RESEARCH ARTICLE

Medication Errors in Anesthetic Practice in Brazil – an Observational Study

Authors:
Julio Cezar Mendes Brandão, MD PhD*[,1], Itamar Souza Oliveira-Júnior Msc, MD PhD[1], Patricia Snches, MD, Msc, PhD[1], João Henrique Silva, MD[1], Luis Antonio Diego, Msc, MD PhD[1], Luciano Costa Ferreira, Msc, MD[1],

Authors' affiliations:

[1] Discipline of Anesthesia, Department of Surgery - Federal University of Sergipe

***Corresponding author:** Julio Cezar Mendes Brandão
Discipline of Anesthesia, Department of Surgery - Federal University of Sergipe – Address: Rua Tennisson Ribeiro, 806, Apt 1002, Grajeru, Aracaju – SE – Brazil.
Zip code: 49040125
Email: juliobrand@hotmail.com

ABSTRACT

Introduction: There is increasing data collection in literature on errors in the drug administration chain. In anesthesiology, emergency and urgency situations favor errors in medications, however, it is not yet clear how some factors can impact the frequency of these errors.

Objective: To evaluate the impact of knowledge of important concepts and fundamentals related to quality and safety in anesthesia in the practice of safe anesthesia as a factor to prevent errors with medications. We tried to determine if the anesthesiologists and medical residents had experienced a medication error and to identify causal factors associated with that.

Method: Observational study with participants of the 61st Brazilian Congress of Anesthesia. The volunteers responded to a semi-structured instrument with issues related to the whole process that could trigger medication errors.

Results: A total of 337 volunteers (42.2% of Anesthesia Resident Physicians and 57.8% of Anesthesiologists) participated in the study. It was observed that 50.7% stated that they had already injected incorrect medications, with a significant difference ($p < 0.00$) between the Anesthesia Resident Physicians (43.6%) and Anesthesiologists (56%). A greater number of working hours and a greater number of hospitals in which they work caused higher percentages of professionals with medication errors. Among the professionals who reported

they had administered erroneous medications due to confusion with ampoules , 33.8% (n = 54) stated that they made a formal report of the adverse event with medications (ARP: 24.1% and MA: 39.2%). 96.9% (n = 155) of the professional ampoules of different medications (or concentrations thereof) in the same drug box (ARP : 93.1% and MA: 99%). In addition, 65.2% stated they have used the same syringe to prepare more than one anesthetic medication (ARP: 75.9%, and MA: 59%).

Conclusions: The percentage of medication errors was significant, and the need to implement policies that will guide the organization, distribution, allocation, and use of medications in the surgical center is evident.

Key words: Medication errors; quality; safety; anesthesia; labeling

1. Introduction:

The administration of medicines is part of multidisciplinary actions involving various professions in the health areas, as well as the logistics, administrative, and support teams. Initially, with the medical prescription, a series of tasks takes place in order to promote the drug delivery by the pharmacist, and it ends with its preparation and administration to the patients, which can be performed by different professionals within the surgical center[1]. In surgical centers, more specifically during the anesthetic act, an important peculiarity is observed: the anesthesiologist prescribes, selects the medication and administers it, which decreases the checking mechanisms. Adverse events and errors associated with patient care have increasingly been noticed, or at the very least, have been perceived more often, discussed, and even tried in courts[1-10]. Medication errors are defined as any avoidable events that have, in fact, or potentially, could have led to, inappropriate use of a medication. A “near miss” is defined as an event that did not involve the actual administration of a drug [7].

In research carried out in the United States, it has been shown that every year, ten thousand injuries occur in that country due to errors related to inadvertent administration of drugs with resembling nomenclatures, commonly called "sound alike drugs". It has been found that approximately 29% of drug-related errors result from the inability to accurately identify the drug to be administered[11].

This study aims to evaluate self-reported medication errors, including the frequency

and cause of medication errors in patients undergoing anesthesia, and the variables that may predispose professionals to making these errors. The anesthesiologists and medical residents were asked to complete a questionnaire describing medication errors or “near-misses” to identify the most common causal or contributing factors that lead to medication errors. In addition, quality and safety in anesthesia and the adoption of so-called safe practices by different anesthesiology services and their consequence in medication errors were also identified.

