

An observational study of intravenous medication errors in the United Kingdom and in Germany

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Key words

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Abstract

Objectives: To investigate the incidence and the severity of intravenous (i.v.) drug preparation and administration errors in two countries and three pharmacy services. **Method:** A disguised observational method was used to record details of the preparation and administration of prescribed i.v. drugs on two wards in each of three teaching hospitals: one with a traditional British ward pharmacy service (TBP) and two hospitals in Germany, one with a traditional ward stock supply (TGP) and one with a satellite pharmacy service (GSP) with unit dose system. Main outcome measures: Errors in i.v. drug preparation and administration and their potential significance.

Results: The number of observed preparations/administrations were: TBP 77/63, TGP 126/109 and GSP 134/106. The preparation error rates were: TBP 22% (95% confidence interval: 13–31%), TGP 23% (16–30%) and GSP 31% (23–39%). The administration error rates were TBP 27% (16–38%), TGP 49% (39–58%) and GSP 22% (14–30%). The percentage of administration errors on the wards with TGP was statistically significantly higher than in the other two services. Common errors at the study sites with TBP and GSP were omissions. Wrong rate of administration occurred most frequently on the wards with TGP. The majority of errors were likely to be of 'moderate' to 'severe' outcome. Careful drug chart reading could possibly reduce omission errors on the wards with TBP. A change of the German nursing law ('Krankenpflegegesetz') to legally entitle nurses to administer i.v. drugs could probably result in better training, national guidelines and standards.

Conclusion: This study found a high rate of i.v. medication errors of moderate to severe significance. Changes in practice should be considered to make i.v. therapy safer for patients.

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Introduction

Intravenous (i.v.) therapy usually needs to be prepared immediately before administration. This may involve dissolving of powder, dilution or transfer of injection fluid from the original vial or ampoule into a container (a syringe or an infusion bag). These processes present multiple opportunities for errors. Thirty years ago Breckenridge investigated preparation and administration of i.v. medication on hospital wards in the United Kingdom (UK)¹. In his report it was summarised that there was a lack of information and guidelines, as well as inadequate prescribing, which resulted into poor quality of care. Following

this report few studies have been performed on the use of i.v. drugs and related medication errors (ME). Three studies investigated only i.v. medication errors: one of them found 151 (84.4%) errors in 179 observed drug administrations², the other reported an error rate of 24.7% for 320 observed preparations and administrations³. A recent study found an error rate of 49% in 430 i.v. drug preparations and administrations⁴. These findings are higher than the error rates, between 3% and 8%, found for oral ME^{5,6}. Some studies investigated preparation and administration of oral and i.v. medication in intensive care units (ICU). A study in a paediatric ICU in Switzerland found 18% errors in 231 observed events⁷. Another study in France reported an error rate of 6% observing 2009 events⁸. This error rate was calculated by dividing the number of errors by the number of observed events. Each of the administrations consisted of several events. A study done in United States (US) in the early seventies identified a total of 21% errors in 100 preparations observed⁹. Observations regarding aseptic technique were also included in two studies^{9,10} showing that the majority of nurses did not follow it. However, error rates of the studies are difficult to compare due to differences in settings, methods and definitions used.

Only a few studies gathered data in different pharmacy services and different countries, using the same methods and definitions to allow a comparison of error rates across different systems. However, none of these studies included i.v. ME. Dean et al.⁵ found an error rate of 3.0% for the traditional British ward pharmacy system and an error rate of 6.9% for the unit dose system of a US hospital. Characteristic types of errors were identified in each system: omission errors occurred frequently in the traditional ward pharmacy system, whereas unordered or incorrect doses were often administered in the unit dose system. Another study compared the British ward pharmacy system with the traditional ward stock system and the unit dose system in two German teaching hospitals⁶. In British hospitals, ward pharmacists initiate drug supply and review prescriptions on their daily ward visits¹¹. In contrast, such patient-oriented pharmaceutical services are rarely provided in German hospitals. The wards have a large stock of commonly prescribed medicines. Few hospitals operate a unit dose system or satellite pharmacy services¹². The study found a higher error rate (8.0%) for the British pharmacy system than for the traditional German ward stock system (5.1%) or the German unit dose system (2.4%)⁶. Again characteristic types of errors were identified in each system.

Therefore, the aim of the present study was to investigate the incidence and the severity of i.v. ME during preparation and administration in two countries and three pharmacy services.

