Peri-Operative Medication Errors in a Tertiary Care Teaching Hospital of a Low-Middle Income Country

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Abstract

Background

Identifying medication errors is one method of improving patient safety. Peri operative anesthetic management of patient includes polypharmacy and various steps prior to drug administration. Our objective was to analyze the medication errors reported in our critical incident reporting system (CIRS) database over the last 15 years (2004-2018) and to review measures taken for improvement based on the reported errors.

Methods

All Critical incidents (CI) reported during January 2004 till December 2018 were retrieved from CIRS database. Medication errors were identified and entered on a data extraction form which included reporting year, patients age, surgical specialty, ASA status, time of incident, phase and type of anesthesia and drug handling, type of error, class of medicine, level of harm, severity of adverse drug event (ADE) and steps taken for improvement.

Results

311 medication errors were reported. Fifty two percent errors occurred in ASA II and III patient, and 43% during induction. Sixty % occurred during administration phase and 65 % were due to human error. Thirty seven percent were ADE, 58 of which were significant, 23 serious and five life-threatening errors. Majority errors involved neuromuscular blockers (32%) and opioids (13%).

Conclusion

Sharing of CI and a lesson to be learnt e-mail, colour coded labels, change in medication trolley lay out, decrease in floor stock and high alert labels were the low-cost steps taken to reduce incidents.

Medication errors were more frequent during administration. Twenty eight percent resulted in significant, serious, or life-threatening events.

Background

Medication error reporting is considered an effective way in improving patient safety and quality of care. The World Health Organization (WHO) in their third global safety challenge aimed to reduce the global burden of iatrogenic medication-related harm by 50% within five years [1]. The three priority areas of medication safety mentioned by them were high-risk situations, polypharmacy, and transition of care. Peri operative anesthetic management of patient encompasses all these three areas. Anesthesiologists are responsible for multiple drug prescription, preparation, dilution, administration, and documentation and monitoring of medication during the perioperative period.

Several publications have reported these errors from high income countries (HIC) but there is lack of published work from low-and middle-income countries (LMICs). Medication errors (MEs) are routinely reported as part of our departmental Critical Incidents Reporting System (CIRS). Khan et al previously reported on critical incidents from our department, occurring between 1997 to 2002, and found that one fifth of reported incidents were related to medication [2].

Our objective in doing this audit was to review and analyze the critical incidents pertaining to medication errors reported in our CIRS database over the last 15 years (2004-2018). Our secondary objective was to identify and review measures taken for improvement and if additional measures were needed.

Methods

The Ethical Review Committee (ERC) of the Aga Khan University waived the requirement for informed consent for this study (ERC no. 2020-3421-8389). In addition, the protocol was reviewed and approved by the Departmental Research Committee. All methods were performed in accordance with the relevant guidelines and regulations.

All critical incidents (CI) reported from 1st January 2004 until December 2018 related to medication errors in adult patients aged 18 and above, were retrieved and then reviewed independently by two authors (SABB and SIRH). In the initial review authors divided the medication errors as follows; errors of medication selection/planning or ordering, dispensing, preparing, administering, documenting, and monitoring, using the operational definitions published by Nanji et.al [3]. All relevant information was entered in specially designed data extraction forms. The extracted data also included year of reporting, patients age, surgical specialty, American Society of Anesthesiologist (ASA) status, time of incident, phase and type of anesthesia, phase of drug handling, type of error, class of medication, outcome in terms of level of harm, severity of adverse drug event (ADE) and any steps taken or that needed to be taken for improvement.

The analysis of type of errors into human error, system error, and equipment error was already present in the Critical Incident Review (CIR) forms available in the system.

The outcome of these errors was then graded by the reviewers into errors with no harm, little potential for harm, potential for ADE, and ADEs. ADE were further divided into significant errors (minor physiological disturbance), serious (major physiological disturbance) and life-threatening (morbidity or mortality) [3]. If an ADE had occurred due to a known allergic reaction it was classified as “no error “.

A second review was conducted to observe any disparity between the two reviewers. A third investigator was consulted (FK) if the discrepancy was not resolved between the two initial reviewers. Data was then entered in Statistical Package of Social Sciences version 19.0 (S.P.S.S.).

