implementation of a formal RCA process. Secondary outcomes included the root causes

identified for each AE type, the number of recommendations generated, and the number of recommendations completed.

### Statistical Analysis

The pre- and post-RCA AE rates (clinical outcome) were categorized by analgesia modality (PCA or epidural) and described by count (percent). The recommendation status designations were also summarized by count (percent). We compared pre- and post-RCA rates using a Mantel–Haenszel chi-square test, and Fisher exact test was used when counts were less than five. Severe pain events were not included in the pre-post analysis as this was a measure of quality rather than safety, and the high number of these events would have dominated the results overall. The level of significance was set at $\alpha = 0{\cdot}05$. We used the Bonferroni method to adjust the overall level of significance for multiple comparisons. Specifically, we divided the $\alpha$ by the number of comparisons presented on each table. These analyses were performed using STATA 10·1 (College Station, TX).

## Results

### Overall Number of Patients and AEs

During the entire study period, from February 2002 to December 2009, a total of 35,384 patients were tracked on

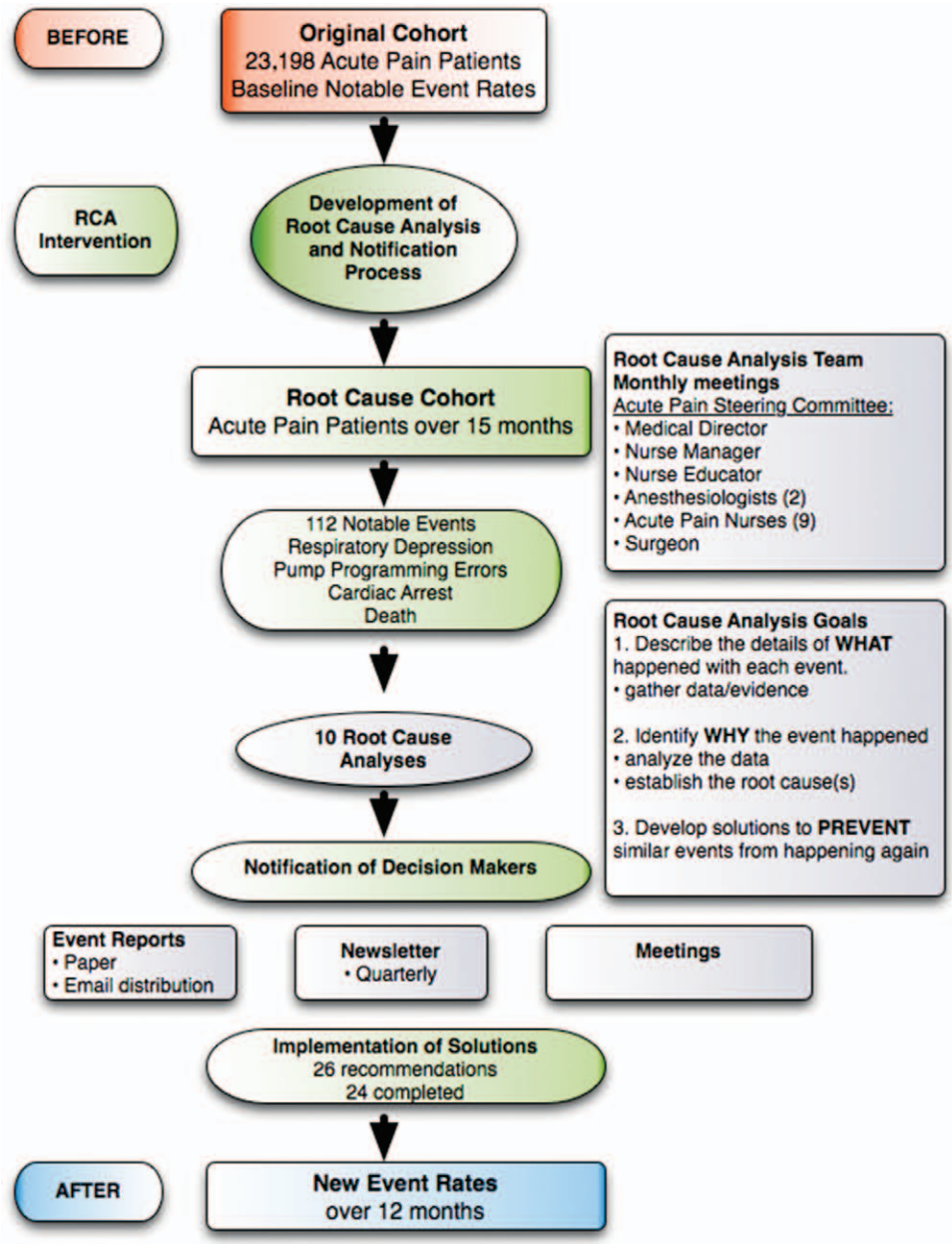


**Fig. 1.** Study flow diagram. RCA = root cause analysis.

the three APSs within HHS. There were 866 AEs of some type or one AE for every 41 APS patients. The flow of patients through the study is illustrated in figure 1, and major milestones for the study are summarized in appendix 1.

### AE Rate before the RCA Intervention

There were 23,198 patients in the before RCA cohort with 658 AEs (or 1 in 35 patients).

### AEs during the Study

Ten of these AE were flagged for formal RCA: one case of cardiac arrest, three cases of severe respiratory depression, one case of severe hypotension, one case of an unresponsive patient, one case of delirium, one case of uncontrolled severe pain, one case of inappropriate anticoagulation, and one case of prolonged or high motor block.

### AE Rate after the RCA Intervention

There were 4,352 patients in the after RCA intervention follow-up cohort with 96 AEs (or 1 in 45 patients). Overall, the combined AE rate in the after RCA intervention group (1.47%) was significantly less than in the before RCA group (2·35%), *P* value less than 0·001.