2. METHOD:

Ethical aspects and delineation: This is an observational study, developed through questionnaires, with medical participants from the 61st Brazilian Congress of Anesthesiology in 2014, who voluntarily, after reading and signing the consent form, answered a structured questionnaire with demographic questions, aspects related to work environment, as well as issues regarding the administration of medicines. This research was approved by the Ethics Committee in Research named Plataforma Brasil (CEP: 37641214.3.0000.5546). The respondents were assured of anonymity.

Research Instrument: MEDICATION ADMINISTRATION ASSESSMENT IN THE SURGICAL CENTER (MAASC)

The instrument used was composed of questions related to the whole process that can trigger medication errors. These questions were designed by the authors in collaboration with members of the Department of Biostatistics and Epidemiology in accordance with other studies in the literature related to this subject as well[1,3-11], which pointed out the important factors related to medication errors in anesthesia. In this instrument all the answers are set in a dichotomous way (yes / no) (Figure 1).

The questionnaire was composed of different sections. The first section requested demographic information and basic information related to the anesthesia practice such as the number of years of anesthetic training, the number of hospitals in which they work, how many hours are worked weekly, if they are board certified for practicing anesthesia as a MD, etc. The second section asked if the respondent had ever administered the wrong drug during the conduct of an anesthesia, questions about wrong labeling, near-misses, drug identification, ampoules with different concentrations of the same drug in the same bin, etc. Also the practitioners were asked if the medication errors were reported or not.

Questionnaire: Medication errors in anesthetic practice in Brazil – an observational study

Age:_____ Gender: (a)Male (b)Female Federation state: _____
How long have you finished your medical residence? _____ I'm a resident ( )
How many Hospitals do you work?_____
TEA: Yes ( ) No ( ) TSA: Yes ( ) No ( )
How many hours do you used to work weekly?
(a) 0-24h (b) >24 to 48h (c) >48 to 72h (d) >72 to 96h (e) >96h

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Have you ever seen any kind of mistake in administering medications at your shift? Yes ( ) No ( )

Have you ever found ampoules of different medications (or concentrations thereof) in the same box of medications?	Yes ( ) No ( )
Have you ever had difficulty distinguishing between different ampules due to the similarity and / or size of letters on them?	Yes ( ) No ( )
Do you work in services that label ampoules with bar codes which end up covering the medication name?	Yes ( ) No ( )
Have you ever seen ampules labeled with erroneous bar codes, with wrong names or wrong medication concentration?	Yes ( ) No ( )
n the surgical center, have you ever come across medications with expired date?	Yes ( ) No ( )
Do any of the places in which you work have a checklist program for anesthesia?	Yes ( ) No ( )
Have you ever made any formal reports of adverse drug events?	Yes ( ) No ( )
Do you usually identify the syringes you use during procedures?	Yes ( ) No ( )
If yes, how is it done:	Pen Labels Others
Do you use the same syringe to prepare more than one anesthetic medication?	Yes ( ) No ( )
Do you use the same syringe to prepare any adjuvant medication (non-anesthetic, such as corticosteroids, antibiotics, proton pump inhibitors, etc?	Yes ( ) No ( )
Have you ever made use of any ampoule with leftover medication in a new procedure with another patient?	Yes ( ) No ( )

Figure 1. Used questionnaire consisting of questions related to the whole process that can trigger medication errors.

Statistical analysis: Data analysis was performed using the SPSS Statistical Package (IBM®, Version 12.0). For comparison between groups, the t-test for unpaired sample was used for the quantitative variables and the Pearson Chi-Square test was used for the qualitative variables. All analyses were considered significant when $p \leq 0.05$.

3. RESULTS:

337 volunteers participated in this study. Twenty-two were excluded because they did not complete the adequate data filling, thus leaving 315 questionnaires for analysis. Of those, 42.2% (133) are Anesthesia Resident Physicians (ARP) and 57.8% (182) are Anesthesiologists (MA). The sample is predominantly male (62.5%), with a mean age of 38.9 ± 12.5 years. This sample isn't representative of Brazil anesthesiologists universally because there are more than 22,000 MD anesthesiologists in that year in Brazil. Despite that, we collected this data in the main anesthesia conference in that country, and we relied on the respondents who decided voluntarily to participate in our research.