Results

One thousand and six critical incidents were reported in 201,111 procedures, in adult patients undergoing anesthesia and surgery during the study period (2004 to 2018). Our initial review identified 336 medication errors. Twenty-five forms were excluded as they did not fulfill the criteria based on the operational definitions used. Fifteen forms were reviewed by the third investigator to resolve disagreements. Three hundred and eleven medication errors were analyzed. Highest number of errors were reported in ENT, neurosurgery, general surgery, and orthopaedics (n = 66, 62, 44 and 32 respectively). The errors were more commonly reported in ASA II and III patient (163 and 90 respectively) and 268 were reported during working hours i.e., 0800 am to 0500 pm. One hundred and thirty-three errors occurred during induction phase of anesthesia (42.8%) and 122 (39.2%) during maintenance phase. Eighty six percent errors occurred during general anesthesia (GA) and 44 (14%) were reported during spinal, epidural anesthesia, combined GA with regional, nerve blocks, and monitored anesthesia care.

Medication errors involved 13 different types of drugs administered in the perioperative period. Most involved drugs were neuro-muscular blockers (32%), opioids (13%), sedative/hypnotics (11%), vasopressors (10%) and local anesthetics (6%). In seventeen of the report's syringes were found without labels.

On analyzing the phase of medication error, handling, and administration (60.5%), preparation (21.5%) and dispensing (12.5%) were the main contributing categories. Selection, documentation, ordering, and monitoring were 8, 6, 3 and 0 incidents respectively. Commonly occurring incidents from each category with their frequency and action taken to bring improvement in system are shown in table 1and 2.

Table 1
Medication errors during drug administration and preparation along with corrective steps that were taken (2004-2018)

Medication administration Errors	n	Corrective steps taken	Medication preparation Errors	n	Corrective steps taken
Overdose	38	Emphasis on dose calculation while making anaesthesia plan	Labelling errors	40	In year 2000 printed colour-coded labels were introduced for cardiac medications, in 2010 for induction agent, muscle relaxant, opioids and local anaesthetics and in 2018 for all medications
Wrong medicine administered	34	Re-enforcement of SSP	Dilution errors	11	This information was shared in CI meeting and followed by lesson to learn email. Reminder on drug stations, “BREAK and MAKE one by one.”
Ineffective neuromuscular blockers (NMBs)	36	Pharmacy informed to ensure cold chain maintenance. Vendor changed and new NMBs added in formulary	Deviation from SSP	11	Re-enforcement of SSP in CI meetings and during on job training
Under-dosage	23	Emphasis on dose calculation while making anaesthesia plan			
Side effects	20	Discussion in departmental meeting and dissemination through “Lessons to Learn” e-mail A separate training session for new trainees proposed to residency committee			
SSP= Syringe Standardization Policy					

Table 2
Medication Dispensing Error with Corrective Steps Taken (2004-2018)

Medication dispensing Errors	n	Corrective steps taken
Ampoule swaps	1	Floor stock (quantity and variety) was decreased in 2007
	1	Medication trolley and floor stock checking in every shift (thrice a day) in 2007
Wrong medication	8	Cross checking of labels and ampoules before receiving from pharmacy
		LASA (Look Alike and Sound Alike) medicine identification and labeling from year2018 by the pharmacy
Syringe swaps	5	Re enforcement of “READ OUT LOUD” before injecting any medicine or connecting any infusion
		Standardized lay out in medication tray, workspace and drug trolley
Non-compliance to narcotic handling	4	Narcotic policy, POE of Narcotics and its dilution by pharmacy started in 2014
Expired drugs on drug trolley	3	In addition to other checks regular audits of whole drug trolley by pharmacy representative at all locations, for correct medication in correct location. Check of its expiry and any breakages. Near expiry (6 months) medicines withdrawn if present

POE=Patient Order Entry

Two hundred and four (66%) errors were classified as human errors, 69 system errors (22%) and 9 equipment errors (3%). In 29 reports there was no error but there was an allergic reaction to the anesthetic medication administered. On further analysis of human errors, there was deviation from standard practice in 32%, failure to check and lack of judgment in 42%, lack of knowledge in 9%, and stress and poor communication in 9% and 8% respectively.

One hundred and ninety-five errors showed no harm (n=88), little potential for harm (n=61) and potential for ADE (n=46). The outcome according to severity was 116 ADEs, out of which 86 were associated with an error. On further break up of 86 ADEs there were 58 significant errors, 23 serious and 5 life-threatening errors.

