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An Observational Study of Breach Of High Risk Medication Policy In A Multispecialty Hospital

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Abstract

This observational study at Indus International Hospital (January-March 2025) evaluated high-risk medication handling compliance, examining 200 medication forms with 343 drug entries. Key findings revealed protocol breaches in both pharmacy (9% pouches missing black dots, 8% lacking dual signatures) and nursing departments (4% missing verification signatures, 4.5% improper storage). Knowledge assessment showed nurses outperforming pharmacists and medical officers. Despite procedural gaps, actual error rates remained low (4-4.5%). The study implemented educational interventions and recommended comprehensive strategies to enhance medication safety protocols.

Keywords: High Risk Medication, Safety Protocol, Handling Compliances, Protocol breaches, High _Alert medication

1. Introduction

According to the World Health Organization (WHO), high-risk medications (sometimes called "high-alert" medications) are drugs that bear a heightened risk of causing significant patient harm when used in error [1,2]. These medications require special safeguards to reduce the risk of errors such as:

- Double-checking dosage calculations.
- Using specialized storage methods.
- Implementing special labelling practices.
- Restricting access.
- Providing additional education to healthcare providers.

The World Health Organization (WHO) has developed several policy recommendations and guidelines for handling high-risk medications as part of their "Medication Without Harm" Global Patient Safety Challenge.[2,3] While the WHO doesn't mandate a single standardized policy document, they recommend healthcare institutions implement policies. Healthcare organizations must establish and rigorously maintain comprehensive protocols for managing high-risk medications.[4,5] Understanding the relevance of high-risk medications helps drive appropriate policy development, resource allocation, and educational efforts to reduce harm and improve patient care across healthcare systems.

2. Objective

To identify and analyse breaches in high-risk medication handling policies and implement evidence-based risk reduction strategies to enhance patient safety in the dispensing and administration of high-risk medications."

This objective encompasses several key components:

- 1. Breach identification and analysis:** Determining the specific nature, patterns, and root causes of policy violations or gaps in high-risk medication management
- 2. Risk reduction strategy development:** Creating or adapting evidence-based interventions to address identified vulnerabilities.

Secondary objectives might include:

- a. Assessing healthcare provider knowledge and adherence to high-risk medication policies.
- b. Evaluating the effectiveness of current safeguards and barriers to proper implementation.
- c. Creating educational interventions to address knowledge gaps.

3. Materials And Method

3.1 Study Design:

An Observational study, carried out in the sector of high risk medication dispensation and documentation of the administration of high risk medications in a multispeciality hospital in Panjab, India from January 2025 to March 2025

3.2 Characteristics Of The Study Site:

Our research was conducted at a mid-sized private hospital with 200 beds. The investigation spanned a three month period from Jan 2025-March 2025. The facilities centralised inpatient pharmacy handles a huge amount of high risk medication doses. The study team tracked the complete high risk medication processes by examine each step from the pharmacy to the final administration of the drug to the patient.

3.3 High Risk Medication Policy:

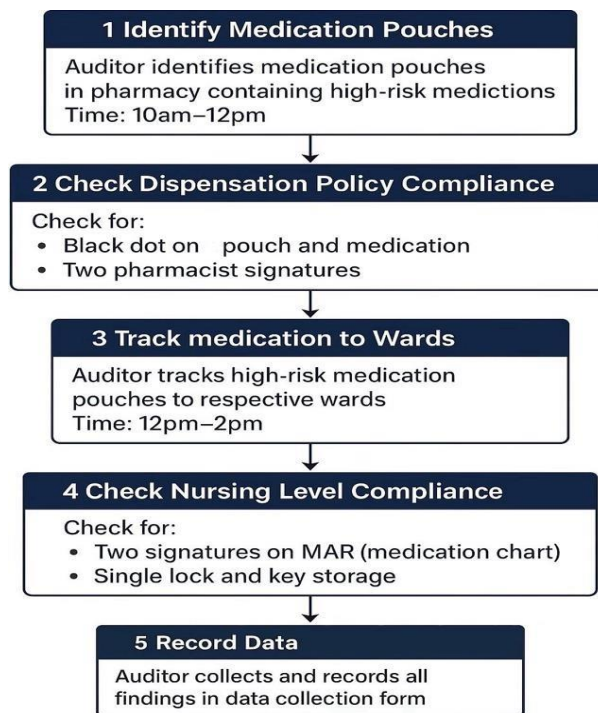
At Pharmacy Level:

Prior to the dispensation of any high-risk medication at Indus International Hospital, all packaging must be clearly marked with a black indicator dot. Additionally, verification signatures from two licensed pharmacists are required on the medication pouch to confirm proper review. This dual- verification process is mandatory for all high-risk medications without exception.