Further epidemiological characteristics, as well as training related aspects among MA and ARP, are described in Table I (Table 1). Among the MAs, 85.8% (145) have a Specialist Degree in Anesthesia (SDA) and 24.7% (40) have a College Degree in Anethesia present in the with College Curriculum of Brazil (TSA), with a mean of 15.3 ± 11.8 years of medical school training.

Table 1. Demographic data.

Variables		Professional		p
		Residents (n=133)	Doctors (n=182)	
Age [1]		29,1±3,2	46,3±11,8	0,00*
Gender [2]	Male	60,2 (80)	64,3 (117)	0,26**
	Female	39,8 (53)	35,7 (65)	
Number of hospitals one works in [1,2]		2,2±1,6	3,2±1,5	0,00*
	1	42,5	14	0,00**
	2	24,4	22,7	
	3	11	22,7	
	4	12	23,8	
	>4	10,1	16,8	
Weekly workload[2]	0 - 24h	0,8	4,4	0,00**
	24 a 48h	0,8	17,6	
	48h - 72h	56,1	42,9	
	72 - 96h	34,1	25,8	
	> 96h	8,3	9,3	

[1]Variable expressed as mean ± standard deviation
[2]Variable expressed as a percentage

* t test for unpaired samples
** chi-square test

The MA group on average, works in more hospitals compared to the ARP group (ARP: 2.2 ± 1.6 and MA: 3.2 ± 1.5; p <0.00). The number of working hours was higher for the ARP group (ARP: 98.5%> 48h / week, MA: 78%> 48h / week, p <0.00) (Table I).

The MAASC instrument showed some significant differences between the percentage of errors observed in the MA and ARP groups. The following shows date for items on medication storage such as, "Have you ever found ampoules of different medications (or concentrations thereof) in the same box of medications?" - (P = 0.02). Results regarding labeling are as follows: "Do you work in services that label ampoules with bar codes which end up covering the medication name?" (p = 0.05), "Have you ever had difficulty distinguishing between different ampoules due to the similarity and / or size of letters on them?" (p = 0.02), and "Have you ever seen ampoules labeled with erroneous bar codes, with incorrect names, or wrong medication concentration?" (p=0.01). The last set of results is regarding expiration date: "In the operating room, have you ever come across medications with an expired date?" (p =0.02). Among all of those comparisons, the percentages were higher for the MA group while compared to the ARP. The percentages were higher for the ARP group on the items about procedures such as: "Do you use the same syringe to prepare more than one anesthetic medication?" (P <0.00), or "Do you use the same syringe to prepare some adjuvant medication (non-anesthetic, such as corticosteroids, antibiotics, proton pump inhibitors, etc)" (p <0.00). Medical anesthesiologists made more formal reports of adverse events than ARP which is show in the following question: "Have you ever made any formal reports of adverse drug events?"(MA: 32.4%, ARP: 17.3%, p <0.00) (Table III).

Table 2 : Answers with "yes answers" distribution

	Residents		Doctors		p
QUESTIONS	%	n	%	n	
Have you ever seen any kind of mistake in administering medications at your shift?	80,5	107	81,1	146	0,49
Have you ever found ampoules of different medications (or concentrations thereof) in the same box of medications?	91	121	97,3	177	**0,02**
Have you ever had difficulty distinguishing between different ampules due to the similarity and / or size of letters on them?	84,1	111	92,3	168	**0,02**

Do you work in services that label ampoules with bar codes which end up covering the medication name?		70,1	61	81,1	103	**0,05**
Have you ever seen ampules labeled with erroneous bar codes, with wrong names or wrong medication concentration?		18,1	23	30,3	53	**0,01**
n the surgical center, have you ever come across medications with expired date?		50,4	67	68,7	125	**0,02**
Do any of the places in which you work have a checklist program for anesthesia?		63,8	83	71,3	129	0,11
Have you ever made any formal reports of adverse drug events?		17,3	23	32,4	59	< **0,00**
Do you usually identify the syringes you use during procedures?		97	129			
If yes, how is it done:	Pen	61,9	73	62,2	84	0,65
	Labels	37,3	44	28,1	38	
	Others	0,8	1	9,6	13	
Do you use the same syringe to prepare more than one anesthetic medication?		71,4	95	51,1	92	< **0,00**
Do you use the same syringe to prepare any adjuvant medication (non-anesthetic, such as corticosteroids, antibiotics , proton pump inhibitors, etc?		89,5	119	67,4	122	< **0,00**
Have you ever made use of any ampoule with leftover medication in a new procedure with another patient?		59,4	79	65,4	119	0,17

