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RESEARCH ARTICLE

The preparation and administration of intravenous drugs before and after protocol implementation

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Abstract *Objectives* This paper reports on a pilot study examining the incidence of nurses' errors in preparation and administration of intravenous drugs. Furthermore, the study aimed to evaluate the short-term effects of implementation of a new protocol for preparation and administration of intravenous drugs. Setting Two nursing departments of internal medicine at a 953 beds University Medical Centre in The Netherlands. Methods By means of a prospective, quasi-experimental design, nurses were observed during the process of preparation and administration of intravenous drugs. Observation was performed before and after the implementation of a new protocol. Seventy-two nurses at two nursing departments were observed during the study. Main outcome measure A mean pre-test and post-test quality score at two departments of internal medicine. Results At baseline, average quality scores for nurses at the two departments were 64 (intervention ward) and 67 (control ward) on a 0-100 quality scale. The pre-test quality scores were not statistically significant for the two nursing

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wards (T = 1.36, df = 55, P = 0.18). After the implementation of the new protocol, nurses at the intervention ward scored better (72) than nurses at the control ward (69). The mean score at the intervention ward was significantly higher than the score in nurses of the control ward (T = -2.20, df = 53, P = 0.04). *Conclusions* The number of errors in the preparation and administration of intravenous drugs is high. This study shows that implementing a protocol for the preparation and administration of these drugs can reduce the number of errors.

Keywords Drug administration routes · Infusions · Injections · Intravenous administration · Netherlands · Nursing research · Parenteral · Practice guideline · Quality assurance

Impact of findings on practice

- Errors in preparation and administration of intravenous drugs occur frequently and can cause irreparable damage to patients.
- Errors in the preparation and administration of intravenous drugs decrease significantly after implementation of a protocol, leading to improved quality of care and patient safety.

Introduction

Patient safety is an important issue in health care today. For the USA it was estimated that more than a million injuries and 44,000–98,000 deaths per year are related to suboptimal care or mistakes made by health care workers [1]. Yet,

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hospitalized patients are, as a rule, vulnerable and they assume that health care will improve, rather than compromise, their health. Therefore, improving patient safety is an important area for practice improvement as well as research, and it covers a large variety of topics such as preoperative cardiac events, surgical items left in patients, pressure ulcers, hospital acquired infections, falls and fall injuries and delirium [2].

Adverse drug events are among the most common types of health care errors [3–7]. In a study by Bates et al. 1% of all adverse drug events were fatal, 12% were life threatening, 30% were serious and 57% were significant [8]. In the same study, 40% of all events were due to mistakes in the process of administering drugs. The risk involved seems especially high in the more complicated medication administration processes, such as in the administration of intravenous drugs.

The preparation and administration of intravenous drugs is a series of complicated technical skills. The consequences of medication preparation and administration errors can be anything from relatively harmless to lethal. Single site studies in the UK and USA confirm that nurses make mistakes in preparing and administering intravenous drugs in 13-84% of all cases [9, 10]. These studies used different definitions for 'errors' in preparing and administering intravenous drugs, thus making comparisons difficult. The study of Taxis and Barber describes the different stages in the process in which errors occur, as well as the clinical importance of these errors [11]. In this study, one or more errors occurred in 49% of all cases of the preparation and administration of intravenous drug doses. Preparation errors occurred in 7%, administration errors occurred in 36% and both types of errors were found in 6% of all cases. 1% of these errors were potentially severe, 29% were potentially moderately harmful and 19% were considered to be minor errors.

Examples of errors observed in practice and described in studies are:

- administering a bolus dose too quickly;
- not inspecting the medicine for expiration date;
- not double-checking the prescribed drug, doses and corresponding patient by a colleague;
- not observing hygiene regulations [11–13].

In conclusion, the evidence of quality and errors in the preparation and administration of intravenous drugs is rather scarce, but points towards a potentially problematic quality of care issues. The study by Cousins et al. compares the intravenous therapy protocols for hospitals in the UK, Germany and France [12]. The study by Anselmi et al. verified the frequency of errors in the preparation and administration of intravenous drugs in three Brazilian hospitals in the States of Bahia [14]. In all hospitals, various

difficulties in the developing and maintaining of intravenous therapy protocols were identified. However, attempts to improve the quality of the process of preparing and administering intravenous drugs are minimal described in the international literature [15, 16]. Yet, the quality of this process is of vital importance in providing safe patient care and attempts at quality improvement deserve to be explored.

These clinical observations, and the motivation to guarantee patient safety, were the reasons to examine the quality and the effects of an attempt towards quality improvement of the preparation and administration of intravenous drugs in a Dutch academic hospital.

