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Patient Safety in paediatrics and neonatal medication

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Abstract

Patient safety needs to be addressed for better health services. This needs a stringent uniform regulatory system. Although, after 2013 Central Drug Standard Control Organisation, CDSCO has laid down regulations for clinical trial, stem cells research, compensation for morbidity and mortality in subjects in clinical trial. There has been data from India on medication errors and patient safety in pediatric, neonatal and anaesthesia setting, knowledge of health professionals on medication errors. Still regulatory body has not laid down standards of patient safety, its audit, insurance and compensation guidelines. Medication errors are prevalent in the hospital settings. Considerable attention to patient safety is not a regular component of medical education, and much research needs to be carried out to understand the causes, consequences, and prevention of healthcare-related adverse events. Pediatric population is three times more suseptible to such errors. Healthcare professionals working in neonatal wards are particularly susceptible to committing errors due to the peculiarities of newborn patients and of the neonatal intensive care unit (NICU) environment.

Keywords: Patient Safety, Paediatrics medication, Neonatal medication.

INTRODUCTION

Global

Patient safety is priority of health care system and has drawn particular attention since the publication of report of "To Err is Human: Building a safer health system." Errors in medical science are not rare or intractable. As per estimate more number of patients were dying of medical error than road traffic accident in United States [1]. Both individual and society become pray to the burden of its consequences. US Food and Drug administration system has a reporting system of medication errors.

India

Drug and cosmetic act came in India in 1940. As per last amendment of this act in 2013 it is essential to report any unexpected event and serious adverse event in a clinical trial. There is a checklist for submission of SAE to Central drug standard control organization. The Government of India has notified the National List of Essential Medicines (NLEM), 2015 [2]. Pharmacovigilance system in India is in a state of development. Still there is no structured format of incident or error reporting and auditing, feedback from various centres, quality improvement marker and trained staff for the same. There are reports on medication errors, knowledge of health care personals, auditing of medication errors from India in recent few years [3-6]. In a recent survey done on knowledge of medication errors from north, west and east regions India it was found 72% of respondents were having average or above average basic knowledge regarding medication errors whereas 94% respondents were having knowledge regarding non-existence of reporting system for medication error in India. These figures suggest that health-care professionals in India are aware about the medication error and therefore establishment of reporting system in India may help in combating the problem of medication errors [7].

Issues in Patient safety

History

Safety Concept emerged in medical system taking a lead from aviation industry, where since 1940 tools development were started to minimize risk. Then came the book in 1994,*Human Errors in Medicine* by Marilyn Sue Bogner which focused on systematic approach on human errors in medical field [8]. In an early chapter of Human Error in Medicine, *Leape*reviews the data from the Harvard Medical Practice Study [9].

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This work was a landmark, in large part because it was the methodologically strongest study of its time to examine the epidemiology of iatrogenic injury.

The link between the patient safety movement and quality improvement movement has often been uncertain: Journalist Michael Millenson's,*Demanding Medical Excellence*, published in 1997, shows how the twodisciplines fit together. Quality, he argues, should be thought of as providing patients with the best possible medical care, and this requires continual progress not only at the highest levels of medical performance but also in shoring up the reliability and consistency of our most routine and basic tasks [10]. The American Medical Association established the National Patient Safety Foundation in 1997.

Definitions

Patient safety is defined as freedom from accidental injury by means of operational system to minimize the likelihood of errors and maximizing the likelihood of preventing them [1].

Medical errors are due to failure of planned action or wrong plan to achieve goals, usually discovered when adverse events occur. Medical errors may lead to large proportion of near miss events, preventable and non-preventable adverse events. *Adverse events* are injuries resulting from medical interventions whereas,*Near miss events* are close calls that don't lead to patient harm, due to chance or timely intervention [1].

The United States National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a *Medication error* 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. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use" [11].

Issues of Patient Safety in Pediatrics and Neonatology

Adverse events occurs three times more common in paediatrics and more so in neonates [12].

Why are newborns more vulnerable for errors?

