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REVIEW ARTICLE

Medication errors in anesthesia: unacceptable or unavoidable?

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Abstract Medication errors are the common causes of patient morbidity and mortality. It adds financial burden to the institution as well. Though the impact varies from no harm to serious adverse effects including death, it needs attention on priority basis since medication errors' are preventable. In today's world where people are aware and medical claims are on the hike, it is of utmost priority that we curb this issue. Individual effort to decrease medication error alone might not be successful until a change in the existing protocols and system is incorporated. Often drug errors that occur cannot be reversed. The best way to 'treat' drug errors is to prevent them. Wrong medication (due to syringe swap), overdose (due to misunderstanding or preconception of the dose, pump misuse and dilution error), incorrect administration route, under dosing and omission are common causes of medication error that occur perioperatively. Drug omission and calculation mistakes occur commonly in ICU. Medication errors can occur perioperatively either during preparation, administration or record keeping. Numerous human and system errors can be blamed for occurrence of medication errors. The need of the hour is to stop the blame – game, accept mistakes and develop a safe and 'just' culture in order to prevent medication errors. The newly devised systems like VEINROM, a fluid delivery system is a novel approach in preventing drug errors due to most commonly used medications in anesthesia. Similar developments along with vigilant doctors, safe workplace culture and organizational support all together can help prevent these errors.

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PALAVRAS-CHAVE
Erros médicos;
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Erros de medicamentos;
Melhora da qualidade

Erros de medicação em anestesia: inaceitável ou inevitável?

Resumo Os erros de medicação são as causas mais comuns de morbidade e mortalidade dos pacientes. Além disso, esses erros aumentam os encargos financeiros da instituição. Embora o impacto varie de nenhum dano a efeitos adversos graves, incluindo o óbito, é preciso estar atento à ordem de prioridades porque os erros de medicação são evitáveis. Na atualidade, com as pessoas cientes e os processos médicos em evidência, frear esse problema é de extrema prioridade. O esforço individual para diminuir os erros de medicação pode não obter sucesso até que uma mudança nos protocolos e sistemas existentes seja incorporada. Muitas vezes, os erros de medicação ocorridos não podem ser revertidos. A melhor maneira de ''tratar'' esses erros é impedi-los. Os erros de medicação (devido à troca de seringa), de overdose (devido a mal-entendido ou preconcepção da dose, mal uso de bomba e erro de diluição), de via de administração incorreta, de subdosagem e de omissão são causas comuns de erro de medicação que ocorrem no período perioperatório. A omissão e erros no cálculo de medicamentos ocorrem comumente em UTI. Os erros de medicação podem ocorrer no período perioperatório, tanto durante a preparação e administração quanto na manutenção de registros. Um grande número de erros humanos e do sistema pode ser responsabilizado pela ocorrência de erros de medicação. A necessidade do momento é parar o jogo da culpa, aceitar os erros e desenvolver uma cultura segura e ''justa'' para evitar os erros de medicação. Os sistemas recém-criados como o VEIN-ROM, um sistema de administração de líquidos, é uma nova abordagem na prevenção de erros de medicação devido aos medicamentos mais comumente usados em anestesia. Desenvolvimentos semelhantes, juntamente com médicos vigilantes, uma cultura de local de trabalho seguro e apoio organizacional, todos em conjunto podem ajudar a evitar esses erros.

Introduction

''To err is human''

An anesthesiologist may inject up to half a million different drugs in his/her professional tenure. The chance of making an inadvertent error is easily fathomable. Anesthetized patients with unpredictable physiological reserves would not display or verbalize any symptoms that an awake patient would, such as hypotension, bronchospasm, arrhythmias or cardiac arrest. Any such error may cause irreversible damage/s. When patients consent for anesthesia, they trust that our training is adequate, judgment is uncompromised and competence validated. It is this responsibility for which we stand accountable.

Medication errors significantly augment the financial cost to human tragedy. Bates et al.[1] found that about two out of every 100 in-patients experience a preventable adverse drug event, resulting in an average increase of hospital costs by $4700 per admission or about $2.8 million annually for a 700 bed hospital. Therefore medical errors should be priority as an urgent, critical, and widespread public health problem. Systems need to be engineered to reduce the likelihood of medication misidentification through approaches such as revision of standards for labeling of drug ampoules and vials and the development of advanced electronic/digital mechanisms that allow ''double-checking'' or drug verification in the operating room.[2]

More people die from medical errors than motor vehicle accidents, breast cancer, or HIV, but unfortunately these statistics never appropriately figure in public media or deliberations. A few horrific cases of erroneous drug administration do make the news headlines, either because they involve a celebrity or due to their egregious nature. Unfortunately, they constitute only the tip of the iceberg. The objective of this review is to discuss safety while administering drugs to patients under anesthesia.

