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Review Article

Medication safety in the operating room: literature and expert-based recommendations

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Abstract

Human error poses significant risk for hospitalized patients causing an estimated 100,000 to 400,000 deaths in the USA annually. Medication errors contribute, with error occurring in 5.3% of medication administrations during surgery. In this study 70.3% of medication errors were deemed preventable. Given the paucity of randomized controlled studies, we undertook a rigorous review of the literature to identify recommendations supported by expert opinions. An extensive literature search pertaining to medication error, medication safety, operating room, and anaesthesia was performed. The National Guidelines Clearinghouse was searched for any anaesthesia or operating room medication safety guidelines.
A total of 74 articles were included. Recommendations were tabulated and assigned points based on a scale revised from a prior study. A total of 138 unique recommendations were identified, with point tallies ranging from 4 to 190. An in-person focus meeting occurred, where the 138 recommendations were reviewed, combined and condensed. A modified Delphi process was used to eliminate items found to be unimportant or those unable to be quantified (e.g. "minimize fatigue"). A total of 35 specific recommendations remained. Adverse events as a result of medication errors occur frequently in the operative setting. There are few rigorous studies to direct medication safety strategies, but this should not lead us to do nothing. The overwhelming consensus regarding best practices should be accepted, and the recommendations implemented. Our list of recommended strategies can hopefully be used to assess local vulnerabilities and institute system solutions.

Key words: anaesthesiology; medication safety; operating room

Human error poses significant risk for hospitalized patients, leading to patient harm and death. Preventable adverse events are estimated to result in between 100,000 to 400,000 deaths in the USA each yr.[1–5] Medication errors contribute to preventable adverse events,[6] and the errors that occur in the operating room are especially problematic, as the anaesthesia provider is typically the only practitioner involved in the entire process, prescribing, formulating, dispensing, and administering the medication, thus removing the protection of double checks that exist in other hospital areas.[7] In one of the only prospective,

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observational studies of medication errors in the operating room, Nanji and colleagues[8] reported that 193 of 3671 (5.3%) medication administrations during 277 operations involved a medication error and/or an adverse drug error, and found that 79.3% were preventable. This rate confirms that of previous retrospective studies. In a survey of South African anaesthetists, 94% reported that they had made at least one error; 22.6% reported at least four errors.[9] A recent study involving self-reported medication errors found an error or near miss in 52/10,574 cases, for an incidence of 0.49%, or one in every 203 cases,[10] echoing the rate reported from New Zealand, (1:133 anaesthetics);[11] South Africa, 0.37% (1:274 anaesthetics);[12] and Japan, 0.22% (1:450 anaesthetics).[13] Common errors include wrong dose as a result of either miscalculation of dose, concentration, or infusion rate; substitution (syringe or ampule/vial swap); repetition (extra dose) and omission (missed dose).[11 14] In all studies, the majority of reported errors were associated with minimal or no harm; however, there are a distressing number of case reports of less common, but lethal or potentially lethal errors, including wrong route,[15–17] miscalculation of dilution or failure to dilute,[18] misprogramming of infusion pumps,[19] administering known allergic drug, and failure to flush a line after a drug.[20 21]

Various techniques to reduce medication errors have been proposed since John Snow advocated the use of a specific chloroform mask to reduce concentration errors with inhaled anaesthesia.[22] Unfortunately, there are few randomized controlled trials that demonstrate the ability of a specific technique to reduce the rate of medication error. Jensen and co-workers[23] recognized this issue in 2004, and undertook a systematic review to identify the evidence available at the time, and to provide recommendations that were at least supported by the Canadian Task Force on Preventive Health Care Level III evidence (i.e. "opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees").[24] In the 12 yr since that publication, numerous consensus statements have been released and a set of recommendations from the Anesthesia Patient Safety Foundation.[7] In the absence of sufficient prospective, randomized trials with evidence on which to base practice, we undertook a rigorous literature review to update Jensen and colleagues, by identifying those recommendations that at least are based on "the opinions of respected authorities"[23 24].

Methods

We performed an extensive literature search to identify publications pertaining to medication error and medication safety in the operating room. Searches included PubMed, Google Scholar, and an internet search for national recommendations (Joint Commission [JC], Center for Disease Control [CDC], Association of periOperative Registered Nurses [AORN], Institute for Safe Medication Practices [ISMP]) as detailed below. The National Guidelines Clearinghouse was searched for any medication safety guidelines for anaesthesia or the operating room.

A PubMed search using the MeSH terms 'Drug/Medication Error, Drug/Medication Safety, Operating Room, Anaesthesia' was conducted. In addition, the references of all articles reviewed were checked for additional pertinent articles. Only peer-reviewed articles were included; we assumed all case reports and editorials were peer reviewed. A review of the retrieved titles was performed by two of the authors for inclusion. We excluded foreign language articles unless the abstract was in English and provided enough detail to be included. If neither the abstract nor article could be retrieved through our academic institutions, the article was excluded. As anaesthesia systems, drugs and equipment have changed significantly over the past decades, we limited the search to articles published between 1/1/1994 and 1/1/2014, a 20-yr span.

Inclusion and exclusion criteria were pre-determined, and revised after the first 10 articles had been reviewed. For inclusion, articles had to contain either recommendations regarding medication safety, or cite contributing factors for errors. Errors or recommendations involving physical mistakes such as a needle tip entering the artery during a regional block, an inadvertent spinal puncture during epidural placement, an adverse drug event not as a result of error or violation (de novo anaphylaxis), or awareness under anaesthesia because of equipment failure were excluded. In addition, drug decision errors were excluded unless it involved preventable harm (giving a drug where the patient was known to be allergic). Single case reports were excluded except in rare occasions, for example, a unique error occurred that was not addressed in other articles, or where it provided the background for a detailed review of the literature and expert opinion.

A search of the National Guideline Clearinghouse was performed using the search terms as listed above. In addition, a guideline or consensus statement mentioned in any reviewed publication was retrieved. We included international standards for medication safety (ISO), but did not include country specific standards.

Data extraction and collection

Each included article was reviewed by the first author (JAW) and by one other author. A specific data extraction form was completed for each article, noting the type of publication (guideline *vs* journal article), whether it was peer reviewed or not, and the method of compiling the recommendations or errors (scientific design, expert consensus, case series or report, literature review of published recommendations). A summary list of all recommendations was created in an iterative fashion.

Recommendations were graded according to the type of publication, using a point scale adapted from Jensen and colleagues[23] and modified by human factors engineers: recommendations based on studies with a scientific design were given a score of 8; recommendations based on a formal consensus of experts (e.g. the recommendations made by the Anesthesia Patient Safety Foundation) or a rigorous review of the literature were given a score of 6; recommendations by a group of experts (not reaching formal consensus or guideline level, but where the experts were widely published in the field of medication safety) were given a score of 4, recommendations based on a case series, such as surveys to collect recollections of errors, were given a score of 4, and individual case reports and editorials by a single individual was given a score of 2. Given the dearth of randomized controlled trials (RCTs), any publication that utilized a scientific design was awarded 8 points. These publications included randomized controlled studies, defined retrospective review of prospectively collected databases (national incident reporting systems such as the National Learning and Reporting System, or the Australian Incident Monitoring System, or local registries specifically created to monitor medication errors), observational studies, and an internet survey that invited anaesthetists to perform drug dilution calculations.