### RCA Results and Recommendations

A total of 26 unique root causes (appendix 2) were identified from 10 RCAs and a recommendation was formulated for each one. For each RCA, the number of root causes (and associated recommendations) identified varied from 3 to 10; the mean was 7·5 per case. The 26 recommendations were applied a total of 76 times, and each one was used a mean of 2.9 times amongst the 10 RCAs. The most common recommendations included: use visual prompts on PCA and epidural pumps to remind staff of the pain monitoring protocols, purchase more portable monitors to facilitate vital sign monitoring, develop a back-to-basics nursing campaign, streamline nursing documentation on an electronic documentation system, and develop an annual e-learning pain management update for nursing staff. The root cause and recommendation types were policy/procedure (41%), environment/equipment (30%), training (17%), fatigue/scheduling (11%), and barrier (1%). Of the 26 action types for the recommendations, one was "eliminate" and the remaining 25 were to "control." The status of these 26 recommendations at the end of the study was 23 (88.5%) were "completed," one (3·8%) was "to be completed," and two (7·7%) were "not to be completed." The two recommendations not completed included: (1) purchase of a new call bell system in one of the intensive care units to replace a defective unit (not completed because this intensive care unit was closed and moved to a new facility) and (2) develop a formal intensive care unit discharge criteria outlining parameters necessary for discharge (not completed because the intensive care unit staff felt this was not necessary as discharge criteria were well described in the literature).

Although eight different types of AEs were assessed using the RCA process, some common themes emerged. In the 10 AEs that were analyzed, most (80%) had significant gaps in recording of vital signs assessments (table 3). Insufficient knowledge of pain management protocols and analgesia principles was a common finding and was identified as a root cause in 80% of the RCAs. Similarly, inadequate ongoing staff pain education (after the initial staff orientation) was noted in the majority (80%) of the cases. Equipment availability issues were also important, with most (80%) of the RCAs reporting insufficient portable

