ORIGINAL ARTICLE

Nurses' violations of a medication administration protocol in Italy: an observational study

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Abstract

The most common errors in hospitals involve the medication administration process and many of these errors are committed by nurses. Errors often result from violations of standardized procedures, safety regulations, or protocols defined within a specific healthcare context for increasing patients' safety. Usually, it is difficult to quantify and analyze violations because they often do not produce immediate consequences for patients' safety. The aim of this research was to investigate the self-perceived and actual rate and nature of violations of a standardized medication administration protocol. For this, we conducted a study based both on systematic covert observations and self-reported measures in a sample of nurses working in different wards of two hospitals in Italy. The main results indicate that, even though the perceived level of adherence to the standardized medication administration protocol was high, the actual rate of adherence was very low. In particular, we observed that nurses are rather observant regarding items that have a clear relation to hazard, and less observant for those that have more to do with their own responsibilities than safety. Moreover, differences in nurses' adherence to the medication administration protocol found among the different wards and the two hospitals suggest that, other than individual factors, organizational and environmental conditions also play a crucial role in the occurrence of violations. Interruptions to work activities were also observed revealing that most of them are not generated by external factors, as expected, but by violations themselves.

Identifying violations and their causes is of crucial importance to finding strategies to reduce them, and consequently to reduce errors that imperil patients' safety.

Key words

Medication administration protocol, Violations, Covert observations, Interruptions, Patient safety

1 Introduction

The U.S. Food and Drug Administration affirms that the most common errors in hospitals regard the medication process [1, 2]. It has been estimated that there is a rate of approximately 1 (reported) error per hospital patient per day [3] and that nurses are usually responsible for 50% of these adverse events. Given the extreme importance of the medication

process, it is necessary to find strategies that make it as safe as possible. One option consists in redesigning the nurses' work environment: taking into account their mental overloading and determining how it can be reduced and how the limits and capabilities of performance can be accommodated [4, 5]. For this purpose, cognitive ergonomics suggests that it can be useful to define standardized procedures that must be followed by nurses during the medication administration process. In fact, listing the actions that must be performed should be useful to help nurses to remember what they have to do, thereby limiting their memory efforts and, consequently, reducing the risk of medication errors [6, 7]. Unfortunately, it has been shown that, once defined, these standardized procedures are often violated and that this represents a frequent antecedent to errors [8]. Violations are deviations from procedures, safety regulations, standards or rules defined within a specific organizational context for achieving the expected results. Violations are important from an organizational point of view because they indicate a deliberate decision of individuals to not respect the rules that the organization takes as its safety standards [9]. They differ with respect to errors; in violations, there is awareness of not operating in accordance with the given protocols. Violations generally occur in social contexts and are generated either by negative motivational factors (e.g. bad example from other members of the group, poor supervision, lack of interest, etc.), or by a discrepancy between given procedures and actual norms in a community of practice [10]. Thus, in some circumstances, violations can also occur for good reasons (goal conflicts, the prescribed procedure does not work, etc.). Reason [8] defines these as 'necessary violations', since, if they do not occur, they lead to a problem instead of to a solution. Generated by positive or negative factors, violations related to the medication administration protocols require further study to better understand why, when and how they occur. In fact, they are mostly self-reported events, habitually underreported [11-16] as observed by Flynn et al. [17] who estimated that the ratio of violations and errors detected by observation and by voluntary reports is 457:1.

The present study was aimed at assessing the magnitude of the issue of medication administration violations in two hospitals in Italy, comparing the frequency and types of self-reported violations of a standardized medication administration protocol with those observed using a covert observational method. Observation method, originally developed in 1962 [12], is considered the most accurate technique for estimating medication violation and error frequency [11, 17, 18]. Thus, in order to avoid or, at least, limit the Hawthorne effect, we decided to conduct covert observations.

In addition, to identify the possible sources of observed violations, they were correlated with the total number of medication administrations performed in each nurse's shift, his/her awareness of being observed, and his/her perceived level of fatigue and stress at the end of each shift.

Interruptions which occurred during medication administrations were recorded and analyzed. Empirical evidence exists on the contribution of interruptions to the medication administration errors [19-21]. Interruptions are defined as anything that stops the workers from performing an immediate task, thereby causing lapses of attention, with a consequent alteration of the cognitive workflow. They are very frequent especially in complex workplaces, such as hospitals, in which workers engage in many tasks at once and where they are recognized as one of the most significant potential threats to patient safety [22, 23].

2 Materials and methods

2.1 Study design and data collection

The study was performed in two different public hospitals located in the north of Italy with a total of 259 beds (155 in one hospital and 104 in the other one) distributed in different wards.

