



Evaluation of a paediatric procedural sedation training and credentialing programme: sustainability of change

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ABSTRACT

Introduction An ongoing comprehensive paediatric procedural sedation (PPS) training and credentialing programme to improve patient safety was introduced into emergency departments (EDs) at a tertiary children's hospital (Royal Children's Hospital; RCH) and a suburban mixed ED (Sunshine Hospital; SH) in Melbourne, Australia. The study aimed to establish whether changes in practice had been sustained 3 years after implementation of the PPS programme.

Method 100 PPS episodes were identified at both hospitals (50 at each hospital) pre-implementation, 6 months and 3 years after implementation. This study retrospectively analysed 11 proxy markers of sedation safety by review of prospectively collected sedation records and medical records. Performance during the three time periods was compared using χ^2 testing.

Results Average age was 6 years and sedations were mainly for fracture reduction and laceration repair. Nitrous oxide and ketamine were the most commonly used agents. Midazolam use decreased over the study period. Six months after implementation at both hospitals relevant proxy markers of sedation safety were significantly improved over the pre-implementation level. Three years after implementation markers of sedation safety were still improved over pre-implementation levels. However, based on a minimum compliance with seven of 11 sedation safety markers both sites deteriorated; RCH from 96% to 80% ($p=0.028$) and SH from 68% to 32% ($p=0.001$).

Conclusion Based on an analysis of proxy markers of sedation safety significant changes over pre-implementation sedation care were maintained 3 years after implementation of a PPS programme. Documentation of sedation safety markers decreased over the study period, more so at the community hospital. To maintain educational gains and system change in sedation safety requires ongoing resources.

Procedural sedation and analgesia for painful and distressing interventions in children has become a standard tool for clinicians in the emergency setting.¹ Many national and international bodies have created policies, guidelines and other documents as a framework for effective and safe sedation.^{2–4} However, the translation of these documents into actual clinical practice is left to individual hospitals and clinicians. Few studies or reviews have investigated issues surrounding the introduction of procedural sedation education programmes for non-anaesthetists.^{5–13}

As a result of the lack of a readily available paediatric procedural sedation (PPS) programme,

such a programme to improve sedation safety was developed and implemented in 2004 at the emergency departments (EDs) of a suburban community hospital and a tertiary paediatric hospital in Melbourne, Australia.^{5–6} This comprehensive and multidisciplinary programme includes a standardised sedation checklist, parent handout and staff education materials, including a manual, lectures, a multiple choice test and staff competencies, and is taught by nurse educators. An assessment of the quality and safety of PPS 6 months after implementation showed significant improvements in important proxy markers of sedation safety including risk assessment, monitoring and documentation.⁶ The PPS programme was developed and implemented with the support of the hospital insurer, the Victorian Managed Insurance Authority.

The key question, however, was whether such a programme would lead to sustained changes in sedation practice years after its introduction, considering that EDs have only limited resources for education and training. We therefore analysed the same proxy markers of sedation safety 3 years after implementation of the PPS programme and compared them with pre and immediate post-implementation data.

METHODS

We performed a chart review of 100 children each before, 6 months and 3 years following the implementation of the PPS programme at the EDs of the Royal Children's Hospital (RCH) and Sunshine Hospital (SH), Melbourne, Australia.

RCH is a tertiary children's hospital with an annual ED census of 66 000 patients. SH is a suburban hospital with a mixed adult/paediatric ED and an annual paediatric census of 22 000 patients.

Fifty patient charts from each hospital were reviewed for the three time periods. The primary outcome measures were changes in documentation of proxy markers of sedation safety (see below).

The sedation programme was implemented at RCH in March 2004 and at SH in April 2003. The pre, 6-month and 3-year post-implementation chart review of patients receiving PPS was undertaken at RCH for the time periods November 2003 to March 2004, September 2004 to January 2005 and October to December 2007, respectively. The pre, 6-month and 3-year post-implementation chart review of patients receiving PPS was undertaken at SH for the time periods January 2002 to February 2003, January to May 2004 and January to May 2007, respectively.

The 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 RCH were consecutive presentations, the 50 pre-programme cases at SH were a convenience rather than a consecutive sample, as described by Priestley *et al.*⁶ This was a consequence of difficulties experienced in identifying children who had undergone ED procedural sedation before the introduction of a sedation procedure code into the ED computer database.

Both 6-month and 3-year post-implementation cases were based on prospectively collected sedation checklists as described previously⁵ and completed by medical and nursing staff during sedations. To identify sedations in which no sedation checklist had been used, we also reviewed the electronic ED logs at both institutions.

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, age in years, sex, type of procedure, sedative agent used, adverse events and sedation safety markers (see below).

