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AN OBSERVATIONAL STUDY ON CAUSES OF INTRAVENOUS MEDICATION ERRORSUSING A FRAMEWORK OF HUMAN ERROR THEORY

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ABSTRACT

Background: Human error theory is increasingly used to study adverse events in medicine, but has not yet been applied to study IV errors in Indian hospitals. The objective of the study was to find out the causes of intravenous preparation and administration errors using a frame work of human error theory. **Methods**: A prospective study using disguised observation was carried out for six monthsin medical, surgery, paediatrics and ICU wards. Nurses were accompanied daily during IV drug rounds. Details of each IV drug preparation and administration, and the errors identified were recorded on a standard data entry form. Human error theory was used to analyse the causes of IV errors**. Results:** IV drugs prescribed for 438 patients were observed during study period, of which 231 (52.83%) were females and 207 (47.27%) were male patients. One or more errors were occurred in the preparation of 421 out of 827 drug doses (50.90%).Preparation errors occurred in 110 IV doses (26.44%), administration errors in 311 IV doses (75.66%). Four hundred and twenty one human errors were identified, lack of knowledge of preparation or administration procedures were frequent failures in handling technology. Almost 110(26.12%) errors were identified in designing of technique. It was found that high work load 96(22.8%) also a reason for human error. **Conclusion:** Human error theory was used to point out intravenous medication errors due to preparation and administration. Our study suggests that experienced and trained personnel's are required to administer IV medication so errors can be minimized or avoided.

KEYWORDS: Human error theory, IV Medication errors, Nurse, Observational study.

INTRODUCTION

A medication error is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Medicationerrors may be committed by both inexperienced and experienced personnel like doctors, pharmacists, dentists and other healthcare providers, patients, manufacturers, caregivers and others.[1]

Medication administration errors occur frequently. A small proportion of errors will lead to serious patient outcomes and even minor errors can leave long lasting effects on the nurses involved.[2] Medication errors can occur at any stage of the medication use process may or may not lead to an adverse drug effects.[3]

Intravenous therapy is a complex process usually requiring the preparation of the medicine in the clinical areas before administration to the patient. There have been reports of deaths and harm following medication errors such as wrong drug, dose, diluent, and cross contamination errors with intravenous therapy. Previous studies have identified errors in preparing and administering intravenous medicines of 13–84% in hospitals within one country.[4] Thirty years ago Breckenridge investigated preparation and administration of IV medication on hospital wards in the United Kingdom. In his report it was summarized that there was a lack of information and guidelines, as well as inadequate prescribing, which resulted into poor quality of care.[5]

Most of the literature on medication administration errors to date has focused on oral medications administered during regular drug rounds. A few examples of medication administration errors arising from IV bolus doses or intermittent infusions have been reported. But we have not been able to find any information describing the prevalence of medication administration errors associated with continuous IV infusions which are usually replaced by nursing staff, once the contents of previous bags have been infused. This is dissimilar to oral/ IV bolus drugs and requires an observer to be

present at the point of preparation and / or administration.[6]

Reason's four stage model of human error theory[7]

We do not know why IV errors occur. Investigating the causes of errors is the first step towards error prevention. Studies on adverse events in medicine have suggested that common causes of medication errors in general include equipment problems; communication problems; lack of training, experience and knowledge; faults in the system; and personal problems. To what extent such factors contribute to IV medication errors remains unknown. Human error theory is increasingly used as a theoretical base to investigate adverse events in medicine, but this approach has not yet been applied specifically to the study of IV errors. Investigations of large scale accidents in high risk industries found that the design of systems, pre-existing organisational factors and the conditions, conventions and procedures for the use of technology place human operators in a position in which human errors can result in disasters. Reason's four stage model of human error theory is depicted in figure 1.