**Table 3.** Vital Signs Assessment Gaps: Duration of Time (h) between Assessments

| RCA | Modality | Adverse Event | Pain | Sedation | RR | Blood Pressure/HR | Sensory/Motor |
|---|---|---|---|---|---|---|---|
| Frequency of Vital Sign Assessment in the Physician's Orders in Hours (H) | | | Q4H | Q2H | Q2H | Q4H | Q4H |
| 1 | Epidural | Hypotension | 6.25 | 6.25 | 6.00 | 6.00 | None |
| 2 | PCA | Cardiac arrest | 6.50 | 8.50 | 3.50 | None | Not applicable |
| 3 | PCA | Respiratory depression | 13.00 | 13.00 | 9.25 | 5.00 | Not applicable |
| 4 | Epidural | Inappropriate anticoagulation | None | None | None | None | None |
| 5 | PCA | Respiratory depression | 6.00 | 5.00 | None | 8.00 | Not applicable |
| 6 | Epidural | Respiratory depression | 5.00 | 5.00 | None | 5.00 | 6.00 |
| 7 | PCA | Delirium | None | None | None | None | Not applicable |
| 8 | Epidural | Prolonged severe pain | 10.50 | Not assessed | None | None | Not assessed |
| 9 | Epidural | Prolonged motor block | 13.00 | 13.00 | 3.60 | 8.00 | 13.00 |
| 10 | PCA | Unresponsive patient | 6.00 | 13.00 | 4.00 | None | None |
| No. (%) | | | 8 (80) | 8 (80) | 5 (50) | 5 (50) | 2 (25) |
| Mean (h) | | | 8.3 | 9.1 | 5.30 | 6.40 | 9.50 |

If the time between assessments was greater than what was ordered by the physician, then this was counted as a gap in vital signs monitoring.
HR = heart rate; PCA = patient-controlled analgesia; Q2H = every 2 h; Q4H = every 4 h; RCA = root cause analysis; RR = respiratory rate.

monitors on the wards. Nurse staffing issues (staff numbers and patient assignments) were identified in five of the RCAs, but only two showed inadequate staffing at the time of the AEs.

### AEs

The pre- and post-RCA AE rates are summarized in table 4. The most common AE identified was uncontrolled severe pain (7.3%), and this was followed by severe hypotension (1.1%), respiratory depression (0.6%), inappropriate anticoagulation (0.3%), pain pump programming error (0.08%), prolonged motor block (0.05%), epidural abscess (0.04%), severe sedation/unresponsive (0.03%), epidural hematoma (0.02%), cardiac arrest (0.02%), delirium (0.01%), and death (0.01%).

The rates of severe uncontrolled pain, respiratory depression, and pain pump programming errors were significantly greater for PCA opioid patients when a continuous infusion was used in comparison with patients treated with PCA boluses alone ($P < 0.001$, <0.001, and <0.001, respectively) or with epidural patients ($P < 0.001$, <0.001, and <0.001, respectively). The rate of respiratory depression was 2.4 times greater for PCA plus infusion patients in comparison with PCA bolus only patients and three times greater in comparison with epidural patients.

The rate of severe hypotension was significantly greater for epidural patients in comparison with PCA opioid bolus only patients ($P < 0.001$) or PCA plus infusion patients ($P < 0.001$). Specifically, the hypotension rate for epidural patients was six times greater than the rate for PCA bolus patients and four times greater than the rate for PCA plus infusion patients.

## Discussion

This 7-yr acute pain safety study at three tertiary care hospitals resulted in information on 866 AEs amongst 35,384

**Table 4.** Pre- and Post-RCA Adverse Event Rates

| Study Period | Pre-RCA | | | | |
|---|---|---|---|---|---|
| Date Range | February 2002 to July 2007 | | | | |
| Analgesia | PCA Bolus | PCA + Infusion | Epidural | All | |
| All adverse events totals | 201 (1.41%) | 26 (3.39%) | 317 (3.88%) | **544** (2.35%) | |
| Analgesia modality totals | 14,270 | 767 | 8,161 | 23,198 | |
| Targeted with RCA | | | | | |
| Cardiac arrest | 2 (0.01%) | 0 (0.00%) | 2 (0.02%) | **4** (0.02%) | |
| Respiratory depression (RR <10 or naloxone resuscitation required) | 109 (0.76%) | 11 (1.43%) | 45 (0.55%) | **165** (0.71%) | |
| Severe hypotension (SBP <80 mmHg) | 68 (0.48%) | 6 (0.78%) | 236 (2.89%) | **310** (1.34%) | |
| Unresponsive/severe sedation | 3 (0.02%) | 0 (0.00%) | 3 (0.04%) | **6** (0.03%) | |
| Delirium | 1 (0.01%) | 0 (0.00%) | 3 (0.04%) | **4** (0.02%) | RCA Study Period from August 2007 to December 2008 |
| Uncontrolled severe pain (pain score ≥6 and not satisfied) | 826 (5.79%) | 199 (25.95%) | 483 (5.92%) | **1,508** (6.50%) | |
| Inappropriate anticoagulation (systemic anticoagulation with indwelling epidural) | — | — | **17** (0.21%) | 17 | |
| Prolonged or high motor block | — | — | **3** (0.04%) | 3 | |
| Other notable events | | | | | |
| Pain pump programming error | 16 (0.11%) | 9 (1.17%) | 2 (0.02%) | **27** (0.12%) | |
| Epidural abscess | — | — | **4** (0.05%) | 4 | |
| Spinal hematoma | — | — | **2** (0.02%) | 2 | |
| Death | 2 (0.01%) | 0 (0.00%) | 0 (0.00%) | **2** (0.01%) | |

