ABSTRACT

Background: High-risk medicines are outlined as those medicines that have a high risk of inflicting pain or death once employed to patients in error. Hence, this work was done to identify key parameters of mishandling observed by the administration on high-risk medication.

Methods: The audit team conjointly assessed compliance with policies and tips associated with the administration of medication. Moreover, key documents including several of the nursing ability checklists were reviewed. The major attributes are taken as ICU, ER, Wards, Pre-Post-Operative & CCU. The measurable elements include documented policies, and procedures for medication administration; close monitoring on records for adverse drug incidents. Analysis revealed that a significant improvement in high-risk medicine accessibility along with the provision of a list of drugs, high-risk medicines were still found at patient bedside in few scenarios. Nurses were found to be highly knowledgeable regarding high-risk medications policies but fall short in executing them at workstations.

Results: Findings suggest that there is a need for revision in policies concerning high-risk medicines placement and storage; and also, they must be separated from the usually used medicines; timely training programs should be conducted for staff and individual attention. Documentation related to high-risk medicines starting from prescription, double authentication, verification, pre-, and post-administration should be improvised. Special attention needs to be paid to reporting medication errors like prescription errors; adverse drug reactions related to high-risk medicine administration.

Keywords: Clinical Pharmacology; Medication Safety; Pharmacoepidemiology; Epidemiology; Medication Error

Introduction

High-risk medicines can be defined as those medicines that have a high risk of causing significant patient harm or death when used in error. High-risk medicines include medicines: with a low therapeutic index that present a high risk when administered by the wrong route or when other system errors occur. Hence, it is required by health services to identify high-risk medicines used within the organization and take appropriate action to ensure that they are stored, prescribed, dispensed, and administered safely^{1,2}. This study also provides an approach to check the hospitalization risk among totally different medications. However, this study was restricted to the aged population and failed to assess age-specific variations. Moreover, some suspected speculative medications indicated in previous studies weren't enclosed in this study³⁻⁷. For instance, separate queries of the EMR system were performed to collect all non-pregnant female patients prescribed doubtless agent medications, taking reversible birth prevention, or with a history of sterilization, extirpation, or climacteric during the course of studies. This data was collected from the patient's current medication list, downside list, and medical and surgical history documentation. Before information assortment, little pilot evaluations were conducted to assure information extraction quality. Based on the EMR prescription records, patients were classified as receiving a bad medication if they were prescribed a minimum of one of the subsequent medications throughout the study period: simvastatin, atorvastatin, pravastatin, lisinopril, topiramate, ondansetron, valproic acid, or paroxetine^{8–12}.

A medication error (ME) is a mistake that causes harm to a patient or puts them at risk of harm. Several studies have found that only a small percentage of MEs are harmful, which could explain why medication reviews at hospital admission reduce the number of MEs while having no effect on length of stay, readmissions, or death. The goal of this research was to identify drugs that cause serious MEs. A literature search of medication reviews and other preventive efforts was also conducted Many medicines may have a high risk of harm when used in error or taken inappropriately. Although errors may or may not be more common than with other medicines, the consequences of errors with high-risk medicines can be more devastating. So, there should be an eye on the nursing staff in the phases before, during, and after the administration of high-risk medication. Keeping it as the key factor, SSB Heart & Multi-specialty Hospital, Faridabad decided to conduct clinical audits in the department of IPD areas on the topic of administration of high-risk medications in a particular interval to bring continuous quality improvement in nursing care. The initial study was carried out in November 2020 and June 2021.

Evidence based criteria

The organization defines a list of high-risk medication(s).

- 1. High-risk medication orders were verified prior to dispensing.
- 2. There are documented policies and procedures for medication administration.
- 3. The organization defines those situations where close monitoring is required 17.