Methods

Setting

i.v. drug preparation and administration were investigated in three large teaching hospitals with different drug supply and pharmacy services: one teaching hospital with a traditional British ward pharmacy service (TBP), one teaching hospital with a traditional German pharmacy service (TGP) with ward stock supply and another German teaching hospital with a satellite pharmacy service (GSP). Appendix 1 gives details of the systems of i.v. drug preparation and administration. On the wards with TBP the original prescription was used as a guide for preparation of the i.v. drug. In both German systems prescriptions were written in the medical notes and transcribed by nursing staff (TGP) or by pharmacists (GSP) (except ICU where a computer system was in use). The transcribed document, which was kept together with the patients' notes at the nursing station, was used for preparation and administration of the i.v. drugs. At all three study sites nurses prepared and administered doses on the wards. On the wards with GSP only, junior doctors were also involved. One of the main differences between the study sites was the service provided by the pharmacy: a daily prescription review by a pharmacist was done on the wards with TBP and the GSP but not on the ones with TGP.

Data collection

Data were collected by one of us (VW) – a research pharmacist – on six consecutive days on each ward between May and June 2000. Disguised observation was used¹³: the medical and nursing directorates were informed about the full purpose of the study; at ward level the study was presented as an exploration of problems related to preparation and administration of i.v. drugs. Participation in the study was voluntary and anonymous. All the peak times of drug administration (e.g. 8 A.M., 12 A.M. and 10 P.M.) were observed more than once in the study period on each ward and observation was spread over the day in order to maximise the number of nurses or doctors observed and the number of different drugs used. The observed nurses and doctors were selected by convenience sampling. A standardised data collection form was used to document observations including the name of the drug, the solvent, the route of administration and the time over which the dose was administered. Doses that had to be administered continuously over 24 hours and medication that had to be given as required, were excluded from the observation as these were given outside peak times of drug administration.

Definition of i.v. ME

An i.v. dose was defined as an administration of a drug directly into the vein via injection or infusion and included preparation of the drug dose. An i.v. ME was defined as any deviation of preparation or administration of an i.v. dose from the original prescription or any act in the preparation or administration, which deviated from the manufacturer's instructions or the hospital drug policy. In the British hospital a drug policy was in use, which summarised information about drugs, their preparation and administration based on accepted scientific literature and recommendations of

the manufacturer. The German hospitals studied had no drug policy. Therefore, the leaflets produced by the manufacturer (Fachinformation), which were especially designed for health care professionals, were used as the definition of correct practice. Errors identified by nurses and patients and corrected before administration were not counted as errors.

Furthermore, the researcher recorded other information on deviations from recommended practice. These deviations were not defined as medication errors. This included the time of administration, aseptic techniques used, the number and types of interruptions where the nurse or the doctor had to leave the place of preparation for more than one minute and the procedure of patient identification.

It was intended that the observer did not review the prescription until after the observation, when the documented data were compared with the original prescription. Nevertheless, on some occasions it could not be avoided that the observer was familiar with the order. Therefore, the observer intervened in one case as she feared the patient could be harmed by an erroneous administration of the i.v. drug. This was still counted as an error.

Data analysis

Definition of the types of errors were based on the classification by Allan and Barker¹⁴ and adapted to the data. Errors were categorised as preparation or administration errors. Preparation errors included preparation of the wrong drug, the wrong dose, the wrong dosage form, the wrong preparation technique, omission errors and preparation of an unordered drug dose. Administration errors were wrong rate of administration, compatibility errors, wrong dose administered and wrong route errors. All categories were mutually exclusive, which means that one error was only classified in one category. A description of each type of error is given in Appendix 2. Preparation and administration error rates were calculated as percentage by dividing the sum of all recorded preparation/administration errors by the sum of the prepared/administered drug doses observed. The 95% confidence interval for each error rate was calculated¹⁵.

To assess the severity of errors an objective method developed by Dean¹⁶ was used. Criteria for assessment were the legal status of the drug, its therapeutic index, the number of times the same ME occurred in the same patient and the deviation from the recommended use. Each of these criteria was individually scored and the scores were added up. The total scoring value gave an indication of the severity without knowledge about the clinical status of the patient. A score below 35 indicated minor severity, a value greater than 35 was associated with a moderate to severe outcome.