The study included two different phases:

- Phase 1 – self-evaluation study: 140 nurses working in different wards of the two hospitals were asked to self-evaluate their adherence to the standardized medication administration protocol previously implemented by the coordinators of the nursing staff and in use in the hospitals routine starting from one year before the beginning of the present study. The medication administration protocol includes 24 actions that nurses are supposed to perform from the beginning to the end of the medication administration process with each patient, plus 5 actions that must be performed once immediately before commencing the administration process (i.e. check of the material available on the medicine trolley; check of the time at which the process must be started, etc.) (see Table 1 for the complete list of the actions). For the self-evaluation, nurses were asked to indicate their perceived level of adherence to each of the 29 actions included in the administration protocol using a 4-point Likert scale (0 = never, 1 = less than 50 percent of times, 2 = more than 50 percent of times, 3 = always).

- Phase 2 – observational study: due to the practical difficulties of performing covert observations during the medication administration process (i.e. training covert observers, doing observations during different shifts, and performing observations in different wards), only 95 out of 140 nurses were randomly selected to participate in Phase 2. Each of these 95 nurses was observed by a covert trained observer, who was asked to indicate how many times he/she correctly performed each single action included in the standardized medication administration protocol. In order to compare these data with those collected in Phase 1, data collected during each nurse's shift were added and transformed in the same 4-point scale (0 = never, 1 = less than 50 percent of times, 2 = more than 50 percent of times, 3 = always) used for the self-evaluation study.

Observers were also asked to indicate if any interruption occurred during the medication administration and what the source of the interruption was. To do this, a checklist was developed regarding how to detect and classify the occurring interruptions. The content validity of the tool was checked by 6 experts who were the 2 head nurses (one per hospital) and 4 charge nurses of different wards. This included the following 8 sources of interruptions: 1) colleagues; 2) physicians; 3) patients' relatives; 4) phone calls; 5) other patients; 6) external operators (ambulance staff, cleaning staff, etc.); 7) emergency situations; 8) violation-driven interruptions. The last category included those "self-generated" interruptions related to or caused by the protocol violations (e.g. the nurse did not bring the medicine trolley into the patient's room and had to interrupt the medication administration to go out and look for the medicine, etc.).

The observers were 8 student nurses in clinical training (4 per hospital) specially trained for this research study. To facilitate convert observations, trying to avoid or limit as much as possible the Hawthorne effect, nurses were told that students would follow them during medication administration to practice. To guarantee validity and credibility of the observation research, it was crucial to minimize the bias caused by the observation itself. Therefore, the students were first educated in observation techniques and employed only after a reliability score, based on agreement between different observers, was reached 90% after repeated practice of recording the drug administration process, and investigated for their reliability.

2.2 Subjects

A total of 140 nurses working in seven different wards (internal medicine, surgery, cardiology, orthopedics, pediatrics, obstetrics and medical oncology) of the two hospitals and selected followed a convenience sampling approach, were included in the first part of the study (self-evaluation study).

A subgroup of 95 operators was then randomly chosen to participate in the second part of the study (observational study). Since the entire medication protocol included 29 single actions and each participant was observed during 1 to 4 shifts of medication administration (the number of patients for each shift varied from ward to ward), the total number of observed

actions was 3382 (calculated as the number of patients x number of actions x number of shifts). At the end of each working shift, all the nurses included in the observational study were asked to indicate their perceived level of fatigue and stress using a visual analogue scale (VAS).

In order to guarantee the participating nurses complete anonymity and to avoid the possibility that matching their data would lead to their identification, the only personal variables collected were the following: gender, ward to which they were assigned, and seniority. The study, including the use of covert observation method, was approved by the local ethical committee of the two hospitals. Covert observations were performed by 3 trained observers, who signed confidentiality agreements to protect the identities of the nurses they were observing. The nursing staff were aware that medication administrations were being observed, and agreed to sign the informed consent, but were not aware of the identity of the observers. The timing of the observations depended on when observers trained in the procedure were available.

3 Results

3.1 Characteristics of the samples

The 140 nurses participating in the self-evaluation study were 115 females and 17 males, plus 8 who did not declare their gender. A subgroup of 92 operators, 82 females and 13 males, was then randomly selected to participate in the observational study. Years of seniority of the two samples are presented in Figure 1.