Some of the strategies that were recommended and were put in place are shown in Table 3. Effects of one of these strategies i.e., provision of color-coded labels in 2007 is shown in Figure 1. (Insert Figure 1 here)

Table 3

Causes and corrective measures taken for serious MEDICATION ERRORS

Incident	n=23	Cause/ Immediate Action	Corrective Measure/ Awareness Created
Patient found hypotensive when received in the operating room	01	Patient shifted to OR after receiving Inj. Hydralazine 15 mg I.V. without any monitoring. Monitoring initiated and Hypotension was treated	Transfer policy was redesigned that sick patients should not be shifted to or from OR without standard monitoring
Epinephrine infusion started because of severe hypotension (70/50, 50/35, 45/35 mmHg)	01	Faulty BP apparatus which showed severe hypotension, no effect of vasopressors seen. On change of BP apparatus BP was 180/110 mm Hg. Epinephrine infusion stopped	Regular calibration of BP apparatus at the beginning of list. Always think about faulty equipment in case of erratic reading
Bupivacaine infusion of 0.125% dispensed instead of 0.0625% entered in POE Nurse started it at the rate of 15mls/hr	01	POE not followed by nurse and pharmacy. Correct infusion started when error discovered	Sharing of incident at CI meeting Stressed upon following POE system
Severe hypertension (210/110 mmHg)	01	Fentanyl given in incremental doses up to 300ug but no response noticed. Near expiry fentanyl was in use	Deferred the use of near expiry medications because of decreased or no efficacy
No effect of inhalational agent observed	02	Empty vaporizer of isoflurane discovered	Machine and medication check by anaesthesia technicians per shift three times per day Low flow anaesthesia stressed to prevent repeated emptying of vaporizers * “Quick machine checklist to be introduced before every case “
Bradycardia and apnea after inter-scalene block initiated	01	Intravascular injection of local anaesthetic	Training of the faculty and residents for Ultrasound guided blocks started in year 2007
Patient developed apnea suddenly after spinal anaesthesia initiated	01	Atracurium given I.V. instead of Mz. Patient was immediately sedated, trachea intubated, and ventilation initiated	Mz was removed as stock items and physician order entry was made mandatory to get Mz. * “To revisit the standardization of syringes “

M=medication, Mz=Midazolam, SucC= SuccinylCholine, POE=Physician Order Entry, Future Plan=*

Incident	n=23	Cause/ Immediate Action	Corrective Measure/ Awareness Created
Atracurium administered instead of saline flush	03	Colour coded labels were not available. Five ml syringe was used for both atracurium and saline flush	Availability of colour coded labels was ensured
No response to treatment after severe hypotension	04	Phenylephrine, diluted and dispensed by pharmacy was not working. New medication prepared and administered	Pharmacy services for the dilution of phenylephrine and ephedrine was withdrawn
SucC was accidently used to flush the I.V. cannula	01	Deviation from routine practice. Mistake was immediately recognized Patient was immediately sedated and trachea intubated	Separate printed saline flush labels were made available after the incident. Practice of reading out loud before giving any medication instituted
Patient found unconscious with oxygen saturation of 45% in recovery room. He had been irritable because of Foley's catheter insertion	01	Mz was administered without POE. Patient regained consciousness after use of flumazenil	Mz was removed from stock items
Papaverine given through I.V. route by relieving staff	01	No formal handover given by primary anaesthetist to the reliever. Antibiotic infusion was being administered. After finishing antibiotic, reliever injected Papaverine	Medication trolley is only meant for preparation of I.V. Medication for local use by the surgeon shouldn't be place on anaesthesia medication trolley. This was communicated to surgical teams.
Syntocinon drip started before start of C-section	01	Deviation from practice	Point reiterated in the CI meeting that do not attach syntocinon drip before it is indicated
Patient did not have muscle relaxation after SucC administered	01	Phenylephrine administered instead of SucC	Alert labels to be put on look-alike drugs
Severe bradycardia and hypotension requiring treatment with glycopyrulate and atropine	01	Patient was already taking calcium channel blocker; induction was with sevoflurane and I.V. lignocaine	Awareness of drug interaction through CI meeting
Patient required re-intubation after extubation	01	After tracheal extubation cannula was flushed with muscle relaxant instead of saline	Readout loud before use of any medication * "Introduce syringe with colour coded plungers"

M=medication, Mz=Midazolam, SucC= SuccinylCholine, POE=Physician Order Entry, Future Plan=*

Incident	n=23	Cause/ Immediate Action	Corrective Measure/ Awareness Created
Patient was not paralyzed after giving SucC but became tachycardiac (120/min)	01	Epinephrine filled in syringe instead of SucC. The alert label was on the top of the ampoule so once opened, it created issue of look-alike drugs	Emphasized that practice should be to break one ampoule, fill it, label it and then take the new one