Objective and Auditing

- 1. Identify and promote good practice regarding medication process especially the high-risk medicine administration.
- 2. Improve the administration of high-risk medications.
- 3. Highlight problems with high-risk medication administration and suggest appropriate solutions.
- 4. Improve team work and communication for avoiding harm with high-risk medication.
- 5. Guide and train the staff to follow the policy of high-risk medication.
- 6. Improve the quality of care by providing safe medication to the patients.
- 7. Find out the wrong practices in high-risk alert medication and correction of those.
- 8. Reduce the occurrence of medication incidents and improve the safety and quality of medicines used 18.

Materials and Methods

The audit team reviewed policies and procedures related to the administration of medication, which can be considered as one of the indicators of nursing excellence. The audit team also assessed compliance with policies and guidelines related to the administration of medication.

Key documents reviewed included many of the nursing skill checklists, clauses from the NABH –Guide Book to Accreditation Standards for Hospitals [4th Edition] Dec 2015, The Standards for Nursing Excellence, and the Nursing Manual of the HCO. Compliance was tested through on-site observations, file reviews, and interviews with staff in different clinical units¹⁹. An overview of audit, audit dates, sampling size and site selected is tabulated in Table 1.

The following techniques were used to collect audit evidence:

- 1. **Review of Documentation:** Relevant documentation was reviewed including drug chart, daily plan of care and applicable standards, and policies.
- 2. **Interviews:** Interviews were conducted with the nursing staff involved in the administration of medication in the patient units.
- 3. **Observations:** Observations were conducted on the clinical floors and patient units regard to the prescription, intending, dispensing, preparation, and administration of medication.
- **4. Site Selection:** Selection of inpatient departments of both critical and non-critical care areas.
- **5. Audit tool:** The copy of the filled audit check was used²⁰.

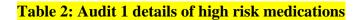
S. No.	Audits	Audited on	Sampling size	Attributes
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1.	Audit: 1	July 2021	20 % in-patients	ICU, ER, Wards, Pre-Post- Operative
2.	Re-audit 1	September 2021	20 % in-patients	ICU, ER, Wards, Pre-Post- Operative
3.	Re-audit 2	November 2021	20 % in-patients	ICU, CCU & Wards
4.	Re-audit 3	January 2022	20 % in-patients	ICU, CCU & Wards

Table 1: An overview of audit attributes of high risk medications

Results

The details of the audit 1 and re-audit 1 conducted are given in Tables 2 and 3.



S.No.	Measurable Element	Clause	Checkpoint	Compliance	Remarks
1	The organization defines a list of high-risk medication(s).	Mom.1.j	The list of high-risk medicines is displayed in each unit.	NC	Not mentioned anywhere.
			Is this list accessible to all the nursing staff?	NC	
2	High-risk medication orders are verified prior	Mom.4.f	These medications shall be given only after written orders.	NC	It's not found in some CCUs.
	to dispensing.		It should be verified by the staff before dispensing.	PC	Double authentications were not placed on many cases.
			High-risk medication should be kept in separate storage under lock.	NC	Inj. KCl was found in the bedside locker in CCU.
3	There are documented policies and procedures for medication administration.	Mom.6	In case of high-risk medication(s), the verification shall be done by at least two staff members (nurse-nurse or nurse-doctor) independently and documented.	PC	Double sign was missing in some cases in MICU.
			The nurses are knowledgeable	PC	Need Training.

			regarding high-risk medications.		
			Training on high- risk medication is given to all nursing staff.	Closed	
			Nurses are empowered to highlight prescription errors noted while verifying the orders.	PC	Implementation to be done.
4	The organization defines those situations where close monitoring is	Mom.7.b	Pre- & post-high risk medicine administration vitals should be checked & recorded.	NC	It's not recorded everywhere, especially in the ward.
	required.		Adverse drug incidents involving high-risk medicines should be reported.	PC	Very few cases are reported.

