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CLINICAL INVESTIGATION

Facilitated self-reported anaesthetic medication errors before and after implementation of a safety bundle and barcode-based safety system

T. A. Bowdle^{1,*}, S. Jelacic¹, B. Nair¹, K. Togashi¹, K. Caine², L. Bussey¹, C. Kruger³, R. Grieve⁴, D. Grieve⁴, C. S. Webster⁴ and A. F. Merry^{3,4}

¹Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA, USA, ²Office of Nursing Research and Department of Biostatistics, University of Washington, Seattle, WA, USA, ³Department of Cardiothoracic Anaesthesia, Auckland City Hospital, Auckland, New Zealand and ⁴Department of Anaesthesiology, Faculty of Medical and Health Science, University of Auckland, Auckland, New Zealand

*Corresponding author. E-mail: bowdle@u.washington.edu

Abstract

Background: Anaesthetic medication administration errors are a significant threat to patient safety. In 2002, we began collecting data about the rate and nature of anaesthetic medication errors and implemented a variety of measures to reduce errors.

Methods: Facilitated self-reporting of errors was carried out in 2002–2003. Subsequently, a medication safety bundle including 'smart' infusion pumps were implemented. During 2014 facilitated self-reporting commenced again. A barcode-based medication safety system was then implemented and the facilitated self-reporting was continued through 2015.

Results: During 2002–2003, a total of 11 709 paper forms were returned. There were 73 reports of errors (0.62% of anaesthetics) and 27 reports of intercepted errors (0.23%). During 2014, 14 572 computerised forms were completed. There were 57 reports of errors (0.39%) and 11 reports of intercepted errors (0.075%). Errors associated with medication infusions were reduced in comparison with those recorded in 2002–2003 (P<0.001). The rate of syringe swap error was also reduced (P=0.001). The reduction in error rate between 2002–2003 and 2014 was statistically significant (P=0.0076 and P=0.001 for errors and intercepted errors, respectively). From December 2014 through December 2015, 24 264 computerised forms were completed after implementation of a barcode-based medication safety system. There were 56 reports of errors (0.23%) and six reports of intercepted errors (0.025%). Vial swap errors in 2014–2015 were significantly reduced compared with those in 2014 (P=0.004). The reduction in error rate after implementation of the barcode-based medication safety system was statistically significant (P=0.0045 and P=0.021 for errors and intercepted errors, respectively). **Conclusions:** Reforms intended to reduce medication errors were associated with substantial improvement.

Keywords: patient safety; syringes; medication errors; medication systems; infusion pumps; anesthetics

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2 | Bowdle et al.

Editor's key points

- Medication errors are a significant concern in anaesthesia patient safety.
- The effects of facilitated reporting and sequential interventions to reduce medication errors were analysed in a single large academic medical centre.
- Using facilitated self-reporting of errors, implementation of a medication safety bundle including smart infusion pumps, and then of a barcode-based medication safety system, was analysed.
- Both interventions resulted in a reduction in facilitated self-reported rates of errors and intercepted errors.
- Further research is needed to clarify the interventions that most effectively prevent anaesthesia medication errors.

Medication administration errors are a significant cause of morbidity and mortality. The rate of anaesthesia medication administration errors is not known with certainty. Error rates based on facilitated self-reporting (self-reporting can be 'facilitated', meaning that self-reporting becomes a part of normal, routine work flow, is expected for every anaesthetic case, and does not require an exceptional action on the part of the provider) range from 0.11%¹ of anaesthetics (with at least one error) to 0.75% of anaesthetics.^{2–5} Studies in which errors are determined by direct observation report higher rates than those that rely on facilitated self-reporting by anaesthesia providers^{6,7}; utilising very broad criteria for medication error, a combined rate of error and adverse medication effects of 5.3% of medications administered has been reported.⁷ Regardless of the true rate of anaesthesia medication administration error, reducing the rate of error should be a priority for all anaesthesia providers.