Incidence

With an aim to establish the frequency and nature of drug administration in anesthesia, Webster et al.[3] performed a study based on 7794 anesthesiologist responses from two hospitals. They documented that the frequency of drug administration error (of any type) per anesthetic case was 0.0075 (0.75% or 1 per 133 anesthetics) with the two largest categories of errors involving incorrect doses (20%) and substitutions (20%), hence concluding that ADE (adverse drug effects) during anesthesia is considerably more frequent than previously reported.

Sakaguchi et al.[4] studied the incidence of anesthesia related medication errors in a university hospital in Japan over 15 years and based on 64,285 anesthesia cases concluded that drug errors occurred in only 50 cases (0.078%), much lower from earlier reported incidence. The reported drugs were most commonly opioids, cardiac stimulants and vasopressors; syringe swap the leading cause of errors and interestingly, the responsible anesthesiologists most likely being doctors with little experience.

Table 1 Incidence of medication errors in key studies.

Study	Study period	Number of anesthetics delivered	Incidence of drug error	Percentage of drug error
Webster et al.[3]	Feb 1998–Oct 1999	10,806	81	0.75%
Sakaguchi et al.[4]	1993–2007	64,285	50	0.078%
Llewellyn et al.[5]	Jul 2005–Jan 2006	30,412	111	0.37%
Cooper et al.[6]	Aug 2007–Feb 2008	10,574	52	0.49%
Zhang et al.[7]	Mar 2011–Sep 2011	24,380	179	0.73%

In South Africa, Llewellyn et al.[5] reported an incidence of 0.37% (111 incidences for 30,412 anesthetics or 1 per 274) with a conclusion that neither the experience of the anesthetist nor the emergent nature of the surgery influenced the incidence and nearly 40% of all errors occurred due to misidentification of drug ampoules. No major complication attributable to ADE-adverse drug effects was reported.

Cooper et al.[6] reported a medication error rate during anesthesia of 0.49% (52 errors from 10,574 case forms or 1 per 203 anesthetics) and a two-fold increase in the rates by anesthesia-in-training providers compared to experienced provider, most commonly due to incorrect dose and drug substitution.

Zhang et al.,[7] in a prospective incident-monitoring study in China reported a medication error rate of 0.73% (179 errors during 16,496 anesthetics), the largest category being omission, incorrect dosage and substitutions, collectively accounting for more than 65% of all errors. These led to serious complications in at least two and inadvertent ICU admissions for five patients. The incidence of medication errors from the above mentioned studies have been complied in Table 1.

When combining the 3 prospective study findings of Webster et al.,[3] Llewellyn et al.,[5] and Cooper et al.,[6] 244 errors were reported in 51,504 administered anesthetics. That gave us a combined incidence of 1 in 211 medication errors in anesthesia practice.[8]

Based on a limited number of prospective studies, the estimated incidence of medication error in anesthetic practice ranges from 0.33% to 0.73%[6,7] per case and unfortunately this rate has not changed substantially over the last 15 years.[4]

The Critical Care Safety Study reported an overall rate of 80.5 medication errors associated with harm per 1000 patient-days in medical and coronary-care patients.[9] In the SEE2 study, the rate of parenteral medication errors was 745 per 1000 patient-days.[10]

In a systematic review by Wilmer et al.[11] to assess incidence of drug events in intensive care units (ICUs), the rates of medication errors (MEs) varied from 8.1 to 2344 per 1000 patient-days, and adverse drug events (ADEs) from 5.1 to 87.5 per 1000 patient-days. The definitions of ADE and ME in the studies varied widely which could have been the cause of this vast variation in incidence.

Historical perspective of medication errors

Look-alike, sound-alike drugs,[12,13] confusing, inaccurate or incomplete drug labels and packaging,[13] swapping of syringe labels,[14,15] swapping of syringes and ampoules,[4] unlabelled syringes,[16] and failure of drug-dose calculation,[17] have all been reported.

