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Brief Report

Time and Motion Study Comparing the Preparation of Ampoules Versus Pre-Filled Syringe for Critical Care Drugs

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Abstract

A range of ampoule-based preparations are currently used for intravenous administration in critical care situations. Many of the same drugs can be provided in pre-filled syringes (PFS), which may limit the time lost in diluting or reconstituting treatments, while also minimising potential for dosing errors. We aimed to: **(1)** determine the average time taken for nurses to prepare a single dose of a range of critical care drugs from an ampoule or prepare a PFS ready for administration; **(2)** assess the consumable requirements associated with the preparation; and **(3)** assess the quality of each preparation, noting any preparation errors. Compared with ampoule-based preparations, PFS preparations, which are ready-to-use with no dilution necessary, were found to have a number of benefits: **(1)** faster to prepare; **(2)** less potential for injury; **(3)** fewer spillages; **(4)** more accurate dosing; **(5)** easier to handle; **(6)** fewer preparation errors; **(7)** fewer consumables used; **(8)** preferred by nurses. Reported potential drawbacks of the PFS were bulky storage; perceived higher cost; potential for complacency during drug preparation and occasional lack of local availability. Hence, PFS use may be particularly beneficial in the following situations: **(1)** emergency situations where time is critical; **(2)** times of high levels of agency nurse usage or when there is a lack of nursing resource to adequately cover the workload; and **(3)** to mitigate risk in the peri-operative setting.

Keywords: Ampoule; Pre-Filled syringe; Time and Motion; Simulation; Market research

Introduction

A range of ampoule-based preparations are currently used for intravenous administration in critical care situations. Many of the same drugs can be provided in pre-filled syringes (PFS) for emergency situations that are dose or time critical. PFS preparations of a correct dose are used as preventative measures to mitigate the risk of medication errors in perioperative settings [1,2] and reduce drug wastage [3]. There are relatively few studies comparing ampoule-based and PFS preparations in terms of drug preparation time, medication or handling errors and consumables used in the same study using a time and motion methodology. This time and motion market research simulation study aimed to: **(1)** determine the average time taken by appropriately trained ward nurses to prepare an appropriate single dose of a range of named critical care drugs from an ampoule or prepare a PFS ready for administration; **(2)** assess the consumable requirements associated with the preparation of each drug; and **(3)** assess the quality of each preparation, noting any preparation errors.

Materials and Methods

This time and motion study was undertaken by 7i Insights Limited as a market research project. The study was conducted in accordance with the guidelines and codes of practice of a relevant market research professional body, the British Healthcare Business Intelligence Association (BHBIA). A study protocol was developed in advance of the research being conducted.

Five experienced ward nurses from the North West of England were recruited for participation in the study.

The nurses were asked to prepare a range of critical care drugs ready for intravenous administration. Seven ampoule-based simulated critical care products were included in the study. Some of these products could be prepared using alternative ampoule sizes and diluent volumes, giving a total of ten ampoule-based variants to be researched (Table 1). The pre-filled syringes used in the study were empty and presented in a twist box.

The order in which the products were prepared for administration was rotated between nurses to avoid any 'improvement with practice' bias. Each nurse prepared three single syringes for each reference drug as outlined in Table 1. Two timekeepers simultaneously recorded the total time taken to prepare the final syringe for each single preparation. Both times were recorded for each attempt and used to calculate means and medians of preparation timings. Timings were not stopped except in the event of an actual injury taking place.

Drug	Ampoule size	Volume from ampoule(s)	Volume of diluent	Final volume
Amiodarone	3 ml	6 ml	4 ml	10 ml
Atropine #1	1 ml	3 ml*	0 ml	3 ml
Atropine #2	1 ml	0.5 ml	0 ml	0.5 ml
Ephedrine #1	1 ml	1 ml	9 ml	10 ml
Ephedrine #2	10 ml	10 ml	0 ml	10 ml
Midazolam	1 ml	1 ml	4 ml	5 ml
Naloxone	1 ml	1 ml	0 ml	1 ml
Ondansetron	4 ml	4 ml	0 ml	4 ml
Rocuronium #1	5 ml	5 ml	0 ml	5 ml
Rocuronium #2	10 ml	10 ml	0 ml	10 ml
Twist box (PFS)	N/A	N/A	N/A	10 ml

*4 ml ampoule used in research as 3 ml ampoule was unavailable; PFS, pre-filled syringe

Table 1: Overview of drug preparations

The nurses were asked to prepare a single syringe from the allocated ampoule(s) as if for clinical use. They were allowed to obtain and use all the necessary consumables that they would normally use. The gathering of the consumables was done in any order. The nurses were asked not to rush and to do everything they could to ensure that the preparation was performed as they would do in their real-world setting. The nurses took a short pause between the preparation of each syringe of a given product, and a short break between each separate drug preparation.