As a result of confusion of ampoules, 43.6% (58) of the ARP's and 56% (102) of the MA's stated that they have injected erroneous medications (p = 0.00). As for the question "Did you confuse ampoules and open the wrong vials," 84.2% (112) of the ARP's and 89.6% (163) of the MA's said yes (p = 0.11). No significant epidemiological and medical training differences were observed in both ARP and MA groups regarding the question "Did you

inject wrong medications because an ampoule confusion?" (Table II).

Table 3. Analysis of epidemiological and work-related characteristics

		Professionals					
		Residents			Doctors		
		Have administered wrong medication					
Variables		Yes	No	p	Yes	No	p
Age		29,4±3,9	28,9±2,3	0,43	46,4±11,2	46,1±12,7	0,83
Gender	Male	53,3 (31)	65,3 (49)	0,21	64,7 (66)	63,8 (51)	0,51
	Female	46,6 (27)	34,7 (26)		35,3 (36)	36,3 (29)	
Time Workload	0-24h	1,7 (1)	0	0,11	2,9 (3)	6,3 (5)	0,31
	24-48h	0	1,4 (1)		16,7 (17)	18,8 (15)	
	48-72h	67,2 (39)	47,3 (35)		40,2 (41)	46,3 (37)	
	72-96h	25,9 (15)	40,5 (30)		27,5 (28)	23,8 (19)	
	>96h	5,2 (3)	10,8 (8)		12,7 (13)	5 (4)	
Number of hospitals one works in		2,6±1,9	1,9±1,2	0,02	3,2±1,4	3,1±1,6	0,46

It was found that 33.8% (n = 54) of those who declared they had administered incorrect medications due to confusion of ampoules (n = 160) stated that they made a formal report about the adverse event with medication (ARP: 24.1% and MA: 39.2%). 96.9% (n = 155) found ampoules of different medications (or concentrations thereof) in the same drug box (ARP : 93.1% and MA: 99 %). Lastly, 65.2% stated they had made use of the same syringe to prepare more than one anesthetic medication (ARP: 75.9% and MA: 59%).

4. DISCUSSION: The results of this study point to a significant and persistent problem in anesthesiology related to errors in medication administration. Nevertheless, there has been little discussion about it. The percentages of both residents and anesthesiologists who injected incorrect medications, and the presence of ampoules of different medications (or concentrations of the same medication) in the same drug box, proved to be an important factor in determining medication administration errors. The results showed 99% percent of positive responses to such a question among MA's who have already injected incorrect medications in patients eventually.

Variables such as weekly work hours and medication errors show a clear relationship between both, evidencing the association

between excessive workload and exhausting labor journeys with the increase of errors incidence in medications. The same is true for the number of hospitals where anesthesiologists and residents work. There is a direct relationship between the quantity of hospitals in which individuals work and the increasing working hours.

In Brazil, unlike developed nations, it is very common to find ARP's working as general practitioners in their spare time, which is highly objectionable, as this may negatively influence the dedication of their time to the specialty. This fact also adds to the job market situation in the area of Brazil, where it is difficult to establish a direct link with the institutions, and that ends up favoring the accumulation of hospitals in which each individual needs to work.