Results

A total of 88 (26%) preparation errors were recorded in 337 preparations (including omissions) and 93 (34%) administration errors were identified in 278 administrations observed. It was not possible to observe both, preparation and administration for each i.v. dose. Most common errors were wrong administration rates (73), omissions (36) and wrong

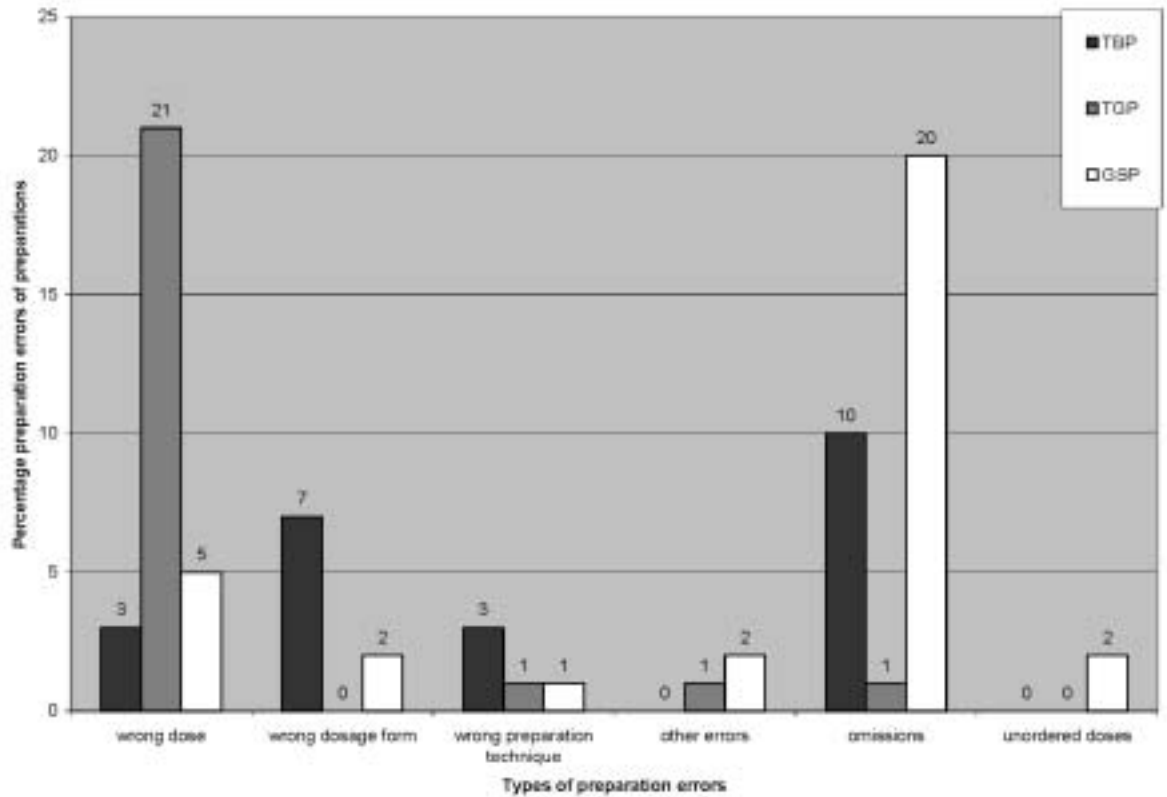


Figure 1 Percentage of preparation errors. TBP – traditional British pharmacy service (n = 77); TGP – traditional German pharmacy service (n = 126); GSP – German satellite pharmacy service (n = 134); n = number of preparation observed.