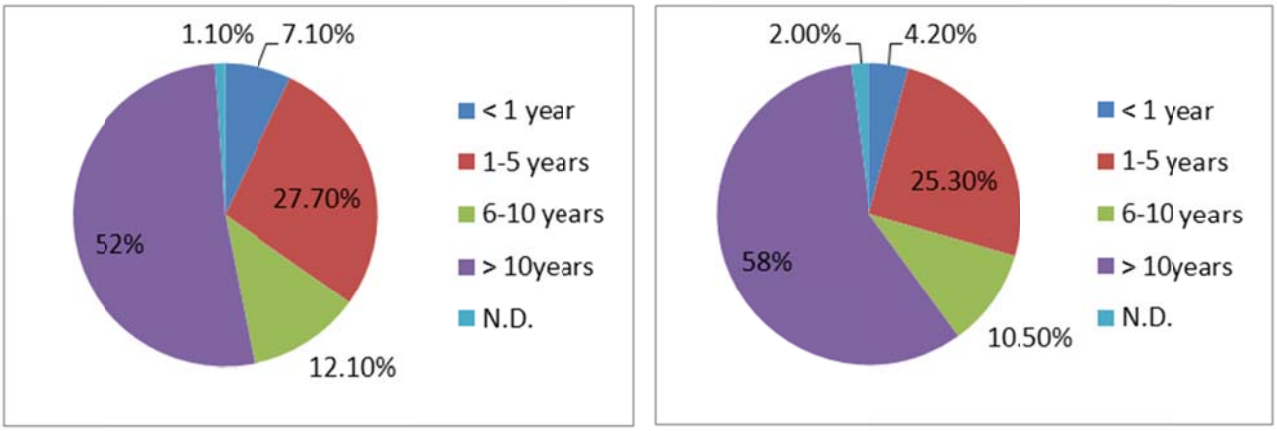

Figure 1. Years of seniority of the sample participating in the self-evaluation study (on the left) and in the observational study (on the right). In both samples more than half of the nurses had a long working experience (more than 10 years)

3.2 Adherence to the medication administration protocol

The percentages of adherence in the self-evaluation and observed conditions are reported in Table 1. Protocol prescriptions that are violated more than 50% of times are: 10) Medicine trolley in the patient's room; 16) Washing hands before each administration; 21) Labeling of the drugs with the patient's code; and 27) Recording of the medication administration only after the patients have taken the therapy.

The last column on the right reports the difference between what nurses affirm they do and what they really do. They often (but not always) tend to overestimate their adherence to the protocol; in particular, they do this for the most violated actions.

Table 1. The self-perceived adherence column indicates the number of times (in %) the nurses declared adhering to the protocol prescription. The observed adherence column indicates how many times they really did, in fact, adhere. The diff column reports the discordance between the two. Values in the table have been obtained calculating the means of subjects' answers and observed violations

Actions	Self perceived adherence (mean %)	Observed adherence (mean %)	Diff
1. Identification of the nurse dedicated to the administration of the therapy	87.2	97.22	+10
2. Checking of the presence on the medicine trolley of alcohol solution for hand washing	100	87.50	-12.50
3. Checking of the presence on the medicine trolley of all the material needed for the medication administration	100	86.69	-13.31
4. Therapy must be given at the correct time	90.8	76.54	-26.26
5. Preparation of infusion therapy in the appropriate areas	87.2	86.77	-0.43
6. Completeness check of the medical prescription	75	99.34	+24.34
7. Request of corrections if the prescription is incomplete	63.7	62.58	-1.12
8. Avoiding writing down the prescription on wrong papers	87.1	93.48	+6.38
9. Checking the integrity of the medicine	98.6	96.46	-2.14
10. Medicine trolley in the patient's room	**45**	**18.19**	**-26.81**
11. Checking the identity of the patient using the electronic bracelet	94.3	99.1	+4,8
12. Checking the correspondence between the patient, the bed number and the prescription	96.4	96.08	-0.32
13. Checking vital signs before the administration	86.5	93.13	+6.64
14. Request of changing prescription if the patient cannot take it	96.6	93.7	-2.9
15. Giving information to the patient	90	89.29	-0.71
16. Washing hands before each administration	**90**	**37.98**	**-52.02**
17. Respect of the KCl protocols	97.8	100	2.2
18. Correct way of medication administration	100	99.96	-0.04
19. Proper use of the solvents for dilution	98.5	99.51	+1.01
20. Combination of drugs in one administration	95	88.23	-6.77
21. Labeling drugs with the patient's code	**68.8**	**47.6**	**-21.2**
22. Correct maintenance of drugs	92.9	100	+7.1
23. Correct administration on the basis of the patient's autonomy	100	99.92	-0.08
24. Not leaving medications on the nightstand	96.4	81.41	-14.99
25. Checking that the patient has taken medicines	99.3	82.86	-16.44
26. Checking the functionality of venous access	98.6	95.38	-3.22
27. Recording the administration only after the patients have taken the therapy	**91.5**	**36.55**	**-54.95**
28. Taking note if the patient does not take the therapy	95.7	82.86	-12.84
29. Monitoring	83.6	81.99	-1.61