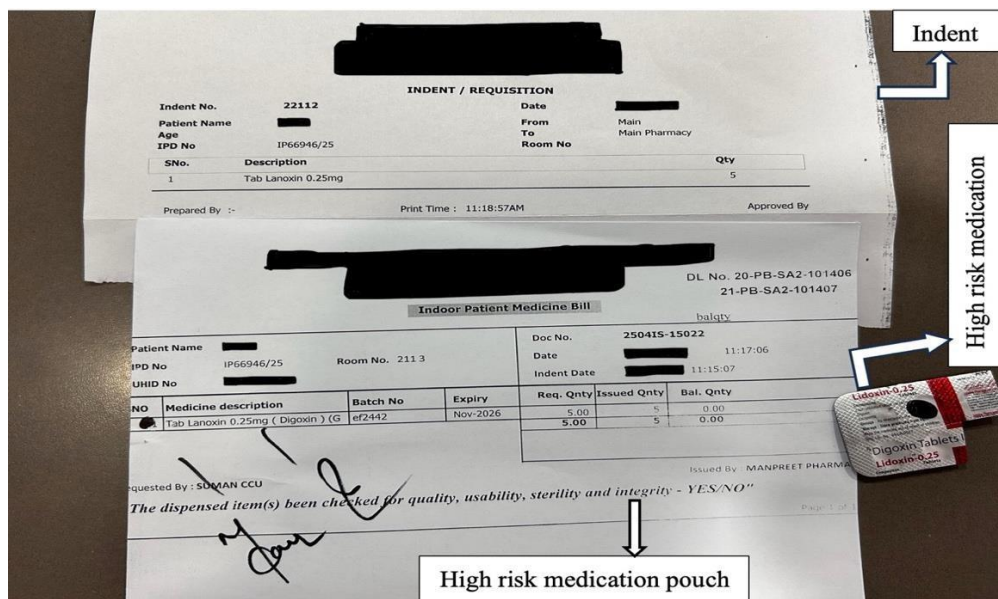
At Nursing Level:

All high-risk medications within Indus International Hospital clinical units must be secured in designated storage units with single-lock security mechanisms, with access restricted to authorized nursing personnel only. Upon administration of any high-risk medication, documentation on the Medication Administration Record (MAR) requires mandatory dual verification signatures from both the administering nurse and a supervising medical officer, establishing an additional layer of safety verification and accountability for all high-risk medication administrations without exception.

3.4 Data Collection Process:



(FIGURE-1)



(FIGURE – 2)

3.5 Data Collection Template

Auditor:	Date of Audit:	Location:			
UHID:	Date of Admission:	Primary Consultant:			
HIGH RISK MEDICATION DETAILS					
	DRUG 1	DRUG 2	DRUG 3	DRUG 4	DRUG 5
DRUG NAMES					
BLACK DOT ON DRUG AND POUCH					
TWO PHARMACIST SIGN					
TWO STAFF SIGN ON MAR					
STORAGE - SINGLE LOCK AND KEY					