Table 3: Re-audit 1 details high risk medications

S. No.	Measurable Element	Clause	Checkpoint	Compliance	Remarks
1	The organization defines a list of high-risk	Mom.1.j	The list of high-risk medicines is displayed in each unit.	Closed	
	medication(s).		Is this list accessible to all the nursing staff?	PC	
2	2 High-risk medication orders are verified prior to dispensing.	Mom.4.f	These medications shall be given only after written orders.	PC	
			It should be verified by the staff before dispensing.	PC	Double authenticatio ns were not placed in a few cases.
		High-risk medication should be kept in separate storage under lock.	PC	Especially in the ward.	
3	There are documented policies and procedures for medication administration.	Mom.6	In case of high-risk medication(s), the verification shall be done by at least two staff members (nurse-nurse or nurse-doctor) independently and documented.	PC	Double sign was missing in some cases.
			The nurses are knowledgeable regarding high-risk medications.	Closed	

			Training on high-risk medication is given to all nursing staff.	Closed	
			Nurses are empowered to highlight prescription errors noted while verifying the orders.	Closed	
4	The organization defines those situations where close	Mom.7.b	Pre- & post-high risk medicine administration vitals should be checked & recorded.	PC	In the wards.
	monitoring is required.		Adverse drug incidents involving high-risk medicines should be reported.	PC	Very few cases are reported.

Figure 1 depicts the comparison of the compliances of the previous audit with the initial one.

- 1. By comparing the previous audit, there are a lot of improvements seen in practices regarding high-risk medication.
- 2. High-risk medicines were being highlighted by an orange highlighter pen.
- 3. Eight rights of medicine administration were started to follow.
- 4. There were still problems with documentation like double authentication on high risk, illegibility of sign, and time of administration in a few cases.
- 5.The nurses are knowledgeable regarding high-risk medications but policies are not completely started to get executed by the nursing staff²¹.

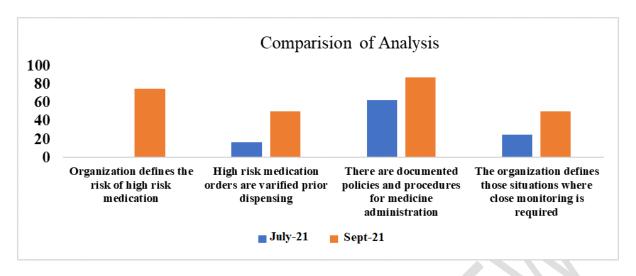


Figure 1: Bar chart depicting the comparison of the compliances of the audit 1 with Reaudit 1

The details of the re-audit 2 and re-audit 3 conducted are given in Tables 4 and 5.

Table 4: Re-audit 2 high risk medications

S. No.	Measurable Element	Clause	Checkpoint	Compliance	Remarks
1	The organization defines a list of high-risk medication(s).	Mom.1,j	The list of high-risk medicines is displayed in each unit.	Closed	
			Is this list accessible to all the nursing staff?	Closed	
2	High-risk medication orders are verified prior to dispensing.	Mom.4.f	These medications shall be given only after written orders.	PC	Certain highrisk medicines are administered via verbal order in emergency situations.
			It should be verified	Closed	

			by the staff before dispensing.		
			High-risk medication should be kept in separate storage under lock.	PC	Certain high- risk medicines are found at the bedside in critical care units.
3	There are documented policies and procedures for medication administration.	Mom.6	In case of high-risk medication(s), the verification shall be done by at least two staff members (nurse-nurse or nurse-doctor) independently and documented.	Closed	
			The nurses are knowledgeable regarding high-risk medications.	PC	Some of the staff members are not aware of categories of high-risk medicines.
			Training on high-risk medication is given to all nursing staff.	Closed	
			Nurses are empowered to highlight prescription errors noted while verifying the orders.	Closed	Medicine prescription error is highlighted.
4	The organization defines those situations where close	Mom.7.b	Pre- & post-high risk medicine administration vitals should be checked & recorded.	PC	In the wards despite repeated training.

monitoring required.	is		drug involving medicines reported.	PC	Very cases reporte	few are d.
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Figure 2 depicts the comparison of the compliance of the previous audits with the last one for the year to analyze the half-yearly quality improvement for high-risk medicine policy laid.

