FAILURE MODE AND EFFECT ANALYSIS (FMEA) OF IV-MEDICATION ERROR IN METTU KARL HOSPITAL, METTU TOWN, OROMIYA REGIONAL STATE, SOUTH WEST ETHIOPIA

BY: SILESHI DUBALE

A RESEARCH PAPER SUBMITTED TO DEPARTMENT OF PHARMACY, COLLEGE OF PUBLIC HEALTH AND MEDICAL SCIENCE, JIMMA UNIVERSTY; IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN CLINICAL IN PHARMACY (MSc)

OCTOBER, 2014

JIMMA, ETHIOPIA

JIMMA UNIVERSITY

COLLEGE OF PUBLIC HEALTH AND MEDICAL SCIENCES

DEPARTMENT OF PHARMACY

FAILURE MODE AND EFFECT ANALYSIS (FMEA) OF IV-MEDICATION PROCESS IN METTU KARL HOSPITAL, METTU TOWN, OROMIYA REGIONAL, SOUTH WEST ETHIOPIA

BY: Sileshi Dubale (B.Pharm)

Advisors:

- **Mr. Sultan Suleiman: (B pharm., M.Sc., Associate Professor and PhD Fellow)**
- **Mr. Abdisa Gurmesa (BSc, MSc in Biostatistics)**

SEPTEMBER, 2014

JIMMA, ETHIOPIA

Abstracts

Background: - Intravenous (IV) medication is integral component of clinical care for hospitalized patient. Errors associated with IV medication can cause detrimental patient outcome. It affects patient life and can increase health care cost. It also involves high risk since it is delivered directly into the patients' blood stream. As part of quality by design (QbD), Failure Mode Effect Analysis (FMEA) is a proactive tool used to analyze risks, identify failures and prioritize remedial measures. The major advantage of FMEA over other quality improvement schemes is the information gathered that makes it easy to identify the priorities of any actions required for improvement.

Objective: - To assess prevalence, causes and severity of IV medication errors using FMEA in Mettu Karl Hospital, South West Ethiopia.

Method: - Hospital based prospective cross sectional study was conducted for one month from January 30 to February 28, 2014 by using direct cross sectional observation of IV medication preparation and administration. Data was analyzed by using SPSS version 16.0 statistical software package. Frequencies of descriptive statistics were presented by using percentages and table. Binary, back ward logistic regression analysis was performed to assess factors associated with IV medication failure mode to identify only significant root causes. We use R-soft ware for rating and categorizing of high Risk Priority Numbers along severity versus occurrence and detectability as failure mode effect analysis standard. Statistical significance was defined at a level of 0.05.

Result: From 123 IV medication preparation, 12 failure modes and 33 associated factors were identified. Aseptic technique was the most observed error, 106(86.2%); Followed by 94(76.4%) of wrong time and 92(74.8%) of wrong rate. Human factor, 71(57.7%) was the most contributing factor observed. Surgical ward (75.0%) and Gynecology ward (62.0%), were the first, and second wards in which IV medication failure mode was observed.

Conclusion: This study shows that there was a serious IV medication failure mode in each wards and needs prompt intervention.

Key words: IV medication process, failure mode, effect analysis.

Acknowledgement

First I would like to praise the Omnipotent and Almighty GOD for his help in my entire journey!

I would like to acknowledge my advisors, Mr. Sultan Suleiman and Mr. Abdisa Gurmesa for their invaluable, constructive and timely comments throughout my work on this research.

I extend my gratitude to Jimma University for giving me this Golden opportunity, and to Mettu Karl Hospital for allowing and hosting me for data collection.

My thanks go to my family (my wife Senait Mekuria my Father Dubale Dhinsa, my Mother Tayitu Nole and my brother Zeleke Dubale) and my friends for their encouragement and supports in many aspects.

Last but not least I would like to acknowledge Patients had willing to be observed and participated in the study.

Table of content Pages

List of Tables **Pages**

List of figures Pages

Acronyms and Abbreviations

ADES= Adverse Drug Events

AHEQ= Agency for Health Care Research and Quality

ASHP= American Society of Health System Pharmacist

DERS =Dose Error Reduction Soft ware

EPA= Ethiopian Pharmaceutical Association

EPHA= Ethiopian Public Health Association

FDA= Food and Drug Act

FMEA= Failure Mode and Effects Analysis

I**OM**=institution of medicine

IPF=International Pharmaceutical Federation

IV= Intravenous

JCAHO= Joint Commission Accreditation of health care organization

LASA = Look Alike and Sound Alike

LOS= Length of Hospital Stay

MEPS = Medication Error Prioritization System

MKH= Mettu Karl Hospital

MOH = Ministry of Health

NCCMRP =National Coordination Council of Medication errors & Prevention

NGO = None Governmental Organization

NTI= Narrow Therapeutic Index

POC= Point of contact

RPN= Risk priority number

SPSS= Statistical package for Social Sciences

UK= United Kingdom

US= United States

USP= United States pharmacopoeia

WHO= World Health Organization

1) Introduction

1.1) Background of the Study

Intravenous (IV) medication is integral component of clinical care for hospitalized patient. However, errors associated with its preparation and administration can cause detrimental patient outcome, affect patient life and increases health care cost. Of all medication errors, Intravenous (IV) medication error involves high risk since it is delivered directly in to the patients' blood stream. Medication errors are any preventable events that may cause, or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional or patient. The errors included prescribing, dispensing, administration, monitoring and patient compliance errors. It is the most common types of injuries experienced by hospitalized patients. The issue received maximum attention in the immediate years after the institution of medicine (IOM) report was published in 1999.The published data demonstrates that approximately 5-10% of all hospital admissions are medicine (drug) related (1-4).

Various factors identified for medication errors can be related with professional practice, health care products, procedure and system. The source of medication errors; therefore, are multidisciplinary and multi factorial. It usually occurs because of the breakdown in the systems that have been developed for handling and processing drugs. Some of the errors result in serious patient morbidity and mortality; compromise the confidence of patient in health care system, and lead to increased health care cost. Administration of the wrong medication, wrong dose, wrong dosage form, by wrong route, at wrong rate, or wrong frequency or with wrong diluents are examples of consequences due to misinterpretation, ambiguity, or lack of knowledge or understanding of elements of the medication order sentence (5, 6).

Hospitalized patients are subjected at least to one medication error per day with at least 1.5 million preventable each year. This reaction leads to an estimated $3.5 billion in addition to health care cost annually to hospitalized patient alone and the medication error is representing between 4^{th} to 6^{th} leading causes of death. Multidisciplinary team comprised of pharmacy, physician, nurses and biomedical engineers performed a failure mode and effect analysis (FMEA) to identify potential failure associated with IV pumps as a major academic medicine center; the study conducted in six hospital departments of three countries showed that 824 doses were prepared and 798 doses administered. The product was either not labeled or incorrectly labeled in 43%, 99%, and 20% of doses administered in the UK, German and French hospitals, respectively. At least one deviation from aseptic technique was observed among 100%, 58%, and 19% of cases in the three countries. In Australian hospital studies IV drug administrations have revealed a higher risk and severity of error than other medication administrations. A significant proportion of errors suggest the main determinant factors are skill and knowledge deficiencies, with errors and severity reducing as clinical experience increases. A proportion of errors are also associated with routine violations which are likely to be learnt workplace behaviors; both areas suggest specific targets for intervention (7-10).

IV medication errors should be minimized as far as possible and the nature should be used so that system could be implemented for prescribing, dispensing and administration of medication. Failure mode and effect analysis (FMEA), as part of quality by design (QbD), is a proactive tool used to analyze risks, identify failures and prioritize remedial measures. To examine the hazards associated with the process of drug delivery to patient. Major advantage of FMEA over other quality improvement schemes is the unique information gathered that makes it easy to identify the priorities of any actions required for improvement, lowering the risk of the medication-use process (11, 12).

Based on this ground, the primary objective of this study was to assess prevalence, causes, severity and effects of IV medication errors using failure mode effect analysis (FMEA) in Mettu Karl Hospital, South West Ethiopia.

1.2) Statement of the problem

The 2000 Institution of Medicine (IOM) report entitled building of health system indicates that 44,000 - 98,000 American die each year because of medication error which results in one of every 854 death. IV medication administration involves injection of fast acting powerful substances directly into the patient blood stream & nothing could be done to stop medication from entering the systemic circulation It is very poor in health care system to know and characterized the problems(2,3,6,12 & 17).

The problem of IV medication can be death, temporary or permanent impairment of body function (structure) than any other category of events. The study of European countries evaluating IV medication process failure mode demonstrated rate of 13-48% in UK, Germany and France. In the UK, a study listed a failure mode rate of 4% in the preparation or administration of IV doses. According to the study conducted in two Australian teaching hospitals, at least one error occurs in the processes of IV medication. From 568 IV medication observed, 69.7% had at least one clinical error and 25.5% of these were serious and the wrong dose was the most frequently occurred error (95 per 101 series error) and the significant proportion of determinant was experience and knowledge deficiency. Malaysian hospital(in Feb. 2013), study show that from total of 349 samples 97.7 % of them was exposed to at least one IV medication error, and the most common errors include the sterility problem and faster rate. Current publications are also still confirming that there is high frequency of IV medication errors and multi factorial causes. The scope of the problem of IV medication process failure mode is very high because 90% of hospitalized patients receive drug via IV rout (4, 6 & 10).

Concurrent use of variety of IV-medications increases the possibility of errors. Preventable or potential risk associated with IV medication was twice higher than oral medication in hospitalized patient. Patient injury resulting from drug therapy area is among the most type of adverse events that occur in hospitals. According to the Agency for Health Research and Quality (AHRQ) adverse drug events result in more than 770,000 injuries and death each year and cost up to $6.5 million per hospital, depending on size. Approximately 1.3 million people are injured annually in the US following medication errors (3, 12 & 13)

IV medication failure mode is the leading cause of death in the US, with the number of deaths exceeding those associated with motor vehicle accidents, breast cancer, or AIDS. It was shown that medication related failure represent the largest single cause of errors in the hospital setting, accounting for more than 7,000 deaths annually, more than deaths resulting from workplace injuries. In US, where IV medication preparation by the hospital pharmacy is the standard of practice and required by the joint commission, errors still occur with IV medication. An analysis of 73,769 IV administration errors reported in a 5 year period to the US pharmacopoeia(USP), Med mark program revealed that 3-5% where harmful (7, 9 & 13)

In today's healthcare world, patient-safety issues are the major concerns. With a view to reduce the risk of medication errors and to improve patient safety, tools such as FMEA enable a prospective analysis of the process of drug delivery to review potential failure modes and their associated causes and to assess which risks have the greatest concern, stimulating the most urgent improvement effort in clinical practice to prevent errors. Thus to achieve the greatest impact in preventing patient harm is to focus on IV medication on the point of care is very important (18).

In my knowledge the prevalence, severity and root causes of IV medication error didn't identified in the Ethiopian Hospital in general and in Mettu Karl

Hospital in particular using FMEA. This indicates that there it is a huge research gap to be filled in this regard.