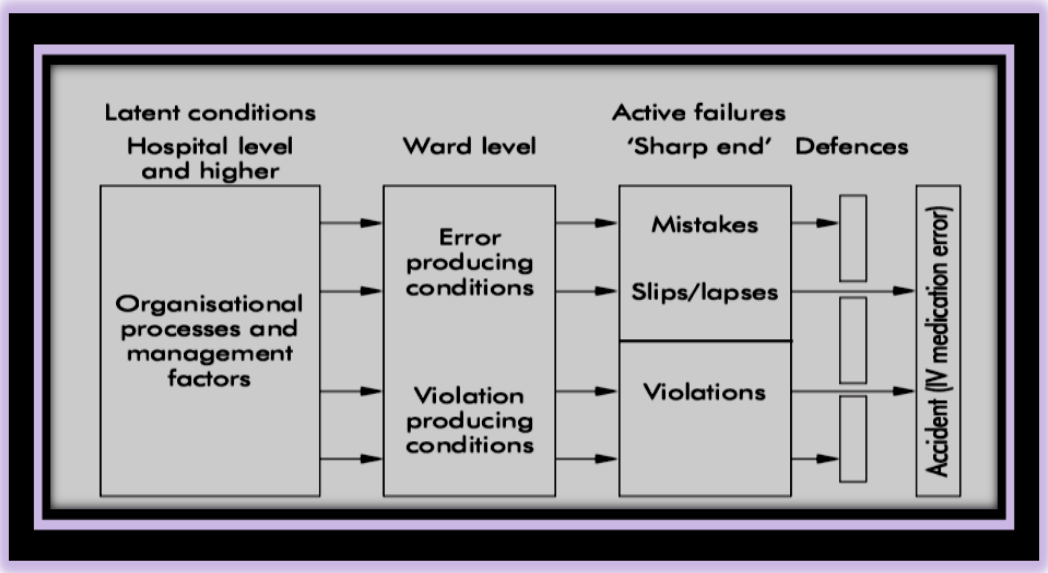

Figure 1:- Reason's four stage model of Human Error Theory.

In a study conducted by **K. Taxis and N. Barber** in two hospitals in UK, 265 IV drug errors were identified during observations of 483 drug preparations and 447 administrations. The most common type of error was the deliberate violation of guidelines when injecting bolus doses faster than the recommended speed of 3-5 minutes. Causes included a lack of perceived risk, poor role models, and available technology. Mistakes occurred when drug preparation or administration involved uncommon procedures such as the preparation of very small volumes or the use of unusual drug vial presentations. Causes included a lack of knowledge of preparation or administration procedures and complex design of equipment.[7]

Even though the literature reports a number of studies onidentifying causes of IV medication errors in various hospitals abroad, the dataavailable on such situation in India is limited. Human error theory is increasingly used to study adverse events in medicine, but has not yet been applied to study IV errors in Indian hospitals. Therefore department of Pharmacy Practice has undertaken a study oncauses of intravenous preparation and administration errors by using a framework of human error theory in a tertiary care teaching hospital for a period of six months.

MATERIALS AND METHODS

A prospective study was carried out for a period of 6 months using disguised observations in Navodaya Medical College Hospital and Research Centre, Raichurin medical, surgery, paediatrics and ICU wards which is 1000 bedded tertiary care teaching hospital. The study was approved by Institutional Ethics Committee of Navodaya Medical College Hospital & Research Centre.

Participants

1) Nurses who prepare and administer IV drugs (sample size = 63).
2) Patients prescribed with IV drugs.(sample size= 438)

Participant selection

Inclusion criteria: Nurses were eligible for the study if:
1. They were registered nurses.
2. They were fully qualified for preparation and administration of IV drugs.

Exclusion criteria

1. All patients visiting outpatients and pharmacy department.
2. Student and trainee nurses were excluded.

OBSERVATIONS

Nurses were observed by a single observer for a maximum number of four times in order toinclude as many as different nurses as possible. During the process of preparing and administeringIV drugs nurses were observed by using the observation list. The nurses are aware of the observationbut unaware about true purpose. The name of nurses, the number of observation by individual nurse and phase of study were registered. Observation took place on different days of week and differenttimes of day and night in all hospital wards. The observer was present during a pre-set series of shift, to represent the variation of nursing hours in nursing practice. The observer was instructed not to intervene when an error was detected except if the error could be the cause of severe adverse event.

Humanistic errors[7]

We have explored the cause of IV drug errors using a framework of human error theory. Error producing conditions relating to human errors (mistake, slips and lapses).

Table 1: Error producing conditions and factors affecting humanistic errors.