- 1. Analysis reveals significant improvement in high-risk medicine accessibility along with the provision of a list of drugs.
- 2.Although considerable improvement is noted in written prescription orders, it has been observed that orders lack legibility in certain departments.
- 3.Moreover, provision for separate segregation is made available in each department but just like in the previous audit high-risk medicines were still found at patient bedside in a few scenarios.
- 3.Close monitoring and underreporting of adverse drug reactions related to high-risk medicine was observed as one problematic sphere which required more attention²².
- 4. Eight rights of medicine administration were followed thoroughly.
- 5.The nurses were observed to be knowledgeable regarding high-risk medications policies but fall short in executing them at workstations.

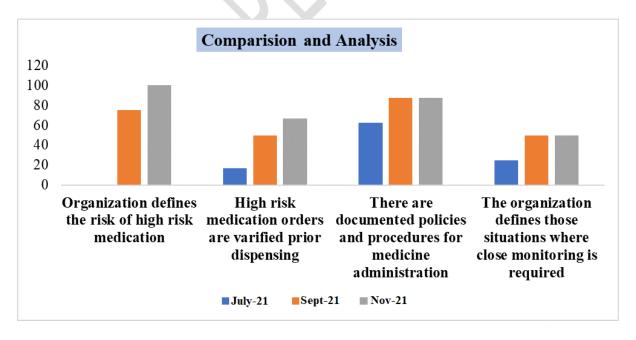


Figure 2: Bar chart depicting the comparison of previous audits with the last one for the year

Table 5: Re-audit 3 details high risk medications

S. No.	Measurable Element	Clause	Checkpoint	Compliance	Remarks
1	The organization defines a list of high-risk medication(s).	Mom.1.j	The list of high- risk medicines is displayed in each unit.	Closed	-
			Is this list accessible to all the nursing staff?	Closed	
2	High-risk medication orders are verified prior to dispensing.	Mom.4.f	These medications shall be given only after written orders.	PC	Certain high-risk medicines are administered via verbal order in emergency situations.
			It should be verified by the staff before dispensing.	Closed	
			High-risk medication should be kept in separate storage under lock.	PC	Certain high-risk medicines are found at the bedside in critical care units.
3	There are documented policies and	Mom.6	In case of high- risk medication(s),	Closed	-

	procedures for medication administration.		the verification shall be done by at least two staff members (nurse- nurse or nurse- doctor) independently and documented.		
			The nurses are knowledgeable regarding high-risk medications.	PC	Some of the staff members (New joiners) are not aware of categories of high-risk medicines.
			Training on high-risk medication is given to all nursing staff.	Closed	-
			Nurses are empowered to highlight prescription errors noted while verifying the orders.	Closed	Medicine prescription error is highlighted.
4	The organization defines those situations where close monitoring is required.	Mom.7.b	Pre- & post-high risk medicine administration vitals should be checked & recorded.	PC	In the wards despite repeated training.
			Adverse drug	PC	Very few

	incidents	cases	are
	involving high-	reported.	
	risk medicines		
	should be		
	reported.		ļ
	•		

Figure 3 depicts the comparison of the compliance of the previous audits with the last one for the year to analyze the half-yearly quality improvement for high-risk medicine policy laid.

- 1. Analysis reveals significant improvement in high-risk medicine accessibility along with the provision of a list of drugs.
- 2.Although considerable improvement is noted in written prescription orders, it has been observed that orders lack legibility in certain departments.
- 3.Moreover, provision for separate segregation is made available in each department but just like in the previous audit high-risk medicines were still found at patient bedside in a few scenarios.
- 4.Close monitoring and underreporting of adverse drug reactions related to high-risk medicine is one problematic sphere requiring more attention.
- 5. Eight rights of medicine administration are being followed thoroughly.
- 6.The nurses are knowledgeable regarding high-risk medications policies but fall short in executing them at workstations²³.