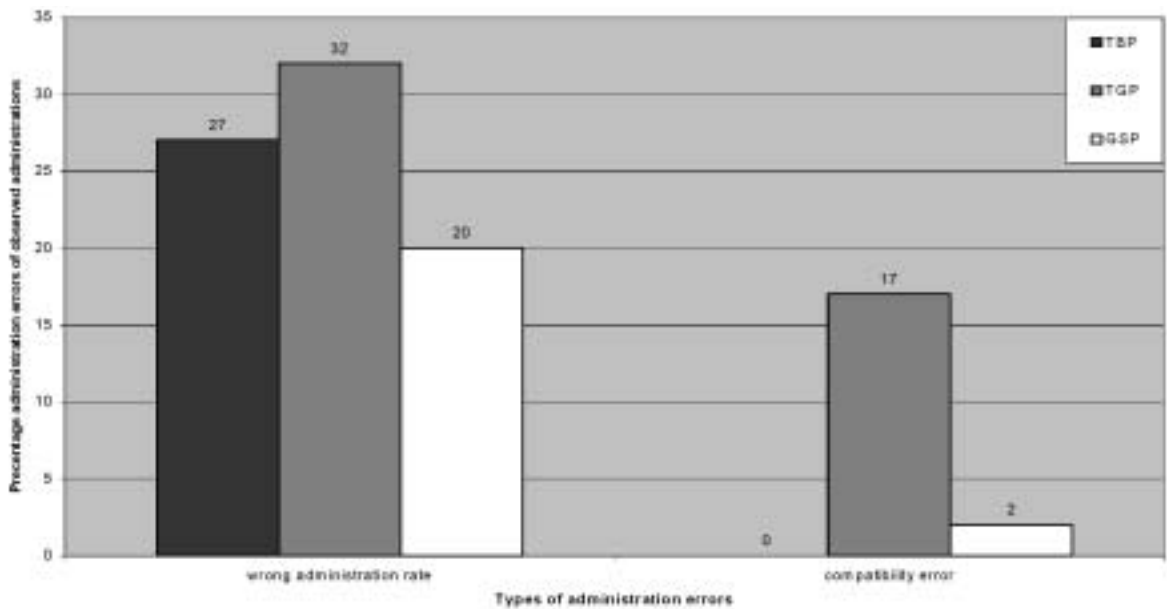


Figure 2 Percentage of administration errors. TBP – traditional British pharmacy service (n = 77); TGP – traditional German pharmacy service (n = 126); GSP – German satellite pharmacy service (n = 134); n = number of preparation observed.

dose (34) (Figures 1 and 2). Over the study period of 36 days, 61 nurses and 3 junior doctors were observed. Only two nurses refused to take part in the study; they told the observer that they just recently obtained their qualification to administer i.v. doses.

The preparation error rates were not statistically significantly different between the three study sites (Table 1). The administration error rate at the study site with TGP was statistically significantly higher than error rates of the other two systems (Table 1). Comparing the different sites the most common

errors were omissions on the wards with TBP and GSP and wrong administration rates on the wards with TGP.

Preparation errors

The wrong dose was prepared in 34 (10%) of all observed cases (Figure 1). The majority of them occurred at the study site with TGP and was mostly due to undissolved drug remaining in the vial. Other dose errors observed were due to foam, lower strength of the product chosen or smaller volume

Table 1 Comparison of error rates in three different pharmacy services

Pharmacy service	Number of observed preparations	Preparation error rate	95% CI	Number of observed administrations	Administration error rate	95% CI
TBP	77	22%	13–31%	63	27%	16–38%
TGP	126	23%	16–30%	109	49%	39–58%
GSP	134	31%	23–39%	106	22%	14–30%

CI – Confidence interval; TBP – traditional British pharmacy service; TGP – traditional German pharmacy service; GSP – German satellite pharmacy service.

than required taken out of the vial. Calculation errors, which led to dose errors, were made in 6 cases (12%) out of 51 preparations where a calculation was required. Wrong dosage form errors were mainly observed in the TBP (5 out of 7 errors) where the patients had no i.v. access and the tablets were given instead of the i.v. formulation of the prescribed drug. In the other two cases that occurred on the wards with GSP, i.v. doses of an analgesic were given instead of oral doses prescribed. Preparation technique errors were observed four times: two errors on the British hospital wards and one at each of the German study sites. In all of these cases the wrong solvent was selected. Other preparation errors included four infusion doses, where unlabelled drug containers were used. New labelling was required in ca. 50% of preparations where infusions were not administered to the patient in their original container labelled by the manufacturer. A total of 36 omissions were counted. A high number of omission errors were observed on the wards with GSP and TBP. Whereas on the British wards first doses of a newly prescribed drug were frequently omitted, analgesic doses were commonly involved in this type of error on the wards with GSP. Three preparations of unordered drugs – metoclopramide, frusemide and piritramide – were observed. All of these errors occurred on the wards with GSP. Wrong drug errors were not observed.