Error producing condition	Factors
Handling technology	Lack of knowledge, routine and experience in • Drug preparation • Drug administration • Inadequate use of technology, e.g. drug charts
Design of technology	Ambiguous manufacturer of leaflets. Unsuitable working environment. Design of drug vial presentations/equipment. Unsuitable preparation procedures
Communication	Communication problems between: • Nurses • Nurses and pharmacists • Doctors and other health professionals, e.g. ambiguous prescriptions
Workload	Several tasks at the same time End of shift Lack of qualified staff
Patient related factors	Limited venous access Non-cooperative patient
Supervision	Lack of supervision of student nurse/agency nurse
Other factors	Trying to save disposable equipment

RESULTS AND DISCUSSION

The study focused on the cause of intravenous preparation and administration errors using a frame work of human error theory in various department of a tertiary care teaching hospital. The data was collected prospectively from 438 inpatients using specially designed data collection form and the causes of errors were analysed using frame work of human errortheory. 438 patients were observed during study period, of which 231 (52.83%) were females and 207 (47.27%) were male patients. Fig.2 describes the demographic details of patients prescribed.

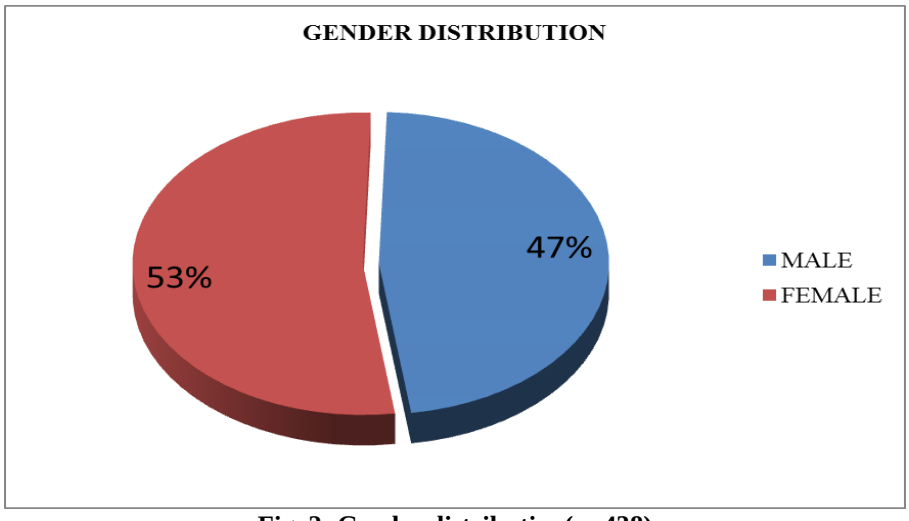

Fig. 2: Gender distribution(n=438)

Most of the prescriptions containing 1 (32.14%) or 2 (25.16%) IV drugs. This is shown in Fig.3.

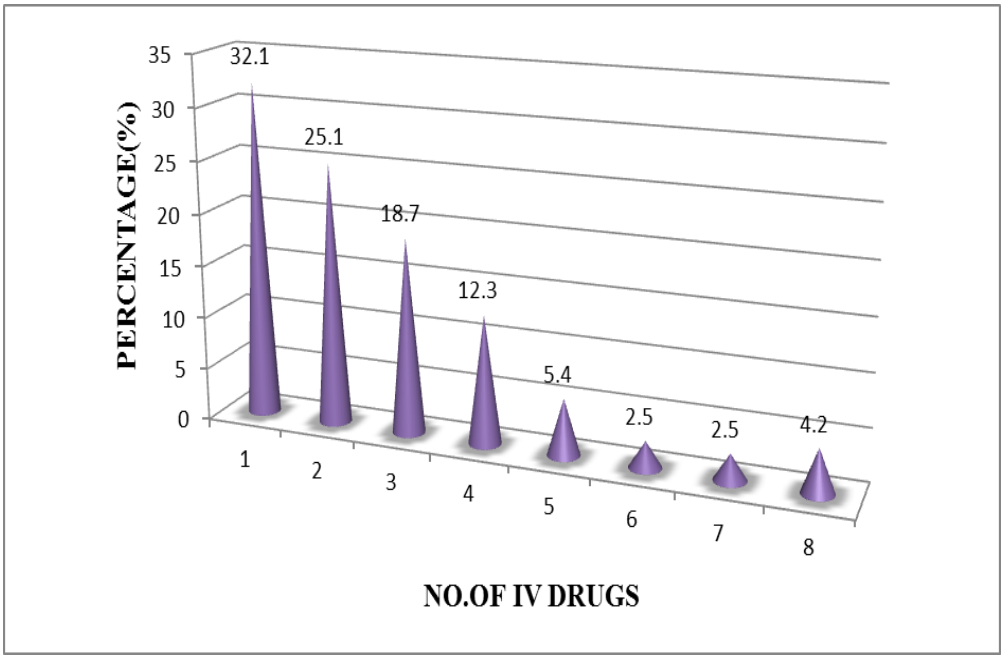

Fig. 3: Number of IV drugs per prescription(n=438)

The commonly prescribed class of drugs are illustrated in fig -4 in which antibiotics are most commonly prescribed followed by nutrients.