Definitions and measurements

Proxy markers of sedation safety were defined as documentation of solid and liquid fasting, weight, allergies, consent, risk assessment, presence of appropriate staff, written drug orders, recording of appropriate vital signs and sedation depth and provision of a discharge handout.

Documentation of vital signs was 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 sign 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 the procedure and post-procedure, respectively. When using ketamine or any other parenteral sedative agent, vital sign recordings were considered 'appropriate' if there was at least one set of full observations of HR, RR, SaO₂ and blood pressure pre-procedure and at least two sets of sedation observations during the 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 a sedation score (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 blood pressure 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 emesis following procedure. We defined failed sedation as insufficient sedation to perform the planned procedure as documented by the treating clinicians.

Evidence of the provision of a post-sedation information handout to parents/carers, not available before the development of the sedation programme, and the completeness of the programme's sedation checklist was assessed on post programme charts. The completeness of the checklist was

defined as 'complete' (14 or more out of 19 checkboxes completed), 'incomplete' (<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 a piloted data collection sheet by two investigators trained in the use of the data collection sheet and then entered into an Excel database. In a portion of records data extraction and data entry was checked for accuracy by a third investigator.¹⁴

Analysis

All data were entered into an Excel software database (version 2003). Statistical calculations were performed on Stata software (version 10.0). Pre and post-programme implementation data from both sites for the three time periods were analysed using χ^2 or Fisher's exact analysis of proportions. The significance level was set at 0.01 for multiple comparisons. We created a summary dataset in which at least seven of the 11 key quality proxy markers had been completed.

RESULTS

We examined 300 patient records, 100 for each time period (50 at each site): pre-implementation, 6 months and 3 years post-implementation. Demographics, agents used and type of procedures are shown in table 1 and were broadly similar over the time periods studied. Nitrous oxide was the most frequently used agent. Midazolam use as a single agent decreased over the study period for the combined site data from 19% to 2%. When analysed by site (table 1), the decrease in midazolam use was mainly due to a change in practice at SH.

Table 2 shows the analysis of key performance indicators for sedation safety over the 3-year study period. Both sites independently showed similar statistically significant improvements compared with baseline data in the key performance indicators when analysed 6 months post-programme. Weight and allergy documentation were very high even during the pre-implementation phase, and showed no further statistically significant change 6 months or 3 years after implementation. When analysed 3 years after implementation of the PPS programme and compared with the 6 months post-implementation period, six markers showed significant deterioration at RCH and three markers at SH. At 3 years post-programme six markers were significantly lower at SH than at RCH. The quality of completion of sedation checklists (see Methods for definitions) was assessed as complete in 68% vs 40%, partly completed in 24% vs 30% and not completed in 8% vs 30% at 6 months and 3 years after implementation, respectively.

Patients with at least seven of the 11 key performance indicators completed were compared with those who did not. At RCH there was an increase from 2% pre-implementation to 96% at 6 months ($p<0.001$) and 80% at 3 years ($p<0.001$). At SH there was an increase from 2% pre-implementation to 68% at 6 months ($p<0.001$) and 32% at 3 years ($p<0.001$). When comparing these summary datasets between 6 months and 3 years there was a downward trend at RCH ($p=0.014$) and a significant drop at SH ($p<0.001$). At both 6 months ($p<0.001$) and at 3 years ($p<0.001$) RCH had higher scores than SH.

No cases of adverse events had been recorded pre-programme. Six months post-programme five adverse events were recorded at RCH and one at SH, 5 years post-programme three were recorded at RCH and four at SH. Two of the adverse events at 6 months post-programme were regarded as serious due to severe recovery agitation in one patient and confusion and

Table 1 Paediatric procedural sedation: demographics, agents used and procedures for RCH and SH

	Pre-programme		6 Months post-programme		3 Years post-programme	
	RCH (n=50)	SH (n=50)	RCH (n=50)	SH (n=50)	RCH (n=50)	SH (n=50)
Mean age (years)	7.1	6.6	5.8	7.0	7.0	6.9
Male:female (n)	29:21	36:14	28:22	33:17	35:15	27:23
Drugs used (n)						
Ketamine	7	11	18	7	7	15
Midazolam	—	19	1	8	—	2
Nitrous oxide	43	16	31	31	42	31
Combination*	—	4	—	4	1	2
Procedures (n)						
Fracture reduce	29	20	11	19	16	16
Laceration repair	11	27	26	20	22	14
FB removal	2	3	6	4	1	7
IV cannulation	6	—	1	3	1	—
Other procedures†	2	—	6	4	10	13

*Combination of agents: nitrous oxide/midazolam, nitrous oxide/fentanyl, midazolam/fentanyl, ketamine/midazolam, nitrous oxide/ketamine/midazolam given at the time of sedation.