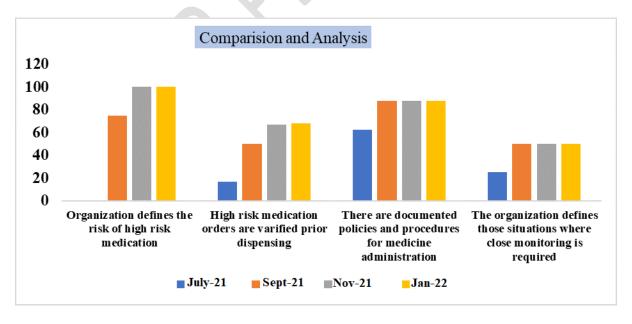


Figure 3: Bar chart depicting the comparison of previous audits with the last one for the year

Discussion

The audits show that lot of enhancements were seen in practices related to risky medication. Eight medication administration rights were followed as a result. Though, some issues with documentation like double authentication on high risk, the incomprehensibility of sign, and time of administration in a few cases were also seen. The nurses were observed to be knowledgeable when it comes to risky medications however policies don't seem to be fully begun to get dead by the nursing employees. Analysis reveals vital improvement in risky drugs accessibility besides the availability of a list of medications. Though tidy improvement was noted in written prescription orders however it's been determined that orders lack legibility in some departments. Moreover, provision for separate segregation was found accessible in every department, however similar to the previous audit, high-risk medicines were still found at the patient side in a few situations. Shut observance and beneath reportage of adverse drug reaction associated with risky drugs was reported to be one problematic sphere requiring additional attention.

Table 6: Summary of observations on high-risk medicines

S. No.	Audit: 1	Re-audit 1	Re-audit 2	Re-audit 3
1.	The list was not displayed in both critical & non-critical departments.	The list was made available in both critical & non-critical areas.	The list was made available in both critical & non-critical areas.	The list was made available in both critical & non-critical areas.
2.	The list was not accessible to all on-floor nursing staff except some senior staff.	The list was not accessible to all onfloor nursing staff except some senior staff.	The list was not accessible to all onfloor nursing staff except some senior staff.	The list was not accessible to all on-floor nursing staff except some senior staff.
3.	The written orders were not found with the exception of a few cases in ICUs.	Written orders were found but not legible & non-compliant with the time written orders were found but not legible & non-compliant with time.	Written orders were found but not legible & non-compliant with the time of administration both in critical & non-critical areas.	Written orders were found but not legible & non-compliant with the time of administration both in critical & non-critical areas.

4.	The drug was not verified by the staff before dispensing in many cases.	Counter checking & double authentication found complaint evidenced by two signatures in the administrative record.	Counter checking & double authentication found complaint evidenced by two signatures in the administrative record.	& double authentication
5.	It has been pointed out by the auditor that some of the high-risk medications were stored in the patient's bedside locker.	The auditor points out that some of the risk medications were stored in patients' bedside lockers in the wards.	The auditor points out that some of the risk medications were stored in patients' bedside lockers, especially in the wards.	The auditor points out that some of the risk medications were stored in patients' bedside lockers, especially in the wards.
6.	Double authentication by at least two medical personnel was not consistent, verifiable, and legible.	Doing a double authentication before administration of high-risk medicines in almost every department.	Doing a double authentication before administration of high-risk medicines in almost every department.	Doing a double authentication before administration of high-risk medicines in almost every department.
7.	Many departments' staffs were not aware of high-risk medicines & laid out policies.	Training on high- risk medication is given to all nursing staff periodically.	Training on high- risk medication is given to all nursing staff periodically.	Training on high- risk medication is given to all nursing staff periodically.
8.	Pre & post-high-risk medicine administration vitals should be checked, but not	Pre & post-high-risk medicine administration vitals should be checked, but not	Pre & post-high-risk medicine administration vitals should be checked, but not	Pre & post-high- risk medicine administration vitals should be checked, but not

