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ERRORS: REVIEW ARTICLE

Medication errors – new approaches to prevention

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Summary

Medication errors in pediatric anesthesia represent an important risk to children. Concerted action to reduce harm from this cause is overdue. An understanding of the genesis of avoidable adverse drug events may facilitate the development of effective countermeasures to the events or their effects. Errors include those involving the automatic system of cognition and those involving the reflective system. Errors and violations are distinct, but violations often predispose to error. The system of medication administration is complex, and many aspects of it are conducive to error. Evidence-based practices to reduce the risk of medication error in general include those encompassed by the following recommendations: systematic countermeasures should be used to decrease the number of drug administration errors in anesthesia; the label on any drug ampoule or syringe should be read carefully before a drug is drawn up or injected; the legibility and contents of labels on ampoules and syringes should be optimized according to agreed standards; syringes should always be labeled; formal organization of drug drawers and workspaces should be used; labels should be checked with a second person or a device before a drug is drawn up or administered. Dosage errors are particularly common in pediatric patients. Causes that should be addressed include a lack of pediatric formulations and/or presentations of medication that necessitates dilution before administration or the use of intravenous formulations for oral administration in children, a frequent failure to obtain accurate weights for patients and a paucity of pharmacokinetic and pharmacodynamic data. Technological innovations, including the use of bar codes and various cognitive aids, may facilitate compliance with these recommendations. Improved medication safety requires a system-wide strategy standardized at least to the level of the institution; it is the responsibility of institutional leadership to introduce such strategies and of individual practitioners to engage in them.

Introduction

Medication errors are common in anesthesia practice (1) and the perioperative setting (2–4). Many cause little or no harm, but some have devastating consequences for patients and, on occasion, for practitioners (1,5–7). In this study, we define error and differentiate it from violation; we present a brief introduction to the frequency and nature of medication errors in pediatric anesthetic practice. We discuss the nature of error. We outline some new approaches to the prevention of these errors.

In doing this, we place emphasis on understanding the nature of error. We introduce the concept of error *management*, of which the *prevention of error* is only one part. We include a brief discussion of blameworthiness in relation to medication errors because adoption of the principle of a *just culture* is an important advance in the promotion of patient safety. Errors may be blameless, but violations often play a part in their genesis, and violations may reflect carelessness. In the pursuit of patient safety, it is essential to focus on the system, but the mind-set of individual practitioners is also of central importance.

Errors, violations and other definitions

An error may be defined as 'the unintentional use of a wrong plan to achieve an aim or failure to carry out a planned action as intended' (5). Stated simply, this can be expressed as follows: 'an error is when someone is trying to do the right thing but actually does the wrong thing' (8). A violation, on the other hand, involves the 'deliberate—but not necessarily reprehensible—deviation from those practices appreciated by the individual as being required by regulation or necessary or advisable to achieve an appropriate objective, while maintaining safety and the ongoing operation of a device or system' (5). The essential difference is that violations involve an element of choice, while errors do not. It follows that errors are not, in themselves, blameworthy (9). However, violations often predispose to error, and a predisposing violation may be blameworthy even if an associated error is not. The blameworthiness of a violation depends on context and degree.

Wheeler provides the following definition of medication error: 'A medication error is an "error in the prescription, dispensing, or administration of a medication with the result that the patient fails to receive the correct drug or the indicated proper drug dosage"' (10). This definition includes outcome. There is a natural tendency to judge events on their outcome, but it is both more logical and more conducive to patient safety, to evaluate errors by the cognitive processes involved in their generation. It is not necessary to have an adverse outcome for an action or decision to be an error (see Box 1). It is also sensible to reference types of error to a single definition of the word. Therefore, we define a medication error as 'any error involving the prescribing, ordering, selection, or administration of a medication.'

Medication errors do not necessarily involve culpable or blameworthy elements, but some might. The choice to practice according to the best available evidence is a key element of safe medication management. This includes evidence about the processes of medication administration as well as evidence about the choices of medications for any given clinical setting. In this context, making every reasonable effort to practice safely does not guarantee an absence of error, and the occurrence of an error does not of itself provide any reason to suspect negligence or other forms of blameworthy behavior. However, choosing to ignore simple steps (such as routinely labeling syringes) widely accepted as important for safety may be construed as a violation and might reasonably be considered blameworthy (9). In recent years, the concept of a 'no-blame' approach to error in healthcare has given way to that of a 'just culture'. In a just culture, the accountability of individuals is evaluated in light of an informed view of human cognition and a recognition that many, but not all, of the things that go wrong in health care have no element of blameworthiness (8,9).