A system failure, that had profound implications for anesthesia in the United Kingdom, was the case of Woolley and Roe, in which two patients were left paraplegic after undergoing spinal anesthesia at Chesterfield Royal Hospital in 1947.[18] At that time, their injuries were thought to be due to microscopic cracks in the local anesthetic ampoules, through which phenol seemed to have seeped during the sterilization process. In fact, it appeared that a batch of reusable spinal needles had not been removed from a bath of acidic descaler and boiled in distilled water before use because a member of staff had called-in sick, and was off-duty,[19] a classic system failure. A fatality was reported when the flow rate of a patient's epidural pump was increased to 125 mL/h by a 'ward nurse' who had intended to give an intravenous fluid bolus, despite the pump being correctly labeled and the patient receiving parenteral fluids via a gravity-fed drip set.[20]

High profile cases of fatalities caused by accidental injection of intrathecal vincristine have resulted in blame, charges and convictions for the individuals involved rather than recognition that they result from system failures.[21] Overdose of anticoagulants resulting in hemorrhage, administration of antibiotics to patients with preexisting history of allergy to such antibiotics, failure to prescribe prophylaxis against venous thromboembolism and adverse drug events with opioids, theophylline, antimicrobials, anticonvulsants, anticancer drugs and muscle relaxants are well known.[22–26] Drugs most commonly involved in serious errors were heparin, epinephrine, potassium chloride and lidocaine, the last being implicated in most fatalities.[27] The accidental injection of intrathecal vincristine rather than methotrexate during chemotherapy for acute lymphoblastic leukemia has devastating consequences and seems to have occurred with depressing regularity.[28]

Wrong medication was the most common type of drug error (48%) occurring perioperatively, followed by overdose (38%), incorrect administration route (8%), under dosing (4%) and omission (2%). Opioids, cardiac stimulants, and vasopressors were the most common culprits. Forty-two percent of wrong medication administration occurred following syringe swap, Drug ampoule swap occurred in 33%, and the wrong choice of drug was made in 17%. The first, second, and third most frequent causes of overdose involved a misunderstanding or preconception of the dose (53%), pump misuse (21%), and dilution error (5%).[4]

In the critical care or high dependency units, errors most often originated in the administration phase (44%) in ICU in

a study by Latif et al.[29] The most common error type was omission (26%). Among harmful errors, dispensing devices (14%) and calculation mistakes (9.8%) were more commonly identified to be the cause in the ICU compared to the non-ICU setting.

Medico-legal consequences

Medical errors can have profound ramifications for patients and families. Once the error has reached the patient, the medical provider, patient and their families are helpless. It adds significant cost to medical treatment, increases morbidity (disability) and may even lead to mortality. Employers, consumers and taxpayers are increasingly demanding that providers of medical care be held more accountable, particularly as the costs of health insurance continue to rise. Several organizations have developed and devoted exclusively to enhance patient safety. Hospitals and doctors can end up footing upwards of million dollar settlements for medical malpractice cases.

It is a chilling reality – one often overlooked in annual mortality statistics: Preventable medical errors persist as the n° 3 'killer' in the U.S. – preceded only by heart disease and cancer – claiming the lives of some 400,000 people each year.[30]

Ninety-three claims (with a total cost £4,915,450) filed under ''anesthesia'' in the NHS Litigation Authority database between 1995 and 2007, alleging patient harm directly by drug administration error or by an allergic reaction, were analyzed. Alleged errors were categorized using systems employed by the National Coordinating Council for Medication Error Reporting and Prevention, the American Society of Anesthesiologists Closed Claims Project and the UK Health and Safety Executive. The severity of outcome in each claim was categorized using adapted National Patient Safety Agency definitions. Sixty-two claims involved alleged drug administration errors (total cost £4,283,677) and 15 resulted in severe harm or death. Half alleged the administration of the wrong drug, in most (16) a neuromuscular blocker. Of the claims alleging the wrong dose had been given (25), nine alleged opioid overdose including by neuraxial routes. The most frequently recorded adverse outcomes were 'awake-paralysis' (19 claims; total cost £182,347) and respiratory depression requiring intensive care treatment (13 claims; total cost £2,752,853). Thirty-one claims involved allergic reactions (total cost 631,773 pounds). In 20 claims, the patient allegedly received a drug to which they were known to be allergic (total cost £130,794). All claims in which it was possible to categorize the nature of the error involved 'human error'. Fewer than half the claims appeared likely to have been preventable by an ''ideal double checking process''.[31]