Aims of the study

The aims of the study were:

- To evaluate the quality of the preparation and administration of intravenous drugs as performed by nurses in general medicine hospital wards;
- To evaluate the effects of the implementation of a protocol on the quality of the preparation and administration of intravenous drugs.

Methods

The study employed a quantitative, prospective, quasiexperimental design. The researcher observed the performance of nurses during the process of preparation and administration of intravenous drugs at two nursing departments of internal medicine at a 953 beds University Medical Centre in The Netherlands.

The study included data collection at baseline (pre-test: 8 weeks), an intervention period while the new protocol was implemented in one of the two wards (2 weeks), and a post-implementation test (post-test: 8 weeks). Nurses' performance in the preparation and administration of drugs was the main focus of the study.

Inclusion

Nurses were eligible for the study if:

- They were Registered Nurses at the departments of internal medicine;
- They were fully qualified for the preparation and administration of intravenous drugs;
- They declared themselves competent in the preparation and administration of intravenous drugs;
- They gave permission for observation by the researcher.

As nurses were also observed during the administration of drugs, patient encounters were part of the observations.

Therefore, an additional inclusion criterion for the observations was:

• Patients receiving drugs should (be able to) give informed consent for the observations by the researcher.

Protocol and observation list

A multidisciplinary team including two researchers, a hospital pharmacist, a nurse practitioner, a ward nurse, an infection control practitioner and an occupational hygienist developed the new protocol, using the knowledge of experts and the evidence from the scarce literature [17–19]. An observation list was directly derived from this protocol. The observation list is a specification of the protocol and consisted of 47 variables (Appendix). The variables represent the steps a nurse has to take in the preparation (30) and administration (17) of intravenous drugs. Some of the steps during the process of preparation and administration had to be repeated more than once. All 47 aspects on the list were observed during all occasions where nurses prepared and administered intravenous drugs.

With the observation list the option "yes", "no", "not applicable" or "missing" could be checked. When the observer was not sure of his observation then one or more aspects were scored as "missing". If the operation of a step was not complete, for example, the nurse did not wait before the disinfection solution to dry, that item was scored as a "no". All variables were given equal weights. Scores on the items were combined in an overall quality score to represent the number of items that were correctly performed. This overall quality score was expressed on a 0–100 quality scale. When all 47 aspects were performed correctly, the quality score for preparation and administration was 100. The scores "not applicable" and "missing" were not used in calculating the overall quality score.

In addition, more general data such as date, department, time of prescription and time of administration were collected. Furthermore, characteristics of the administration process (bolus dose injections, intermittent infusion or continuous infusion) were always registered.

Observation

At both the pre- and post-test phases, nurses were observed by a single observer for a maximum number of four times, in order to include as many different nurses as possible. During the process of preparing and administering intravenous drugs, nurses were observed by using the observation list. Nurses were aware of the observation but unaware of its true purpose [20, 21].

The names of the nurses, the number of observation by the individual nurse and the phase of the study were registered.

Observation took place on different days of the week, at different times of the day and night, and at both hospital wards. The observer was present during a preset series of shifts, to represent the variation of working hours in nursing practice.

It was determined beforehand when intervention would be necessary. The project team decided that in case of preparation of the wrong drug, preparation of the wrong dose, preparation with the wrong diluent, administration using the wrong route and administration to the wrong patient, the researcher should not only score the errors, but also intervene by talking to the nurse about these potentially harmful errors.

Intervention

The intervention was the implementation of the protocol regarding the preparation and administration of intravenous drugs at one of the departments, the intervention department. Implementation took place, during a one-time 45 min department meeting by means of a presentation of the pre-test results and a 15 min film with and without the presentation of errors in the preparation and administration of intravenous drugs. In addition, questions were answered and current practices versus the new protocol were discussed. For instance, one of the items discussed was the disinfecting of the hands in combination with the wearing of gloves. Nurses thought that when they wore gloves they do not have to disinfect their hands.

Following the presentation, the new protocol was available to all the nurses at the ward. To give all the nurses the opportunity to study the new protocol, the post-test took place 2 weeks after the introduction.

Statistical analysis

At the item level, differences between the two groups and measurements were analyzed using cross table and chisquare tests. The standard deviations for the two groups were not statistically different. Overall quality scores were checked for normal distributions and satisfied this condition. For both pre- and post-test scores, potential differences in nurses' level quality score between the two departments were analyzed using the independent samples T-test for statistically significance ($P \le 0.05$). As nurses could be observed several times, clustering of data at the level of nurses was present in this study. Therefore, the mean quality scores of nurses over 1–4 observations were used in the analyses of the effects of the protocol implementation. In addition, we explored the relevance of the type of administration route for quality scores using a One Way ANOVA technique ($P \le 0.05$).