Note: bold items are those in which the observed adherence was less than 50%

3.3 Differences between wards

Due to practical reasons, such as the availability of covert observers, observations were performed only in the following wards: cardiology, surgery, orthopedic, and medicine (hospital A); surgery, orthopedic, medicine, obstetrics, pediatrics, and neonatology (hospital B). Comparing the different wards within the same hospital and the same wards between the two, we found significant differences ($p < 0.005$) in the nurses' adherence to the protocol (the main significant differences were found in the actions: 7, 12, 16, 21, 24, 25, 27).

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3.4 Awareness of being observed

At the end of the study, the 95 nurses participating in the Phase 2 of the study were asked about their awareness of having been observed. Forty-five percent of them declared they knew they were being observed, 37% did not notice it, 17% were not sure about it, and 1% did not answer.

3.5 Fatigue and stress

Fatigue and stress occurred in nurses participating in the observational study were measured on a VAS ranging from 0 to 10 at the end of each shift. The mean of the perceived fatigue was 4.85 (S. D. = 2.57) and the mean for the perceived level of stress was 4.49 (S. D. = 2.42).

3.6 Observed interruptions

Number and type of interruptions observed during the 3382 actions performed by the 95 nurses included in the observational study are reported in Table 2. The most frequent interruptions were self-generated by the violations themselves, so they were classified as "violation-driven".

No significant differences were found in the number and sources of interruptions occurred in the 2 hospitals.

Table 2. This table indicates the frequency of the different types of interruptions observed during the medication administrations. A total of 688 interruptions were recorded

Type of interruption	Frequency %
Violation-driven	80.95
Patients' relatives	5.08
Other patients	3.48
External operators	2.76
Colleagues	2.50
Physicians	2.47
Phone calls	2.32
Emergency situations	0.44

3.7 Correlation analyses

Different correlation analyses between the dependent variables and the adherence to the protocol have been performed showing that:

- The total number of therapy administrations is negatively correlated with the adherence to the procedures (r = -.71; $p < .05$);
- The awareness of being observed is positively correlated with the adherence to some of the actions (16, 21, 27) (r = .67; $p < .05$; r = .80; $p < .05$; r = .58; $p < .05$);
- No significant correlations were found between fatigue and stress and the adherence to the protocol.

4 Discussion

We used the method of self-report associated with a covert observation approach to assess the medication violation rate, and we found high rates of medication violations and non-adherence to the prescribed guidelines as well as a significant

discordance between self-reported and observed violations.

Regarding the observed violations, we noticed that of 29 actions, four of them are violated more than 50% of the time, and six others are violated more than 15% of the time. Reasonably assuming that all the 29 actions have been included in the protocol to increase patients' safety, these percentages appear unacceptable especially in healthcare settings in which every patient deserves safe care and should have the utmost confidence that they will not be harmed. Thus, analyzing the different violations, it must be noticed that they are not just random or for convenience. Conversely, for items that have a clear relation to hazard (e.g. Action 17: Respect of the KCl protocols), nurses are quite observant, but for those that have more to do with charges than safety and that matter less than a Kcl violation (e.g. Action 16: Washing hands before each administration; or Action 21: Labeling drugs with the patient's code) the percentage of adherence is very low. These data seem to indicate that nurses engage in deliberate violations on the basis of their personal evaluation of the importance of each action, instead of doing it because of their cognitive overload. This consideration is also supported by the observed lack of significant correlations between the number of violations and the level of fatigue and stress they perceived at the end of the observed working shift. Nevertheless, the negative correlations between the total number of therapy administrations and the adherence to the protocol suggest that nurses skip the procedures (or at least those that are considered less relevant) when they repeat the same actions many times per shift.