1.3) Significance of the study

This study is very vital to dig out information about IV medication process failure mode frequency and the root causes. It helps for the prioritization of IV medication errors risk severity, gives clues for planning and implementations of risk reduction strategy. It also can be very important for scaling up and application of new hospital reform and pharmaceutical care philosophy in the hospital and the involvement of all health care team for solving drug related problems.

It helps policy makers to prepare guidelines and standards for medication error patient safety practice. Finally it can serve as base line information for further studies to be carried out all over the country since such kind of research using this method was not done before in the country as far as the knowledge of the researcher is concerned.

1.4) Conceptual framework

The conceptual frame work for the study is presented in Figure 1 using model of Fishbone diagram also called Ishikawa diagram after its innovator.

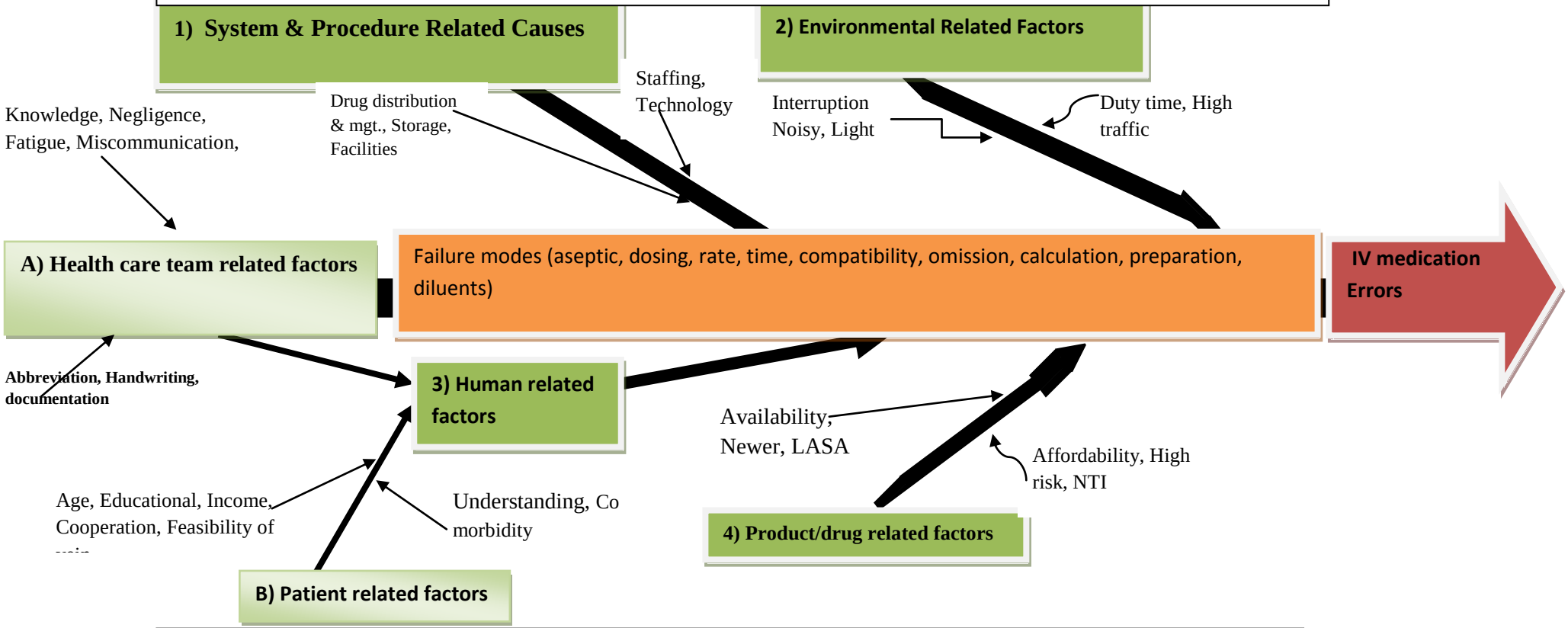

Figure 1: Ishikawa (Fish bone) diagram of root causes analysis of IV medication errors as conceptual frame

2) Literature Review

Most health professionals working in hospital wards may not adhere to the "5R's" (right patient, right drug, right dose, right route and right time) and may also lack knowledge about medication, including the indication, patient age, route, action, adverse effect, contraindication and drug-drug interaction. A simulated study in England found that 14.2% of 150 orders were converted from milligram to millimeter incorrectly, with the maximum dose deviation of 400 furthermore, 32.7% of drug doses drown up in syringe were in correct. An evaluation the reports from the Australian Bureaus of statistics revealed that errors occurred in 15-20% of drug administration when floor stock (using bulk stock medication) was used versus 5-8% when patient-specific dose were dispensed by pharmacist. Supplying the products in ready to administer form, e.g. prefilled syringes sealed systems requiring minimum manipulation before use, investing in reconstitution devices, providing training, considering a role of IV specialist practitioners, enrolling of hospital pharmacist in hospital care are some preventive measures for IV medication errors (1,3 & 5)

It is estimated that as much as 60% of drug related morbidity and mortality are preventable yet a paucity of research exists on how medication mishaps contribute to the course of hospitalization. For a number of reasons, outcomes researcher and health service researchers face several challenge in capturing the impact of medication errors on patients' outcome and quality of care. First, data source and the interpretation are hampered by lack of homogenous data source and the preponderance of duplicative or proprietary systems to systematically evaluated medication practice and patient out came. Second, the enormous demand of clinical care limits the amount of information that can be documented in routine clinical; practice. Studies on adverse events in medicine have suggested that common causes of IV medication errors in general include equipment problem, communication problem, luck of training, experience and knowledge, faulty in the system and personal problems. To what extent such factors contribute to errors remains mostly unknown (7, 9).

Despite of the health professionals' best practical effort to provide safe and effective pharmaceutical care, research has increasingly identified an alarming incidence of unintended harm to hospitalized patient. In the land mark 1999 Harvard medical researchers 13 million injuries occur national wide to patient receiving hospital care, the report suggest that more death occur annually from medication errors than from industrial accident. Medication errors are costly from financial perspectives; the national estimate of costs to hospital is two billion dollars per year including malpractice cost and cost of injury. Intravenous therapy is complex process usually requiring the preparation of the medicine in the clinical area before administration to the patient. There is a growing awareness of the importance of the design and implementation of system of care on the risk of medication error and to carryout safe medication practice. The design of procedure and implementation of system for preparing and administering of IV medicines was thought likely to be influenced by national factor such as legislation, health care system requirement professional standards, university curricula and delivery of education and training for health care staffs (8-14)

Study in Czech Republic hospitals in the year 2012 show that, the most common errors were improper dosage (60.9%), wrong medication (19.3%), and erroneous route of administration (12.9%). The most frequent medication errors appeared using drugs affecting the nervous system (psycholeptics and antiepileptics), antibiotics, and drugs affecting the respiratory system. The study also show that, nurses administering the drugs were responsible for 43.0%, physicians prescribing the drugs for 36.8%, and pharmacists dispensing the drugs for 20.2% of the errors. Of 25 patients with severe drug intoxications, 60.0% were children less than 5 years of age treated with pharmaceuticals affecting the CNS, and 28.0% patients over 60 years of age with chronic application of theophylline, digoxin, or lithium. The conclusion indicates that extremity of the errors are shown two high-risk categories: children of less than 5 years of age, in whom the dose was not correctly adjusted, and elderly people with chronic medication and insufficient control of their medication level. Therefore, the measures

for risk reduction should focus primarily on them. Human errors theory is increasingly used as theoretical bases to investigate adverse events in medicine, but this approach has not yet been applied specifically to the study of IV medication errors (16, 17).

Canadian study of 2007 on errors associated with IV infusion therapy in critical care as part of a quality improvement initiative, a prospective, observational audit show that omissions or discrepancies related to documentation accounted for 92.7% of all errors. The most common errors identified were incomplete labeling of IV tubing (1779 or 31.5% of all errors), omission of infusion diluents from the medication administration record (474 or 8.4% of all errors), and discrepancy between the medication order as recorded in the patient's chart and the IV medication that was being infused (105 or 1.9% of all errors). It was concluded that strict definitions of errors and direct observation methods allowed identification of errors at every step of the medication administration process and documentation discrepancies were the most prevalent type of errors (16-18).

FMEA is a method used to assess complex processes according to a standardized approach with a view to identifying the elements that carry a risk of causing harm and, consequently, prioritizing remedial measures. The FMEA approach also enables each of the elements comprising a process under investigation to be attributed a cumulative numerical value, the risk priority number (RPN), which can be used to prioritize the action to be taken because it is a numerical rating of the severity, probability and delectability of each failure mode. According to Paola and et al 2012 study in FMEA of drug delivery process in Padua university Hospital pediatric ward Italy, A total of 37 high-risk failures were identified, plotted in with 71 associated causes and effects. None of the steps in the drug administration process were free of potential failure modes. Study of potential risk factors of medication administration errors Besancon University Hospital (France), April 2003 indicate that, medication administration error rate was 14.9%. Dose errors were the most frequent (41%), 10% of them were estimated as potentially life-threatening. Nurse workload and incomplete or illegible prescriptions were two independent risk factors of Medication Administration Errors. It

was indicated that the quality of the medication administration process needs to be optimized in hospitals in order to minimize the incidence of iatrogenic preventable problem (12, 15 &17).

Health care failure analysis study in a Spanish university hospital, a reduction in prescription errors was achieved by providing training for prescribers on updating prescription procedures, improving clinical decision support and automating the software connection to the hospital census (relative risk Reduction (RRR 22.0%;). Validation errors were reduced after optimizing time spent in educating pharmacy residents on patient safety, developing standardized validation procedures and improving aspects of the software's database (RRR, 19.4%;). Two actions reduced dispensing errors: reorganizing the process of filling trolleys and drawing up a protocol for drug pharmacy checking before delivery (RRR, 38.5%;). HFMEA facilitated the identification of actions aimed at reducing medication errors in a healthcare setting, as the implementation of several of these led to a reduction in errors in the process of drug prescription, validation and dispensing (18).

Study on anti-infective medication by using the Failure Mode and Effect Analysis in January 2013, conducted at the medical clinic of a hospital in the State of Goiás showed the total results of 52 failure modes, 79 effects of failure, and 285 causes of failure. The causes were related to: the management of organizational processes, human resources, physical and material structure. A total of 298 actions for improvement were recommended for 215 causes of high and average priority, 81.9% of which were short-term priorities(19).

A prospective ethnographic study using disguised observation study carried out on two wards in German non-university hospital showed that, one or more errors occurred in the preparation and administration of 58 of 122 IV drug doses (error rate 48%). Of doses, 4 had potentially severe errors (3%), 38 (31%) potentially moderate errors and 16 (13%) potentially minor errors. Common errors included multiple step preparations and the co-administration of potentially incompatible drugs as intermittent infusions. It

was concluded that there was high incidence of IV drug errors was found in the study hospital. Effective strategies to reduce potentially harmful errors, measures could include a reduction in the number of ward based IV drug preparations, improvement of staff training and the introduction of ward-based clinical pharmacy services was recommended (20)

The study conducted to determine the frequency of medication errors that occurred during the preparation and administration of IV drugs in an intensive care unit of one of the largest teaching hospitals in Tehran during 2006, the number of errors identified were 380/4040 (9.4%). Of those, 33.6% were related to the preparation process and 66.4% to the administration process. The most common type of error (43.4%) was the injection of bolus doses faster than the recommended rate. It was found that the IV rounds conducted at 9:a.m. had the highest rate of error (19.8%) (21).