The drugs were prepared as per their relevant SPCs. Reading time was excluded from the recorded timings.

A tray and sharps bin were provided in the immediate proximity of the workspace where the preparations took place. All consumables used during the preparation of each vial or ampoule were placed directly into the tray during or after the preparation process. All consumables were counted and the confirmed number of each type of consumable was recorded immediately within the study documentation. All sharps were disposed of in the sharps bin.

All preparation errors were accurately captured in the study documentation. Preparation errors included spillage of diluent prior to dilution of drug and spillage of an ampoule. When such events occurred, the nurse continued the preparation, the time was recorded and the error was recorded in the study documentation. Additional ampoules of diluent or drug required due to a spillage were noted in the study documentation.

This was a simulated exercise; the study took place in a mock clinical environment and only non-hazardous liquids were used. No patients were involved in the study and the preparations were

disposed of safely. The protocol outlined the procedure for identifying and reporting any safety issues and adverse events (Table 2). As this was a simulation of a real-world clinical environment, some simulated equipment was used in the research (e.g. regular syringe needles to simulate filter needles, a cupboard to simulate a fridge for storage of some preparations etc).

Both the nurse and timekeepers must be aware of any safety issues and/or adverse events that occur during the preparation of any given ampoule.
All safety issues and adverse events related to the use of any of the drugs must be: • recorded in accordance with Accord pharmacovigilance / recorded appropriately in the study documentation • reported as an adverse event where applicable
The following scenarios may arise with respect to safety issues and/or adverse events: **Safety event where the nurse can immediately continue or continue with minor treatment:** • Should the nurse suffer a minor safety event, such as a minor scratch or abrasion that requires no or minimal self-treatment (e.g. removal of gloves, clean and cover with sticking plaster before continuing), the preparation of the drug should cease, the event should be recorded in the study documentation. • This should not count as one of the three attempts and should be recorded separately. • The nurse should still complete the preparation of 3 syringes without additional issues **Safety event where the nurse is unlikely to or cannot continue imminently:** • Should a safety issue or adverse event occur resulting in the nurse not being able to continue imminently (e.g. deep cut), the nurse should stop the preparation of the drug and seek medical care immediately. The preparation should be captured as failed and the event captured accurately in the study documentation. • The study team and nurse should assess whether the nurse is able to continue with the study in the context that the nurse's safety is the primary concern.

Table 2: Protocol for safety issues and adverse events.

At the end of each day, the participating nurses were asked to complete a short qualitative questionnaire. They were asked their opinions regarding various elements of the study (e.g. preparation of syringes from vials and use of the PFS). They were asked to rate their preference for ampoules vs PFS on a 5-point scale ranging from "I strongly prefer ampoules" to "I strongly prefer PFS". The criteria were **(1)** speed of preparation; **(2)** avoidance of injury; **(3)** accuracy of dosing; **(4)** storage considerations and **(5)** overall preference. The nurses were also asked to rate the simulation compared with their real-world situation in terms of: **(1)** the process followed; **(2)** the preparation time take; **(3)** the consumables used and **(4)** any storage or packaging issues. The 4-point rating scale options were 'very similar', 'somewhat similar', 'not very similar' and 'not at all similar'.

Results

Preparation Timings

Overall, the mean preparation time for all 10 ampoule preparations was 137.2 seconds. The mean preparation time by individual product ranged from 105.7 seconds to 191.7 seconds (Table 3). The mean time for the PFS preparations was 33.1 seconds (range from 10 seconds to 44 seconds).