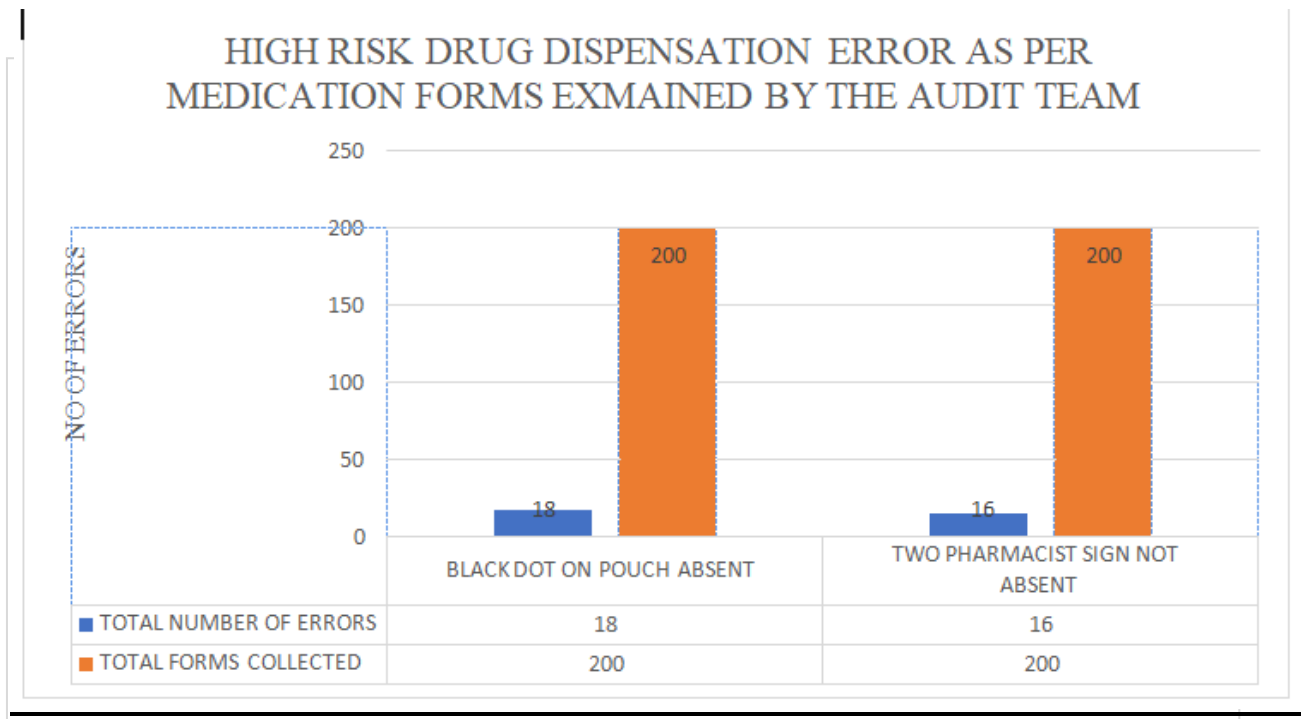
4. Results

As Per Audit For Pharmacy Department

A comprehensive audit of medication management practices revealed significant compliance issues at both pharmacy and nursing levels. The study team examined 200 medication forms containing 343 individual drug entries. At the pharmacy level, 17 out of 343 drug entries (5.0%) had missing black dot markings on the medication itself, while 18 out of 200 pouches (9.0%) lacked the required black dot identification. Additionally, 16 medication forms (8.0%) were missing the mandatory dual pharmacist verification signatures.

• **Errors Identified During Dispensation Of Medicines At Pharmacy: -**

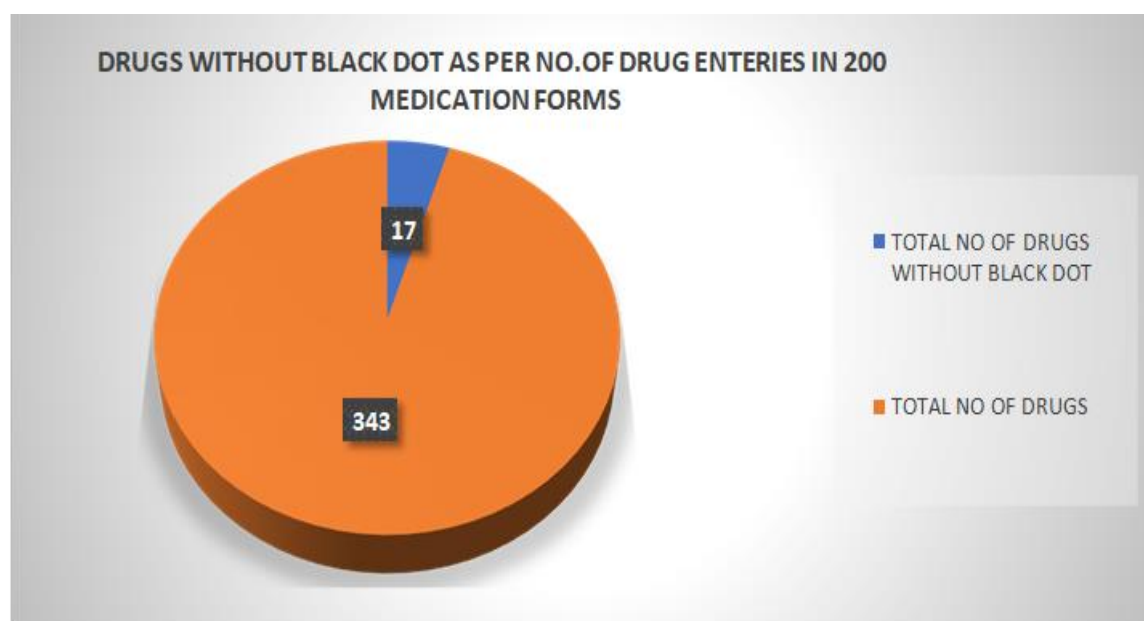
1. **BLACK DOT ON POUCH**
2. **TWO PHARMACISTS SIGN**
3. **DRUGS WITHOUT BLACK DOT**



(FIGURE – 3)

The analysis of (FIGURE-3) titled as high-risk drug dispensation errors as per medication forms examined by the audit team revealed absent black dots on medication pouches in 9% of cases (18/200) and missing dual pharmacist signatures in 8% of cases (16/200), highlighting gaps in safety protocol implementation for visual identifiers and verification procedures.