We utilised facilitated self-reporting of anaesthesia medication administration errors to compare the rates of errors before and after implementation of a medication safety bundle including 'smart' infusion pumps with built-in medication libraries, and a barcode-based medication safety system.

Methods

We obtained approval for these studies from our institutional review board. We utilised facilitated self-reporting of anaesthesia medication administration errors from August 2002 to May 2003 and from February 2014 to December 2015 (the number of anaesthesia cases during this 13-yr period increased from approximately 17 000 to 30 000/yr; however, the fundamental organisation and governance of the anaesthesia service was reasonably constant) at the University of Washington Medical Center. Anaesthesia care was provided using the anaesthesia care team model that includes attending anaesthesiologists, nurse anaesthetists, residents, and fellows. From August 2002 to May 2003, anaesthesia providers were asked to complete an anonymous medication error survey paper form (Supplementary material; Appendix 1) for every case. Any member of the anaesthesia care team could complete the survey. The survey form asked whether a medication administration error (as used here, the term 'error' does not require

that an adverse effect has occurred as a result of the error; e.g. the inadvertent administration of i.v. epinephrine resulting in tachycardia and myocardial ischaemia is an error with an adverse effect. The inadvertent administration of i.v. lidocaine that does not result in any clinically apparent effect is an error without an adverse effect.) or intercepted error occurred (an intercepted error is defined as any incident with the potential to become an error, e.g. drawing up the wrong medication into a syringe but discovering the error before administering the medication, or picking up the wrong syringe but discovering the error before administering the medication) (an intercepted error has also been referred to by Webster and colleagues² as a 'pre-error'). If an error or intercepted error did occur, the survey called for additional information about the nature of the incident by checking boxes and filling in blanks on the form, including whether there was a minor or major adverse effect or an injury. Minor or major adverse effects were defined as transient or reversible effects of the medication, whereas an injury was defined as being permanent. The difference between minor or major adverse effects was subjective and left to the judgment of the provider who submitted the data. This form was designed to deliberately replicate a previous similar study that took place from 1998 to 1999 in New Zealand.² When anaesthesia records were submitted without completed medication error survey forms, office staff contacted providers to remind them to return the medication error survey.

From 2003 to 2014, a 'medication safety bundle' was implemented in stages, consisting of coloured syringe barrels and special syringe labelling for succinylcholine and epinephrine (Supplementary material; Appendix 2), an increase in the use of pre-drawn syringes prepared by our pharmacy or commercially, the use of 'flag' labels on some 'high risk' syringes (Supplementary material; Appendix 2), removal of certain high risk medication ampules (epinephrine, phenylephrine) from our medication trays, and the use of programmable 'smart' infusion pumps with medication libraries [from May 2007 onward, all infusion pumps used were Alaris Carefusion (Becton Dickinson and Company, Franklin Lake, NJ, USA)]. Implementation of the smart infusion pumps was accompanied by a hospital-wide effort to standardise infusions. The pharmacy mixed and labelled medications for infusion in almost all instances, and provider preparation of medications for infusion was discouraged. These measures were not introduced simultaneously, and the mix of pre-drawn and provider prepared syringes was not constant because of variable availability of pharmacy and commercially pre-drawn syringes.

After implementation of a computerised Anaesthesia Information Management System (AIMS) and a decision support software tool [Smart Anaesthesia Manager (SAM), described previously⁸], we reinstituted the medication error survey in February 2014 as a computerised reporting form that must be completed in order to close the anaesthesia record (a so-called 'hard stop'). The computerised form (Supplementary material; Appendix 3) looks different from the preceding paper form but seeks to collect essentially the same information.