Product	Observations n*	Mean (seconds)	Median (seconds)	Max (seconds)	Min (seconds)
Amiodarone	30	191.7	177	255	121
Atropine #1	30	162.3	157	224	129
Atropine #2	30	121.5	116	159	86
Ephedrine #1	30	176.7	165	347	122
Ephedrine #2	30	116.1	112	165	98

Midazolam	30	149.3	150	193	106
Naloxone	30	119.1	117	165	81
Ondansetron	30	105.7	104	136	85
Rocuronium #1	30	111.4	111	127	88
Rocuronium #2	30	118.5	112	215	97
Twist box (PFS)	30	33.1	36	44	10

*5 nurses x 3 attempts x 2 timekeepers = 30 recordings per preparation; PFS, pre-filled syringe

Table 3: Preparation timings.

Recorded Events

A total of 73 events were recorded during the study period (Table 4). All five nurses experienced recorded events, although two nurses had substantially fewer events than the other three (11 out of 73 events, or 15.1%).

	Injury		**Spillage**		**Dosing error**		**Other preparation issues**			
	Actual	Near miss	Actual	Near miss	Actual	Near miss	Air in syringe	Difficult handling	Preparation error	Total
Amiodarone	0	1	0	0	0	1	2	0	2	6
Atropine #1	0	1	0	0	0	0	0	1	2	4
Atropine #2	0	0	2	0	2	0	2	2	1	9
Ephedrine #1	0	2	2	1	0	4	1	2	2	14
Ephedrine #2	0	1	0	0	0	1	1	0	1	4
Midazolam	0	0	0	0	0	0	3	1	0	4
Naloxone	0	2	0	0	3	0	2	1	0	8
Ondansetron	0	1	0	0	0	1	3	1	0	6
Rocuronium #1	0	1	1	0	0	0	2	3	1	8
Rocuronium #2	0	2	3	0	0	0	2	2	1	10
Twist box (PFS)	0	0	0	0	0	0	0	0	0	0
Total	0	11	8	1	5	7	18	13	10	73

PFS, pre-filled syringe

Table 4: Recorded events.

The events occurred across all products to a varying degree. There was no obvious correlation between recorded events and use of diluent (e.g. amiodarone, ephedrine #1, midazolam), opening more than 1 ampoule of active drug (e.g. amiodarone, atropine #1) or using only part of an ampoule of active drug (e.g. atropine #2).

The most frequent reported events occurred with ephedrine #1 with 14 out of 73 (19.2%) events. It was noted that this product required the largest volume of diluent (9 ml) in its preparation, which may have been one reason for the relatively high number of reported events.

Consumable Use

The preparation of PFSs involved fewer of almost all types of consumables vs ampoules, with only the mean number of needles and mean number of aprons for ampoules being the same as for PFSs.

Preference For Ampoules vs PFS

In almost all criteria in the qualitative questionnaire, four out of five or all the nurses stated they "somewhat prefer" or "strongly prefer" the PFS. The exception was storage considerations, where one nurse indicated a preference for ampoules. Of the remaining four nurses, two nurses reported that they had no preference in terms of storage considerations between ampoules and PFS, one nurse stated they somewhat preferred PFS and one nurse stated they strongly preferred PFS.

The nurses reported potential drawbacks of the PFS. These were: **(1)** bulky storage; **(2)** higher cost; **(3)** potential for complacency during drug preparation **(4)** occasional lack of local availability.

It was noted that, in terms of 'overall preference', all nurses answered "strongly prefer PFS" (Figure 1).