- **High Risk Drugs Dispensed Without Black Dot:**

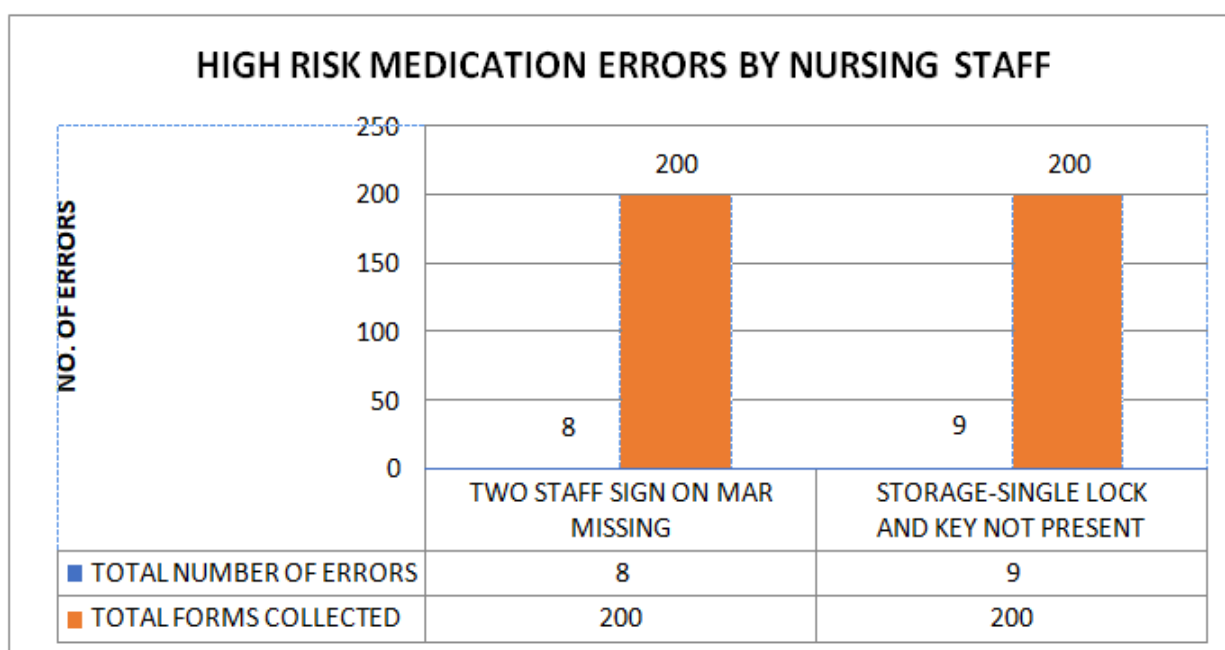


(FIGURE-4)

The (FIGURE-4) titled "HIGH RISK DRUGS DISPENSED WITHOUT BLACK DOT" demonstrates that among 343 high-risk medications evaluated, only 17 (4.96%) lacked the required black dot identifier, indicating a 95.04% compliance rate with safety marking protocols for potentially dangerous pharmaceuticals. This high adherence rate suggests effective implementation of medication safety standards for high-risk drugs.

As Per Audit For Administration At Nursing Department

The nursing compliance assessment as per high risk policy identified critical medication safety concerns: 4.0% of medication administration records (8 instances) lacked required dual nursing verification signatures, while 4.5% (9 cases) failed to meet nursing storage security standards by using only single lock mechanisms. These findings indicate urgent areas requiring immediate nursing intervention to strengthen medication safety protocols and ensure full compliance with established nursing practice standards.



(FIGURE -5)

The (FIGURE-5) titled as high-risk medication errors by nursing staff in two categories: "Two Staff Sign on MAR Missing" (8/200 forms, 4% error rate) and "Storage-Single Lock and Key Not Present" (9/200 forms, 4.5% error rate), showing similar but concerning error frequencies in critical medication safety protocols.

Health Care Professional Knowledge Evaluation Result:

The Indus International Hospital (IIH) risk management study team developed a ten-question questionnaire to evaluate healthcare professionals' knowledge of high alert medication policies. The questionnaire contained basic questions regarding high-risk drug management policy and was given to medical officers (n=20), nurses (n=24), and pharmacists (n=10).