According to a randomly selected medical and surgical department at Aarhus University Hospital, Denmark study, there was in each stage the frequency of medication errors were, ordering: 167/433 (39%), transcription: 310/558 (56%), dispensing: 22/538 (4%), administration: 166/412 (41%). The most common types of error throughout the medication process were: lack of drug form, unordered drug, omission of drug/dose, and lack of identity control. There was a need for quality improvement, as almost 50% of all errors in doses and prescriptions in the medication process were caused by missing actions process (23).

Alan P. and Michael A. et al study show that medication errors reported by pharmacy staff using the online database from April to September 2011 were categorized into one of three classes based on a severity scale and depicted in a simple three-tiered structure. MEPS scores with a value above 20 are classified as high priority. The greatest reduction occurred for those “missing information” error types in which a medication could not be dispensed or administered until the information was obtained, such as missing drug, dose, route, dosage form, or dosage interval. Results from this study indicate that the methodology followed represents a readily adaptable and generalizable

approach to collecting comprehensive data regarding medication-related errors. As a result of this process, the majority of facilities participating experienced statistically significant reductions in errors (24 & 25)

In Ethiopian Hospital there is no data that indicates the prevalence and severity of IV medication errors, using FMEA. But one study showed that, in Jimma University Specialized Hospital ICU ward, more than half (51.8%) were labeled as medication administration errors (22).

3) Objectives

3.1) General objective

To assess prevalence, type, causes, and severity of IV medication errors using failure mode effect analysis (FMEA) in Mettu Karl Hospital, South West Ethiopia.

3.2) Specific objectives

- ✓ To determine prevalence of IV medication Failure Modes in Mettu Karl Hospital, South West Ethiopia.
- ✓ To identify types of IV medication errors in Mettu Karl Hospital South West Ethiopia
- ✓ To analyse severity of IV medication Failure Modes in Mettu Karl Hospital, South West Ethiopia.
- ✓ To assess the root causes of IV medication errors in Mettu Karl Hospital, South West Ethiopia.

4) Method and participants

4.1. Study area

The study was conducted at Mettu Karl Hospital south west Ethiopia. Mettu Hospital is Zonal Hospital found in Mettu town Ilu Ababora Zone Oromiya National state south west Ethiopia, 600 Kilo-meters far from Addis Abeba, the capital of the country. Mettu Hospital was established in the year 1948 GC and was renewed in 1985 by the Germany organization called "Menschen für Menschen", and because of this its name was changed to Mettu Karl Hospital (MKH) to remember the head of the organization Karlheinz Böhm. MKH serves a total of 2.1 million people from the south west of the country including Oromiya, Gambella and Southern Nations & Nationalities and people national regions with total 199 beds (14)

4.2) Study design and period

Hospital based prospective cross sectional study was conducted for one month from January 30 to February 28, 2014.

4.3) population

4.3.1) Source population

All patients admitted in Mettu Karl Hospital wards and on IV medication.

4.3.2) Study population

All patients admitted in Mettu Karl Hospital wards and on IV medication and who full fill the inclusion criteria

4.3.3) Sample size and sampling technique

There was no any sampling technique and sample calculation used because all admitted patients on IV medications in the study wards during study period were included.

4.4) Inclusion and Exclusion Criteria

4.4.1) Inclusion Criteria

All admitted patients and patients on IV drug during the study period and who had willingness to be observed were involved in the research.

4.4.2) Exclusion Criteria

Patients on blood transfusion were not involved in the study

4.5) Study variable

4.5.1) Dependent variables

- ✓ IV medication errors

4.5.2) Independent variables

- ✓ System/ procedure related factors
- ✓ Human related factors
  - ➢ Health care team related factors
  - ➢ Patient related factors
- ✓ Environmental related factors
- ✓ Product/drug related factors

4.6) Data collection procedure, instrument and data collectors

Structured questionnaire standard formats prepared from previously done researches with some modification were used as the instrument of data collection and data was filled by direct observation of IV medication preparation and administration. Physician medication order sheets nurse medication administration records and condition of medication administered was observed on spot.

Two nurse and two pharmacists who collect data were trained on how to collect data and failure modes and fill the questionnaire. One pharmacist and the investigator checked the completeness and consistency of the questionnaire, observation and the collected data.

Multi disciplinary team was formed from medical doctors, nurses, pharmacists. The team rated the severity of the primary dependent variables (IV medication errors) based on clinical judgment experience. Occurrence and observability of the failure mode were rated based on standard literature. For the process failure and its causes, the corrective measures and point of control was planned during the data collection.

4.7) Data processing Analysis and preparation

All the data entered, compiled and analyzed by using SPSS version 16.0. Frequencies of descriptive statistics were presented by using percentages and table. Back ward binary logistic regression was conducted to identify factors associated with IV medication failure mode to identify only significant root causes. The investigator used R-soft ware for rating and categorizing of high risk RPN along severity versus occurrence and detectability as FMEA standard. Statistical significance was defined at a level of 0.05.

4.8) Data quality control

To ensure the validity and reliability of the data, training and demonstration was given to data collectors and supervisor by principal investigator. Pretest of data collection tool was done on 5% of patients on IV medication and fluid therapy. Data was checked for completeness, clarity and consistency by supervisor and principal investigator and any clue about the purpose of the study was not informed to health professionals since it may create awareness and deviate from routine IV medication process.

4.9) Ethical consideration

Prior to data collection, the researcher obtained official letter permission from Jimma university post graduate and research office. The letter of permission was written to Mettu Karl Hospital requesting the cooperation of the hospital to allow the researcher to conduct the study on there. In addition, oral permission was obtained, and during data collection patients' and health care professionals willingness was asked and data collection was done.

4.10) Dissemination plan

The findings of the study will be disseminated to Mettu Karl Hospital, Zonal health office, Regional health office, MOH and different NGOs working on medication safety issues, and control measures identified and prioritized will be forwarded for implementation. The results of the study will be presented on national and international professional association like EPA, EPHA and international pharmacy associations. Finally attempt will be made to publish on reputable peer reviewed journal.

4.11) Operational definition and Terms

- ✓ **Aseptic technique errors:** Deviation from recommended practice (e.g. not washing hands before preparing drugs, contaminating drugs or IV lines)
- ✓ **Deteriorated drug:-** Using expired, un labeled or previously opened drug
- ✓ **Drug incompatibility: -** Co-administration of two or more incompatible drugs at the same time in the same line.
- ✓ **Dose omission errors:-** Doses not given before it is next due/Failure to administer an ordered dose to a patient
  - **Dosing magnitudes:-**
  - ✓ **Potentially significant errors: -** Dose error may result in adverse effects or inadequate therapy (e.g. ordering or administering of high dose of ±1.4-4.0 times the normal dose.
  - ✓ **Potentially serious errors: -** Dose might have resulted in serious toxic reactions or inadequate therapy for a serious illness (e.g., ±4-10 times the normal dose.
  - ✓ **Potentially fatal errors: -** Ordering medication >/<10 times the normal dose; a dose of a medication that would potentially result in pharmacologic effects or serum concentrations associated with fatal toxic reactions; a drug that had the potential to produce a life-threatening reaction in the patient and a dose of a life-saving drug that was too low if not given the patient may affected due to lack of the drug (26).
  - **Failure mode:** Different ways can a process or sub-process fail to provide the anticipated result and we can use interchangeably with IV medication error.
  - **Medication risk criteria.** The risk associated with a particular drug was determined conservatively, using the three criteria listed below (26).
    - ✓ **Potentially toxic nature of drug.** Drugs were considered "high risk" if they had a narrow therapeutic index and were included on the USP's list of high-risk medications.
    - ✓ **Intensity of patient monitoring.** For example, dopamine was considered a moderate-risk, not a high-risk drug, because patients receiving dopamine therapy are usually closely monitored, so a medication error would more likely be detected before harm ensued.

- ✓ **Moderate-risk IV medications** (e.g., milrinone) = For these drugs an overdose greater than 5 times the institution-established maximum limit was considered to have the potential to cause severe harm (potentially life-threatening).
- ✓ **High-risk IV medications** (e.g., heparin): For these drugs an overdose greater than 2.5 times the maximum institution-established limit was considered to have the potential to cause severe harm (potentially life-threatening).

- **Inappropriate storage:** Product not used immediately after reconstitution or storing used or opened drug at bed side of the patient.
- **Medication preparation:-** Reconstitution, dilution or concentration of medications before administration.
- **Process:** What to be evaluated (IV medication preparation and administration)
- **Point of Contact (POC):-** who is responsible for oversight
- **Risk priority number: -**hazard scoring parameter and it is the product of occurrence(O), severity(S) & detection(D) (RPN= O*S*D)(12)

  For rating scale used to assign the value of occurrence (O), severity(S) and detection (D) scores in the failure see annex

- **Un authorized drug error:-**Administration of un prescribed drug to the patient
- **Wrong time:** Dose administered out of ordered time $\pm$ 30 minutes.
- **Wrong rate**: Administration of the drug faster than usual intended rate 3-5 minutes.
- **Wrong diluents: -**Incorrect diluents and volume used e.g. diluents used by piercing IV bag without considering sterility and air entry.

5) Results

5.1) Socio demographic characteristics of admitted patients in Mettu Karl Hospital during the study period

Totally 123 IV medication preparations and administration were observed. ost of the patients admitted in Mettu Karl Hospital during the study period were in the age group of 15 – 50 (54.5%). Regarding their gender, majorities of them 74(60.2%) was female. Concerning the religion, most of the patients were Orthodox 49(39.8%), followed by Muslim 40(32.5). The educational level of most patients was grade 1-8(36.6%). The income of majority 59(48.0%) of patients' was less than five hundred Ethiopian Birr per months, and most of them 60(48.7%) were travel to the Hospital about 20- 100 KM, and live in Urban area, 77(62.6%).(Table 1)

Table 1: Socio demographic characteristics of admitted patients in Mettu Karl Hospital from January 30 - February 28, 2014

Socio demographic characteristics	Categories	N	%
Age(yr)	**≤14y**	**31**	**25.2**
	15-50	**67**	**54.5**
	50+	**25**	**20.3**
Sex	**Male**	**49**	**39.8**
	Female	**74**	**60.2**
Ethnicity	**Oromo**	**76**	**61.8**
	Amhara	**25**	**20.3**
	Tigre	**16**	**13.0**
	Others	**6**	**4.9**
Religion	**Orthodox**	**49**	**39.8**
	Muslim	**40**	**32.5**
	Protestant	**31**	**25.2**
	Other	**2**	**1.6**
Monthly income	**<500**	**59**	**48.0**
(ETB)	**500-1000**	**46**	**37.4**
	>1000	**18**	**14.6**
Educational status	**Illiterate**	**39**	**31.7**
	1-8 grade	**45**	**36.6**
	9- 12	**22**	**17.9**
	>12	**17**	**13.8**
Distance from hospital	**<20km**	**48**	**39.0**
	20-100km	**60**	**48.7**
	>100km	**19**	**15.3**
Resident	**Rural**	**46**	**37.4**
	Urban	**77**	**62.6**

Key: other (Ethnicity= Yemen, Nuer, Shekicho and Religion = Not following any Religion)

5.2) Distribution of health care team participated in medication preparation and administration in MKH from January 30 - February 28, 2014

The figure below shows that most of IV medications were prepared and administered by 94(76.4%) nurses, and 1(0.80%) of pharmacists. This reveals that the pharmacists were the least health care team who participated in IV medication preparation and administration practice.