Administration errors

The most common type of administration error on all wards was the wrong rate error (Figure 2). Seventy-three (eighty-eight percent) out of eighty-three injections were given faster than recommended (usually three to five minutes for an i.v. push). Some nurses gave the drug dose in one single shot, others more slowly but still double or three times faster than the recommended time. The smallest number of administration errors occurred at the study site with GSP

where junior doctors gave many of the i.v. doses observed. When two or more drugs were administered compatibility errors were noticed in 20 out of 209 (10%) doses. These doses were administered at the same time with another i.v. medication as additive or through the same catheter. Most of the errors were recorded in the German ICU (18 out of 20). Fifty-nine (twenty-eight percent) possible incompatibilities were recorded for which no information about the compatibility of the drugs used was available and therefore not considered as errors. Wrong route errors have not been observed.

Severity

On all wards the majority of i.v. ME had a scoring value of more than 35 indicating potentially moderate or severe outcome (Table 2). High scoring values (69 or 81) were associated with the administrations of bolus doses, which were faster than recommended by the manufacturer (usage not according to the manufacturer's instruction) and which occurred repeatedly in the same patient. A slightly higher rate of errors with potentially minor clinical outcome were found on the wards with GSP, which were due to the smaller number of wrong rate errors and the smaller number of repetitive errors occurring in the same patient.

Other deviations from the recommended practice

In many cases the aseptic technique used and the time of administration deviated from the recommended ones. Only 6% of the professionals washed or disinfected their hands before starting preparation of the drug dose in the ICU and on the wards with GSP compared to 90% on the wards with the TBP and the TGP. The fact that on the surgical ward with TGP all i.v. doses were prepared in advance in one procedure to be administered by the next shift might have helped make washing hands routine. The rubber tops of the vials were not disinfected in 86% of the

Table 2 Severity of i.v. medication errors

	Percentage of all errors					
	TBP	95% CI	TGP	95% CI	GSP	95% CI
Scoring value of <35 (minor clinical outcome)	27%	12–41%	10%	3–16%	31%	20–42%
Scoring value of > 35 (moderate to severe clinical outcome)	74%	59–88%	90%	84–97%	69%	58–80%

CI – Confidence interval; TBP – traditional British pharmacy service; TGP – traditional German pharmacy service; GSP – German satellite pharmacy service.

preparation observed. Sterile equipment was touched in 4% of the preparations and in 7% of the administrations. The actual time of administration deviated in 47 out of 278 doses more than 1 hour from the time of administration given on the prescription.

Some situations were observed that could have resulted in errors. Interruptions – mainly phone calls – were recorded in 10 (3%) preparations. All of them occurred on wards where the phone was close to the place of i.v. preparation. Other situations were related to the procedure of patient identification, which differed in each hospital. Wristbands were used on wards with TBP, where in 11 out of 63 administrations no comparison was made between the patient's hospital number on the wristband with the hospital number written on the drug chart. Since no wristbands were used at the German study sites, patients' identification was difficult in some cases, such as an administration at night when a patient was confused and could not confirm his name. In another case where patient name signs were attached to the beds, a blanket concealed the sign and resulted in a potential error: a nurse prevented her colleague from administering a dose ordered for another patient in the same room. Although none of the practices actually resulted in an error, they were identified as potential sources for errors.

Discussion

In each of the study sites an error was observed in approximately a quarter of the preparations and the administrations. An exception was the study site with TGP where almost half of the administrations were erroneous. The most frequent types of errors were omissions, wrong doses and wrong administration rates. Characteristic types of errors were identified at each study site. The differences in practice between them that may have contributed to the errors are discussed hereafter.

A statistically significantly higher administration error rate was identified on the wards with TGP, than at the two other hospitals. One possible explanation is that on the wards with TGP nurses administered i.v. doses, in contrast to the other German hospital where mainly junior doctors performed this task. Doctors were taught about clinical consequences of wrong administration rates. Similarly, British nurses were only entitled to administer i.v. drugs if they had received training in i.v. drug preparation and administration¹⁷. In contrast, there was no compulsory training in i.v. drug administration for German nurses. This may be related to the German nursing law (Krankenpflegegesetz 1982)¹⁸, which does not list i.v. drug administration as a nursing task; hence, i.v. drug administration is not included in the curriculum of vocational training¹⁹. Another explanation for the higher administration error rate is the difference between the study sites; a high rate of compatibility errors was found on the ICU of the TGP. The number of compatibility errors on this ward should be seen in the context of the high opportunity for errors: patients in this unit received an average of five i.v. drugs at the same time and a three-lumen-catheter gave only limited i.v. access without drug interference. Finally, there was no daily prescription review by pharmacists on the wards with TGP. A project in a

large teaching hospital in Germany, which already offers this service, has shown that a pharmacist could suggest ways of administration to avoid incompatibilities²⁰. Additionally, there is a need for more information about compatibility of drugs since in 28% of administrations observed no information about compatibility was found.