In November 2014, after 10 months of computerised medication error data collection, a previously described barcode-based medication safety system⁹ was implemented, and data collection was continued for another 13 months, through December 2015. (At the time of medication preparation, the Codonics vial barcode scanner reads the barcode on a medication vial, speaks the name of the medication, displays the name of the medication on a splash screen, and prints a syringe label that is compliant with international and local

Anaesthetic medication administration errors | 3



standards for syringe labels. At the time of medication administration, the syringe label is scanned using a hand-held barcode scanner. The SAM system speaks the name of the medication and displays the name of the medication on a dose entry screen where the dose can be entered manually. This system is specifically intended to prevent vial swap and syringe swap errors. Providers used the system to prepare syringes from vials, and our pharmacy utilised the system to label syringes that were prefilled in the pharmacy. See Supplementary material; Appendix 4.)

Medication administration errors were classified using the original system devised by Webster and colleagues² with several modifications (Supplementary material; Appendix 5). As there were only two cases in which there was more than one error recorded, the first error recorded was used, and the results are expressed as the rate of cases with an error reported per 100 cases (%) (i.e. number of cases with a reported error divided by the total numbers of cases \times 100).

The timeline of the study is shown in Figure 1. Table 1 summarises the relationship between vial swap, syringe swap, and infusion-related errors and various countermeasures.

Statistical analysis

Incidence within each time interval is presented as number (%) and 95% confidence interval (CI) on the percent. The main

outcomes were considered to be the incidence of cases with an error or intercepted error. A two-sample test of proportion was used to compare the incidence of error or intercepted error before and after implementation of smart infusion pumps (2002-2003 vs 2014) and a barcode-based medication safety system (2014 vs 2014-2015). To account for multiple comparisons, the Holm-Bonferroni method was applied to the six primary analyses which compared errors, intercepted errors and the sum of errors and intercepted errors in 2002–2003 vs 2014 and 2014 us 2014-2015. Secondary outcomes were also evaluated using a two-sample test of proportion. All statistical comparisons were performed using STATA version 11.0 (StataCorp LP, College Station, TX, USA). A control (Shewhart) chart showing the biweekly incidence of error during the three phases of the study served as a secondary form of statistical analysis.^{10,11}

Results

Paper medication error survey

From August 2002 through May 2003, 11 709 forms were returned, representing a response rate of 90% (Table 2). There were 73 reports of errors (0.62% of anaesthetics) and 27 reports of intercepted errors (0.23% of anaesthetics), for a total of 100 errors and intercepted errors (Table 2 and Fig 2). The types of errors and intercepted errors reported are shown in

Table 1 Relationship between syringe swap, vial swap, and infusion-related errors and various countermeasures

Error type	2002–2003	Countermeasure 2014	Countermeasure 2014–2015
Syringe swap	Syringes prepared by providers from vials, labels made by providers by hand, few prefilled syringes with proper labels	Increased use of prefilled syringes with proper labels (reduction of provider prepared, hand-made labels), coloured syringe plungers or 'flags' for high risk drugs (epinephrine, phenylephrine)	Barcode-based drug safety system with proper labels for all syringes, facility for scanning barcode on syringe label before administration
Vial swap	Few prefilled syringes, high risk vials present in drug trays (epinephrine, phenylephrine)	Increased use of prefilled syringes, removal of high risk vials (epinephrine, phenylephrine)	Barcode-based drug safety system
Infusion related	Infusion pumps without medication menus, infusion concentrations seldom standardised, many infusions prepared by providers instead of pharmacy	Smart infusion pumps, standardised infusion concentrations, pharmacy prepares all drugs for infusion	Smart infusion pumps, standardised infusion concentrations, pharmacy prepares all drugs for infusion

4 | Bowdle et al.