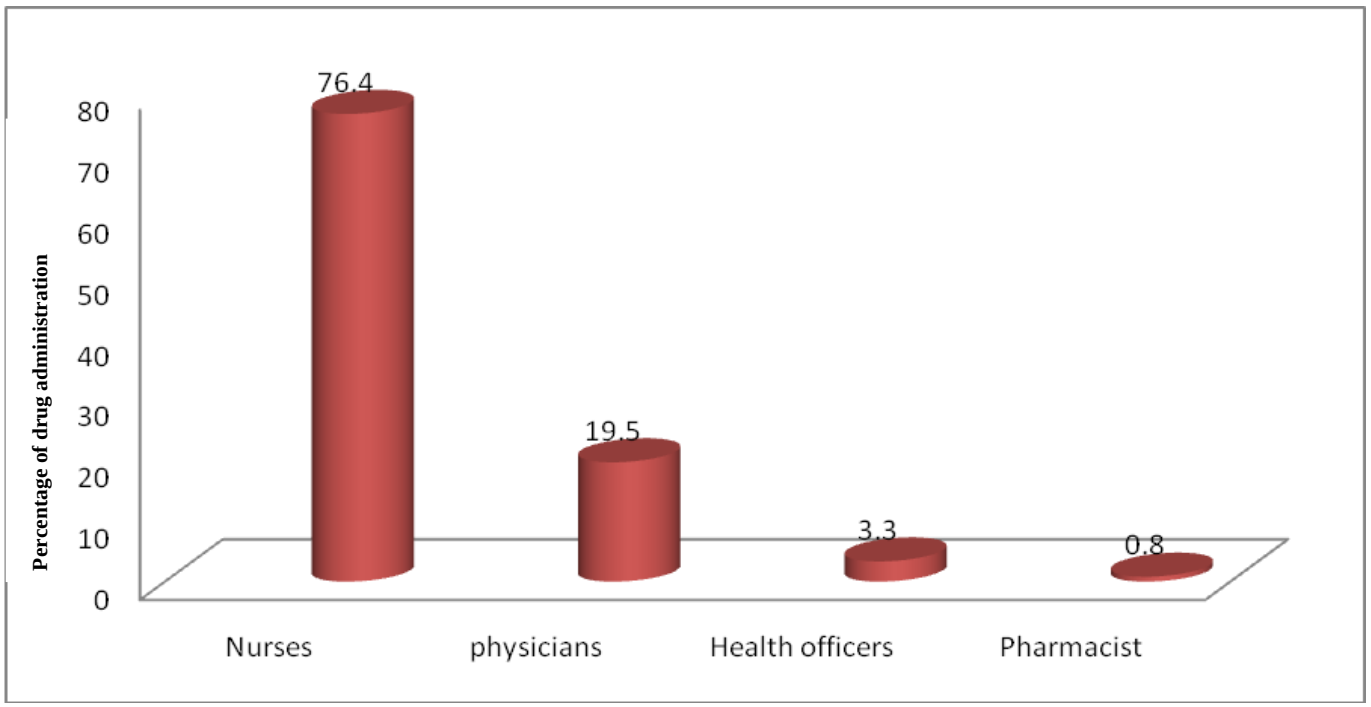

Fig 1- Distribution of health care team participated in medication preparation and administration in MKH from January 30 - February 28, 2014

5.3) Distribution of categories of IV medication preparation and administration error observed admitted in Mettu Karl Hospital from January 30 - February 28, 2014

According to the table 2 below, antibiotics 58(47.2%) were the most IV drugs preparation and administration error observed in Mettu Karl Hospital during the study period and followed by analgesics, 38(30.9%) and cardiovascular, 8(6.5%) drugs.

Table-2: Distribution of categories of IV medication preparation and administration error observed in Mettu Karl Hospital from January 30 - February 28, 2014

S. N.	Drug categories	Frequency	%
1	Antibiotics	58	47.2
2	Analgesics and anti inflammatory drugs	38	30.9
3	Cardiovascular and renal system drugs	8	6.5
4	CNS drugs	7	5.6
5	GI drugs	5	4.1
6	Endocrine drugs	4	3.3
7	Minerals/vitamins	2	1.6
8	Respiratory drugs	1	0.8
Total		**123**	**100**

5.4) Distribution of top ten specific IV drug preparation and administration error observed in Mettu Karl Hospital Mettu from January 30 - February 28, 2014

According to figure 2 below ceftriaxone was the most IV drug (27%) to which preparation and administration error was most observed. Diclofenac 31(14%) and Tramadole, 30 (13.6%) were the second and third most IV drug preparation and administration error observed.

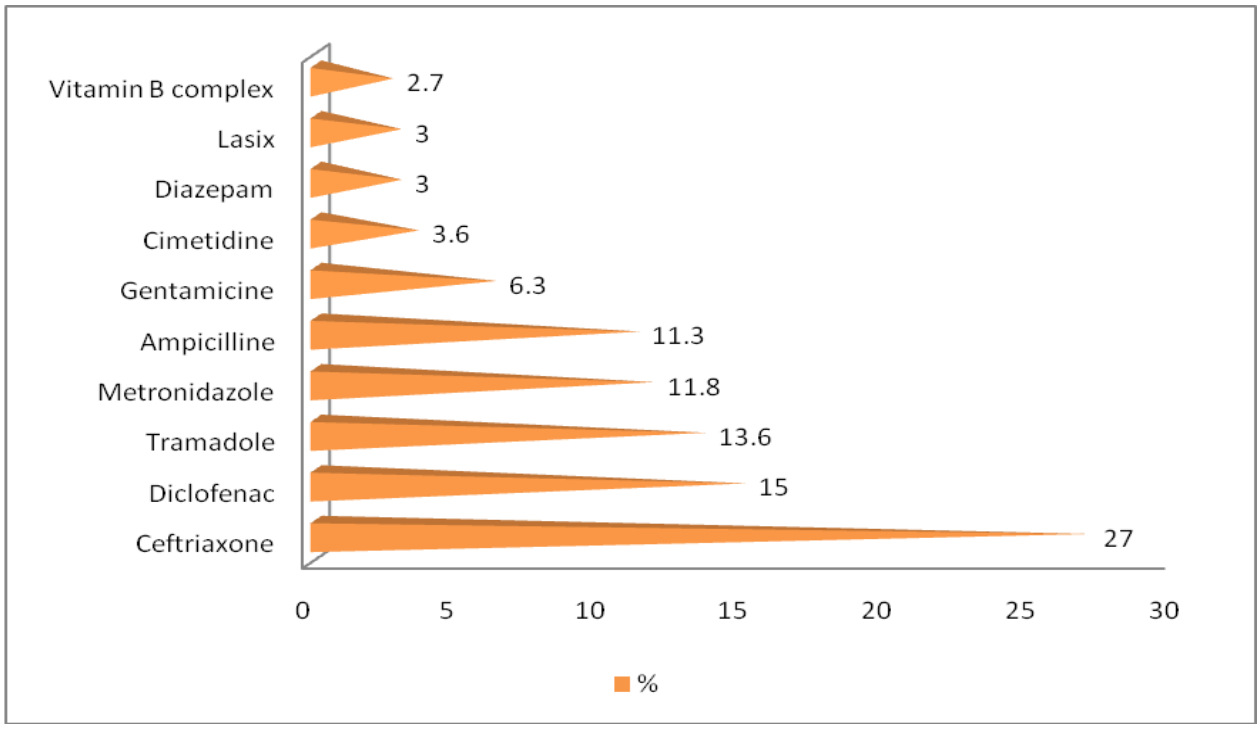

Fig 2: Distribution of top ten specific IV drug preparation and administration error observed in Mettu Karl Hospital from January 30 - February 28, 2014

5.5) Percentages of total IV medication failure mode observed in Mettu Karl Hospital from January 30 - February 28, 2014

From 123 IV medication prepared and administered, a total of 70(56.9%) Failure Modes were observed. (Figure 3)

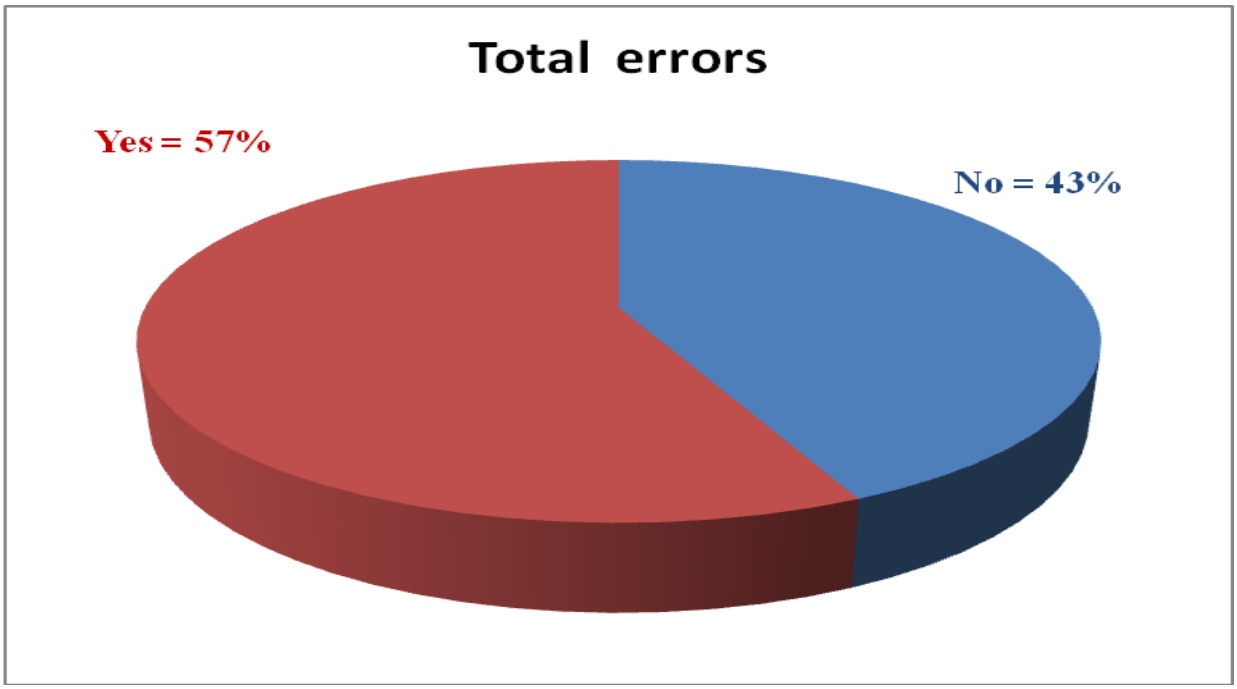

Fig 3: Percentages of total IV medication failure mode observed in Mettu Karl Hospital from January 30 - February 28, 2014

5.6) Distributions and severity of IV medication process failure mode identified in Mettu Karl Hospital from January 30 - February 28, 2014

This study identified that, from 12 failure modes of IV medication errors, aseptic technique error 106(86.2%), wrong time error 94(76.4%) and wrong rate errors 92(74.8%) were the first, second and third most observed failure modes. Under dosing errors 23(18.7%) is the least failure mode observed. Concerning the severity of the error, the most fatal errors were observed related with wrong rate 29(23.6%), wrong time 15(12.2%) and wrong preparation technique 14(11.4%).