	recorded in many	recorded in a few	recorded in a few	recorded in a few
	cases.	cases.	cases.	cases.
9.	Adverse drug	Adverse drug	Adverse drug	Adverse drug
	incidents	incidents involving	incidents involving	incidents
	involving high-	high-risk medicines	high-risk medicines	involving high-
	risk medicines are	are not always	were reported.	risk medicines
	underreported	reported.		were reported.

Conclusion

The findings imply that regulations surrounding the placement and storage of high-risk drugs should be revised; they should also be isolated from commonly used medicines; and timely training programmes for employees and individual attention should be provided. The present analysis shows that there were various issues with paperwork, such as duplicate authentication on high-risk documents, illegibility of signatures, and administration time. Despite the fact that all nurses are educated of high-risk drugs, the nursing staff does not follow the regulations. During the previous year, compliance for high-risk drugs was greatly improved in terms of accessibility, storage, and listing. Documentation for high-risk drugs has improved, but it still requires a more convergent emphasis, starting with prescriptions, double authentication, verification, pre- and post-administration vitals, and readability. However, policies laid down on high-risk medicines are being followed throughout the hospital but special attention needs to be paid to reporting medication errors like prescription errors & adverse drug reactions related to high-risk medicine administration. It was observed that there is a need for indivisible knowledge for staff placed on the floor because lack of knowledge was one of the obstacles. Some of the recommendations are enlisted in the Table 7.

Table 7: Recommendations on high-risk medicines

Recommendation for list of high-risk medicines				
S. No.	Audit: 1	Re-audit 1	Re-audit 2	Re-audit 3
1.	_	In charge should give awareness regarding the display of high-risk medication to the staff assigned under.	-	-

2.	In charge and supervisors will counter-check the medication chart to improve the documentation status of high-risk medications like double authentication on high-risk, illegibility of sign, and time of administration.	In charges and supervisors will counter-check more strictly the medication chart to improve the documentation status of high-risk medications like double authentication on high-risk, illegibility of sign, and time of administration.	medications like double authentication on high-risk,	In charges and supervisors will counter-check more strictly the medication chart to improve the documentation status of highrisk medications like double authentication on high-risk, illegibility of sign, and time of administration.
3.	On-floor training on high-risk medicine administration should be given to the nursing staff by the supervisor and in charge.	Effective training should be increased regarding the administration of high-risk medication.	-	-
4.		Vigorous training by senior staff to junior staff regarding the practical aspects of high-risk medicine administration.	=	-
5.	In charge should take initiative to maintain track of whether the high- risk medicines policies are getting	In charge should take initiative to maintain track of whether the highrisk medicine policies are being	Supervisors, in charge, and on floor nursing staff should be pressed on the importance of reporting	Supervisors, in charge, and on floor nursing staff should be pressed on the importance of

	executed by the nurse.	followed by on- floor nursing.	prescription errors related to high-risk medicine for betterment in the quality of clinical practice.	reporting prescription errors related to high-risk medicine for betterment in the quality of clinical practice.
6.	Re-audits on the same checklist should be done with periodic intervals to bring continuous quality improvement.	Re-audits on the same checklist should be done with periodic intervals to bring continuous quality improvement.	Re-audits on the same checklist should be done with periodic intervals to bring continuous quality improvement.	same checklist should be done with periodic
7.	Proposed Re- Auditing Period: July, 2021	Proposed Re- Auditing Period: September, 2021	Proposed Re- Auditing Period: November, 2022	Proposed Re- Auditing Period: January, 2022

DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

Ethical Approval:

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

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