Neonates is a vulnerable group for dosing and dispensing errors because neonates have a rapidly changing body surface area and weight; a rapidly developing system of drug absorption, metabolism and excretion; an inability to communicate with the provider; and off-label or unlicensed drug usage. Most of the drugs used in neonates are available in dosages and units ready for dispensing in children or adults. This needs a lot of calculation and has a potential for errors.

Further, emergency department has a high volume and acuity of work, more stress and noise, less time available per patient and dissimilar patients. Untrained staff, understaffing, less accurate equipment adds to errors. Errors of medication has been reported to be as high as 15 % in neonates as compared to adults where it may vary 3-5% [13].

There is scarcity of data about pharmacokinetics, dosing, clinical use, efficacy, and safety of many medications in the newborn results in the frequent use of unlicensed or off-label drugs in the neonatal population. It was documented that approximately 10% of prescriptions in NICU were for unlicensed medications, while 55% were off-label [14, 15]. Safety of margin is very narrow in neonates and even small errors can cause long term consequences.

Strategies for patient safety

Patient safety can be ensured by under three prong approach: Identifying the errors, reporting and disclosure of errors, Plan-do-study-act (PDSA cycle for preventing the errors.

Medication is one of the most common intervention hence errors are common in various steps of medication

Various steps where medication error happens in indoor patients

- Delay in giving emergency drug
- Age of patient,
- Correct patient
- Decision of medicine
- Prescription writing
- Preparation (dilution amount, solution, concentration)
- Frequency (under special situations: preterm age of life, renal/hepatic dysfunction, meningitis)
- Rate
- Route
- Recording
- Monitoring

Hence, error is responsibility of whole team (Physician, Nurse, and Pharmacist)

Error Identification: [16-19]

- Audit: Medical record review and prospective by Audit team blinded to interventions
- Patient satisfaction questionnaire
- Audit of morbidity and mortality
- Self-reporting of Incidents
- Event Surveillance program
- Learning from verbal autopsy
- Trigger tools
- Fish-bone analysis

Error Reporting and disclosure to patient

Transparency and open disclosure can reduce risk to institution, but there are some fear among the health care team regarding the disclosure.

Disclosure needs a proper communication with the family, hence should be done by trained team. There should be clear law of the country, state and institutions on compensation issues. This also calls for malpractice insurance scheme. Incident reportingsystem on voluntary basis differently for various speciality has been evaluated to be one of the most effective measure of patient safety as it picks up even near misses [20]. This system survives only when confidentiality and anonymity is maintained and reporting is non –punitive.

Interventions of proven efficacy for Patient safety [21-23]

- Education and training of staff (structured, on regular basis, with reward for good work) [24]
- Multi-dimensional learning: Continuous medical education, e-learning, WHO patient safety curriculum, simulation based learning. Introducing it in curriculum of medical school [25-27]
- Pre-printed prescription order sheet than the blank sheet for orders [28]
- Protocol implementation than the personal practice [20-22]
- Computerized provided order entry than the manual entry [29, 30]

- Use of drug formulary/ database [20-22]
- Introduction of dose card/ drug sheet
- Double checking of prescription writing and lifesaving drugs
- Unit drug dose distribution system [31]
- Use of calculators/ MS excel programs/ Apps for dose calculation /computerized algorithms [32, 33]
- Introduction of wrist band bar code [34,35]
- Colour –coded pre-filled syringes [36]
- Use of emergency ruler (Broselowpediatric emergency tape/German pediatric emergency ruler) [37, 38]
- Increased role of pharmacy in preparation of drugs [39]
- Working hours of residents needs to be addressed specially in night shifts [40]
- Real time audit [41, 42]

CONCLUSION

An efficient error reporting system which can help aggregate all the information on medication errors occurring nationwide and keep the public informed should be highly recommended. We need to measure what all we do, making the results public. Patient safety can be ensured through multiple interventions aimed at improving the medication process. Additional cost-effectiveness data on interventions to reduce pediatric medication errors would benefit policy makers and medical leaders as they choose between multiple possible interventions. Reducing medication errors presents an important opportunity for improving the quality and diversity of current research.

Further, physicians should share adequate knowledge about the risks and benefits of the intake of medications. They need to develop a better communication with patients and Physicians must clarify uncertainties if any, about any medication. For the public safety it si necessary that physician are up to date in their knowledge for medications.

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