(Table 3)

Table 3: Distributions and severity of IV medication process failure mode identified in Mettu Karl Hospital from January 30 - February 28, 2014

S.N	Failure Modes	IV medication Error observed				
		No	Yes			
		(N/%)	NS	S	F	Total
			(N/%)	(N/%)	(N/%)	N (%)
1	Aseptic technique error	17(13.8)	38(30.9)	58(47.2)	10(8.1)	106(86.2)
2	Wrong time	29(23.6)	34(27.6)	45(36.6)	15(12.2)	94(76.4)
3	Wrong rate	31(25.2)	23(18.7)	40(32.5)	29(23.6)	92(74.8)
4	Wrong calculation	37(30.1)	37(30.0)	36(29.3)	13(10.6)	86(69.9)
5	Wrong preparation techniques	41(33.3)	23(18.7)	45(36.6)	14(11.4)	82(66.7)
6	Wrong diluents type &/or volume	49(39.8)	32(26.0)	37(30.1)	5(4.1)	74(60.2)
7	Over dosing error	60(48.8)	13(10.6)	41(33.3)	9(7.3)	63(51.2)
8	Drug omission error	61(49.6)	23(18.7)	36(29.3)	3(2.4)	62(50.4)
9	Drug compatible error	73(59.3)	13(10.6)	32(26.0)	5(4.1)	50(40.7)
10	Unauthorized drug given	86(69.9)	15(12.2)	14(11.4)	8(6.5)	37(30.1)
11	Deteriorated drug given	89(72.4)	10(8.0)	20(16.3)	4(3.3)	34(27.6)
12	Under dosing error	72(58.5)	23(18.7)	26(21.1)	2(1.6)	23(18.7)

Key: NS=No significant (mild error), S= Significant (moderate to severe error), F= Fatal (life threatening error),

T= Total error observed, N= Number observed

5.7) Distribution of wards and time at IV medication process failure mode observed in Mettu Karl Hospital from January 30 - February 28, 2014

From 123 IV medications failure mode observed, surgical ward 15 from 20 observations (75%), gynecology ward 18 from 29 observations (62%), medical ward 19 from 34 observation (55.9%) were the first second and third ward error observed and ICU 6 from 11 observation (54.5%) and pediatrics ward 12 from 19 observation (41.4%) were the forth and fifth wards at which IV medication failure mode observed. Regarding the time at which IV medication failure mode observed, regular working time 38 from 63 (31.0%) and work shifting time 8 from 14 (57.1%), Week end working time 6 from 11 (54.6%) were the first, second and third time at which IV medication failure mode observed and night duty were 17 from 35 (48.6%) were the least time at which IV medication failure mode observed.

5.8) Process cycle at which IV medication failure mode observed in Mettu Karl Hospital from January 30 - February 28, 2014

From the total of IV medication process cycle observed, more than half 64(52%) of IV medication failure mode were observed at medication/drug administration process cycle and drug preparation process cycle 41(33%) was the second process cycle at which the failure mode was observed during the study period.(Figure 4).

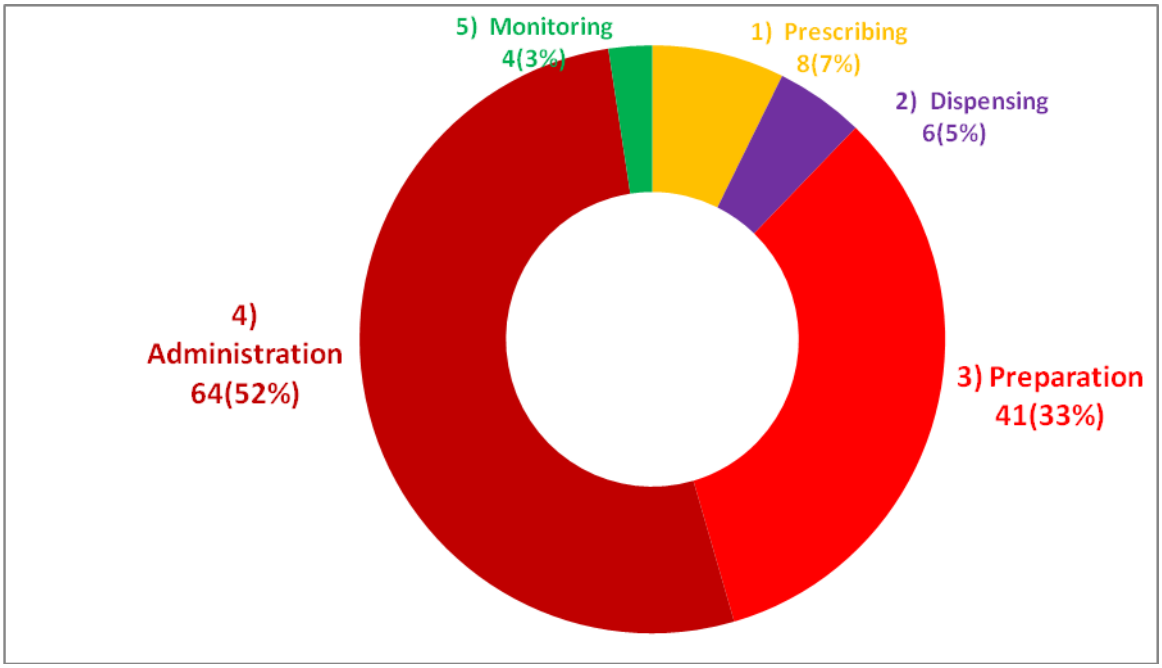

Fig 4: percentage of the process cycle at which IV medication Failure Mode observed in Mettu Karl Hospital from January 30 - February 28, 2014

Table 4: Some Examples of IV medication failure modes observed in MKH from January 30 - February 28, 2014

S.N	Examples of IV medication failure mode Identified during study period
1	Almost all IV medications were prepared by diluents taken from IV bag by piercing the bag without using antiseptic swipe due to lack of distilled water
2	Diclofenac 75 mg IM BID prescribed but not given due to lack of observing order sheet
3	Gentamicin 80 mg IV TID given two days after discontinuation of order because of the drug was at bed side of the patient
4	Cloxacillin 200 mg IV was administered for 6 year child two times within 30 minutes
5	Ceftriaxone 1gm PRN was given instead of BID due to wrong order
6	Un prescribed diazepam was administered IV at night duty time
7	Expired Ampicillin was dispensed and administered without checking the label
8	Most of the time previously opened vial and syringe was used due to storing of used drug and syringe at patient bed side
9	Vancomycin IV was administered at fast rate less than one minute
10	Metronidazole was prescribed but ceftriaxone was administered for more than a week due to lack of assessing order sheet
11	IV Tramadol was prescribed but IV diclofenac was administered
12	Un diluted powder of crystalline penicillin was administered IV push with particle because of patient over load to mix very well
13	The remaining (un utilized left over) gentamicin was sealed with plaster and re administered without following sterility due to shortage of drug.

5.9) Examples of the serious IV medication process failure mode, potential cause, potential effect and severity observed and corrective action planed to be implemented in study wards of Mettu Karl Hospital from January 30 - February 28, 2014

Based on risk priority number, from 12 IV medication failure modes identified aseptic technique error (RPN=125), over dosing error (RPN=100) and wrong preparation errors (RPN=80) were the top three prioritized failure modes. (Table 5)

Table 5: Examples of the serious IV medication process failure mode, potential cause, potential effect and severity observed and corrective action to be taken in study wards of MKH from January 30 - February 28, 2014.

Process	Potential failure modes	Potential causes	Potential effect	D (1-5)	O (O 1-5)	S (1-5)	RPN/HS (O*S*D)	Action to be taken	POC
IV medication Preparation and administration	Aseptic technique error	Problems of drug distribution system, Storing of opened/used drug at pt. bed side, lack facility in the wards, high traffic area/care giver over flow, knowledge deficit	Un sterile IV medication administered	**5**	**5**	**5**	**125**	In service training, Increasing facility, Maintenance	Hospital administrative, Nurses, Pharmacists
	Wrong time error	Fatigue of the staff, Lack of the drugs, patient income status to buy the drug, miscommunication, high traffic area, affordable & availability the drugs, trained, Patients delay to buy the drug	Drug administered at wrong time	4	5	5	100	Training, Increasing supply, Restricting care givers over flow, Providing free services for pt., Good communication, Observation	Nurses, Patient Pharmacists Hospital administrative Physicians
	Wrong rate	Luck of new technology, Knowledge deficit of the staffs, negligence of the health care teams, fatigue, lack of experience, work over load, interruption	Drug administered at faster than recommended rate	4	5	4	80	Smart pump technology, Training of the staffs, shorter duty time, Involving experienced staffs	Nurses Hospital administrative
	Wrong calculation	Knowledge defecate, lack of experience, fatigue, verbal ordering , negligence lack of documentation	Wrong concentration of the drug administered to the patient	3	5	5	75	Training Involving experience staffs	Nurses Pharmacist Physicians
	Wrong preparation techniques	Noisy area, duty time, knowledge deficit, miscommunication, light dissemblance, lack of facilities, lack of guide lines	Wrongly prepared drug administered	4	4	4	64	Training, observation Involving experience staffs , guide line preparation	Nurses Pharmacist Hospital administrative

Table 5: Continued.

