



Evaluation of the impact of a paediatric procedural sedation credentialing programme on quality of care

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Abstract

- Objectives:** The aim of the present study is to describe changes in documentation, risk assessment and patient care resulting from implementation of a credentialing process for medical and nursing staff in paediatric procedural sedation (PPS) in two EDs – one an urban mixed ED and the other a specialist paediatric ED.
- Methods:** Chart review of 100 patients undergoing PPS prior to and 100 patients following introduction of the PPS programme. Information was extracted from medical records and sedation checklists. Demographics, drugs used, procedure performed and elements of the pre-procedural, intra-procedural and post-procedural care were compared pre- and post implementation of the PPS programme.
- Results:** Significant improvements in the post-implementation period compared with pre-implementation were seen in: frequency of documentation of informed consent (87 vs 15%, $P < 0.0001$); evidence of performance of a pre-procedural risk assessment (87 vs 1%, $P < 0.0001$); and appropriate recording of vital signs (58 vs 27%, $P < 0.0001$). Improvements were also noted in documentation of weight, allergies, fasting status and recording of drug orders. There were no adverse events recorded in the pre-programme period and 6 recorded in the post-programme period.
- Conclusion:** The implementation of a PPS credentialing programme into these two EDs resulted in significant improvements in risk assessment, monitoring and documentation of important information related to safe PPS. These improvements should result in improved quality and safety of PPS.
- Key words:** *evaluation, paediatric, sedation.*

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Introduction

Paediatric procedural sedation (PPS) is commonly used in Australian EDs. Increasing numbers of children are having their fractures manipulated, wounds repaired and foreign bodies removed, in a safe and comfortable fashion within an ED prior to being discharged home.

In 2002 Everitt *et al.*¹ published a survey of 45 EDs in Australia and New Zealand, which demonstrated that 39 of 40 paediatric or mixed adult/paediatric EDs were using sedation. However, the same study showed a wide variation in practice regarding the use of sedation in children. The authors recommended the development of evidence-based clinical guidelines to improve our approach to PPS. Since that time the use of evidence-based guidelines within Australasian EDs has increased substantially and there are a number of guidelines available in the literature upon which to base an individual department's PPS guideline.^{2–10} However, the existence of guidelines is only part of the answer – ED staff need to understand and become proficient in how and when to use guidelines as part of their normal practice. Evidence from studies that examine the effect of consistent practice of guidelines confirms the benefit of this approach.^{11–13} There are very few studies in the procedural sedation literature that investigate outcomes associated with the use of guidelines^{14,15} and none that examine the effects of differing methods of PPS training and credentialing on the quality of PPS. An association between adherence to a structured PPS programme and reduction in complications of sedation has been reported by Hoffman *et al.* in a formal evaluation of the use of a hospital wide structured model to reduce sedation-related adverse events.¹⁵ A number of case series report the use of a quality assurance tool to measure adverse events and adherence to guidelines^{16,17} and another measures the beneficial effect of introducing a preprinted audit form for completion by staff performing PPS.¹⁸

In 1995 the Quality in Australian Health Care Study reported that 51% of adverse events were considered preventable and this finding led to a number of strategies to make our processes of care and environments safer by lessening the potential for individual and system errors. There is an increasing recognition of how the ED environment contributes to the potential for adverse events and the gradual development of strategies to reduce this risk.^{19,20} Among a large number of proposed strategies, major recommendations focus upon the development and facilitation of teamwork,²¹ efforts to instil a departmental culture of safety, system-based

modifications such as the introduction of weight or length-based dosing tools,^{22,23} in combination with effective strategies in staff training and education.^{24,25}

In this issue of the journal, Babl *et al.* describe the development and implementation of a risk reduction strategy for ED PPS.²⁶ This comprised of a modular training and assessment programme aimed at improving proficiency in the use of PPS. The programme was administered to over 250 staff of two EDs. The aim was to ensure that all PPS performed within those departments would be provided by credentialed medical and nursing staff following guidelines relating to important aspects of pre-procedural, procedural and post-procedural care.

In the present study we evaluate the impact of this PPS training and credentialing programme on the quality and safety of PPS in two EDs.