The events that occurred during the RCA study period are included in the overall event totals but not the pre- or post-RCA event numbers. The event percentages are calculated as per their respective analgesia modality and overall (except in the case of epidural-related events). The pre- and post-RCA event numbers were compared using a Mantel–Haenszel chi-square analysis. Notable event totals exclude severe pain events. Bonferroni adjusted $\alpha$ is 0.05/13 = 0.004, where 13 = the number of comparisons. The bold entries highlight the overall results and the *P* values which are statistically significant.

PCA = patient-controlled analgesia; RCA = root cause analysis; RR = respiratory rate; SBP = systolic blood pressure.

patients. Formal RCA (over a period of 15 months) of 10 of these AEs resulted in 26 unique recommendations, of which 24 were either completed or in the process of being completed after 1 yr of follow-up. The resulting impact on patient safety (amongst a cohort of 4,352 APS patients) was that the overall AE rate was reduced from 1 event per 42 APS patients to 1 in 68. RCA was associated with reducing the incidence of respiratory depression and severe hypotension, but not severe pain, cardiac arrest, severe sedation, delirium, inappropriate anticoagulation, epidural abscess or hematoma, or death. The incidence of pump programming errors was also reduced after the RCA intervention, but this AE was not addressed during the study (as one did not occur during the intervention or follow-up period).[8] The most common root causes that were identified during the RCA process were insufficient vital sign monitoring, inadequate pain education updates for ward nurses, and difficulty accessing portable monitors on the wards. With regard to the inadequate vital sign monitoring, 8 of the 10 cases had significant gaps between vital signs assessments, and some of these gaps were as long as 13 h.

The most common events identified were severe pain (1 in 14), severe hypotension (1 in 90), respiratory depression (1 in 170), inappropriate anticoagulation of epidural patients (1 in 360), and pump programming errors (1 in 1,250). It is not exactly clear why the incidence of severe pain went up after the RCA intervention, but it may have been related to the move to reduce the dose of PCA opioids. This increase in severe pain underscores the reality that safety interventions may result in some unintended harm, and that the benefits they may bring could have a cost. Patients treated with PCA opioids plus a continuous infusion of IV opioids had a significantly greater incidence of severe uncontrolled pain (4 times), respiratory depression (2.4 times), severe hypotension (1.3 times greater than PCA bolus patients), and pump programming errors (12 times). The increase in severe pain with continuous infusions likely reflects the practice whereby patients having surgeries

| Post-RCA | | | | Pre *vs.* Post | Pre *vs.* Post | Pre *vs.* Post |
|---|---|---|---|---|---|---|
| January 2009 to December 2009 | | | | (Proportion) | chi-square | Fisher |
| PCA Bolus | PCA + Infusion | Epidural | All | *P* Value | | |
| 30 (0.91%)<br>3,298 | 1 (1.41%)<br>71 | 33 (3.36%)<br>983 | **64** (1.47%)<br>4,352 | **<0.001** | <0.001 | <0.001 |
| 0 (0.00%)<br>14 (0.42%) | 0 (0.00%)<br>1 (1.41%) | 2 (0.20%)<br>3 (0.31%) | **2** (0.05%)<br>**18** (0.41%) | 0.239<br>**0.024** | 0.537<br>0.035 | 0.243<br>0.025 |
| 12 (0.36%) | 0 (0.00%) | 22 (2.24%) | **34** (0.78%) | **0.003** | 0.004 | 0.002 |
| 3 (0.09%) | 0 (0.00%) | 0 (0.00%) | **3** (0.07%) | 0.149 | 0.325 | 0.158 |
| 0 (0.00%)<br>332 (10.07%) | 0 (0.00%)<br>19 (26.76%) | 0 (0.00%)<br>90 (9.16%) | **0** (0.00%)<br>**441** (10.13%) | 0.386<br>**<0.001** | 0.857<br><0.001 | >0.999<br><0.001 |
| — | — | **4** (0.41%) | 4 | 0.683 | 0.913 | 0.763 |
| — | — | **1** (0.10%) | 1 | 0.614 | 0.857 | 0.497 |
| 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | **0** (0.00%) | **0.027** | 0.047 | 0.016 |
| —<br>— | —<br>— | **0** (0.00%)<br>**0** (0.00%) | 0<br>0 | 0.386<br>0.540 | 0.857<br>0.721 | >0.999<br>>0.999 |
| 1 (0.03%) | 0 (0.00%) | 1 (0.10%) | **2** (0.05%) | 0.061 | 0.234 | 0.120 |