Table 2 Summary of results. Data are n (%) or range. *p value for 2002–2003 vs that in 2014. [†]P values were significant after applying the Holm–Bonferroni method to the analysis of errors, intercepted errors, and errors plus intercepted errors. [‡]P value for 2014 vs that in 2014–2015. Attending anaesthesiologist/resident/CRNA nurse anaesthetist/both (attending plus CRNA nurse anaesthetist or resident). Data were missing from seven cases (2002–2003), 30 cases (2014–2015 baseline), and 19 cases (2015 after barcode safety system). [§]Drug infusions included gravity and pump driven infusions. Antibiotic infusions were excluded from this category. During 2002–2003 both syringe pumps and peristaltic pumps were in use; none of these pumps contained preprogrammed drug libraries designed to prevent programming errors. During 2014–2015 gravity infusions were rarely used (except for antibiotics). All syringe and peristaltic pumps used during 2014–2015 contained drug libraries intended to minimise programming errors. AIMS, Anaesthesia Information Management System; CI, confidence interval

	2002–2003 paper form	2014 AIMS form after drug safety bundle	2014–2015 after barcode-based safety system
Total patients Errors	11 709 73 (0.62) (95% CI, 0.48–0.77)	14 572 57 (0.39) (95% CI, 0.29–0.49) P=0.0076*†	24 264 56 (0.23) (95% CI, 0.17–0.29) P=0.0045†‡
Intercepted errors	27 (0.23) (95% CI, 0.14–0.32)	11 (0.075) (95% CI, 0.031–0.12) P=0.001*†	6 (0.025) (95% CI, 0.0049–0.045) P=0.021†‡
Errors + intercepted errors	100 (0.854) (95% CI, 0.69—1.02)	68 (0.0467) (95% CI, 0.36–0.58) P=0.0001*†	62 (0.256) (95% CI, 0.19–0.32) P=0.0005*†
Attribution [‡]	24/53/10/6	7/25/3/4	4/24/3/10
Major adverse effect	7 (0.060) (95% CI, 0.016—0.10)	1 (0.0069) (95% CI, -0.0066 to 0.020) P=0.015*	5 (0.021) (95% CI, 0.0026-0.039) P=0.29±
Minor adverse effect	15 (0.13) (95% CI, 0.063–0.19)	3 (0.021) (95% CI, -0.0027 to 0.044) P=0 0009*	7 (0.029) (95% CI, 0.0075–0.050) P=0 62†
Injury Infusion [§]	0 (95% CI, 0–0) 29 (0.25) (95% CI, 0.16–0.34)	0 (95% CI, 0-0) 8 (0.055) (95% CI, 0.017-0.1) P-0 0001*	0 (95% CI, 0-0) 23 (0.095)† (95% CI, 0.056-0.13) P-0 18†
Vial swap	6 (0.051) (95% CI, 0.01–0.092)	5 (0.034) (95% CI, 0.004–0.064) P=0.5048*	0 (95% CI, 0.0–0.0) P=0.004‡
Intercepted vial swap	7 (0.06) (95% CI, 0.016-0.1)	2 (0.014) (95% CI, -0.005 to 0.033) P=0.04*	2 (0.0082) (95% CI, -0.0032 to 0.02) P=0.6062‡
Syringe swap	11 (0.09) (95% CI, 0.04—0.15)	1 (0.007) (95% CI, -0.007 to 0.02) P=0.001*	2 (0.0082) (95% CI, -0.0032 to 0.02) P=0.88
Intercepted syringe swap	6 (0.05) (95% CI, 0.01–0.1)	0 (95% CI, 0.0–0.0) P=0.0063*	0 (95% CI, 0.0–0.0)

Supplementary material (Appendix 6), and each error is described individually in Supplementary material (Appendix 7). The incidence of reversible adverse effects is shown in Table 2. There were no cases of permanent physical injury related to medication administration error.