Definition

Many investigators have adopted James Reason's classification from 1990, which draws widely from the aviation and nuclear industries as well as medicine[32] in which he classified errors as ''slips'', ''lapses'' and ''mistakes''. ''A slip results from a failure in the execution of an action, whether or not the plan behind it was adequate to reach its objective''.[32] Slips are said to be skill-based, occurring during the execution of smooth, automated and highly integrated tasks that do not require conscious control or problem solving.[33] For example, writing the ''year'' incorrectly in the date shortly after a new year is a slip.[21] ''Lapses involve memory failure, and may only be apparent to the person who experiences them'',[32] an example being forgetting to administer antibiotic prophylaxis prior to tourniquet inflation. Slips and lapses occur when actions do not go as per the plan, mistakes happen when a plan proves insufficient. The operator is cognizant of the problem and begins to use rules or knowledge to solve it. ''A mistake is likely to occur when knowledge or rules are lacking''.[32] For example an anesthesiologist was condemned of manslaughter after failing to identify a disconnected tracheal tube for a prolonged period, until the patient experienced a cardiac arrest and unfortunately perished.[21,34]

What is a medication error?

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines medication error as ''A medication error is 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. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use''. The Council urges medication errors researchers, software developers, and institutions to use this standard definition to identify errors.

Classification

Moyen et al.[35] compiled a few definitions in the year 2008 (Table 2). On July 16th, 1996, NCC MERP adopted a Medication Error Index that classifies an error according to the severity of the outcome (later revised in Feb 20, 2001). The index considers factors such as whether the error reached the patient and, if the patient was harmed, to what degree (Fig. 1). We have simplified and given a practical classification of medication errors during anesthesia in Table 3. Medication errors can occur either during preparation, administration or record keeping.

Genesis of error

The Generic Error Modeling System distinguishes failures in decision making (mistakes) from failures in the implementation of decisions (action failures).[32] Action failures, often made unconsciously, are typically slips or lapses. Thaler and Sunstein have presented a view that places less emphasis on the distinction between actions and decisions, and more emphasis on the degree to which the underlying cognitive processes are automatic or conscious.[36] In this view, rule-based errors have much in common with slips and lapses. Wegner has stressed the point that conscious effort to avoid

Table 2 Definitions compiled by Moyen et al.[35] in 2008.

Near miss	The occurrence of an error that did not result in harm.
Slip	A failure to execute an action due to routine behavior being misdirected
Lapse	A failure to execute an action due to lapse in memory and a routine behavior being omitted.
Medical error	The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.
Medication error	Any error in the medication process, whether there are any adverse consequences or not.
Adverse drug event (ADE)	Any injury related to the use of a drug. Not all adverse drug events are caused by medical error or vice versa.
Preventable ADE	Harm that could have been avoided through reasonable planning or proper execution of an action.

error may, ironically, have the opposite effect.[37] Taken collectively, a key message of this substantial body of research is that simply trying harder to avoid errors is unlikely to be successful on its own: it is also necessary to make processes and systems safer.[38]

Cooper and colleagues[6] have identified several risk factors in a critical incident analysis to study preventable mistakes. Maximum errors were due to either inadequate experience (16%) or due to inadequate familiarity to equipment or device (9.3%) whereas haste and inattention or carelessness, each amounted to 5.6% of errors during anesthesia.[39] In the parallel world of aviation, specifically on the flight deck; with very similar safety and error issues, these same trends are reflected. The top three causes in both environments are identical; unfamiliarity with situation, unfamiliarity with equipment and failure to follow your own prescribed safety protocols (pre-flight check versus machine check).

Various other factors exist in operating rooms giving rise to a high incidence of medication errors during the conduction of anesthesia. Lack of staff, overtime and odd working hours, inattention, poor communication, carelessness, haste