Box 1 A medication error with a good outcome

An anesthetist decided to administer a bolus of ephedrine to treat the unexpected sudden onset of profound hypotension in a simulated patient. He accidentally administered 100 μg of epinephrine (the two drugs were presented in similar formats). It then became apparent that the cause of the hypotension was a (simulated) accidental total spinal anesthetic and that the indirectly acting ephedrine may well have been ineffective. Thus, epinephrine, which is directly acting on receptors, was arguably a better choice, and this error might well have produced a better outcome than the intended action. Nevertheless, it would still have been a failure to carry out a plan as intended. In fact, the plan itself would have been imperfect so this is an illustration of one error canceling another.

An adverse drug event (ADE) is 'any injury related to the use of a drug' (11). This should include any injury related to the omission of an indicated medication. Some, but not all, ADEs are preventable. Some preventable ADEs are caused by errors alone, but in others, violations may also play a part.

The frequency of medication errors in pediatric anesthesia

There have been many estimates of the frequency of medication error in anesthesia in adults (1) and a number in pediatrics (12,13). Reports of medication errors in children typically come from subsets of adult orientated studies and tend to lack detail. Many reports lack denominator data and/or are based on incident reports in which it is difficult to know how many actual events were reported. It is also likely that at least some medication errors are made without the practitioner being aware of having made them. Facilitated incident reporting of errors in adult anesthesia practice suggests a rate of approximately one error per 135 anesthetics (1). In patients in the neonatal intensive care unit and postnatal wards of a university-affiliated urban general hospital in New Zealand, ADEs occurred at the rate of 2.1 per 100 prescription episodes, 12.9 per 100 admissions and 22.1 per 1000 patient days (14). About half were classified as preventable, and the estimated annualized cost of these was approximately NZ$87 000. The greatest rate per 1000 patient days was seen on the surgical pediatric ward. Nearly half of the ADEs were

classified as serious, and 15% resulted in persistent disability or were considered life-threatening. In addition, many *potential* ADEs were identified. Medication errors in children appear to be more common in intensive care settings than other clinical areas, and approximately 12% appear to result in harm; children are at higher risk in the perioperative setting than adults for harm from this cause (2–4). Thus, there is every reason to believe that these errors represent an important risk to pediatric patients, before, during, and after anesthesia.

The nature of medication error in children

Children undergoing anesthesia are subject to the same errors as adults, but they may be more vulnerable than adults because of immaturity of physiological systems, and several factors increase the likelihood of medication errors in children. These are discussed latter. Similarly, medication errors during anesthesia may be seen as simply a subset of the overall problem of medication errors in hospital, but there are some differentiating features of this setting. Anesthesia is the only area where medications are typically prescribed, prepared, administered, and recorded by a single individual (an anesthesiologist or anesthetist) without any other health professional to check or monitor the process. This fact increases the risk to patients of an error, but it also creates an unparalleled opportunity for the misuse of controlled drugs. In addition, it may create for practitioners some risk of being wrongfully suspected of misusing drugs.

Medication errors (in any age group) may occur through commission or omission. The former involves the wrong drug, the right drug inadvertently repeated (so-called insertion errors), the wrong dose, the wrong route, or the wrong time. In errors of commission, harm may occur through unintended effects of incorrect actions [e.g., inadvertently administering dopamine instead of doxapram has caused cardiac arrest and death (9)]. In errors of omission harm may occur through the absence of intended effects (e.g., nosocomial infection after the omission of prophylactic antibiotics, or awareness during inadequate anesthesia).

Medication errors dominated critical incidents relevant to pediatric anesthesia reported recently to the UK National Reporting and Learning System: unintentional additional medication doses were the most prevalent, but wrong drug, wrong dose, and wrong route errors were also common; analgesics and antibiotics were the commonest medications involved in these errors (6). In reports from intensive care or high dependency units, 61% of medication incidents were associated with drug administration and 26% with prescription (7).

Dosage errors of one sort or another are particularly common in children (15,16). Growth, maturation, and size are critical determinants of dose. Clearance, the pharmacokinetic parameter dictating maintenance dose, is immature at birth and matures over the first few years of life. Bupivacaine toxicity in infants receiving continuous regional neuronal blockade has occurred through failure to appreciate immature clearance (17). Clearance has a nonlinear relationship to weight (18): when clearance is expressed using a linear function (e.g., $l{\cdot}h^{-1}{\cdot}kg^{-1}$), it is highest in the 1 to 2-year-old age band, decreasing throughout childhood until adult rates are achieved in late adolescence. Drug dose scaled directly from adult dose ($mg{\cdot}kg^{-1}$) will typically be inadequate. Failure to recognize this point has resulted in inadvertent systematic underdosing of HIV-infected children in the United Kingdom and Ireland with antiretrovirals (19). The use of remifentanil parameters derived from adult studies for infusions in children results in lower concentrations than anticipated because clearance expressed per kilogram is higher in children (20). This may actually be advantageous, because hypotensive effects will be correspondingly less pronounced (21).