Methods

We performed a chart review of 100 patients prior to and 100 patients following the implementation of the PPS programme at the ED of Sunshine Hospital and Royal Children's Hospital, Melbourne, Australia. Sunshine Hospital is a suburban hospital with a mixed adult/paediatric ED (annual paediatric census of 22 000 patients). Royal Children's Hospital is a tertiary children's hospital with an annual ED census of 56 000 patients. Fifty patient charts from each hospital were reviewed both pre-implementation and post-implementation. The primary outcome measures were changes in documentation of PPS – in particular changes in obtaining informed consent, pre-procedural risk assessment and monitoring of vital signs. The secondary outcome measure was the recorded rate of adverse events in children undergoing PPS before and after programme implementation.

The programme was implemented at Sunshine Hospital in April 2003 and at Royal Children's Hospital in March 2004. Pre- and post-implementation chart review of patients receiving PPS was undertaken at Sunshine Hospital for the periods January 2002–February 2003 and January–May 2004, respectively. Pre- and post-implementation chart review of patients receiving PPS was undertaken at Royal Children's Hospital for the periods November 2003 – March 2004 and September 2004 – January 2005.

Selection of cases for the 100 pre-implementation cases was performed by examining electronic ED data relating to children's episodes of care and reviewing

medical records to select those children who had received procedural sedation. Whereas the 50 pre-programme cases at Royal Children's Hospital were consecutive presentations based on ED log procedure codes, the 50 pre-programme cases at Sunshine Hospital were a convenience rather than a consecutive sample. This was as a consequence of difficulties experienced in identifying children who had undergone ED procedural sedation prior to the introduction of a sedation procedure code into the ED computer database. The method of case identification consisted of retrieving histories of children who had long ED stays with diagnosis of laceration or fracture and identifying children who had undergone procedural sedations. Post-implementation cases were primarily based on prospectively collected sedation checklists as described in Babl *et al.*²⁶ and completed by medical and nursing staff during sedations after implementation of the sedation programme. In addition we identified post-implementation cases where sedation checklists had not been completed through a review of the electronic ED logs.

A data collection sheet was designed for use in abstracting data from medical records and the sedation checklists. Data collected included date and time of sedation, medical record number, age in years, sex, type of procedure, sedative agent used, fasting status for liquids and solids and evidence of documentation of the following: weight, record of consent, evidence of risk assessment (see Babl *et al.*²⁶ for details) and allergy status. Further information collected included presence of appropriate number of credentialed staff, drug, dose, route of administration and presence of a written drug order.

Documentation of vital signs was also analysed and defined as 'appropriate' or 'inappropriate' as per the consensus judgement of the authors. When using nitrous oxide and oral or intranasal midazolam, vital signs recordings were considered 'appropriate' if there was at least one full set of observations of heart rate (HR), respiratory rate (RR) and oxygen saturation (SaO₂) recorded pre-procedure, during procedure and post-procedure, respectively. When using ketamine or any other parenteral sedative agent, vital signs recordings were considered 'appropriate' if there was at least one set of full observation of HR, RR and SaO₂ and BP pre-procedure and at least two sets of sedation observations during procedure and post-procedure, respectively.

Description of depth of sedation by nursing or medical staff either as a verbal description of sedation depth (pre-implementation of sedation programme) or

the Wisconsin sedation score¹⁵ (post-implementation of sedation programme) was recorded in addition to the occurrence and the nature of adverse events.

Major adverse events were defined to include apnoea, airway malposition requiring correction, hypoxia (SaO₂ < 92%), hypoventilation (RR < 10/min), hypotension (drop in systolic BP of more than 20 mm Hg), bronchospasm, seizure, significant recovery agitation requiring intervention, emesis during sedation, pulmonary aspiration, anaphylaxis or admission to hospital as a result of PPS. Minor adverse events were defined to include transient rash, mild recovery agitation not requiring intervention or vomiting following procedure. In addition we recorded 'failed' sedations defined as insufficient sedation to perform the planned procedure as documented by the treating clinicians.