Computerised medication error survey after implementation of a medication safety bundle

During the period from February 2014 through November 2014, 14 572 computerised medication error survey forms were completed (Table 2); the response rate was 100% because the anaesthetic record cannot be closed without completion of the medication error form. There were 57 reports of errors (0.39% of anaesthetics) and 11 reports of intercepted errors (0.075% of anaesthetics), for a total of 68 errors and intercepted errors (Table 2 and Fig. 2). The rate of reported errors and intercepted errors was less than found in 2002–2003 (P=0.0076 and P=0.001 for errors and intercepted errors, respectively). The types of reported errors and intercepted are shown in Supplementary material (Appendix 6), and each error is described individually in Supplementary material (Appendix 7). The proportion of reported errors resulting in major or minor adverse effects decreased substantially compared with that in 2002–2003 (from 0.060% to 0.0069%, P=0.015 and from 0.13% to 0.021%, P=0.0009 for major and minor adverse effects, respectively). Reported errors associated with medication infusions were significantly reduced in comparison with those recorded in 2002–2003 (P<0.001; Table 2). The rate of reported vial swap error was not significantly different from that found in 2002–2003, but the rate of reported syringe swap error was significantly reduced (P=0.001; Table 2).

Computerised medication error survey after implementation of barcode-based medication safety system

From December 2014 through December 2015, 24 264 computerised medication error survey forms were completed (Table 2) for a response rate of 100%. There were 56 reports of errors (0.23% of anaesthetics) and six reports of intercepted



Fig 2. Rates of self-reported errors and intercepted errors (near misses) are shown for each phase of the study. AIMS, Anaesthesia Information Management System.

errors (0.025% of anaesthetics), for a total of 62 errors and intercepted errors (Table 2 and Fig. 2). The reported rate of errors and intercepted errors was less than that found in 2014 before implementation of the barcode-based medication safety system (P=0.0045 and P=0.021 for errors and intercepted errors, respectively). There was a 41% reduction of reported errors between 2014 and 2014-2015. [Because the identities of the providers were not known for the data from 2002 to 2003, we were unable to assess for the effect of clustering during that time interval. However, we were able to assess for the effect of clustering during the 2014 and the 2014-2015 time intervals. A logistical regression was performed to assess the effect of the barcode-based medication safety system on error rate. To account for clustering effects within each anaesthesia practitioner (anaesthesia resident physicians or nurse anaesthetists), we chose a generalised estimated equation logit model using the exchangeable correlation structure or an equal-correlation model. Implementation of the barcodebased medication safety system was associated with a reduction in rate of errors by 41% (odds ratio=0.59; 95% CI, 0.40–0.88).] The types of reported errors and intercepted errors reported are shown in Supplementary material (Appendix 6), and each error is described individually in Supplementary material (Appendix 7). Vial swap errors in 2014-2015 were significantly reduced compared with those reported in 2014 (P=0.004; Fig. 2). Routine audits of syringes found on anaesthesia cart tops showed near 100% compliance with scanning vials with the Codonics[™] machine, that is, all syringes

prepared by providers were labelled with Codonics[™] labels. Compliance with scanning the barcodes of syringe labels before administration was much lower, as reported in a previous publication.⁹

A control (Shewhart) chart encompassing the entire study period is shown in Figure 3.

Discussion

Our data collected during 2002–2003 were intended to deliberately replicate a study of facilitated self-reporting of anaesthetic medication error performed in New Zealand and published by Webster and colleagues² in 2001. Our results are remarkably similar to theirs. They reported an error rate of 0.75% and an intercepted error rate of 0.4%, compared with 0.62% and 0.23%, respectively, in our study. A similar rate of error has also been reported by Chinese,³ South African,⁵ and US⁴ investigators who used a similar study methodology.

When the incidence of reported medication error was measured again in 2014, syringe swap errors and errors associated with infusion pumps were significantly reduced in association with implementation of a medication safety bundle consisting of measures to improve syringe and infusion pump safety. During 2002–2003, medication infusions accounted for 29 out of 100 total reported errors and intercepted errors. There was a significant reduction in the proportion of reported errors and intercepted errors associated with medication infusions in 2014 and 2014–2015, after implementation of

6 | Bowdle et al.