**Table 5.** Advantages and Disadvantages of the RCA Process

| Advantages |
|---|
| • It is a systematic and comprehensive tool that focuses on identifying problems with the system |
| • The process adds credibility to the issues and recommendations that are generated |
| • The multidisciplinary team-based approach ensures that multiple perspectives are used when attributing root causes and potential solutions |
| • Patients (and their families) experiencing adverse events are reassured by the knowledge that appropriate steps were taken to prevent similar incidents from recurring |
| • For adverse events, clinical staff and hospital administration can claim that they did their best to determine what happened and how to prevent similar cases in the future |
| • Formalizing the process of recommendation management by assigning specific designates (for each recommendation) and email reminders decreases the chance of recommendations getting lost to follow up |
| Disadvantages |
| • The RCA process takes a lot of time and energy to complete |
| • Follow-up designates who were not part of the RCA meetings are less likely to buy into the recommendations |
| • It is difficult to bring all the key stakeholders together for RCA meetings |
| • The results of an RCA are partially dependent on the biases of the participants |
| • The more time that goes by after a critical incident the less impact the results of an RCA have because staff feel things change over time |
| • If RCA is not part of the routine safety process of a hospital, then the hospital administration is less prepared to respond to the resulting recommendations |
| • Some recommendations, although credible, may not be feasible because of insufficient hospital funding |

RCA = root cause analysis.

with known pain management challenges are more likely to be treated with a continuous infusion. Hypotension (not surprisingly) occurred significantly more frequently amongst patients treated with epidurals. The incidences of rare AEs were: death (1 in 8,800), epidural hematoma (1 in 5,400), epidural abscess (1 in 2,700), and cardiac arrest (1 in 5,000).

The strengths of this study are that it included a very large cohort of patients, used a comprehensive and thorough RCA process (based on the U.S. Veteran Affair's National Center for Patient Safety and Canadian Patient Safety Institute RCA frameworks), included participation of hospital leadership, and implemented an online reporting system to ensure that recommendations were not "lost to follow-up." It also included three different hospital sites, representing a wide scope of clinical services and encompassing both pediatric and adult patients.

It is challenging to distinguish the direct impact of the RCA process on AE reduction in this study as opposed to the more general effect of a positive impact on performance (in this case safety) simply because people knew they were being studied (an effect referred to as the Hawthorne effect in studies of workplace behavior).[9] Indeed, the notably lower rate of AEs during the RCA phase of the study may support this conclusion. In our opinion, there is a direct effect of the RCA process: the study team has been under study conditions since 2002 and actively tracking AE. The addition of the RCA process was an extension to an existing monthly quality assurance safety meeting, which we believe supports a direct impact of the RCA process as the main driver of the observed changes. More importantly, the AE rate remains low (1.47%) 3 yr after the last RCA case was completed, suggesting a persistent system and behavior change.

The before–after design of our study did not control for temporal changes to the system apart from the RCA intervention. Hence, it is possible that some of the changes in the event rates could be attributed to factors (*e.g.*, improved education amongst staff, increased focus on safety by hospital administration, better management of patient's comorbidities, and so on) other than the study intervention. Another weakness of our study is that some outcomes may have been underestimated. Our estimate of postoperative delirium was very low (0.01%), much lower than other estimates of postoperative cognitive dysfunction that have been as high as 41% in older patient groups.[10] This difference is likely due to the fact that our APS team was trained and focused on capturing the main analgesia outcomes (pain scores, side effects, and the more common AEs: death, respiratory depression, hypotension, medication errors, pump programming errors, epidural site infection, and motor block) and only picked up clinically obvious cases of acute cognitive dysfunction.