	Wrong diluents	Un necessary storage of drug products at bed side, negligence, miscommunication lack of documentation, facility, supply problems	Drug prepared with wrong diluents and administered	3	5	4	60	Training , good communication , increase supply and improve facility	Administrative, nurses & pharmacists
	Over dosing error	Un necessary storage of the drug at bed side, negligence of the staff, miscommunication within the health care teams, lack of documentation and reporting to the next responsible person, multiple morbidity of the patient illegible hand writing	High dose drug administered	2	5	5	50	Training, avoiding storage of drugs at bed side, practicing good hand writing	Nurses, physicians, pharmacists
	Drug omission error	Lack of adequate staffing, noisy area, lack knowledge fatigue of the staff luck of understanding the patients, affordability & availability of the drug	Drug is totally not administered	3	5	3	45	Training, remainders, increasing staffs	Patients, nurses pharmacists
	Deteriorated drug given	Storage problems , dispensing problems,	Expired, unlabeled, unsterile drug administered	2	4	5	40	Training, proper storage double checking, supervision	Nurses
	Drug compatible error	Knowledge, lack of check list	Un compatible drug administered	2	4	4	32	Training, guide line preparation Separation of IV lines & syringes	Administrative, nurses & pharmacists
	Under dosing error	Low supply, prescription	Low dose administered	1	4	4	16	Training, pt. education supervision, increase supply	
	Un authorized drug given	Storage, patient push	Un prescribed drug given	1	5	3	15	Training, avoiding storage of drugs at bed side, good communication	Administrative, physicians, nurses & pharmacists

Key: D= Delectability O= Observablity S= severity, RPN = Risk priority number, HS = Hazards score, POC= Person of contact or process control

5.10) Priority matrix, plotting severity against probability (O×D) of IV medication failure modes from January 30 - February 28, 2014 in Mettu Karl Hospital

According to the figure below the severity was analyzed by plotting the RPNs of higher risk failure modes in a priority matrix which is a graph divided into four colored areas reflecting different levels of priority for action. Area 1 (red) urgent action required; area 2 (orange) a prompt action required; area 3 (yellow) scheduled actions required; area 4 (green) only monitoring required (12, 24 & 25).

The priority matrix gave each of the errors, graphical evidence of which steps, in the complex process of administering drugs, more urgently needed corrective action to reduce the risk of failures. Aseptic technique error(RPN=125), Wrong time error(RPN=100), Wrong rate error (RPN= 80) (Figure 5)

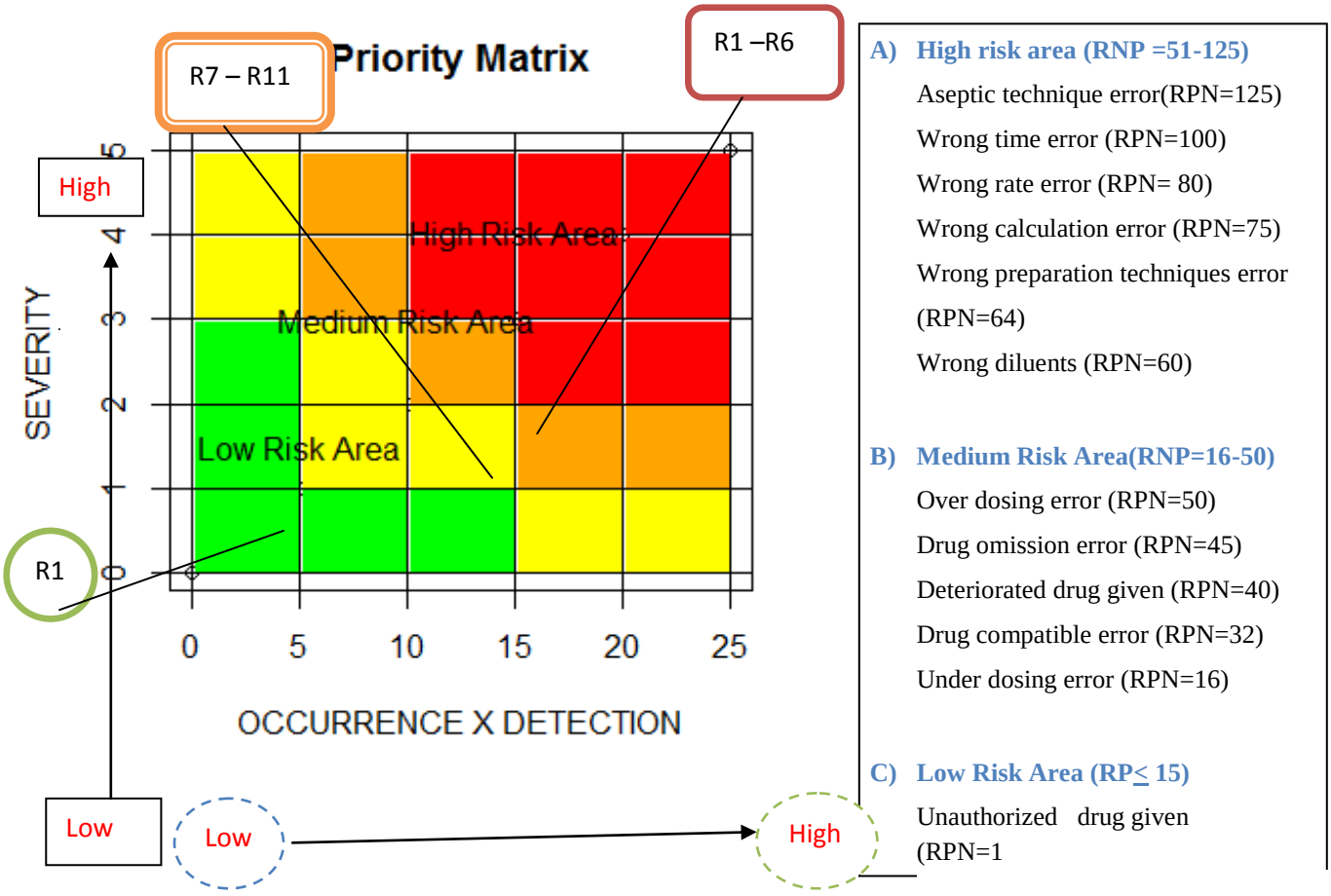

Fig 5: Priority matrix, plotting severity against probability (O×D) from January 30 - February 28, 2014 in Mettu Karl Hospital.

Results and Discussion[11]

- ✓ Besançon University Hospital 21% and 42% of medication administration error was life threatening and significant respectively in ICU
- ✓ May be due to the presence of different types of ICU based on specialty like GU, CV and Thoracic Surgery Unit in their Hospitals

M. Lisby *et al. 2005*

5.11) Root causes and its association with some of each IV medication failure modes

The leading cause of IV medication preparation and administration failure mode in this study area was human factor 71 (57.7%), (both patient related 96 (78.0) and health care team related 46 (37.4%) and followed by system or procedure related factors 62 (50.4%), and environmental factor 42 (34.1%). Product /drug related factors 39(31.7%) were the least to cause IV medication errors. For each person the outcome was whether the patients developed IV medication errors or not. From the type of IV medication errors we consider Aseptic technique errors, Wrong time, Wrong rate, Wrong diluents, Wrong preparation technique and Wrong calculation failure modes. Aseptic technique error was highly associated with availability of the product (p-value=0.011), and pharmaceutical distribution system of the Hospital (p-value=0.049). Drug distribution system of the Hospital was also highly associated with wrong time error (P-value=0.004). Availability (p-value=0.011) and affordability of the drug (p-value=0.006) are highly significant to cause wrong time errors. And wrong rate error was significantly associated with experience of health care team (p-value =0.046) and lack of technology (p-value=0.046).

We used a backward method to identify significant covariates that can be included to the model, and drug storage system, facility, high traffic area and knowledge have no significant relationship with the risk of developing Aseptic technique errors. Availability has a significant relationship with the risk of developing Aseptic technique errors. The odd of having drug storage problem causes aseptic technique errors is 12.866 times more than no drug storage problem. Availability, affordability and drug distribution have a significant relationship with the risk of developing wrong time error. The odds of having drug distribution system problem causes wrong time error 0.072 times than those having no drug distribution system problem. Lack of technology, duty time, fatigue and lack of experience have a significant relationship with the risk of developing wrong rate error. All the confidence intervals constructed did not include one number this support the relationship between the predictor variables and the outcome variable. The odds of having lack of technology cause wrong rate error 9.570 times than those having no lack of technology. Noisy area,

fatigue, verbal ordering of the drug and lack of documentation have a significant relationship with the risk of developing wrong calculation. Negligence has no significant relationship with the risk of developing wrong calculation. The odd of having noisy area during medication preparation and administration causes wrong calculation 9.690 times than having no noisy area. Noisy area, duty time, knowledge and miscommunication have no significant relationship with wrong preparation technique. Lacks of technology, affordability of the drug to buy, experience and availability of the drug and other products in the Hospital have a significant relationship with wrong diluents error. (Table 6)

Table 6: Multivariable logistic model of IV medication failure modes in Mettu Karl Hospital from January 30 - February 28, 2014

S. No	Categories: errors	Associated root causes	OR (95% CI)	P-Value
1	Aseptic technique errors	Drug storage system		
		Yes	12.866(.857-193.192)	0.065
		No	1	
		facility		
		Yes	9.051(.813-100.741)	0.073
		No	1	
		high traffic area		
		Yes	0.045(.001-1.496)	0.083
		No	1	
		knowledge		
		Yes	15.390(.875-270.824	0.062
		No	1	
		Availability		
		Yes	41.966(2.345-751.093)*	0.011
		No	1	
		Constant	0.163	0.138
2	Wrong time error	Drug distribution		
		Yes	0.072(.012-.430)**	0.004
		No	1	
		affordable		
		Yes	3.523(1.44-8.595)**	0.006
		No	1	
		Availability		
		Yes	41.966(2.345-751.093)*	0.011
		No	1	
		Constant	1.218	0.547
3	Wrong rate error	Technology		
		Yes	9.570(1.041-87.997)*	0.046
		No	1	
		duty time		
		Yes	0.013(.001-.144)**	0.000
		No	1	
		fatigue		
		Yes	13.012(1.448-116.962)*	0.022
		No	1	
		Experience		
		Yes	9.273(1.881-45.708)**	0.006
		No	1	
		Constant	0.842	0.713

Table 6: Continued.

4	Wrong calculation	Noisy area		
		Yes	9.693(2.333-40.273)**	0.002
		No	1	
		fatigue		
		Yes	0.215(.051-.916)*	0.038
		No	1	
		verbal		
		Yes	0.221(.054-.911)*	0.037
		No	1	
		Negligence		
		Yes	0.442(.167-1.173)	0.101
		No	1	
		documentation		
		Yes	4.126(1.233-13.802)*	0.002
		No	1	
		Constant	0.816	0.561
5	Wrong preparation technique	Noisy area		
		Yes	0.391(.130-1.177)	0.095
		No	1	
		Duty time		
		Yes	0.365(.113-1.178)	0.092
		No	1	
		Knowledge		
		Yes	2.359(.928-5.996)	0.071
		No	1	
		Miscommunication		
		Yes	15.119(.402-7.198)	0.854
		No	1	
		Constant	2.341	
6	Wrong diluents error	Technology		
		Yes	4.099(1.137-14.779)*	0.031
		No	1	
		affordable		
		Yes	0.121(.014-1.068)*	0.013
		No	1	
		Experience		
		Yes	9.273(1.881-4.708)**	0.006
		No	1	
		Availability		
		Yes	4.966(2.345-5.093)*	0.011
		No	1	
		Constant	307	

Strength and limitation of the study

Strength

Being the failure mode and effect analysis the study has strength for adapting of the new method in the country. Additionally it has strength on prioritizing the severity of identified failure modes and proposing remedial action and responsible bodies

Limitation

The major limitations of the study were lack of literature to compare and contrast failure modes in Ethiopian hospital. Lack of laboratory equipment and system of therapeutic drug monitoring to assess plasma drug concentration for evaluation of fatality of the errors observed.