(solid lines). The lower control limit (LCL) is zero. The mean from each phase of the study is carried through into the next phase as a reference (dash-dot line).

infusion pumps with medication libraries along with efforts to standardise infusions provided by the pharmacy and discourage providers from mixing their own infusions. Of 29 reports of infusion related errors in 2002-2003, 13 were errors definitely or possibly related to a programming error or in a single case the use of the wrong-sized syringe in a syringe driver. The use of smart pumps would most likely have prevented these errors (because of the use of medication libraries or syringe drivers that recognise the syringe size). During 2014 and 2014-2015, there were 31 reports of infusion-related errors. Only two of these errors appeared to be related to programming errors in which a non-standard concentration of remifentanil was used and the concentration was incorrectly entered into the pump. This is consistent with several other studies showing that 'smart' infusion pumps reduce errors.^{12,13} However, infusion pumps with medication libraries appear to mainly prevent certain programming errors (such as entering the incorrect medication concentration), but do not prevent all types of errors associated with infusion pumps (such as entering the wrong dose, or failing to connect the tubing to the patient). In a study of smart infusion pumps in a cardiac surgery intensive care unit, Rothschild and colleagues¹⁴ found that medication libraries were bypassed frequently. It seems likely that there were other factors, in addition to the smart pumps, that resulted in a reduction in reported medication infusion errors, including but not limited to standardisation of infusion concentrations.

In late 2014 we implemented a barcode-based anaesthesia medication safety system,⁹ inspired by the system originally devised by Merry and colleagues.¹⁵ This system is intended to

specifically prevent vial swap and syringe swap errors. The rate of reported medication errors and intercepted errors declined significantly after implementation of the barcodebased safety system, and reported vial swap errors declined. Reported syringe swap errors were unchanged, but the rate was low, with only one syringe swap error in the 2014 study period before the implementation of the barcode-based medication safety system, and two syringe swap errors afterwards (in these two cases, the syringe barcodes were not scanned before administration). It is interesting that the largest reduction in syringe swap errors occurred between the baseline period, 2002-2003, and the 2014 study period after implementation of various enhancements to syringe labelling, and increased use of prefilled syringes, but before the implementation of barcode scanning. This tends to support the importance of syringe labelling features in the prevention of syringe swap errors, although this study was not designed to specifically test the effect of any particular syringe labelling feature on syringe swap error.

Control (Shewhart) charts are often used to assess the effects of quality improvement interventions by plotting the incidence of an event over time in order to observe trends or shifts in the data and the relationship to interventions. The control chart of this study (Fig. 3) suggests that the incidence of reported errors was lower in 2014 compared with 2002–2003 and declined again in 2014–2015 compared with 2014. The presence of 11 consecutive data points in 2014 below the centerline (mean) of the 2002–2003 data, and the presence of 12 consecutive data points in 2014–2015 below the centerline of the 2014 data suggest that the changes were the result of the

Anaesthetic medication administration errors | 7

interventions rather than random variation.^{10,11} The reduction in reported syringe swap errors and errors associated with infusion pumps after introduction of the medication safety bundle also supports the effectiveness of the intervention, because there were specific measures intended to prevent syringe swap errors and to prevent infusion pump errors. Likewise, the reduction in reported vial swap errors in 2014–2015 compared with that in 2014 followed introduction of a barcode-based medication safety system specifically intended to prevent vial swap errors.

Although reported vial swap errors declined significantly after implementation of the barcode-based safety system, the reduction in the overall reported rate of medication error (from 0.39% to 0.23%) was not accounted for entirely by the reduction in reported vial swap errors. It is possible that non-specific factors associated with the barcode-based system resulted in improvements in medication safety. These factors could include increased education and awareness about medication safety, improved labelling of syringes (Codonics[™] printed labels instead of handmade labels for syringes that are prepared from vials by providers), and a generally heightened awareness associated with implementation of the new system.