Analyzing the differences in protocol adherence between different wards we also notice that the same action is often differently violated depending on the ward and the hospital. These data are difficult to interpret, but seem to indicate that organizational factors, other than individual ones, play a fundamental role in performing violations. This can be mainly argued by the evidence that the same action (for example, action 21: Labeling drugs with the patient's code) is strongly violated in cardiology, surgery and medicine, but not in orthopedic in the hospital A, while it is strongly violated in orthopedic, but not in obstetrics, pediatrics and neonatology in the hospital B. There are no plausible reasons for this, except the possibility that pervasive cultural and organizational factors that characterize different wards and hospitals drive nurses toward the adherence or non-adherence to specific actions. Other than the violations discussed above, there are other frequent violations, such as "Action 10: Medicine trolley in the patient's room" that can be attributed to a deliberate choice (as the previous ones), or to environmental factors, such as the size of the hospital room or the excessive closeness between beds, that prevent the possibility to perform the action as prescribed by the protocol. Environmental factors can also offer an alternative explanation for those violations occurring in some wards/hospitals, but not in others. The lack of significant correlations between the awareness of being observed and the adherence to some of the actions reinforces the hypothesis that at least some of the violations are caused by environmental factors that cannot be changed by the single nurse. Different studies support these considerations showing that heavier workload, non-supportive physical environments and inadequate staffing negatively affect individuals' performance and willingness to report errors [24, 25]. Coherently with these evidences, Karow [26] showed that redesigning work processes and interdisciplinary communication decrease medication errors and increase error reporting.

Identifying motivations related to the different violations is of crucial importance to reducing them. For those that have more to do with charges than safety it could be useful to raise the nurses' awareness about the importance of such actions and procedures, instead of just imposing them on the nurses. Conversely, for those violations more related to external aspects, such as environmental elements or organizational factors, it is necessary to act on these variables in order to create the conditions to increase the adherence to the protocols and to facilitate the nurses' actions, perhaps providing systematic and environmental improvements for recording real-time data and increasing patients' safety [27].

Interventions aimed at reducing the external obstacles are also necessary to prevent what we called "violation-driven interruptions" (80.95% of the observed interruptions), that are self-generated interruptions derived by the presence of a violation (i.e. the nurse interrupts the medication process because she has to take a pill on the medication trolley left out of

the room). Even though it is necessary to complete the ongoing process, such kinds of interruption, as any other, represents a pause in the working flow that can have negative effects on the correct completion of the entire process. If this interpretation is correct, we can argue that following the given procedure is useful not only in reducing the number of violations and errors, but also the incidence of interruptions (and consequently, even the number of violations and errors eventually generated by them).

Shifting from a person-centered to a system perspective on potential contributing factors to medication errors [28], Reason [29] proposed that, although individuals are responsible for the quality of their work, a system approach can be useful to reduce medication administration errors due to organizational factors. Other than having centralized risk regulations procedures (including standardized protocols), high-risk organizations need to increase their level of organizational resilience, learning to deal with variability and fluctuations increasing their activities of adjustment, adaptations and compensation [30]. This can happen through a distributed process in which local personnel and managers pool their efforts to identify, interpret and respond to actual and emerging situations and risks, implementing or proposing to implement any changes that might result useful in improving work practices [31].

Another very important point that emerged from our study regards the discrepancy between self-reports and observations. Our data show that nurses tend to declare doing better than they really do, highlighting the importance of conducting naturalistic observational studies in order to have a realistic view of the situation [32]. We argue that this happens mainly because of a very deep-seated culture of blame, largely diffused in the Italian healthcare environment that prevents nurses and healthcare professionals in general, from reporting their violations and errors because of the fear of being blamed and punished [33]. Obviously this is just a theoretical assumption that would need to be proved by further investigations that possibly overcome the limitations present in this study. In particular, it will be necessary to collect observational data using more sophisticated techniques (such as a video camera) that guarantee true covert observations that do not interfere with the nurses' activities. Moreover, in observing how, when and where nurses violate existing protocols, it is of primary importance to gain more knowledge on how to design and implement routines for safe medication that are appreciated and used by them.

This study presents at least two important limitations. First, due to the practical difficulties of conducting covert systematic observations, we were forced to limit the sample size of the observed nurses. As a consequence of this, the generalizability of results is limited. The second limitation concerns the ethical issue of what observers did when they noticed the violation. As the aim of the study was to record the violations in a natural setting, observers were only asked to annotate them without interfering with the nurse's activity. Such procedures could incur ethical controversies, especially if serious errors occur during observations.

Despite these limitations, compared to previous studies on medication administration errors, this research has the advantage of directly comparing self-reports with systematic observations. This comparison can be useful to educate workers starting from their real and perceived violations.

5 Conclusion

Incidence of protocol violations occurring throughout the medication administration process depends on hospital ward, step in the process, and type of action, and it is usually underestimated by nurses. Further research is necessary to determine whether these violations really worsen safety, and for those that do so, how to reorganize the system to reduce the need to violate protocol to perform tasks. Moreover, nurses must be made more aware of their violations in order to make them more responsible for their actions.

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Competing interest

The authors have no competing interests to declare.

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