Despite the challenges in organizing and managing the RCA process and its resulting recommendations, the RCA approach offers numerous advantages over the current alternatives (such as discussing AEs in a more informal manner). Most importantly, RCA encourages staff to address system issues and the resulting recommendations are given much more credibility through the endorsement by senior administration, which in turn increases the chances of the

recommendations being implemented. Some of the biggest obstacles in conducting RCAs were getting all the key stakeholders together for the necessary meetings, identifying the most responsible person to follow up with specific recommendations, getting buy-in for recommendations, and getting safety recommendations completed when there were significant costs involved. For example, the study team's recommendation for a wireless respiratory monitoring system involves a capital investment of hundreds of thousands of dollars upfront and tens of thousands of dollars annually to maintain such a system. Based on our experience with this process in the three hospitals under study, we summarize the advantages and disadvantages of the RCA technique in table 5.

Other studies have shown benefits from the RCA process. A 2005 retrospective study involving 100 Veteran Affairs acute and long-term care facilities, which used RCA to examine the incidence of falls and related injuries, demonstrated that 176 RCAs resulted in 745 actions, and 61% of these were completed.[11] Subsequently, 34% of the facilities reported a reduction in falls and 39% reported a reduction in major injuries from falls. A 2008 narrative review article by Percarpio *et al.*[12] assessed the evidence for RCA in published literature. This study found that RCA emerged in the literature in the late 1990s and since then 11 case studies have been published that measure RCA effectiveness, 3 using clinical outcome measures (before/after RCA AE incidence rate comparisons) and 8 using process measures (percent of actions implemented). All 11 studies reported an improvement in safety with the RCA process. Our current APS RCA study is an addition to the small number of studies that have prospectively assessed the effectiveness of the RCA process by measuring both clinical and process outcomes. Given that our study showed safety improvement in three different institutions with different surgical services (general, orthopedic, gynecology, vascular, urology, and plastics) and patient populations (pediatric and adults), it is possible the benefits of the RCA process we observed could be realized in other hospitals.

In conclusion, our study found that after the introduction of a formal RCA process with comprehensive follow-up of the recommendations, there was an improvement in the overall safety of the APS, and specifically a reduction in the incidence of respiratory depression, severe hypotension, and pain pump programming errors. The incidence of serious AE amongst APS patients is low but remains a concern because this can be viewed as an iatrogenic illness that can affect all patients. The next research steps should include a system-level RCA study where participating hospitals are randomized to a formal RCA process or standard care, and the study budget should include funding to assist in implementing the recommendations.

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## Competing Interests

The authors declare no competing interests.

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**Appendix 1.** Study Milestones