†Other procedures: examination under sedation, abscess drainage, hernia reduction, immunisation, lumbar puncture, urinary catheter insertion, relocation joint, application of plaster, foreskin release.

FB, foreign body; IV, intravenous; RCH, Royal Children's Hospital; SH, Sunshine Hospital.

vomiting requiring an admission for observation in another. All other adverse events were mild and mainly related to vomiting. There were two failed sedations 6 months and three failed sedations 3 years after implementation; one of these was referred for general anaesthesia. There were no cases of pulmonary aspiration, hypoventilation or hypoxia and no patient required invasive interventions or intubation.

DISCUSSION

This is the first study to evaluate the long-term sustainability of implementing a paediatric procedural sedation education and credentialing programme to improve patient safety in the ED setting. Both study EDs jointly developed and implemented the programme; for the first 12 months of the programme nurse educator funding was available through a grant by the semi-governmental hospital insurer at both sites. Both sites significantly improved sedation practice 6 months after implementation based on a review of 11 proxy markers of sedation safety.⁶ Thereafter, at both sites medical and nursing staff were expected

to continue to be credentialed upon commencing work in the ED. However, at the tertiary hospital a portion of nurse educator time was designated for the PPS after the initial grant funding expired. At the suburban hospital nurse educator time was limited overall, and non-paediatric and other paediatric ED education topics were competing with the process of educating and credentialing ED staff for PPS.

Based on a review of proxy markers for sedation safety, documented sedation care was still significantly better than at baseline at both sites 3 years after implementation of the PPS programme. However, at both sites, care had significantly deteriorated compared with 6 months after implementation. Although other factors may also have played a role, it is likely that the more pronounced drop-off at the suburban hospital was mainly due to a lack of educational resources to teach medical and nursing staff. Although both sites are teaching hospitals with high junior medical and nursing staff turn-over, the tertiary children's hospital ED has higher numbers of specialised paediatric emergency medicine nursing staff and 16 hours per

Table 2 Evidence of recording of information or performance of key tasks in children undergoing procedural sedation: pre-programme, 6 months and 3 years post-programme for RCH and SH

Documented	6 months post-PPS*			3 years post-PPS*			6 months vs 3 years post-PPS		6 months vs 3 years post-PPS		RCH vs SH	
	Pre-PPS* Yes RCH	Yes RCH	p Value	Pre-PPS* Yes SH	Yes SH	p Value	Yes RCH	p value	Yes SH	p value	post-PPS	p value
Fasting												
Liquids	16	46	<0.001	8	33	<0.001	42	0.218	35	0.668		0.096
Solids	16	46	<0.001	9	37	<0.001	46	1.00	35	0.656		0.005
Weight	47	48	1.000	42	46	0.357	43	0.081	42	0.218		0.779
Consent	6	47	<0.001	9	40	<0.001	43	0.182	29	0.017		0.002
Risk assess	1	50	<0.001	0	37	<0.001	41	0.003	21	0.001		<0.001
Allergies	49	50	1.000	48	49	1.000	46	0.117	47	0.617		1.000
Appropriate staff† ‡	0	50	<0.001	0	48	<0.001	42	0.006	21	<0.001		<0.001
Written drug	6	37	<0.001	32	21	0.016	33	0.001	21	0.589		0.016
Appropriate vitals† ‡	15	36	<0.001	12	22	0.035	23	0.008	18	0.414		0.309
D/C handout§	0	44	<0.001	0	17	<0.001	27	<0.001	9	0.232		0.003
Depth sedation	0	49	<0.001	0	25	<0.001	37	0.001	10	0.002		<0.001

*Based on n=50 at each time point at each hospital.

†Definition: see Methods section.

‡No requirement to record pre-programme.

§Not available pre-programme.

DC, discharge; PPS, paediatric procedural sedation programme; RCH, Royal Children's Hospital; SH, Sunshine Hospital.

day of paediatric emergency medicine consultant cover available. At the suburban hospital ED few paediatric specialised nursing staff were employed and only 18 hours per week of paediatric emergency consultant cover and 8 hours per week of paediatrician cover was available on the paediatric side of the department, although general emergency medicine consultant cover was available 15 hours per day.

No adverse events had been recorded pre-implementation, but a number of adverse events were recorded during the assessment period 6 months as well as 3 years post-implementation. Rather than indicating a higher number of adverse events per se, we interpret the sustained improved recognition and recording of adverse events following implementation of PPS as a marker of higher sedation quality. Although we report adverse events, the dataset is too small and was not intended to draw conclusions on sedation safety. However, in large ED-based series both nitrous oxide^{15 16} and ketamine^{17 18} have been found to have a good safety profile.