Pharmacodynamics has been inadequately studied in children and especially in infants. This is partially attributable to a lack of effect measures (e.g., spectral edge frequency, bispectral index, entropy, and cerebral state index) in young people undergoing anesthesia. The paucity of integrated pharmacokinetic–pharmacodynamic (PKPD) studies involving total intravenous anesthetics (22) predisposes to increased awareness in children (23,24). There is not yet an adequate means of monitoring the effect of anesthesia in infants, and this also contributes to anesthetic vapor administration errors, a major cause of morbidity and mortality with halothane (25).

Infants are unable to swallow pills, but pediatric oral formulations are not available for the majority of commercially available medications. When no liquid oral formulation is available, intravenous preparations are often administered orally (e.g., midazolam, propranolol), without adequate information about their hepatic extraction ratio or the effect of the diluent used to improve palatability: this may lead to inappropriate dose (26).

Children generally require smaller doses than adults. Because medications are packaged for adult use, dilution is commonly required in anesthesia practice. This

predisposes to dosage errors (15,16), often in the form of 10-fold overdoses (27).

Technique is particularly important in the administration of medications to small children and babies. Part of the volume of medication may easily be retained in the dead space of any part of an intravenous administration set or syringe, with the result that the desired effect may not be obtained. Alternatively, additional doses of medication may be given inadvertently on account of this dead space medication, and the effect may then be excessive and potentially lethal (28). Apnea, bradycardia, hypotension, and hypotonia have been reported in a premature neonate weighing 1.6 kg after an overdose of morphine, arising from the additional medication in the 'dead space' of the syringe (29).

Dilution may also be necessary to maintain osmolality low enough to prevent phlebitis (i.e., below 600 mosmol·l ^{1}). The amount of diluent required for drugs such as pentamidine and ganciclovir increases the risk of heart failure in critically ill children (30,31).

Although medications are usually prescribed on a weight basis (e.g., in mg·kg ^{1}), children are not often weighed. A survey of 100 children's notes in a busy emergency department revealed that only 2% were weighed prior to prescribing (32). Twenty-nine per cent of physicians' estimates, 40% of nurses' estimates, and 16% of parents' estimates differed from actual weight by more than 15% (33). The accuracy of methods to estimate weight also varies (34,35).

Understanding medication errors

Error

We think it reasonable to assume that essentially all anesthesia providers are motivated to administer medications correctly. Thus, ADEs seldom occur because of any intention to harm. Rather, they occur because of the inherent human propensity for error and because the system by which medications are administered during anesthesia (see Table 2) is complex and tightly coupled (36,37), with numerous latent factors predisposing to failure (38).

Reason has described a General Error Model (39) that is based on an attempt to understand the cognitive processes at play when error occurs. There is much theoretical and empirical research to inform such an understanding. In his model, errors are divided into action failures (slips and lapses) and decision (or planning) failures (rule-based or knowledge-based errors) (8,39): decision failures are also known as mistakes. More recently, Thaler and Sunstein (40) have shifted the emphasis from the distinction between actions and thoughts. Instead, they explain that there are two systems with which we both think and act. The automatic system is uncontrolled, fast, effortless, associative, unconscious, and skilled. Slips and lapses (39) occur in this cognitive mode, but some rule-based decisions may also fall into this category. Human cognition functions predominantly through pattern recognition, and many skilled activities depend on recognizing complex situations as a whole (i.e., as patterns) and responding by reference to prestored schemata (which are, in effect, also patterns), within the subconscious memory (39). This is highly efficient, but may lead to error for many reasons, including distraction, incorrect interpretation of situations, and poor training (leading to the learning of unsafe automatic responses to certain situations). The reflective system, by contrast, is controlled, effortful, slow, deductive, and conscious. Rule-based decisions may be conscious or unconscious (i.e., they may fall into either system), but a key feature of these decisions is that they are inductive and feed-forward (39). Reflective decisions [also called knowledge-based (39) or deliberative (9) decisions] are deductive, and progress is made through evaluating feedback and through an iterative process of trial and error. The term knowledge-based error places emphasis on the incomplete picture one often has of the world. A practitioner's own knowledge (acquired from training and experience) is only a small part of this. There are many other sources of important information, such as patients' notes or the knowledge of other people, but these may not be accessible to (or accessed by) the person making a decision about which medication to administer (see Box 2).