| Event | Date | Comment |
|---|---|---|
| • Hamilton Acute Pain Safety Study presented at the fourth Annual Hamilton Health Sciences Symposium | May 31, 2007 | The study methods were presented to clinical staff and hospital administrators. |
| • HSOS launched | July 1, 2007 | HSOS is a web-based adverse event–reporting system with RCA and action plan follow-up tools used for the study. |
| • CPSI RCA framework morning workshop | July 19, 2007 | The study team was introduced to the RCA process and techniques |
| • RCA 1—Severe hypotension | August 9, 2007 | 23 RCA meeting attendees |
| • RCA 2—Cardiac arrest | September 10, 2007 | 19 RCA meeting attendees |
| • CPSI RCA framework full-day workshop | | Hospital staff (administration, risk management, select nurses) and the study team received a detailed instruction on the RCA framework. |
| • RCA 3—Respiratory depression | November 14, 2007 | 20 RCA meeting attendees |
| • RCA 4—Inappropriate anticoagulation | December 19, 2007 | 14 RCA meeting attendees |
| • RCA 5—Respiratory depression | January 22, 2008 | 13 RCA meeting attendees |
| • RCA 6—Respiratory depression | February 26, 2008 | 21 RCA meeting attendees |
| • Interim study results posted in an acute pain newsletter distributed to all hospital staff | March 31, 2008 | A newsletter insert highlighted the goal of lowering PCA morphine dosages in opioid-naive patients. |
| • Vital signs monitoring round table discussion | April 15, 2008 | The Chief of Nursing Practice (from the three study hospitals), the Chair of the Medical Advisory Committee, and the study team met to discuss the problem of insufficient vital sign monitoring of acute pain patients. |
| • RCA 7—Delirium | May 1, 2008 | 13 RCA meeting attendees |
| • RCA study recommendation follow-up strategy meeting | May 8, 2008 | The study team, the Chair of the Medical Advisory Committee, and the Director of Quality and Patient Safety met to assign follow-up designates for all outstanding study recommendations. |
| • Interim results from RCAs 1–7 presented to the Hamilton Health Sciences newly formed Quality of Care Committee | June 6, 2008 | The committee included the Chair of the Medical Advisory Committee and all the Vice Presidents responsible for clinical services. |
| • RCA 8—Prolonged severe pain | June 24, 2008 | 9 RCA meeting attendees |
| • Interim study results presented at the 2008 Ontario Anesthesia Meeting | October 5, 2008 | "Using RCA to Reduce Adverse Events on an Acute Pain Service" |
| • RCA 9—Prolonged motor block | October 23, 2008 | 10 RCA meeting attendees |
| • RCA 10—Unresponsive patient | December 12, 2008 | 18 RCA meeting attendees |
| • Final study recommendations presented to the Hamilton Health Sciences Quality of Care Committee | April 3, 2009 | RCAs 1–10 presented and plans were to made to follow up the recommendations that were pending feedback |
| • Final study recommendations presented to the nursing administration | April 16, 2009 | The Chiefs of Nursing Practice, the Chief Nursing Executive, and the study team met to discuss the implementation of the nursing-related recommendations. A back-to-basics working group is formed. |
| • The Ontario Ministry of Health *via* the Nursing Graduate Guarantee Program funded the back-to-basics Leaders Project | November 11, 2009 | 10 full-time point of care nurses will be funded for a pilot project that will act as "back-to-basics" leaders to address issues with vital signs monitoring and other safety issues. |
| • Final study results to be presented at the fifth Hamilton Health Sciences Patient Safety Symposium | May 18, 2010 | |

CPSI = Canadian Patient Safety Institute; HSOS = Hospital Safety Occurrence System; RCA = root cause analysis.

**Appendix 2.** Root Causes, Action Plans, and Their Status

| No | Root Cause | Recommendation | Action Type | Status | RCAs |
|---|---|---|---|---|---|
| Barriers | | | | | |
| 1 | There is confusion over who is the most responsible physician for management of hypotension | Redesign the epidural orders and make the admitting physician responsible for the management of hypotension | Control | To be completed | 1 |
| Environment/equipment | | | | | |
| 2 | There are no visual prompts to remind staff of the acute pain monitoring protocols | Create laminated cards with the APS vital signs monitoring protocols and attach them to the PCA and epidural pumps | Control | Completed | 1, 2, 3, 5, 6, 8, 9, 10 |
| 3 | There are insufficient portable monitors on the ward | Purchase more portable monitors, so there is one in every surgical ward room | Control | Completed | 1, 2, 3, 5, 6, 8, 9, 10 |
| 4 | The unpredictable and sudden nature of respiratory depression increased the likelihood that there was a significant delays in the recognition and management | Pilot a remote respiratory monitoring system on a selected surgical ward that features pulse oximetry as well as an automated notification feature that will alert all clinical staff to signs of respiratory depression. | Eliminate | To be completed | 2, 3, 5, 6, 10 |
| 5 | There is no alert in the pharmacy order entry system that cautions against ordering contraindicated anticoagulants in epidural patients | Program warning alerts into the pharmacy system | Control | Completed | 4 |
| 6 | The call bell system in this ICU was not fully functional at the time of the event | Purchase a new call bell system for this ICU | Control | Not to be completed (*In an upcoming hospital reorganization this ICU will be closed)* | 7 |
| Fatigue/scheduling | | | | | |
| 7 | Nurse staffing model on surgical ward was not flexible enough to staff up to patient acuity | Ensure clinically appropriate staffing plans are in place on the wards that take APS patients | Control | Completed | 1, 3, 7 |
| 8 | A team-based nursing model (with a mixture of RNs and Registered Practical Nurses) on the ward decreased the accountability for patient care | Support an initiative that reorganizes nursing care into a collaborative model where there is more accountability with direct lines of responsibility | Control | Completed | 5, 6 |
| 9 | There is no acute pain nurse coverage on weekends or holidays, and the anesthesiologist is not available until late in the afternoon for rounds | Train the recovery room nurses in acute pain management and use them for pain rounds on weekends and holidays | Control | Completed | 5 |