Since failure mode effect analysis needs longer time, to implement and intervene, to prioritized variables, short time of observation was the great limitation for implementation and analysis of post intervention phase and therefore the study was limited only on pre implementation phase as base line assessment.

Direct observation may hide routine work and bring behavioral change of health care team that may under estimate medication errors

6) Discussion

In this study 123 IV medication preparation and administrations were observed. The study tried to assess the prevalence, causes, severity and risks of IV medication errors using health care failure mode effect analysis (HFMEA).

Almost all IV medication was prepared by nurses (76.4%), and pharmacists ware the least (0.8%) involved in IV medication preparation. This indicates that participation of pharmacist in preparation and/or administration of IV drug is much less than the Global Hospital Pharmacy Population Survey (6%). This discrepancy can be due to the fact that in the United States and European countries, IV drug preparation by the hospital pharmacy is the standard of practice and required by the Joint Commission (3, 7).

From 123 IV medication preparation and administration observed, there were a total of (56.9%) failures mode observed. It was nearly equal with IV medication error observed in three Brazilian hospital during 2006 (57.8%) and less than the study of two major teaching hospitals in Sydney Hospitals, Australia (69.7%). This difference is may be because involvement of much specialty wards, long time study period and large sample size in their Hospital (4).

The finding is greater than IV medication error observed in Air Bus hospital, Denmark, in 2005(43%), and IV medication errors in Jimma University specialized Hospital ICU (51.8%). The discrepancy is may be due to the fact that, the design and participant wards difference (21, 22).

From 12 failure modes, aseptic technique 86.2%, wrong time 76.4%, wrong rate 74.8%, and wrong calculation 69.9% were among higher prevalence failure modes identified. In contrast, with the study of three European countries (UK, Germany and France) there was wrong diluents error 1%, 49%, 18%, respectively and wrong rate error was 49%, 21%, 5%, respectively in each

country this difference is may be due to long time study period multi center and multipurpose Hospital involvement of the three countries. At least one aseptic technique error observed was in UK (100%), Germany (58%) and France (19%) was related with our study (10)

It was quietly different from IV medication error type identified in Air Bus hospital, Denmark, in 2005, the most common types of error throughout the medication process were: lack of drug form, unordered drug, omission of drug/dose, and lack of identity control, this discrepancy may be due to the fact that the difference in study design tools (21).

Common medication administration errors in the ICU of JUSH was attributed to wrong timing (30.3%), dose omission (29.0%) and missed doses (18.3%) among others, this difference is due to difference in the study ward. Errors associated with antibiotics were high in medication administration errors in Mettu Karl Hospital 58(47.2%) was the first category at which failure mode observed, almost similar with Jimma University Specialized Hospital ICU (36.7%) and the two major teaching hospitals of Sydney (two-thirds) (4, 22).

Regarding fatality of each categories of IV medication failure mode, there was about 23.6% of wrong rate error, 11.4% wrong preparation technique and 10.6% wrong calculation errors are among fatal error observed. According to Besançon University Hospital (France) study, no potential fatal errors were observed, 10% were estimated as potentially life-threatening and 26% potentially significant. German non-University hospital study only potentially severe errors 3%, potentially moderate errors 31% and potentially minor errors 13% identified. The differences may be due to utilization of advanced technologies for IV medication administration and dose calculation like smart pump infuser and computer based dose calculation (17, 20).

Surgical ward (75%) and gynecology wards (62%) were the most wards in which higher prevalence of IV medication failure mode observed. Air Bus study show that six of 43 (14%) in the medical department and 1 of 56 (2%) in the

surgical ward this is may be due to the fact that IV medication is administered for all patients in admitted in surgical ward in our case. According to Besançon University Hospital (France) 21% and 42% respectively of medication administration error was e life threatening and significant in ICU. May be due to the presence of different types of ICU based on specialty like Geriatric Unit, Cardiovascular and Thoracic Surgery Unit in their Hospitals (17, 21)

From total IV medication observed, most of the failure modes were observed at regular working time (31.0%). However, according Jalan University, Malaysian study in 2013 administration at 8.00am (work shifting time) was significantly associated with a higher rate of medication error (6). This discrepancy was may be due to more date was collected during day time in our case.

From total of IV medication process cycle observed, greater than half (52%) of IV medication failure mode was observed at medication/drug administration process cycle and drug preparation process cycle (33%) was the second step at which the failure mode observed during the study period. According to Air Bus study, the frequency of medication errors were observed highly at level of ordering (39%), transcription (56%), dispensing (41%) (21). This differences may be because of study design difference, in our case the observation was limited only on medication preparation and administration and physicians order sheet and nursing medication chart at patient bed side.

Based on detectability, occurrence and severity rating, during the study period, the priority matrix gave each of the errors, graphical evidence of which steps, in the complex process of administering drugs using R-soft ware, more urgently needed corrective action to reduce the risk of failures. Aseptic technique error(RPN=125), Wrong time error(RPN=100), Wrong rate error (RPN= 80), need urgent intervention

The priority matrix of this study identified that from 12 of IV medication failure modes, six of them need urgent intervention (Aseptic technique error, Wrong time error, Wrong rate error, Wrong calculation error, Wrong preparation techniques error, Wrong diluents). With high RPN 60-125, it is similar in number with risk priority number identified in Padua University Hospital of pediatric ward in Italy, but it was different in type of IV medication failure modes identified almost related with wrong calculation (wrong calculation for the dose of bolus and infusion, wrong calculation for the rate, transcription error in new therapy, failure to notify time of infusion therapy start and failure to identify the diluted drug before storing in the refrigerator. According to Alan Polnariev, the Medication Error Prioritization System(MEPS) study in the June 2014, all medication errors reported by pharmacy staff using the online data-base were categorized into one of three classes based on a severity scale, scores with a value above 20 are classified as high priority in contrast to our study the RPN value above 60 categorized as high risk. It was almost similar by observation of, no harm to the patient. The difference was due to difference in study participant and tools of assessment (pediatrics and medication calculation related tools in case of Lago P. et al) and difference in priority seting standard in case of Polnariev A et al (12, 24)

From 12 failure modes and 33 associated factors identified, the leading cause of IV medication preparation and administration errors in this study area was human factor (57.7%), (both patient related (78.0) and health care team related (37.4%) and followed by system or procedure related factors (50.4%), and environmental factor was the least to cause IV medication errors. Aseptic technique error was highly associated with availability of the product, and pharmaceutical distribution system of the Hospital. Drug distribution system of the Hospital was also highly associated with wrong time error. Availability and affordability of the drug are highly significant to cause wrong time errors. And wrong rate error was significantly associated with experience of health care team and lack of technology. Similar study show that, nurse workload and

incomplete or illegible prescription were two independent risk factors of medication and administration error ETsso et al study and no statistical difference between the error rate per patient in the wards in case of LISBY M etal. (17, 21).

7) Conclusion and Recommendation

7.1) Conclusion

This study revealed that there was high prevalence of IV medication failure modes with multiple factors; greater than half of patient ware at least exposed to one IV medication error per day. Antibiotics and Analgesics were most commonly encountered drug categories in medication preparation and administration failure modes

Most of the failure modes were identified with high risk priority number and serious to cause patient harm. Human related factors and system related factors were the most contributing factors to cause patients' harm in the Hospital. Based on the priority matrix, from 12 IV medication identified 6 of them should be intervened with in short period of time.

Finally the study showed that there were serious IV medication and administration errors and each of them were caused by several factors identified as listed in the result. A multidisciplinary approach to solve the problem of medication errors should be practiced. Prompt intervention is very important to reduce the risk of IV medication error identified and prioritized

7.2) Recommendation

Mettu Karl hospital should increase the availability of drugs and other pharmaceutical products, and staffing of health care teams.

In-service training should be given to health professionals who are directly or in directly involved in IV medication preparation and administration practices.

Inappropriate drug storage at patient bed side should be avoided and central storage and preparation of IV medication should be adopted and pharmaceutical care services should be practiced in the Hospital wards.

Patients who cannot afford to buy drugs should get free serves in Mettu Karl Hospital and/or patient should get drug by affordable cost.

Different professional standards like nursing and pharmacy practice standards, save and conducive environment for IV medication preparation and short duty time should be arranged for staff involving IV medication preparation and administration practices in the hospital.

Hospital should allocate budget for maintenances, infrastructures and different equipments as well as utilization of new technologies like smart pump infuser.

Guide line on how to prepare and administer IV medication should be prepared by Hospital managements and adhered during medication preparation and administration by health care teams.

Control and reporting mechanism of IV medication error should be practiced in the Mettu Karl Hospitals.

Ministry of health Regional health bureau and different non governmental bodies who work in patient safety issues should focus and work on prevention of medication errors and patient harm

Further study should be conducted in large scale across the country to identify more problems and to implement control mechanism.

References

1. POTE S, TIWARI P, D'CRUZ S. Medication prescribing errors in a public teaching hospital in India: A prospective study. Pharmacy Practice. 2007 5(1):17-20.

2. Taxis K, Barber N. Causes of intravenous medication errors: an ethnographic study. Qual Saf Health Care. 2003;12:343–8.

3. Shane R. Current status of administration of medicines. Am J Health-Syst Pharm. 2009;66 (3):42-8.

4. Westbrook JI, Rob MI, Woods A, Parry D. Errors in the administration of intravenous medications in hospital and the role of correct procedures and nurse experience. BMJ Qual Saf. 2011; 20:1027-34.

5. Parshuram CS, To T, Seto W, Trope A, Koren G, Laupacis A. Systematic evaluation of errors occurring during the preparation of intravenous medication. CMAJ. 2008 178(1):42-8.

6. Ong WM, Subasyini S, Medication Errors in Intravenous Drug Preparation and Administration. Med J Malaysia 2013; 68(1).

7. Anselmi ML, P. M, Santos CBd. Errors in the administration of intravenous medication in Brazilian hospitals. Journal of Clinical Nursing 2007;16:1839–47.

8. Simpson JH, Lynch R, Grant J, Alroomi L. Reducing medication errors in the neonatal intensive care unit. In: Princess, Hospital RM, Parade A, 2ER GG, Scotland, , editors. UK 2004. p. 480–2.

9. Husch M, Sullivan C, Rooney D, Barnard C, Fotis M, Clarke J, et al. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. BMJ. 2005;14:80–6.

10. Cousins DH, Sabatier B, Begue D, Schmitt C, Hoppe-Tichy T. Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. Qual Saf Health Care. 2005 14:190–5.

11. ADACHI W, LODOLCE AE. Use of failure mode and effects analysis in improving the safety of IV drug administration. Am J Health-Syst Pharm. May 1, 2005;Vol 62.

12. Lago P, Bizzarri G, Scalzotto F, Parpaiola A, Amigoni A, Putoto G, et al. Use of FMEA analysis to reduce risk of errors in prescribing and administering drugs in paediatric wards: a quality improvement report. BMJ. 2012;10 (1136/bmjopen):001249.

13. ZAKHAROV S, TOMAS N, PELCLOVA D. Medication errors—an enduring problem for children and elderly patients. Upsala Journal of Medical Sciences. 2012;117:309–17.