There are limitations imposed by the study design, as typical of any continuous quality improvement initiative. As this was a study of facilitated reporting, and not a controlled trial, it is not possible to know with certainty what accounts for the reduction in the rate of errors. There was a lengthy time interval between 2003 and 2014 during which no medication error data were collected. During the study period, the method of reporting changed from a paper-to a computer-based form. Although this could have affected reporting, the content of the two forms was nearly identical and the proportion of completed forms was very similar (90% and 100%, respectively). We cannot exclude the possibility that there was a decline in reporting of medication errors over time, although we have no particular reason to suspect that this occurred. Other systematic (non-random) changes may have occurred during the course of the study that affected the rate of error.

As with several previous studies,^{2–5} our unit of analysis was the case. It is conceivable that a change in the number of medications administered per case over the period of the study could have influenced the results. For example, a decrease in the total number of medications administered might result in a decrease in reported errors without any change in the actual rate of errors per medication. Conversely, an increase in the number of medications administered per case over the period of the study might have caused the rate of reported errors to increase in the absence of interventions to prevent errors. Our data for the average number of medications administered per case beginning in 2008 is 16, and has not changed significantly over the past 10 yr.

It is important to understand that facilitated self-reporting is not the same as random incident reporting. With facilitated self-reporting, providers are asked or required to complete an incident report for every case. Webster and colleagues¹⁶ showed that providers completed a facilitated medication error self-reporting form at a rate of 85% consistently over a period of 5 yr. In addition, they showed that the incidence of self-reported medication errors was nearly identical at two different hospitals during that period. Furthermore, an intervention designed to reduce medication errors resulted in a substantial reduction in medication errors but only for those cases where the intervention was applied. These findings suggest that facilitated self-reporting can be a robust method for following trends in the incidence of errors and for detecting the effect of an intervention. Peterfreund and colleagues¹⁷ showed that facilitated self-reporting of anaesthesia adverse events using a computerised data collection system connected to the computerised anaesthesia record substantially increased reports of adverse events compared with random incident reporting. Facilitated self-reporting undoubtedly underestimates the true rate of errors, although the extent of underreporting is unknown, and has been the subject of debate.¹⁸ We believe that the main utility of facilitated selfreported medication error data is to identify trends and to give insight into the mechanism of errors, rather than to determine the 'true' incidence of errors. Our overall goal is not simply to measure medication errors, but to understand and eliminate them.

In summary, facilitated self-reported error and intercepted error rates were reduced from 0.62% and 0.23%, respectively, in 2002-2003 to from 0.23% and 0.025%, respectively, by 2014–2015 (a 63% reduction in reported errors). The evidence from this study suggests that improved syringe identification features were associated with reduced syringe swap errors, infusion pumps with medication libraries and standardised infusions were associated with reduced errors involving infusions, and the use of a vial barcode scanner-syringe label printer was associated with reduced vial swap errors. Prevention of anaesthesia medication administration errors is a work in progress, but our data suggest that deliberate efforts to reduce errors can lead to substantial improvement. Further research is necessary to clarify which interventions most effectively prevent anaesthesia medication errors and to devise additional novel methods for preventing errors.

Author's contributions

Study design: T.A.B., C.S.W., A.F.M. Data collection: T.A.B., S.J., C.K., D.G., R.G. Data analysis: T.A.B., S.J., L.B. Drafting of the manuscript: T.A.B. Editing of the manuscript: S.J., K.T., K.C., C.K., D.G., R.G., L.B. Design of computer systems used for computerised data collection, data collection, data analysis, editing of the manuscript: B.N., C.S.W., A.F.M. Statistical analysis: K.T., K.C.

Declarations of interest

AFM is a director and shareholder in Safer Sleep LLC and is a consultant to Fisher and Paykel Healthcare. CSW is a shareholder in Safer Sleep LLC. The other authors have no interests to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2018.09.004.

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8 | Bowdle et al.

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