Ethical considerations

Approval from the local Medical Ethics Committee was obtained.

Results

At the pre-and post-test, 132 observations were performed; 66 observations at each ward. Seventy-two nurses were observed in the study.

In 56% of the cases, the nurses were observed at the pretest as well as the post-test (45% control department, 66% intervention department). The demographic data are summarized in Table 1. There were no significant differences in any of the demographic data for the two departments.

All of the included nurses gave permission for observation by the observer.

During the study, intervening at the intervention department was necessary on two occasions: once due to preparation of the wrong dose during the pre-test and once due to preparation of the wrong drug during the post-test. In these cases, the nurses corrected their mistakes after the observer had intervened. The mistakes were registered as errors. Intervening at the control department was not necessary.

Nurses working at the control department had a mean quality score of 67 during the pre-test. Nurses from the intervention department scored 64 at this point in time. Pre-test scores were not significantly different for the two nursing wards (T = 1.36, df = 55, P = 0.18). In addition, within each department there was no significant difference in quality scores for the administration by bolus dose injections, intermittent infusion and continuous infusion

 $(\alpha \le 0.05)$. The mean overall quality score during the pretest was 66 for bolus dose injections (n = 38), 65 for intermittent infusion (n = 76) and 66 for continuous infusion (n = 18). The quality score for bolus dose injections differed for the two departments (T = 2.63, df = 36, P = 0.01). At the control department the quality score for this administration route was 71, while at the intervention department the score was only 64. For administration by intermittent infusion or continuous infusion, no significant differences between the wards were found.

Fifteen variables had pre-test quality scores >90% at both departments (Appendix). These variables referred to the preparation of the correct drug, correct doses, making a calculation for the solution to be made, using the right diluent, using the prescribed quantity of this diluent, using the prescribed method of preparation, applying the prescribed administration route, keeping syringe, needles and/ or transfer needles sterile, being sure that the medication completely dissolves, having—at the final stage—the prescribed dose of the drug to be administration by the nurse who prepared the drug, administrating the drug before the end of sell-by after preparation and administration of the drug to the right patient.

Eight variables had pre-test scores less than 20% at both departments (Appendix). The scores referred to checking the expiration date, inviting colleagues to double-check the prescription, inspecting the diluent for expiration date, hand washing prior to preparation, using disinfectant gauze to break/open the ampoule, mixing the acquired infusion solution by wheeling, inspecting the solution for clarity and inspecting the intravenous catheter for phlebitis or extravasation prior to administration.

The mean quality scores of nurses at the control and intervention department are summarized in Table 2. At post-test, nurses at the intervention department scored significantly better (72) than nurses at the control department (69) (T = -2.20, df = 53, P = 0.04). At the intervention department, significant improvement on 8 criteria (P < 0.01) was found (Table 3).

Table 1 Pre-test $(n = 57)$ and
post-test ($n = 56$) demographic
data for all nurses at the two
departments

Pre-test			Post-test						
	Control	Intervention		Control	Intervention				
Number of nurses	26	31	Number of nurses	29	27				
Male	5	5	Male	6	3				
Female	21	26	Female	23	24				
Mean age	37	37	Mean age	36	35				
Minimum	23	23	Minimum	23	23				
Maximum	58	58	Maximum	56	57				
Mean years of experience	9	9	Mean years of experience	8	7				
Minimum	0	1	Minimum	0	1				
Maximum	32	30	Maximum	25	30				

Table 2 The quality of preparation and administration of intravenousdrugs at pre- and post-test observations (0–100 quality range)

	Control d	epartment	Intervention departme			
	Pre-test [n]	Post-test [n]	Pre-test [n]	Post-test [n]		
Mean quality score of all nurses	67 [26]	69 [31]	64 [29]	72 [27]		
Mean quality score of nurses who were observed at both pre- and post-test	67 [17] (Sd. 5,9)	69 [23] (Sd. 5,6)	65 [17] (Sd. 4,6)	72 [23] (Sd. 5,9)		

In the post-test, 37% of the 27 observed nurses at the intervention ward, were involved the new training. We checked for the effects of 'exposure to the intervention' by comparing the scores for nurses who did or did not attend the protocol introduction meeting. There was a significant difference between the mean score of nurses at the intervention department who were observed during the post-test and who had participated in the department meeting (n = 10, score = 75) as compared to those who were observed during the post-test but who had not attended the meeting (n = 17, score = 70) (T = 2.27, df = 64, P = 0.03).