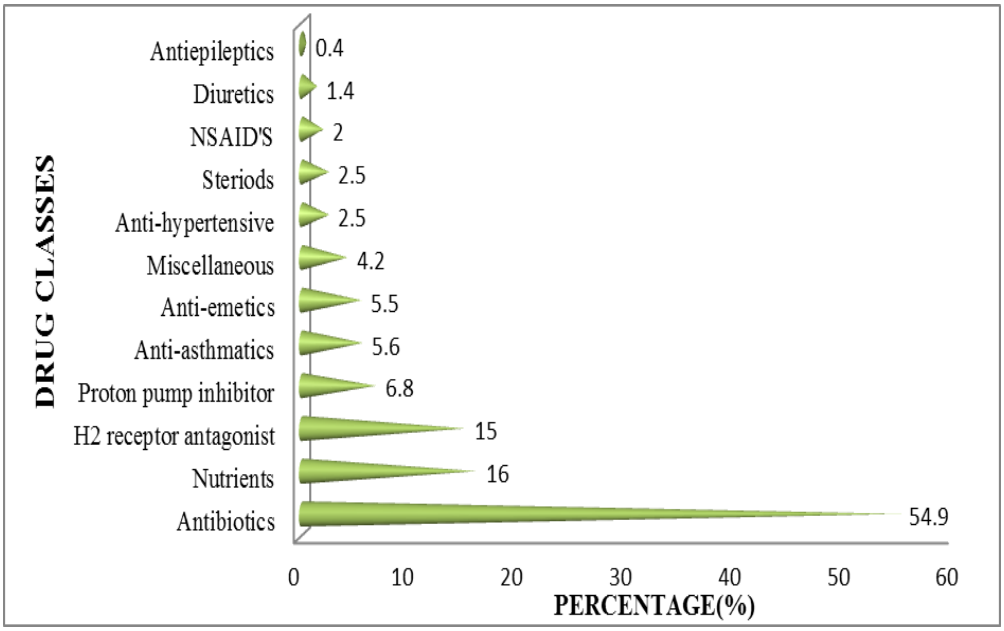

Fig. 4: Categories of drugs prescribed (n=1201)

One or more errors were occurred in the preparation/administration of 421 out of 827 drug doses (50.90%). Preparation errors occurred in 110 IV doses (26.44%), administration errors in 311 IV doses (75.66%). The comparision of preparation and administration error rates in different rates and confidence interval is calculated in four different wards are listed in Table 2. Procedural failures are presented in table 3.

Table 2: Comparison of error rates in four different wards

Ward	No. Of preparations observed	Preparation		95% CI	Number of administrations observed	Administration		95% CI
		Error	Rate			Error	Rate	
Medical	126	36	28.57	20.68% to 36.46%	143	109	76.22	± 69.24% to 83.2%
Surgery	134	32	23.88	16.66% to 31.1%	118	89	75.42	67.65% to 83.19%
Pediatric	77	14	5.19	0.24% to 10.14%	69	54	84.37	75.8% to 92.94%
ICU	79	28	35.44	24.89% to 45.99%	81	59	72.83	63.14% to 82.52%

Table 3: Procedural failures (n=827)

1	Failure to check allergies	552
2	Failure to read medication label	89
3	Failure to expire air from syringe	523
4	Failure to check patient identification	323
5	Temporary storage of medication in unsecure environment	545
6	Failure to record medication administration on medication chart	87
7	Non-aseptic technique	318
8	Failure to check pulse/blood pressure before administration	557
9	Failure to check blood sugar level prior to administering insulin	12
10	Failure of two nurses to sign the dangerous drug register	03
11	Failure of two nurses to check preparation	544
12	Failure of two nurses to witness administration of a dangerous drug	565
13	Failure of two nurses to sign medication chart	553
14	Failure to inspect medication for the expiration date	123