We also recorded evidence of the provision of a post-sedation information handout to parents or carers. Lastly, an assessment of the quality of completion of the programme's sedation checklist was made on post-programme charts. Quality of completion of the checklist was defined as 'complete' (14 or more out of 19 checkboxes completed) 'missing information' (<14 checkboxes completed) or 'not completed' (sedation undertaken without a sedation checklist or with a checklist without any checkboxes completed).

All medical record and sedation checklist data were obtained and entered onto the data collection sheet by a single investigator trained in the use of the data collection sheet and then entered into STATA database by a second investigator.

Pre- and post-programme implementation data from both sites were analysed using χ^2 -analysis of proportions.

Results

We examined 100 PPS episodes pre-programme and 100 post-programme. Age and sex distribution and type of procedures were similar pre- and post-implementation of the sedation programme. (Table 1). Nitrous oxide was the most frequently used agent in both groups and there was an increase in ketamine use and a concomitant reduction in the use of Midazolam in the post-programme group compared with the pre-programme groups.

Table 2 shows the changes in documentation and key performance indicators pre- and post implementation of the sedation programme. In particular documentation of fasting status, risk assessment, 'appropriate' vital

signs and depth of sedation showed significant improvements in documentation.

No adverse events were recorded in the 100 pre-programme cases of PPS. There were two major (severe recovery agitation [one] and confusion and vomiting requiring admission [one]) and four minor adverse events (mild recovery agitation [three], incomplete upper airway obstruction not requiring intervention [one]) recorded in the post-programme period. There were no cases of pulmonary aspiration, hypoventilation or hypoxia.

Table 1. Paediatric procedural sedation: demographics, agents used and procedures

	Pre-programme (n = 100)	Post-programme (n = 100)
Mean age (years)	6.8	6.4
Male : female (n)	65:35	69:31
Drugs used (n)		
Ketamine	18	25
Midazolam	19	9
Nitrous oxide	59	60
Combination of agents†	4	6
Procedures (n)		
Fracture reduction	49	30
Laceration repair	38	46
Foreign body removal	5	10
IV cannulation	6	4
Other procedures‡	2	10

†Combination of agents: nitrous oxide/midazolam, nitrous oxide/fentanyl, midazolam/fentanyl. ‡Other procedures: Examination, abscess drainage, hernia reduction, immunization, lumbar puncture, urinary catheter insertion.

There were two cases of reported failed sedation in the post-programme group. In the first case a 5-year-old boy received oral midazolam and inhaled nitrous oxide to effect repair of a facial laceration. Sedation was inadequate to complete repair and the procedure was converted to repair under general anaesthesia in the operating theatre. The second was a 3-year-old girl who also received the combination of oral midazolam and inhaled nitrous oxide to facilitate laceration repair. Despite inadequate sedation (sedation score = 6) the repair was completed in the ED.

In the post-programme group of 100 cases the sedation checklist was completed in 68 cases, partially completed in 24 cases and not completed at all in eight cases.

Discussion

The present study reveals a significant increase in the performance of a pre-procedural risk assessment, recording of consent, drug orders, vital signs and the depth of sedation, following staff credentialing in a PPS programme. It demonstrates improvement in all aspects of documentation and vital signs monitoring following the programme. We recognize that a direct link between improved documentation and improved patient safety has not been shown but such a link is likely.

Hoffman *et al.* have previously reported that the adverse event rate in procedural sedation was reduced among 960 children who underwent all elements of a structured process model for PPS.¹⁵ Performance of a structured pre-procedural risk assessment was the most

Table 2. Evidence of recording of information or performance of key tasks in children undergoing procedural sedation

Documented	Pre-programme (n = 100)	Post-programme (n = 100)	Significance (Pearson χ^2 -test)
Fasting status			
Liquids	24	70	$P < 0.001$
Solids	25	83	$P < 0.001$
Weight	89	94	NS ($P = 0.20$)
Consent	15	87	$P < 0.001$
Risk assessment	1	87	$P < 0.001$
Allergies	97	99	NS ($P = 0.31$)
Appropriate staff†	0	98	N/A
Written drug orders	38	58	$P < 0.004$
Appropriate vital signs	27	58	$P < 0.001$
Discharge handout‡	0	61	N/A
Depth of sedation	0	74	$P < 0.001$