M=medication, Mz=Midazolam, SucC= SuccinylCholine, POE=Physician Order Entry, Future Plan=*

Discussion

Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer [This chart review identified 311 drug related incidents (30.9% of total 1006 reported incidents) over a period of fifteen years. Human error contributed in 66% of the MEs and 32% of the errors showed a deviation from standard practice. Medication, handling, and administration accounted for 60% of the reports. Thirty eight percent of the errors resulted in harm to the patients. Out of 86 ADEs reported there were 23 serious and 5 life-threatening errors (28%). The actual harm that came to the patients was 1.6%. Neuromuscular blockers, narcotic analgesics, sedatives, and vasopressors contributed in 67% of the errors.

There are different methods to detect and report medication errors or ADEs, like self -reporting, incident reporting, manual chart review, automated computerized surveillance or direct observation. Each has its value and limitations, but all highlight the problematic areas that need attention. Critical incident analysis is a process of collecting and reviewing reports in a way that helps in identifying trends in terms of frequency and harm. The process identifies contributing factors, and is helpful in education, research, development of policies, guidelines budget and planning, to provide safe anesthesia care [5, 6]. It is a low-cost measure of value in LMICs.

Our hospital serves as a tertiary care center in the area. A CI reporting program was initiated in our department in year 1995. These incidents are periodically reviewed and presented in departmental academic meetings where staff is also reminded on how to and when to fill the CI forms [7]. Once the error is reported the root cause must be analyzed, preventive measure instituted and shared with others. Quality Improvement Issues (QII) meetings were initiated in the department in year 2000, where errors were selected for taking further action and corrective strategies were prioritized. All incidents are reported anonymously on voluntary basis. This simple quality improvement and risk reduction measure helped us in improving the standard of anaesthetic care in our setup with low resources, where the lowering cost is an important aspect of implementing new safety measures [8].

Several corrective strategies related to medications were put in place. Strategies that had significant effect were standardization of syringe sizes for specific drugs, and changes in printed self-adhesive

labels where the drug name and concentration were made bold. Another additional strategy was the change in the floor stock that was reduced for some medications. The supervision of trainees for drug dilutions was made more stringent by trainers, and a file “standard dilution of vasoactive medication” was made available in the operating room (OR) suite. It was also observed that one person responsible for all phases of medication handling was an error reduction strategy and was recommended. Syringe standardization for different medication had already been in place in the department but CI still resulted due to deviation from the standards. One of the possible reasons of this deviation was the “subjective practices” without following the set standards. One of the steps in reducing such errors was regular reminders and presentation in departmental CI meetings which were followed by a “lesson to learn” e mail generated by the departmental CI coordinator after each meeting and shared with all staff.

One third of the MEs were classified as human errors (HE). These usually happened because of personnel preferences and non-adherence to existing standard processes. The hospital also switched the manuals of policies and guidelines from hard copies to the online version during 2010 to 2015. All new inductees in the department were also instructed during the orientation program to go through these online resources. There is still no formal sign off that they have read and understand. It could be one of the reasons of deviation from practice when systems in place are not followed properly. The future task is to ensure compliance to this step. Repetition of HE after corrective measures have been put in place is regarded as negligence. Its recurrence can only be prevented by sharing these reports, educating, training, and updating the existing staff as well as new employees in the department.

As regards phase of drug handling, over-dosage was the most common administration error followed by wrong medicine, in-efficient medication, and under-dosage. The common causes of 38 cases of over-dosages were misunderstanding either verbal orders or deviation from standard dilutions. This is similar to what was reported by Sakagudin et al who observed communication error as a main cause rather than lack of knowledge [9]. They rectified such errors by standardization of oral instructions (for e.g., “Inject 1.5 cc, 6 mg of Vecuronium out of ampoule containing 4mg/cc”.) and making it a rule to repeat the given instructions [9].

The causes of administration of wrong medication in our study were syringe swap or ampoule swap and deviation from syringe standardization. In the OR there are two common mechanisms responsible for error during administration processes. The first was during preparation of the medication syringe from drug vial/ampoule by choosing wrong ampoule and diluting it to an unintended concentration. The second possibility was by accidentally picking up of wrong syringe/ampoule i.e., “syringe swap” which may happen because of distraction, inattention, or heavy workload. An observation was that breaking all ampoules at the same time and then filling all the syringes increased the risk of filling wrong medication in a syringe as well as label swap, it was reinforced to open and fill ampoules one by one. Lobaugh et al reported an incidence of administration errors (65%) close to our findings but studied it in pediatric cases [10]. In contrast Sanduende et al documented 42% errors during this phase [11]. Use of prefilled syringe has decreased preparation errors in some places [12]. We practice this for a few medications like opioids, but

the rest are prepared by the anesthesiologist pre- induction. However, from the LMIC perspective it needs to be remembered that there is an additional cost involved in provision of pre-filled syringes.