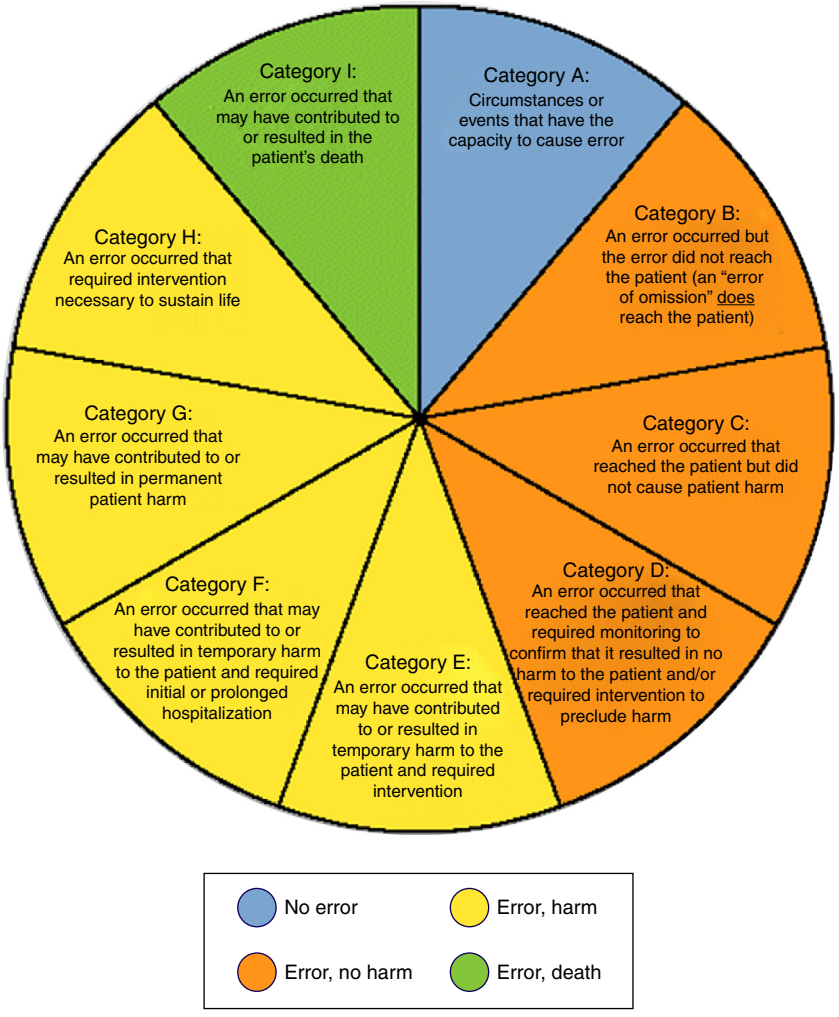

Figure 1 National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP, 2001).

Table 3 Practical classification of medication errors during anesthesia.

Errors during	Errors observed
Preparation of the drug	Similar looking vials/ampoules placed together (misidentification of ampoules) Unlabeled syringes Not checking the label (including expiry date) prior to administration Different concentration in the syringe and incorrect label. (Incorrect dilutions esp. relevant in pediatric patients).
Administration of the drug	Near misses. Wrong patient identification. Incorrect dose (inadequate or in excess) esp. in pediatric patients. Different personnel for preparation and administration of drug. Syringe swap. Wrong route of administration. Incorrect timing of administration. Omission, repetition or substitution of drug.
Recording of the drug delivered	Adverse event not recognized. Reluctance amongst doctors to admit the error. Failure to report an error during medication.

and fatigue are the common factors related to medical and paramedical personnel.[19,40–45] Causes of medication administration errors are tabulated as unsafe acts, local workplace culture and organizational decisions in Table 4.[46]

Table 4 Causes of medication administration errors in hospitals.[46]

Category	Causes
Unsafe acts	Slips and lapses Rule/knowledge based mistakes Violations Others
Local workplace factors	Patient Policies and procedures Ward based equipment Health and personality Training and experience Communication Interruption and distraction Workload and skill mix General work environment Medicines and supply storage Local working culture Supervision and social dynamics
Organizational decisions	High level/strategic decisions.

Possible management of erroneous drug administration

Training of anesthesiologists begins with preparation, labeling and arranging drugs before start of a case. Errors may occur due to multiple reasons; lack of experience, low vigilance (especially during maintenance of anesthesia), inappropriate labeling/identification/selection or stressful operation theater milieu. Medication errors by anesthesiologists in operation theater or intensive care units can unfortunately be fatal. Since these errors are preventable and potentially lethal, every attempt should be made to reduce these errors in order to provide safe anesthesia.

Often drug errors that occur cannot be reversed. The best way to 'treat' drug errors is to prevent them. More than half

Table 5 Recommendations by Jensen et al.[48]