†No requirement to record pre-programme. ‡Not available pre-programme. N/A, not applicable; NS, non-significant.

significant single element in risk reduction. In our study conduct of a pre-procedural risk assessment was performed in 87% of the patients following programme implementation, compared with 1% in the pre-programme group. An apparent increase in adverse events in the post-implementation group most likely represents both improved identification and recording of adverse events. The PPS education programme highlighted the range of adverse events that can occur during PPS. It is likely that ED staff did not recognize certain minor occurrences as adverse events until they had completed the PPS programme. Therefore, both recognition and subsequent recording of adverse events increased following PPS programme implementation. Improvement in quality of PPS can be inferred from these two elements.

Documentation of weight, allergies, fasting status and consent all improved in the post-implementation phase of our study and are likely markers of quality of care. Appropriate vital signs recording reflects staff understanding of the importance of monitoring with an enhanced ability to identify and correct complications as early as possible during a procedure. Appropriate monitoring resulted in the early detection of respiratory compromise and intervention in a study looking at the utility of a quality assurance tool for PPS.¹⁶ The same study demonstrated a higher rate of complications in children with underlying medical conditions and an American Society Anaesthesiologists physical status score²⁷ of III or IV and in children under 1 year of age further strengthening the importance of a pre-procedural risk assessment.

Consideration of fasting status is an important aspect of pre-procedural assessment as the risk of emesis and pulmonary aspiration may increase with shorter durations of fasting. Although no definite association between pre-procedural fasting and adverse events has been demonstrated most authorities recommend a careful consideration of the risks and benefits of PPS in patients who have recently eaten or drunk.²⁸⁻³⁰

Recording of the depth of sedation was rarely performed pre-programme but improved significantly post-programme. Neither department had ever had a requirement to record sedation depth prior to the programme so the results are hardly surprising. The real value of recording depth of sedation probably lies in serial measurements allowing identification of deeper states of sedation in which even greater vigilance of airway, ventilation and circulatory state are required. Inadvertent deep sedation is associated with a higher rate of complications when compared with lighter seda-

tion ('conscious sedation')¹⁵ so monitoring and recognition of changes in sedation depth are an important part of decreasing the risk of complications.

Our intention is that the use of our sedation checklist will favourably guide safe practice by becoming a form of an aide memoire for staff who have undergone credentialing in PPS. Adoption of this tool into a department should lead to a high degree of sustainability of such an intervention.

The tracking of sedation quality and adverse events has been identified as an important part of quality assurance and continuous quality improvement in sedation.³¹ We are planning to continue to audit the sedation checklists to improve sedation practice in both EDs.

We utilized many of the strategies recommended by Gilbert to limit potential biases of a chart review.³² Among the strategies used in our study were the generation of explicit definitions and criteria of variables and methods of categorizing imprecise or missing information. A single investigator who underwent training reviewed all the records and a second investigator checked 10 charts while blinded to the information obtained by the first reviewer, to ensure a high inter-rater reliability was achievable, prior to embarking on the full number of reviews. A number of meetings were held between the investigators through the data abstraction process to review and refine definitions and resolve areas of ambiguity. Having said this, results of chart reviews must be interpreted with some caution. Actions and events might have occurred during the episode of care and not been recorded, while the act of recording something by ticking a checkbox (e.g. performance of a risk assessment), does not always mean it has been conducted.

Although we made every effort to identify consecutive cases in the pre-programme group at Sunshine Hospital, case identification was difficult without a sedation specific procedure code in the electronic ED log. It is possible that brief episodes of sedation were systematically excluded by this method of case identification. However, the proportion of nitrous oxide sedations, which was the main agent used for brief sedations, was the same in the pre- and post-implementation phase.

Although the EDs where the PPS programme was introduced cover a range of ED settings, the findings reported in the present study might not be generalizable to all EDs. In particular, the implementation of the programme was supported by a grant from the hospital insurer.

Conclusion

The implementation of a PPS credentialing programme into these two ED resulted in significant improvements in risk assessment, monitoring and documentation of important information related to safe PPS. It is hoped that these improvements will result in higher levels of quality and safety of PPS.

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Competing interests

None declared.

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