Discussion

This study describes the effect of the implementation of a protocol on the quality of care of preparation and administration of intravenous drugs by nurses. After the implementation of the protocol, we observed a modest significant improvement at the intervention department, whereas no quality improvement was found at the control ward. There are a few studies which also described the effect of an educational intervention on the quality of care of preparation and administration of intravenous drugs, such as using an interactive CD-ROM program [15] and introduction of dedicated medication nurses [16]. 417

However, most studies described errors in the process of preparation and administration of intravenous drugs and made recommendations about how to minimize the errors [9, 10, 22].

Medication errors range from those that have little or no impact on the patient to those with very serious consequences. In this study, we did not assess the clinical importance of intravenous drug errors. It is difficult to identify the clinical effects of errors because of the delay between the occurrence and the identification of errors and the outcome in one patient may not reflect the likely outcomes in groups of patients as a whole [23].

Potentially severe errors such as preparation of the wrong doses, choosing wrong solvents and administration of bolus doses within insufficient time, are examples of intravenous drug errors that could be severe. They occurred less frequently than previously reported [13].

There was a significant difference between the mean scores of nurses at the intervention department who had participated in the department meeting as compared to those who had not attended the meeting. Despite that, the post-test scores for the nurses who attended the education session are similar to the whole post-test intervention ward group. Perhaps the availability of, and giving attention to the new protocol to all nurses at the ward was equal to, or more effective than the education session itself. Alternatively, carry-over effect from nurses who attended the department meeting to nurses who were not present could explain the lack of the difference between the two subgroups.

Possibly the short period of implementation and the minimum investment caused the modest improvement in quality of care. To accomplish a major change in the attitude and the competence of nurses, a more multi-faceted strategy might be needed. Only 37% of the 27 observed nurses at the intervention ward, were involved the new training. Another strategy for better up take should be to have more nurses attend the training. In addition, the implementation could be strengthened with additional

Table 3 Observation items with significant differences for pre- and post-test at the intervention ward in % of the total number of observations; n = 66 at both measurements

Variable	Pre-test [n]	Post-test [n]	Р
Inspects medication for the expiration date.	6% [52]	65% [54]	0.000
Inspects diluent for the expiration date.	0% [52]	28% [57]	0.000
Disinfects hands prior to preparation.	15% [66]	53% [66]	0.000
Breaks/opens ampoule with diluent using disinfectant gauze.	15% [61]	43% [65]	0.000
Disinfects the ampoule with medication.	83% [54]	98% [51]	0.010
Inspects the solution for clarity.	5% [66]	20% [66]	0.007
Informs the patient about administration of the drug.	76% [66]	94% [65]	0.004
Inspects the intravenous catheter for phlebitis or extravasation prior to administration.	15% [55]	43% [65]	0.001

methods such as improved working conditions and teaching and testing of technical skills. Furthermore, it is important to consider systems approaches to reduce medication errors [24].

Observation methods for studying medication preparation and administration errors could have influenced the results. Even when all precautions are taken to minimize the effects of observation, it is still possible that the presence of a researcher may affect nurses' behavior [21].

Some nurses told the observer that they miss some steps in the total process of administration when the observer is not there. Therefore, the error rate may have been even higher in the absence of the researcher.

This implies that scores for the quality of the preparation and administration of intravenous drugs in this study are probably somewhat biased towards more positive scores. As the procedure was identical for the two groups however, this does not threaten the validity of the effects of the intervention.

Prudence is called for when generalizing the results to other departments or other hospitals. The two departments, which were involved in this study, are departments where the incidence of preparation and administration of intravenous drugs is high. Both departments were internal medicine departments where doctors and nurses often treat patients with infectious diseases. Possibly, the nurses at these departments are more aware of the importance of hygiene and infection prevention than nurses at other departments.

Conclusions

The number of errors in the preparation and administration of intravenous drugs is high. Our study identified an unobtrusive significant difference between pre-test and post-test quality of preparation and administration of these drugs after the implementation of a new protocol. Therefore, we conclude that even with limited means and investments, the quality of the preparation and administration of intravenous drugs can be improved. The protocol developed during the pre-intervention period contributes to the improvement of the quality of preparation and administration of intravenous drugs in nursing practice.

Given the limited quality of the preparation and administration process, investing more time and money in attempts at improvement seems justified. Without these attempts, the need for patient safety in everyday patient care might be insufficiently met.