Review of the written intravenous therapy procedures in the study hospitals revealed that aseptic requirements included hand washing before the procedure and cleaning ampoules, vials and intravenous infusion closures. These process errors associated with poor aseptic technique were the result of failure of the implementation of procedures rather than the availability or design of the procedures themselves. The frequency with which aseptic process errors were observed in the study hospitals in the UK and Germany indicate that these were routine violations.[8] In our studies aspectic technique violated includes Cannula caps kept aseptically(25), Sterile bottle caps touched(33), Vial tops and cannula not disinfected(37), Hands not disinfected(52), Not cleaned preparation area(56), Hands not washed(48) and not wearing gloves(67) which are listed in Table 4. Similar studies was done by Cousins DHet al in UK, German and French hospitals. Nurses in the French hospital were observed to clean the preparation area (81%), wash hands (91%), and swab vial tops (96%) while results were much poorer in the UK and in the German centres with preparation area cleaned in 2% of cases overall, hands washed in 3% of cases, and vial tops swabbed in 1% of cases in the UK hospitals and 42% of cases in the German hospital.

Table 4: Aseptic technique violated (n=318)

1	Cannula caps kept aseptically	25	7.86
2	Sterile bottle caps touched	33	10.3
3	Vial tops and cannula not disinfected	37	11.6
4	Hands not disinfected	52	16.3
5	Not cleaned preparation area	56	17.6
6	Hands not washed	48	15.0
7	not wearing gloves	67	21.0

Most drug preparations followed the same procedure – namely, injection of a solvent (about 10 or 20ml) into the drug vial and drawing of the dissolved drug. Slip included the failure to notice that a drug had not dissolved completely or misreading a drug label.[9] Table 5 gives a detailed breakdown of factors which contributed to mistakes, slips and lapses. Four hundred and twenty one human errors were identified, lack of knowledge of preparation or administration procedures were frequent failures in handling technology. These findings are similar to the study conducted by Taxis K and Barber N (2003) that showed a detailedbreakdown of 136 factors which contributed to mistakes, slips and lapses. Handling and design of technology were by far the most common contributing to 67 (79%) and 27 (32%) human errors respectively. Lack of knowledge of preparation or administration procedures were frequent failures in handling technology.

High work load 96(22.8%) and destructions when carrying out several tasks at the same time were observed in 63 errors (65.62%). There was a lack of supervision of the nurse 19(4.51%). Patient related factors include a lack of venous access or unwillingness to cooperate with drug administration.

Communication problem were identified between nurses and also between nurses and doctors. Similar studies was done by Taxis and Barber (2004) in German hospital. They also found communication problem between nurses, nurses and pharmacist and between doctors and nurses.[10]

Table 5: Errors producing conditions (n=827) relating to421 human errors (mistakes, slips and lapses)

Error producing condition	No. of human errors (%)	Factors
Handling technology	421(100)	Drug preparation (n=110)
		Drug administration(n=311)
		Inadequate use of technology(n=1)
Designing of technique	110(26.12)	Ambiguous manufacture of leaflets(n=8)
		Unsuitable working environment(n=24)
		Design of drug vial presentation equipment(n=32)
		Unsuitable preparation procedures(n=46)
Work load	96(22.80)	Several tasks at same time(n=63)
		End of shift(n=21)
		Lack of qualified staff(n=12)
Patient related factors	69(16.38)	Limited venous access(n=21)
		Non co-operative patient(n=48)
Supervision	19(4.51)	Lack of supervision of student nurse(n=19)
Other factors	43(10.21)	Discarding of disposable equipment(n=43)
Communication	12(2.85)	Communication problem between nurses(n=8)
		Communication problem between nurses and pharmacists(n=00)
		Communication problem between doctors and nurses (n=4)

CONCLUSION

A lack of written policies and standard as well as lack of training of nurses of administration of drug were found. Daily prescription review by pharmacy could possibly prevent compatibilityerrors found in the wards. Explaining the nurses the clinical consequence of IV medication or drug errors or wrong injection can potentially reduce the rate of errors. The causes of these errors were multifactorial and included experience and professional back ground.

In order to prevent error successfully more research is needed to investigate IV medication error and statistics andit is evident from the study that pharmacist's intervention is effective in reducing the number of IV medication errors.

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