Single agent sedation using midazolam at the suburban hospital was found to fall significantly over the study period from 38% to 4% (table 2). Before the development of the current guidelines and education programme, staff were more familiar with midazolam due to previously recommended local protocols. As familiarity with more efficacious agents (ketamine and nitrous oxide) and safe processes evolved, midazolam use decreased. The reduction may also reflect emerging evidence and departmental observations suggesting a number of issues with midazolam including: unpredictable sedation,^{19 20} paradoxical reactions with restlessness^{19 21} and poor palatability.²² In addition, midazolam does not reduce the incidence of emergence dysphoria associated with ketamine.²³

The sustained changes at both sites despite the decrease in teaching resources is possibly due to system and culture change after the introduction of the PPS. Even if a number of new staff were not credentialed for PPS, it is likely that there was a general expectation of existing staff that sedation checklists would be used and minimum safety checks in terms of fasting, risk assessment, exclusion criteria and preparedness before PPS would be triggered. Ultimately, however, based on the differential experience at the two hospitals, which had initially achieved the same level of change before diverging in terms of sedation practice, it appears that the more educational resources are available, the more can change be sustained.

It is difficult to draw lessons from this analysis on how a PPS programme should ideally be structured. Krauss and Green⁹ in a recent review set out basic lessons based on the US experience. They recommend creating basic and advanced skills training programmes involving didactic sessions, web-based learning modules, simulation-based training, a minimum number of supervised sedations and a written examination. Anaesthetists could help establish programmes for ongoing skill maintenance and quality assurance. Training and credentialing in PPS are at this time subject to stricter legal and regulatory requirements and expectations in the US than elsewhere.⁹ A number of PPS programmes can be accessed on-line via the Paediatric Sedation Society website (<http://www.pedsedation.org>), but few studies compare different approaches to paediatric sedation training in terms of outcomes. There are a number of studies showing that more training leads to higher scores in various testing situations. In a randomised educational intervention a multifaceted paediatric sedation course was more effective in improving physician knowledge and understanding of sedation guidelines and practices than unstructured, self-directed learning.⁸ When comparing non-anaesthetist graduates of a simulation-based sedation safety

course with those who did not complete such a course, the simulation-based sedation safety course was shown to enhance physician performance during paediatric procedural sedation.¹⁰ A teaching seminar on paediatric procedural sedation in emergency physicians improved subsequent testing.¹³

Limitations

This study has a number of limitations. Outcomes were based on an examination of prospectively completed sedation records and a retrospective medical chart review during the three study periods. We tried to optimise the quality of the review as set out by Gilbert *et al*¹⁴ by using pre-set definitions and criteria of variables and case selection, a trained abstractor, a piloted standardised data collection instrument and double abstraction and double entry of a portion of the records. However, the abstractor was not blinded to the study's purpose. Actions might have occurred and were not recorded; conversely ticking a box on the sedation checklist does not mean a certain action had occurred. Although the implementation of the programme and the subsequent evaluation periods were staggered by 6 months between the hospitals, we doubt that this influenced our results. Finally, the choice of the cut-off of the summary data (seven of 11 proxy markers of sedation safety) was based on a consensus judgement of the authors.

CONCLUSIONS

Based on an analysis of proxy markers of sedation safety, significant changes over pre-implementation sedation care were maintained 3 years after implementation of a PPS programme. Documentation of sedation safety markers decreased over the study period, more so at the suburban hospital with fewer educational resources. To maintain educational gains and system change in sedation safety requires ongoing resources.

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Competing interests None.

Ethics approval This study was conducted after audit approval by the Royal Children's Hospital human research and ethics committee and by the Western Office for Research, Melbourne.

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Images in emergency medicine

Presumed steroid-related scleromalacia and blunt ocular trauma

A healthy 64-year-old woman was attempting to open a door when a relative reached out to assist. Unfortunately, his finger directly caught her right eye causing 8-ball hyphaema and extensive superior globe rupture. Emergency primary repair was performed despite poor visual prognosis.¹ Her sclera was extremely brittle and thinned which made wound apposition technically difficult (see figure 1).

Further questioning revealed previous subconjunctival steroid injections 45 years ago for episcleritis.

This mechanism of injury is unusual to cause globe rupture, which is more commonly seen with high-velocity projectiles or sports such as squash, golf or paintballing. We postulate that her steroid injections could have weakened this area of sclera, or she had an original diagnosis of scleritis, resulting in scleromalacia. Patients with atypical features should be further investigated in order to identify any predisposing pathology.

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Figure 1 Photograph following primary repair illustrating extent of globe rupture following blunt trauma from an index finger.

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