In the British hospital, omissions were the most common errors. The drugs that were needed for the preparation of these omitted doses were available on the wards. Since it was found that, predominantly, the first doses of a newly prescribed drug were omitted a possible explanation for the errors was that nurses overlooked a drug recently prescribed on the chart. The omissions observed on German wards appeared to have a different cause. Nurses often decided to omit regularly prescribed analgesics if the patient was free of pain at the time the dose was due. They appeared to regard the analgesic doses as 'as required' medication even though they were prescribed as regular regime. This suggests they did not understand the principle of analgesic treatment and the avoidance of breakthrough pain. An attempt to discuss the prescription with the physician was not observed; these omissions were not documented in the patients' notes. According to the scoring values of these errors, 12 of them were of moderate and one of minor severity. Unordered drug doses included piritramid (analgesic), which was regarded to be more effective than the analgesic that the patient had been prescribed.

Dose errors were frequently observed in both German systems. This may be due to the different products licensed in Britain and Germany. For example, mezlocillin, an antibiotic, which was frequently used on German surgical wards, has not been licensed in the UK. The researcher observed that, for example, mezlocillin dissolved more slowly than other antibiotics. Therefore, dose errors due to undissolved mezlocillin occurred only in the German hospitals and significantly contributed to the number of dose errors recorded on German wards (5 out of 32).

In all three hospitals most errors were of potentially moderate and severe significance. Due to the higher risks of i.v. drugs it was expected that the majority of errors would be of greater severity than the errors occurring with oral medication¹⁶. A comparison to other studies needs to be done cautiously because other methods of severity assessments were used, for example errors were judged by health care professionals (physicians, pharmacists, nurses)^{3,21}. However, similar to the present study, in other studies health care professionals also judged over 60% of i.v. ME as errors of moderate to severe significance^{3,8}.

The limitations of the study are that it was carried out mainly on surgical wards, and that observations were done over six consecutive days on each ward. Different clinical specialities and longer periods of data collection may be associated with other rates and types of errors. Potential limitations of the observational method are the observer effect (individuals may behave differently when they are observed) and the observer error (reliability of the observer)¹³. However, in a study investigating the influence of the observer it was reported that this did not significantly affect the error rate²².

In agreement with other studies, which included an analysis of aseptic techniques^{9,10}, the present results showed that the majority of staff did not follow aseptic techniques (for example, touching the sterile tip of a syringe or omission of hand washing). Microbiological testing would be necessary to assess the significance of such deviations. There is a lack of detailed guidelines or policies on aseptic techniques. For example, the hospital drug policy used on the British wards just cautioned nurses to follow 'aseptic techniques', which was not further specified.

Recommendations

Some observed types of errors seem to be characteristic of one kind of service. A change in the procedures regarding preparation and administration can potentially prevent some errors. Suggestions made are:

- Omission errors found on British wards could possibly be reduced if drug charts were read more carefully to check for newly prescribed drugs. Better communication between prescriber, nurse and pharmacist could also reduce omissions.
- A lack of written policies and standards as well as lack of training of nurses in administration of i.v. drugs were found in Germany. A change of the legal framework in Germany to entitle nurses to administer i.v. drugs could improve the situation if linked to national education guidelines and standards.
- A daily prescription review by pharmacists could possibly prevent compatibility errors found on the wards with TGP.
- Explaining to nurses the clinical consequences of a wrong injection rate can potentially reduce wrong rate errors.
- Drug knowledge could support nurses in making decisions about the omission of doses such as analgesics or diuretics as found at the study site with GSP.
- Pharmacists can have a potential role in teaching staff about preparation and administration of i.v. medication.
- More research is needed to investigate consequences of deviating from recommended aseptic techniques.
- Providing a centralised intravenous admixture service (CIVAS) or purchasing ready-to-use products should be investigated to reduce preparation errors.

This study found a high rate of i.v. ME of moderate to severe significance. Characteristic types of errors were identified in each system. Changes in practice should be considered to reduce the i.v. ME rate and make i.v. therapy safer for patients. In order to prevent errors successfully, more research is needed to investigate i.v. ME and their causes.