A key point emerges clearly from the empirical and theoretical research into error: simply trying harder to avoid error, on its own, is unlikely to be successful.

Box 2 A lapse leading to a knowledge based (or deliberative) error

A medication allergy was known to a patient (who had a compli cated history with many comorbidities) and documented in the notes. A resident anesthesiologist read the notes, but in an otherwise comprehensive hand over, forgot to communicate the allergy to an attending anesthesiologist who took over the case halfway through the surgery. This was a lapse (39). In consequence, a decision by the attending to administer the medication in question was based on inadequate knowledge: this was a knowledge based error (39), also known as an error of deliberation or a deliberative error (8). The example illus trates how one error can lead to another. Failures of this sort have been identified as particularly difficult to address with technology (9).

Indeed, it may even have the ironic effect of increasing the risk of certain errors (41,42). Conscientious determination to practice safely does have a role in the avoidance of violations, but it will not, of itself, guarantee the avoidance of pure error: if medication error is to be reduced, at least some redesign of the methods used to administer medications will also be necessary.

The objectives of medication administration – the traditional view

The objectives of medication administration are often summarized in the 'five rights': the right patient, dose, medication, time and route of administration (43). We suggest a sixth 'right': a right (or accurate and comprehensive) record of the medications administered and of any medications wasted (notably unused portions of ampoules of controlled drugs). It is, perhaps, understandable that less attention is paid to errors in recording than to errors in prescribing or administering drugs, but an accurate and complete medication record may be important clinically, for audit, for inventory management or medico-legally. There are many reasons for errors in recording (44). One that is particularly relevant to the sixth 'right' is that people tend to record the medications they believe they have administered. In fact, many medication errors pass unnoticed. It is also true that many medication errors do not, in the end, cause harm. But these two points are not synonymous. For example, one anesthesia provider might administer a dose of gentamicin, fail to record this, and then hand over the anesthetic to another, who gives what he believes to be the sole dose of the drug. This error might never be identified and will not be reflected in the record, but otological or renal harm may well result. Another relevant point is that anesthesia providers who wish to misuse controlled medications may find it easy to falsify their records to conceal their misuse. Thus, the accurate tracking of medications administered during anesthesia is part of careful medication practice.

It is noteworthy that, in the USA, the Joint Commission has issued new standards that place greater emphasis than before on safety in medication management (45) and that at least some recent surveys have targeted medication management during anesthesia (46).

The objectives of medication administration – a modified view

The emphasis on the rights of medication administration is useful, but an excessive focus on avoidance of error may prove counterproductive. The goal is patient safety. Measures to mitigate the consequences of error may be more effective than undue efforts to avoid all errors: the obvious analogy here is provided by airbags in automobiles – but error reducing measures such as speed limits also matter. There are several ways to reduce the consequences of error.

Not all errors are equal in their potential to cause harm, and it seems sensible to stratify the relative risk of different types of error and consider exchanging dangerous errors for less dangerous ones. Using color coding by class of drug may not reduce the number of errors, but within-class errors may be less likely to cause serious harm than between-class errors.

Removing concentrated potassium chloride from the operating room reduces the potential for one particularly dangerous type of medication error.

Mitigation of medication error is more likely to be possible if one knows that an error has been made. Given the relatively high risk of awareness arising from medication errors in anesthesia, monitoring consciousness is an obvious element of an overall error management strategy. Measures to objectively track medications that have been administered are also important. One such method involves the retention of all used ampoules and vials in an orderly fashion (9), beginning afresh for each anesthetic. In this way, any doubt about what might or might not have been given can readily be resolved. One can also use prompts. These may be simple (e.g., placing an ampoule of antibiotic on the working surface ready to be administered at the appropriate time) or may be provided through technology (e.g., computer generated prompts to administer antibiotics).

The use of bar codes at the time of medication administration (9) seems likely to result in more accurate record keeping than manual records or computerized systems that depend on retrospective entry of medication names and times of administration.

A systems view of medication administration error

The process of medication administration involves many steps (47), beginning at the manufacturing stage, and ending with safe disposal of empty ampoules and incompletely used medications, and an accurate record (Table 2). Attention to the overall system of medication administration is important in preventing medication errors; many of the issues have been discussed in greater detail elsewhere (1,9,48). A systematic review of the literature identified 98 relevant references (14 with experimental designs or incident reports and 19

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