1	The label on any drug ampoule or syringe should be carefully read before a drug is drawn up or injected.
2	Legibility and contents of labels on ampoules and syringes should be optimized according to agreed standards in respect of some or all of font, size, color and the information included (NB, there may be some disagreement on the detail of how this should be achieved).
3	Syringes should be labeled (always or almost always).
4	Formal organization of drug drawers and workspace should be used with attention to: tidiness; position of ampoules and syringes; separation of similar or dangerous drugs; removal of dangerous drugs from the operating theaters.
5	Labels should be checked specifically with a second person or a device (such as a bar code reader linked to a computer) before a drug is drawn up or administered.
6	Errors in intravenous drug administration during anesthesia should be reported and reviewed.
7	Management of inventory should focus on minimizing the risk of drug error (e.g.; a drug safety officer and/or a pharmacist should be appointed for the operating theaters and any changes in presentation should be notified ahead of time).
8	Similar packaging and presentation of drugs contribute to error and should be avoided where possible.
9	Drugs should be presented in prefilled syringes (where possible) rather than ampoules (either for emergency drugs or in general).
10	Drugs should be drawn up and labeled by the anesthetist who will administer them.
11	Color coding by class of drug according to an agreed national or international standard should be used – of the syringe, part of the syringe, or of the syringe or ampoule labels.
12	Coding by syringe position or size or by the needle on the syringe should be used.

Table 6 Brief description of similarities and differences between ISO 26825:2008 and the Labeling recommendations.[46]

	ISO 26825:2008 (or related standards)	Labeling recommendations
Clinical situations where labels should be used in anesthetic practice	On syringes containing medications used during anesthesia	All other medications and all containers and lines prepared or administered by anesthesiologists, including: Infusions Injections for use on the sterile field Medications in syringes that will accompany patients to other clinical areas Lines and catheters
Information required	Pre-printed generic name of medication Concentration of syringe contents	Depends on label type. For bags, bottles and syringes label inclusions are as follows: Patient name (given name and family name) Patient Identifier (ID) Active ingredient/s (medicine/s) added to the bag or syringe Amount of medicine/s added (including units) Volume of fluid (mL) – total in bag, or syringe Concentration (units/mL) Diluent (for syringes) Date and time prepared Prepared by (signature) Checked by (signature) Route of administration (where not specified by wording and color)
Color coding and border indicative of medication class		Route of administration

Table 7 APSF consensus recommendations for improving medication safety in the operating room.[49]

Standardization	High-alert drugs (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to use form that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically controlled smart device containing a drug library. Ready-to-use syringes and infusions should have standardized fully compliant machine-readable labels.
Technology	Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (barcode reader) and a mechanism to provide feedback, decision support, and documentation (automated information system). Additional ideas.
Pharmacy/prefilled/premixed	Routine provider-prepared medications should be discontinued whenever possible. Clinical pharmacists should be part of the perioperative/operating room team. Standardized pre-prepared medication kits by case type should be used whenever possible.
Culture	Establish a ''just culture'' for reporting errors (including near misses) and discussion of lessons learned. Establish a culture of education, understanding, and accountability via curriculum and CME. Establish a culture of cooperation and recognition of the benefits of STPC within and between institutions, professional organizations, and accreditation agencies.

APSF, Anesthesia Patient Safety Foundation.

of surveyed people believed that suspending doctors who have committed clinical errors is an effective prevention strategy.[47] There are various evidence-based recommendations of which a few are quoted in Tables 5–7.[46,48,49]

Pre-printed peel-off flag labels on ampoules and vials are a less expensive alternative to pre-filled syringes to facilitate correct labeling. The medication name on user-applied labels should be matched to that on the relevant ampoule

or vial at the time of drawing up any medication. All lines and catheters should be labeled. Any medicine or fluid that cannot be identified (e.g., in an unlabelled syringe or other container) should be considered unsafe and discarded.[37]

In the era of robotic and more advanced surgeries, it is time that anesthesiology advances in engineering thereby enhancing safe patient care. The envisioned fluid delivery system, named VEINROM distinguishes the fact that prime cause of EDA is the adaptation of the universal Leur locking mechanism to all prevalent intravenous drug delivery systems. Presently all kinds of syringe ports on the fluid delivery system are able to interlock with any syringe nozzle by nature of the inherent Leur design, thus predisposing an adverse event to occur. VEINROM proposes one syringe port for each of the seven most common drug categories used in anesthesiology and critical care.[50]

Conclusion

All medical errors do not cause harm. No anesthesiologist intentionally executes a mistake, but errors are unforgiving as they can cost a human life. In an era where patients' knowledge and awareness about diseases and their management is increasing, clinicians need to be more vigilant to avoid unfortunate outcomes and medico-legal claims. All efforts should be made in reporting and prevention of medical drug errors.

Current safety protocols in intravenous drug delivery have not changed over the past 60 years. We think it is time to incorporate electronic and digital concepts to encourage evolution of anesthesia-related drug delivery system.

We infer that ''to err may be human, but in healthcare, to err repeatedly is foolish and perhaps criminal''.

Conflicts of interest

The authors declare no conflicts of interest.

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