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Appendix 1 *Details of the systems of i.v. medication preparation and administration*

	<i>TBP</i>	<i>TGP GS</i>	<i>TGP ICU</i>	<i>GSP</i>
Pharmacy supply of drugs	Mainly as stock drugs	Mainly as stock drugs	Mainly as stock drugs	Individual patient's dispensing
Ordering	Pharmacy	Nurses	Nurses	Pharmacy
Preparation and administration of drugs	Registered nurses	Registered nurses	Registered nurses	Registered nurses and junior doctors
Documentation of prescription	Drug chart	Patients notes	Computer system	Patient's notes
Location of the prescription chart	Patient's bedside	Nursing station	Patient's bedside	Nursing station
Transcription of prescription	No	Yes	No	Yes
Document used for preparation of i.v. drugs	Drug chart	Blackboard in the treatment room	Computer system	Preparation card
Location of preparation	Treatment room	Treatment room	Bench at the patient's bedside	Bench at the nursing station
Documentation of administration	Drug chart	Administration chart	Computer system	Administration chart
Location of the administration records	Patient's bedside	Nursing station	Patient's bedside	Nursing station

TBP – Traditional British pharmacy service; TGP – Traditional German pharmacy service; GS: general surgical ward; TGP – Traditional German pharmacy service; ICU: Intensive care unit; GSP – German satellite pharmacy service.

Appendix 2 *Mutually exclusive categories of preparation and administration errors*

<i>Preparation errors</i>	<i>Descriptions</i>	<i>Examples</i>
Wrong drug	Preparation of a drug, which was not the prescribed one	Flucloxacillin used instead Oxacillin
Wrong dose preparation	The amount of drug prepared differed from that prescribed	1g Flucloxacillin used instead of 2 g
Wrong dosage form	Formulation of drug deviated for the one prescribed	Amoxycillin oral used instead of Amoxycillin i.v.
Wrong preparation technique	Procedure of preparation did not comply with the recommendation of the manufacturer or hospital drug policy	Omeprazole diluted in water for injection instead of sodium chloride
Omission error	An i.v. dose prescribed but not administered until the next dose was prescribed. An intended omission where a drug could harm the patient was excluded (for example a dehydrated patient who was prescribed for a diuretic ^a)	I.v. Omeprazole 40mg prescribed but not administered
Unordered drug	Administration of a drug dose which was not prescribed	I.v. dose of Metoclopramide administered without prescription
Other preparation error	All other preparation errors, which were not included in the categories, used above	Unlabelled drug container used

Appendix 2 *Continued*

<i>Administration errors</i>	<i>Descriptions</i>	<i>Examples</i>
Wrong administration rate	Faster (+15%) than the one recommended	Injection of Frusemide 10 times faster than the recommended 4 mg/min
Compatibility error	Two or more drugs given simultaneously – as additives or via the same lumen of the catheter – which were not recommended to be used in combination because of known incompatibility ^b	Cefotaxime and Frusemide administered in combination
Wrong dose administered	A dose was administered to the patient which deviated from the prescribed dose	This category of error was not observed
Wrong route errors	The route of administration deviates from the prescribed one	This category of error was not observed

^a The observer could not be present at the bedside all the time until the next dose had to be given. The researcher checked the notes carefully for a documented reason of omission. If nothing was documented in the notes an omission was counted.

^b The first reference used was the drug policy of the British hospital and the German manufacturer's leaflet for health care professionals (Fachinformation). Additional information was obtained from Trissel 'Handbook of injectable drugs'²³ and in some cases directly from the company. If no data were found this was not defined as an error but recorded as 'possible incompatibility'.

Appendix 3 *The most common drugs concerned with the observation of errors*

	<i>Antibiotics</i>	<i>Diuretics</i>	<i>Analgesics</i>	<i>Other drugs</i>
TBP	Amoxicillin Co-Amoxiclav Flucloxacillin Metronidazole	Frusemide	–	–
TGP/GSP	Ampicillin plus Sulbactam Cefazolin Cefotaxime Cefuroxime Ciprofloxacin Flucloxacillin Gentamicin Metronidazole Mezlocillin	Frusemide Spironolactone	Metamizole Piritamide	Acetylcysteine Ranitidine

TBP – Traditional British pharmacy service; TGP – Traditional German pharmacy service; GSP – German satellite pharmacy service.