The vast majority of surveyed professionals eventually encountered medication errors in their work routine, reaching 81% of the professionals surveyed. Also, on a very frequent basis, professionals cite that they found the same medication but with different presentations / concentrations in the same storage box, which can lead to confusion during routine use, more often at critical times of urgency and emergency. There are several studies in the literature[1,5,7,9,12] evidencing the administration of medications in inadequate concentrations to the respective route used, leading to complications and increasing hospital morbidity. Jacobson et al[12] cite the use of morphine in an equivalent dose for epidural (1-2mg) being at times erroneously administered via spinal anesthesia, in which the dose should not exceed 150 mcg, about 10 times lower than the presentation of the ampoule for epidural anesthesia. This may occur as a result of confusion in medication administration due to similar ampoules being allocated in the same storage box by the team that organizes the medications in the surgical room. It is not uncommon to find ampoules of the same drug with different concentrations but with the same or very similar uniformity standard of the label, description, size, shape, color, etc. The only difference is in the zero number position (order of magnitude) showing the concentration, which greatly facilitates confusion when selecting ampoules. Support team members who assemble medication boxes sometimes lack the proper training to differentiate these ampoules and do not know how much this can affect clinical behaviors by allocating them together in one box with the name of the medication. For instance, a box of medications labeled "morphine", which doesn´t point out the specific concentration it should contain in the vial, causes all "morphines" of different concentrations to be placed in the same box, culminating in the same error and increasing the chance of erroneous administration to patients, since different concentrations are administered by different routes (venous, epidural, and spinal anesthesia, for example).

In case the anesthesiologist does not check the dose and characteristics of the ampoule, he/she may end up using it in the wrong route of administration. When given in an inadequate dose as mentioned above, with a different order of magnitude (10 or 100 times more, for example), the result, in the case of morphine specifically, might be a

respiratory failure, leading to the need for orotracheal intubation and invasive ventilation support, which increases the length of hospital stays and the morbidity of these patients [12].

A possible explanation for the greater prevalence of these reports among MAs is due to the work experience itself. Since MA's have experienced more stressful situations, they become more attentive to the issues of labeling, storage, and validation of medications. They incorporate those habits into their routine. The learning curve requires that APR's manage items such as performing the procedure, filling in anesthetic records, deadlines, and surgical steps, which in many cases divert some of the attention that should be poured into checking the items.

There are also other factors that make recognition of ampoules and medications difficult. The similarity, size, colors, letters and model of the ampoules were cited as significant factors in the confusion [1,2,4-10,13-15]. Considering all the training received by anesthesiologists, those arguments should not be used as justification for the medication errors. Such medical specialty is often subject to stressful situations and is commonly exposed to emergency and urgency surgeries, causing decision-making while choosing numerous medications and other conducts in the anesthetic induction to be fast, fomenting the error by the lack of complete analysis of ampoules and all other items of use in a situation of stress. Often, in these stressful situations which require a prompt response, the anesthesiologist presumes that in the respective boxes there are medications in the doses established for the boxes (or according to the history of that place), incurring a serious error.

In order to modernize the medication delivery process, computerization has been increasing, as well as the labeling of ampoules with bar codes[13,14,16,17] which will streamline the medication orders processing. These actions may look good and safe however, it is not uncommon to find reports about bar code labeling which ended up covering the ampoule part that is supposed to show the basic and essential information of the medications. This unfortunately brings no rare accounts describing the finds of labeling errors, causing the wrong medications to be injected into the patients. All of this leads us to the surprise in this research, that almost a third of the interviewees eventually in their practice came across errors related to the packaging process of ampoules with incorrect bar codes. This indicates something very serious, evidencing an error in the attempt to correct other possible errors, bringing even more insecurity to the safety culture practice in anesthesiology [13,14,16,17].

There is also a large gap in the number of respondents who reported having committed medication errors and those reporting adverse events. Much information is still lost with this large percentage of omitted data, evidencing how much the stimulating adherence to checklist programs and reports of adverse events still needs to be developed. There are many cultural barriers to be overcome.

Nanji et al.[5] ,in a study published in Anesthesiology, have shown that one in

twenty medications given preoperatively, results in medication error or an adverse event. They also showed that more than a third of medication errors led to some harm to patients, demonstrating very high and alarming numbers.

This was a pioneering work on the subject in Brazil with such public. We have been able to approach doctors from all states of the country, even though the sample of the professionals which attend conferences of the specialty is skewed. Faced with alarming numbers, we realize the need to implement policies that could guide the organization, distribution, and allocation of medications in the surgical center. It is also clear the importance of medication identification and checking by the professional who will administer the medication to the patient as they are directly responsible, as well as stimulating the updating of professionals who work directly with patients in the perioperative period. Educational policies and training of resident physicians as well as training of more critical professionals should be fostered in order to change these numbers.

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