Labelling also played important role in these errors. There is a controversy whether color coding of labels decreases or increases MEs. It was also observed that some incidents happened at times of shortage of color-coded labels resulting in use of white stickers which resulted in wrong medications being administered in 23 reports. Cheeseman and colleagues noted that addition of color to labels increased the speed of recognition; while Haslam and colleagues state that the process of implementing the International Color Coding System increased their rate of medication errors due to a change in the system [13, 14]. In our experience there was a decrease in ME after the introduction of standardized color-coded labels for frequently used medications in year 2007 as shown in figure 1. These colored labels were initially only applicable to medications that were prepared by anesthesiologists in OR. In 2018 our department adopted international color-coded labels for all medications used. Abeysekera et al recommended further investigations to determine if color coded printed labels were effective in reducing medication error [15].

According to a report by the Australian Incident Monitoring Study, neuro-muscular blockers (NMB) and opioids were the most frequently administered drugs in cases of wrong medication [15]. We also observed the same trend in our study, though NMBs were the highest number of errors (n=102), but one of these were “ineffective medicine” where response of medicine was not achieved after a full calculated dose. Another impact of this inefficacy of NMBs is decreased satisfaction of surgical colleagues as well as frequent repeated doses and increase in cost. Action was taken by the pharmacy in ensuring cold chain and change of vendor (shown in Table 1). In contrast to our findings Kentaro et al reported opioids and cardio-stimulants/vasopressors as the most common medications found in their study [16].

The harm because of ME can vary from minor physiological disturbance to life threatening morbidity and mortality. The incidence reported in literature varies from 0.01–11% [2, 17, 18]. In our patients this figure was 1.6% without any mortality. This was similar to a Brazilian study by Thomas et al where they found morbidity and mortality with irreversible damage in 1.75% patients [19]. Nanji et.al from USA also reported a similar incident (1.6%) of life-threatening events, none were fatal [3].

In order to prevent ME one needs to improve knowledge, increase reporting and sharing of incidents, vigilance; simulation-based teaching, orientation of the set standards to the new inductees in the department and development of clear communication. In 2019 Nanji identified several such strategies and further updated it in 2020 based on the recommendation of multi-regional associations for patient and medication safety to prevent perioperative MEs and/or ADEs. These were based on technology solution, standardization, elimination of lookalike medication vials and labels, pharmacy solution, and improvement in institutional culture [20]. Keeping the limitations of LMIC in mind we propose cost effective process-based interventions. Whether one uses technology or process, the first and foremost thing is to strengthen, design and comply with the processes of institution and the existing guidelines. Medication lay out is important to prevent syringe swaps and we applied it by keeping all cardiac

medications in a separate bin at a separate place and it worked well. High alert labels on medications was one of the strategies that we found effective in preventing MEs.

Based on our review, we plan to introduce some further strategies within the department. One of these is an anesthesia drug checklist before every case, revision of syringe size for sedatives, implementation of change of practice to break, fill and label one ampoule at a time, before breaking the second ampoule, and introduction of syringes with color coded plungers. We also plan to introduce medication safety workshops based on common incidents, at least once a year. We are also deliberating whether to form a group or committee to monitor medication errors and provide weekly pictorial alerts. All new trainees, faculty members and technicians must go through all the guidelines and policies during orientation week and a simple quiz can be developed to certify that they have read as well as understood.

There are certain limitations to our study: firstly, it is a single Centre observation study, reporting was voluntary, and it was a retrospective review of a database. This could miss some unreported incidents as well as factual details of reports. CIR has its own limitation like under reporting, physician bias and their own perspective in the report [21], lack of denominator, lack of sensitization of the value of reporting and delayed action after group discussion.

Conclusion

Our review has revealed that medication errors are frequent during conduct of anesthesia. Although many are readily caught and corrected, one tenth resulted in serious and life-threatening outcomes. MEs mostly occurred at the time of administration. Sharing of incidents during CI meetings and following it by a lessons to learn e-mail, introduction of color coded labels and high alert labels, change in medication trolley lay out, were some of the low cost strategies put in place to reduce incidents. This study thus shows the importance of medication error reporting as an initial step towards documenting MEs and using this information to devise preventive strategies.