(*Continued*)

**Appendix 2.** (*Continued*)

| No | Root Cause | Recommendation | Action Type | Status | RCAs |
|---|---|---|---|---|---|
| 10 | Inequitable nursing patient assignments, whereby complex patients are not allocated optimally, increases that chances that some nurses will not be able to keep up with their workload | Ensure that the existing ward patient acuity measurement tool is used consistently in the clinical setting as a guide to determine appropriate nursing assignments | Control | Completed | 6 |
| 11 | There is no pharmacist role whereby medication regimens are routinely reviewed. | Hire a pharmacist for this surgical ward and ensure that analgesia medications are routinely reviewed | Control | Completed | 7 |
| Policies/procedures | | | | | |
| 12 | There is no formalized ICU discharge criteria | Create a formalized discharge criteria outlining parameters for transferring a patient from the ICU to the ward | Eliminate | Not to be completed ("Discharge criteria well documented in the literature") | 1, 3 |
| 13 | There were insufficient vital sign assessments | Develop a "back-to-basics" nursing campaign that emphasizes the importance of regular vital sign assessments | Control | Completed | 1, 2, 3, 5, 6, 8, 9, 10 |
| 14 | The lack of a unified patient assessment flow sheet that incorporates APS patient monitoring protocols created a barrier to staff completing prescribed APS vital signs and assessments | Create a unified vital signs flowsheet—in the upcoming e-documentation system—that includes pain assessments | Control | Completed | 1, 3, 5, 6, 8, 9, 10 |
| 15 | The "transfer of accountability" process does not incorporate the acute pain orders | Incorporate APS monitoring into the transfer of accountability process | Control | Completed | 1, 3, 5, 6, 8, 9, 10 |
| 16 | There is no hospital policy that clearly stipulates which anticoagulants are contraindicated in patients with epidurals | Develop policy for anticoagulation in patients with epidurals | Control | Completed | 4 |
| 17 | There is no preprinted physician order set for anticoagulating patients with epidurals | Develop a set of preprinted orders for anticoagulation of patients with epidurals | Control | Completed | 4 |
| 18 | Some of the anesthesia staff have less experience with PCA dosing, especially when using alternatives to morphine and for pediatric patients | Implement a system whereby the APS nurses screen all PCA and epidural orders to ensure that the dosing parameters are appropriate | Control | Completed | 7 |
| 19 | The ICU considered a closed unit and does not contact APS with modifications to the analgesia orders | Develop a policy whereby the ICU staff contact the APS for modification of epidural or PCA orders. | Control | Completed | 8 |

(*Continued*)

**Appendix 2.** (*Continued*)

| No | Root Cause | Recommendation | Action Type | Status | RCAs |
|---|---|---|---|---|---|
| 20 | The ICU vital signs flowsheet does not include pain parameters | Modify the current ICU flowsheet to include acute pain assessments | Control | Completed | 8 |
| 21 | There is inconsistent management of patients with sickle cell disease in terms of investigations, pain control, treatment, and monitoring | Develop a care pathway for patients with sickle cell disease and vaso-occlusive crisis | Control | Completed | 10 |
| Training | | | | | |
| 22 | There is no annual acute pain education update for nurses, and clinical staff often has insufficient knowledge of acute pain issues. | Develop an annual acute pain e-learning update for nurses | Control | Completed | 1, 2, 3, 5, 6, 7, 8, 9, 10 |
| 23 | The PCA morphine dose was relatively large | Encourage anesthesia staff to lower PCA opioid dosages | Control | Completed | 2, 3 |
| 24 | PCA by proxy (pressing of button by anyone other than the patient) increased likelihood of narcosis | Place warning tags on all PCA pumps stating: "for patient use only" | Control | Completed | 2 |
| 25 | Inappropriate PCA use increases the risk of opiate overdose | Update the patient education process to include proper use of PCA instruction | Control | Completed | 2 |
| 26 | Anesthesia residents have insufficient experience to troubleshooting epidural problems | Increase the residents exposure to acute pain management by having them do rounds whenever they are assigned to the preoperative clinic | Control | Completed | 9 |

APS = acute pain service; ICU = intensive care unit; PCA = patient-controlled analgesia; RNs = registered nurses.