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Appendix

Scores in % of all observation items per measurement and department

Variable		1st measurement				2nd measurement			
	N	contr (%)	int (%)	S*	N	contr (%)	int (%)	S*	
1. Correct drug	132	100	100	_	132	100	99	_	
2. Correct doses	132	100	99	_	132	100	100	_	
3. Inspects medication for the expiration date (§)	99	11	6	_	103	8	65	+	
4. Asks colleague to double-check the prescription	57	15	3	_	44	10	4	_	
5. Looks up preparation procedure in a handbook	132	53	24	+	132	50	17	+	
6. Makes a calculation for the solution to be made	4	100	100	-	2	-	50	_	
7. Ask colleague to double-check calculation	4	0	67	-	1	-	100	_	
8. Gets the right diluent	117	98	95	-	124	100	98	_	
9. Inspects the diluent for the expiration date (§)	102	2	0	-	109	0	28	+	
10. Washes hands prior to preparation	132	3	14	-	132	9	24	_	
11. Disinfects hands prior to preparation (§)	132	49	15	+	132	38	53	_	
12. Wears gloves during preparation	132	39	24	-	132	50	27	+	
13. Uses disinfectant gauze to break/open the ampoule (§)	102	5	15	-	115	6	43	+	
14. Disinfects the ampoule with medication (§)	112	86	83	-	111	87	98	_	
15. Waits for the disinfection solution to dry	95	86	67	_	102	81	88	_	

continued									
Variable		1st measurement				2nd measurement			
	Ν	contr (%)	int (%)	S*	Ν	contr (%)	int (%)	S*	
16. Disinfects injection point of infusion bag	83	82	91	_	68	90	78	_	
17. Waits for the disinfectant to dry	71	76	53	_	58	68	52	-	
18. Uses the prescribed quantity of solvent	119	98	98	_	124	100	100	_	
19. Uses the prescribed method of preparation	130	98	100	_	131	100	100	_	
20. Uses the prescribed administration process	132	100	100	—	132	100	100	_	
21. Keeps syringe, needles and/or transfer needles sterile	127	98	92	—	131	99	100	_	
22. Takes care that the medicine completely dissolves	106	96	93	_	116	98	97	_	
23. Mixes the acquired infusion solution by wheeling	118	11	7	_	124	24	21	_	
24. Inspects the solution for clarity (§)	132	0	5	_	132	0	20	+	
25. Has-at the final stage-the prescribed dose of the drug to be administered	132	94	91	_	132	97	99	_	
26. Puts a completely filled out label on the infusion bag/syringe	97	7	30	_	76	19	10	_	
27. Gets NaCl 0.9% to flush the infusion system (because of incompatibility of the medicine with the infusion solution)	30	86	96	-	37	100	100	-	
28. Keeps syringe, needles and/or transfer needles sterile	84	100	96	_	76	100	100	_	
29. Writes his/here initials in the medication administration system	132	94	86	_	130	97	97	_	
30. Writes the deviate time of administration in the medication administration system	30	78	75	_	8	80	67	_	
31. Administration done by the nurse who prepared the drug	131	100	94	_	129	97	100	_	
32. Administrates the drug before the end of sell by after preparation	129	99	98	_	124	98	100	_	
33. Inform the patient about administration of the drug (§)	132	71	76	_	129	72	94	+	
34. Administrates the drug to the right patient	132	100	100	_	129	100	100	_	
35. Inspects the IV infusion system for phlebitis and/or extravasation prior to administration (§)	116	10	15	_	129	25	43	-	
36. Arranges for new infusion needle in case of phlebitis/extravasation	2	-	50	_	1	0	_	_	
37. Disinfects the injection point of the infusion system or the infusion needle	93	83	96	_	94	95	97	_	
38. Waits for the disinfectant to dry	84	35	20	_	90	37	32	_	
39. Rinses out the drip with compatible infusion solution	33	100	83	_	36	83	75	_	
40. Uses a new coupling	75	67	96	+	54	58	91	+	
41. Administrates the medication using the prescribed administration time	130	89	61	+	128	80	66	_	
42. Regulates the controller according to the described rate	85	95	87	_	69	100	100	_	
43. Keeps needles, coupling and/or drip sterile	129	97	100	_	129	100	100	_	
44. Administers all of the solution with medicine	113	88	96	_	108	100	97	_	
45. Rinses out the drip with compatible infusion solution	109	43	63	_	89	56	76	_	
46. Describes the medication administered on the patient list in case of short stay or continued infusion	96	82	78	_	73	80	61	_	
47. Stays in the patient's room after administrating the drug	116	21	18	-	110	30	25	_	

* = observation item with significant differences for the control department and the intervention department

(S) = observation item with significant differences for pre- and post-test at the intervention department

contr = control department

int = intervention department

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