Declarations

Competing interests: None

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Author's contribution:

SA conceived the concept and worked on design, intellectual content, literature search, data acquisition, preparation, editing, and review of the manuscript.

FAK conceived the concept and worked on intellectual content, data acquisition and editing of the manuscript.

SR worked on the design, literature search, intellectual content, data acquisition and reviewed the manuscript.

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Figures

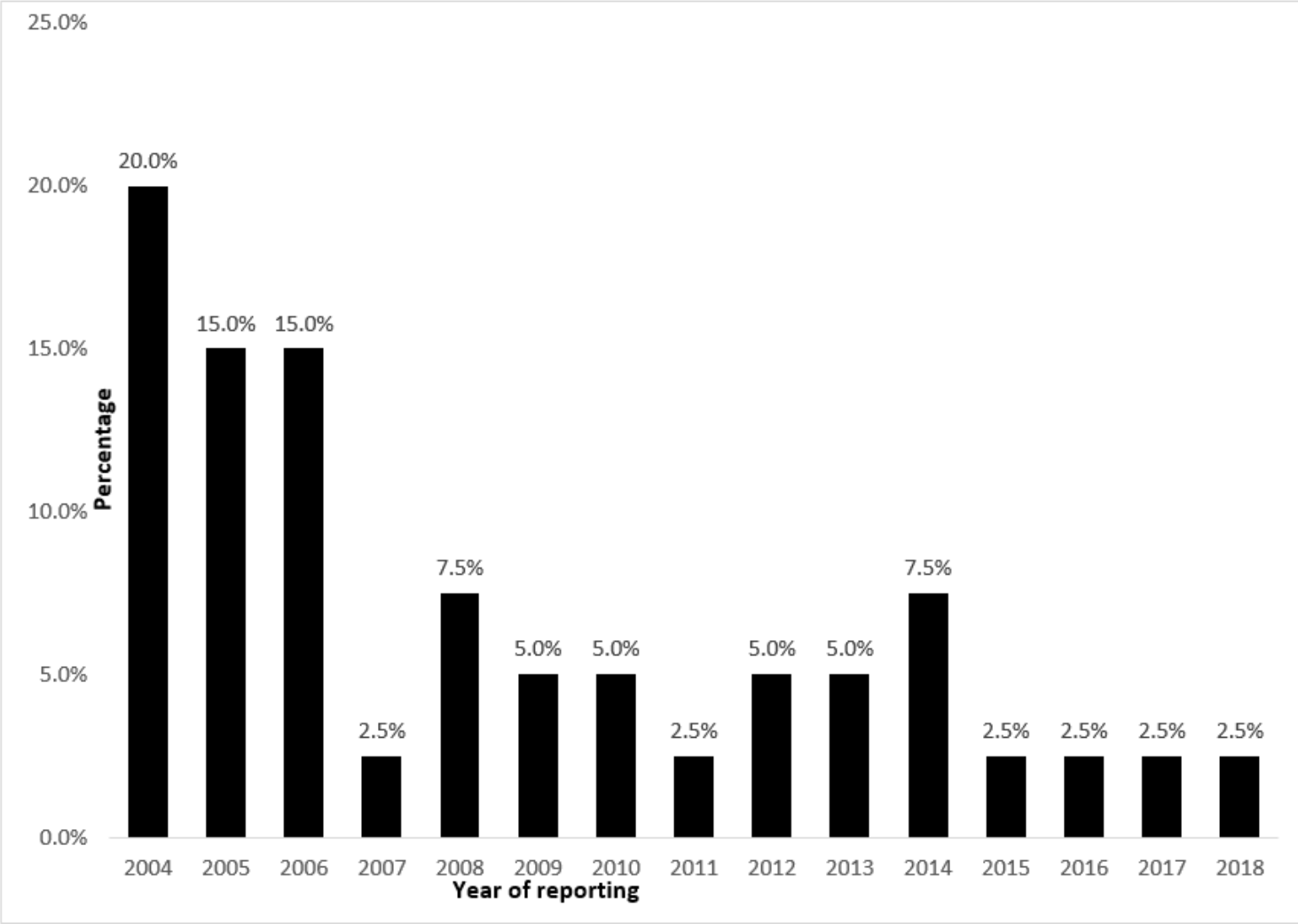

Figure 1

Percentage of labelling errors during medication preparation (2004-2018)