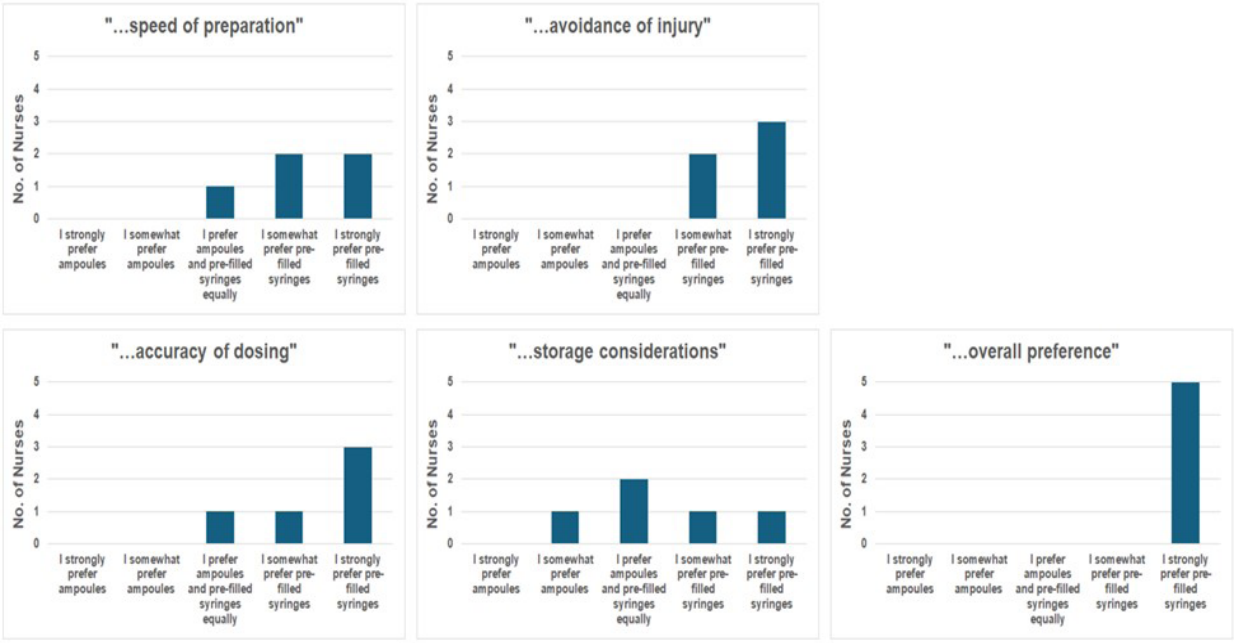

Figure 1: Nurse preference for ampoules vs PFS.

Differences vs Real-world Setting

Across all criteria, most or all of the nurses felt that the simulated environment was "very similar" or "somewhat similar" to their usual real-world setting.

Limitations

The nurses reported that some real-life activities were excluded from the simulation. These included the time taken to access the secure drug preparation room (typically a card key or PIN code), the time taken to wash hands, obtaining a key for the fridge and a key for the controlled drug cupboard from the nurse in charge, computer access, computer printing of syringe labels, seeking counter-signature to approve medication especially for controlled drugs such as midazolam, interruptions from colleagues on a busy ward, familiarity of the nurses' own drug preparation area.

It was reported that the venue lighting was adequate. However, nurses noted that lighting would be brighter in an actual drug preparation area, especially when checking liquid in ampoules, some of which were dark glass.

Discussion

The results from this study were consistent with the few available studies comparing ampoule-based preparations with PFS in terms of speed of preparation and dosing errors [2,3].

There were a number of strengths of the study, most notably relating to the pre-agreed study protocol that provided robust procedures for implementation of the methodology, observation of the activities and qualitative feedback.

The main limitations of this study were the small sample size (n=5) and the lack of statistical testing on the results. The nurses were recruited from the North West region of England, and may therefore not be considered as a representative sample from the UK. In addition, there were several other limitations.

There were a number of equipment items missing in the simulation that would normally be used in a real-life situation, although alternatives to the missing items were provided. These included filter needles, large swabs for cleaning the trays (small swabs were provided), 2 ml syringe (nurses reported that a 1 ml syringe can be difficult to expel air accurately), cannula attachments, and syringe bungs / caps. There were also different nurse observers on different days, and this could potentially result in variation in reportable events. However, all significant events were recorded. There was an awareness by the participants that they were being observed and this potentially may have changed their behaviour (e.g. improved speed / productivity in the short term or pressured them into making more mistakes than they would normally do). Whilst the nurses noted several minor differences with how the simulation replicated the real-world setting, the feedback from the qualitative questionnaire suggests that the nurses felt that, for the purpose of the research, the simulation was sufficiently realistic across a range of criteria. Finally, there was some variability in the timings which can be explained by different techniques and consumables used by the different nurses.

Conclusions

This research suggests that PFS use may be particularly beneficial in the following situations: (1) emergency situations where speed of preparation and administration into the patient is a priority and where mistakes and injuries can occur more often when the preparation is rushed; (2) at times of high levels of agency nurse usage or when there is a lack of nursing resource to adequately cover the work volume; and (3) to mitigate risk in the peri-operative setting. Often agency nurses are not authorised to prepare medications for administration, placing even greater burden of time and pressure on the permanent nursing staff.

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Ethical Considerations

Ethical approval was not required due to the nature of this study

Conflicts of Interest

Robert J. Parrish has no conflicts of interest. Steven. A Fenwick is an employee of Accord Healthcare Limited.

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