14. Mettu Karl Hospital 2014 firist quarter report.

15. Szczepura A, Wild D, Nelson S. Medication administration errors for older people in long-term residential care. BMC Geriatrics 2011 11(82).

16. Summa-Sorgini C, Fernandes V, Lubchansky S, Mehta S, Hallett D, Bailie T, et al. Errors Associated with IV Infusions in Critical Care. Can J Hosp Pharm. 2012;65(1):19–26.

17. ETsso, Cornette Christian, Limat S, Mourand JeanL, Becker M, t J-PEtieven, et al. Observational study of potential risk factors of medication administration errors. Pharm World Sci. 2003; 25(6): 264–8.

18. Vélez-Díaz-Pallarés M, Delgado-Silveira E, Carretero-Accame ME, Bermejo-Vicedo T. Using Healthcare Failure Mode and Effect Analysis to reduce medication errors in the process of drug prescription, validation and dispensing in hospitalised patients. BMJ Qual Saf 2012;10(1136):1–11.

19. Elisa A, Camargo Bd, Helena SS, Cassiani DB. Prospective risk analysis of the anti-infective medicatio administration process. Rev Latino-Am Enfermagem. 2013;21:233-41.

20. Taxis K, Barber ÆN. Incidence and severity of intravenous drug errors, in a German hospital. Eur J Clin Pharmacol 59 815-7.

21. LISBY M, NIELSEN LP, MAINZ J. Errors in the medication process: frequency, type, and potential. International Journal for Quality in Health Care 2005;17(1):15–22.

22. Agalu A, Ayele Y, Bedada W, Woldie M. Medication administration errors in an intensive care unit in Ethiopia. International Archives of Medicine. 2012;5(15).

23. Fahimi F, Ariapanah P, Faizi M, P BS, Namdar R, Ardakani MT. Errors in preparation and administration of intravenous medications in the intensive care unit of a teaching hospital: An observational study. Australian Critical Care 2008;21: 110—6.

24. Polnariev A. The Medication Error Prioritization System (MEPS): A Novel Tool in Medication Safety. P&T. June 2014;39 (6).

25. Cimino MA, Kirschbaum MS, Brodsky L, Shaha SH. Assessing medication prescribing errors in pediatric intensive care units. Pediatr Crit Care Med 2004;5(2).

26. Crass R. Improving intravenous (IV) medication safety at the point of care: Retrospective analysis of pooled data using an innovative IV Harm Assessment Index. CareFusion San Diego, CA(2003)**.**

Annex

1) Questioner formats

Jimma University Public health and medical science college pharmacy department

Name of principal investigator**: Sileshi Dubale Dhinssa**

Study area Mettu Karl Hospital Wards

Research fund by Jimma University

Research objective: To assess magnitude frequency and determinants for IV medication preparation and administration errors in Mettu Karl Hospital, south West Ethiopia.

Significance of the study: To dig out information about IV medication preparation errors frequency and causes. It can contributes to bring clues for IV medication errors prevention, use of advanced technology for IV drug preparation and administration. It also serves as base line information for further studies to be carried out all over the countries.

Study procedure: The data collectors will directly observe IV medication preparation and administration and from questioner prepared health care team will respond their opinions on IV medication errors.

Risk: No risk

Benefit: the study is beneficial for improvement of quality use of IV medication and to prevent medication errors in the wards.

Confidentiality: the study is not included patient as well as health care team name.

Whom to contact: for any incontinency and doubt please contact :**Sileshi Dubale** cell phone **+251 917806080**, email sileshi.dubale@ju.edu.et or sileshi.dubale@gmail.com

Questionnaire for evaluation of IV medication errors using failure mode effect analysis (FMEA)

Instruction: -This format is only for research purpose and no need of writing patient and health professionals name

- Please tick (✓)to appropriate box or record on space provided.

I) Socio-demographic characteristics of the patient

1. Card No. ---------- 2. Age A) ≤14 □ B) 15-50 □ C) 50+ □ 3. Sex A) Male □ B) Female □

4. Wards A) Gynecology& Maternity □ B) ICU □ C) Medical □ D) Pediatrics □ E) Surgical □

5. Ethnicity (A) Oromo □ (B) Amahara□ (C) Tigre □ (D) Other specify □

6. Religion (A) Muslim □ (B) Protestant__ (C) Orthodox__ (D) other specify____

7. Monthly income (A) <500birr □ (B) 501-1000Birr □ (C)>1000 Birr □

8. Educational status (A) Illiterate □ (B) 1-8 □ (C) 9-12 □ (D)>12 □

9. Distance from the hospital (A) <20km □ (B) 20-100km □ (C)>100 □

9. Residence (A) Urban□ (B) Rural □

10. Number of Drug ordered/administered at once 1) one drug 2) two drugs 3) three drug 4) > four drugs

II) Drug is prepared & administered by (A) Nurse □ (B) physician □ (C) Pharmacist □ E) health officers □ (F)other specify_____

III) Categories of IV medication preparation and administration failure mode observed

(A) Analgesics/anti inflammatory □ e.g._____ B) Antibiotics □ e.g._____ (C)Cardio-vascular/renal drugs □ e.g._____(D) Endocrine drugs □ e.g._____(E) GI drugs □ e.g._____ (F) Minerals/vitamins □ e.g._____ (G) CNS drugs □ e.g._____ (H) Respiratory drugs

□ e.g._____ (J) other specify _____e.g._____

IV) Time of IV medication failure mode observed

(A) Regular working time □ (B) Night duty time □ (C) During shift change □ (D) weekend □

V) Types of IV medication process failure mode

S.N	Categories of IV medication errors	Error observed			
		No	Yes		
			NS	S	F
1	Aseptic technique error				
2	Deteriorated drug given				
3	Under dose drug given				
4	Over dose drug given				
5	Drug omission error				
6	Drug compatible error				
7	Un authorized drug given				
8	Wrong calculation				
9	Wrong diluents				
10	Wrong dosage form error				
11	Wrong preparation techniques				
12	Wrong rate				
13	Wrong time				
14	Other specify				

Key: NS=No significant (mild error), S= Significant (moderate to severe error), F= Fatal (life threatening error), T= Total error observed

Examples of error observed _____

VI) The error observed due to the process step of

1) Prescribing error □2) Dispensing error □3) Preparation error □4) Administration □5) Monitoring □

VII) Causes for failure mode of IV medication process

A) System and procedure related factors

1) Drug distribution and management systems Yes□ No□ 2) Drug storage system Yes□ No □

3) Facilities Yes □ No □ 4) Staffing /over load Yes □ No □ 5) Technology Yes □ No □ 6) other specify _____

B) Environmental

1) Interruption Yes □ No □ 2) Noisy area Yes □ No □ 3) Light disturbance Yes □ No □

4) Duty time Yes □ No □ 5) High traffic / care giver over flow Yes □ No □ 6) other specify _____

C) Human related factors

i) Health care team related factors

1) Knowledge Yes □ No □ 2) Negligence Yes □ No □ 3) Fatigue Yes □ No □Experience Yes □ No □

4) Miscommunication Yes □ No □ 5) Abbreviation Yes □ No □ 6) Illegibility of handwriting Yes □ No □ 7) Verbal ordering Yes □ No □ 8) Lack of documentation and reporting for next responsible Yes □ No □ 9) other specify _____

ii) Patient related factors

1) Age Yes □ No □ 2) Educational level Yes □ No □ 3) Income status Yes □ No □

4) Cooperation Yes □ No □ 5) Lack of feasibility of veins Yes □ No □

1) Lack of understanding Yes □ No □ 7) Co morbidity Yes □ No □ 8) other specify ___

D)Product/drug related factors

1) Availability Yes□ No □ 2) Newer Yes□ No □ 3) LASAYes □ No □ 4) Affordability Yes □ No □ 5) Deteriorated Yes□ No □ 6) High risk Yes □ No □ 7) Narrow Therapeutic IndexYes □ No □ 7) other specify _____

VIII) Examples Corrective action to be taken to prevent IV medication errors and in study wards of MKH Mettu town during study period.

Action to be taken/suggestion should be given for control measures	**POC**
In service training Y□ N□	Hospital administration Y□ N□
Increase staffing Y□ N□	
Short duty time Y□ N□	
Maintenances Y□ N□	Prescribers Y□ N□
Supervision Y□ N□	
Unit dosing dispensing Y□ N□	
Increase supply Y□ N□	
New technology Y□ N□	

Central preparation Y□ N□	Pharmacists Y□ N□
Minimizing care giver over flow Y□ N□	
Using reminders Y□ N□	Nurses Y□ N□
Double checking Y□ N□	
Process changing Y□ N□	
Good communication Y□ N□	Patients Y□ N□
Improving hand writing Y□ N□	
Avoiding abbreviation Y□ N□	
Daily updating of order Y□ N□	
Not to reuse drug or syringes Y□ N□	
Not storing drug at bed side Y□ N□	
Avoiding oral order Y□ N□	
Guide preparation Y□ N□	
Avoiding storing similar drug together Y□ N□	
Involving experienced staff only Y□ N□	
Drug information for pt. Y□ N□	Other specify _____
Other specify	

Key: D= Detectability O= Observablity S= severity, RPN = Risk priority number, HS = Hazards score, POC= Person of contact

Failure Mode Effect analysis of IV medication errors

This form is used only for multi disciplinary experts' teem clinical judgment for scoring of identified IV medication errors severity

Please score for the following identified failure mode of IV medication errors (1-5)

In your opinion if the following IV medication errors is happen what will be the score of severity of each failure modes

Please tick (✓)to appropriate box from 1-5) based on key given bellow

S.N	Categories of IV medication errors identified	Severity scoring number					Remark
		1	2	3	4	5	
1	Aseptic technique error						
2	Deteriorated drug given/ expired or unlabeled drug given						

3	Under dose drug given						
4	Over dose drug given						
5	Drug omission error/if prescribed drug is not given						
6	Drug in compatibility error/administering incompatible drug with the same syringe						
7	Un authorized drug given//un prescribed drug given						
8	Wrong calculation						
9	Wrong diluent type &/or volume						
10	Wrong preparation techniques						
11	Wrong rate						
12	Wrong time						

Key: 1= No harm, 2= Minor harm, 3= Moderate harm 4= Sever harm, 5= Very sever harm

2) Rating scale used to assign the value of occurrence (O), severity(S) and detection (D) scores in the failure

Occurrence (O)		**Severity(S)**		**Detection(D)**	
Score	**Failure mode probability**	**Score**	**Description of injury**	**score**	**Likelihood of Detection**
1	Remote: failure unlike to occur(1 in 10000 episodes)	1	No injury or pt. monitoring only	1	Very high: detected 9/10 times
2	Low: relatively rare failure(1/1000)	2	Temporary injury need intervention or treatment	2	High detected 7/10 detected times
3	Moderate: occasional failure(1 /200)	3	Temporary injury with longer hospital stay or increased level of care	3	Medium: detected in 5/10
4	High :recurrent failure(1/100)	4	Permanent effect on body function	4	Low: detected 2/10times
5	Very high: common failure(1 in 20	5	Death or permanent loss of major body function	5	Remote: detected 0/10 times

Thank you for genuineness!