Scoring Criteria

Correct responses received one point while incorrect answers received zero points. The individual scores within each professional category were aggregated, and mean scores were calculated to analyze performance across different healthcare roles.

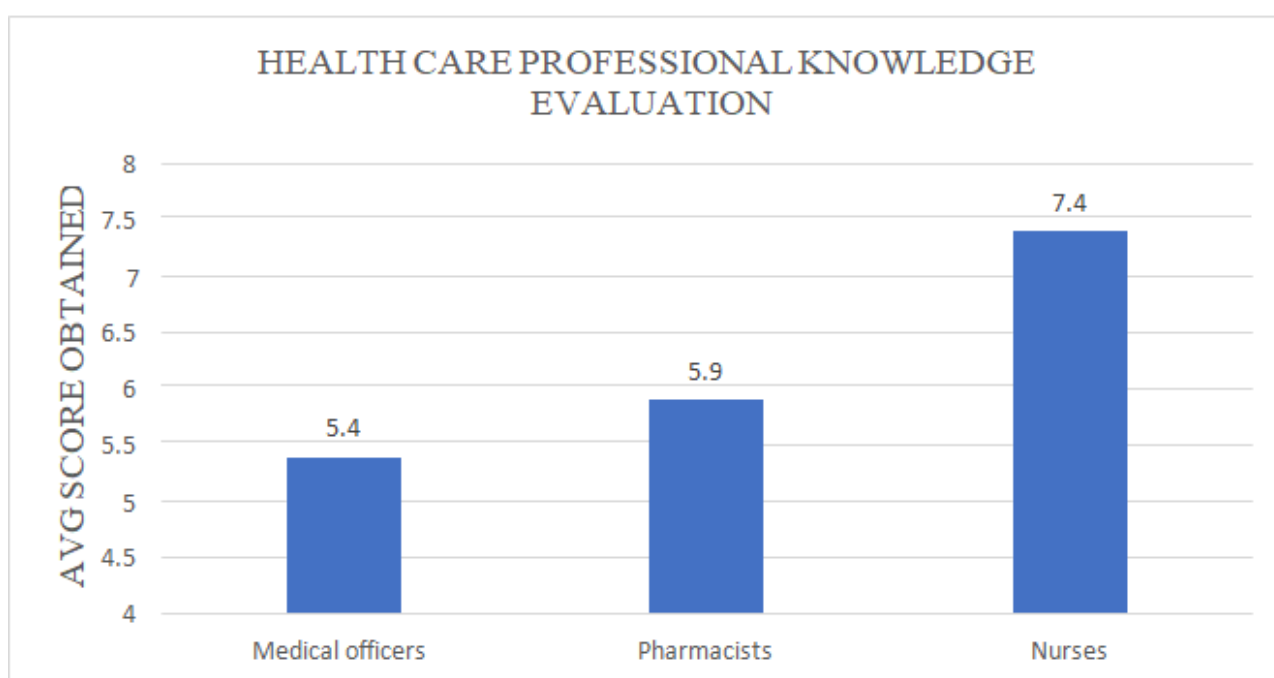


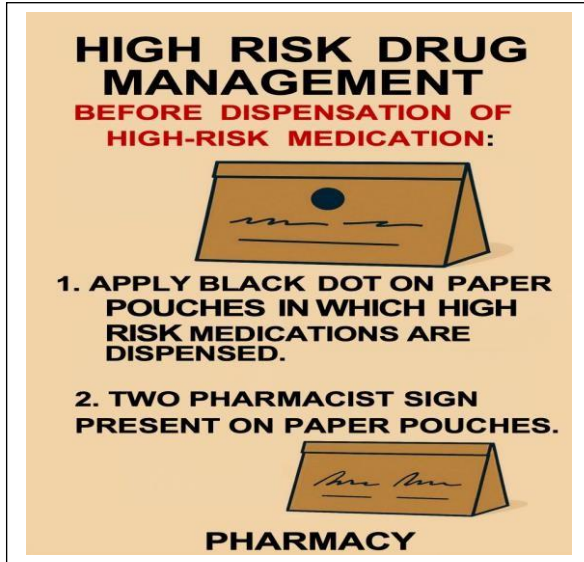
FIGURE 6

The (FIGURE-6) titled "Health Care Professional Knowledge Evaluation" displays average evaluation scores for three healthcare professional categories. Nurses achieved the highest average score of 7.4, significantly outperforming pharmacists who scored 5.9, while medical officers received the lowest average score of 5.4. This notable disparity suggests nurses demonstrated superior

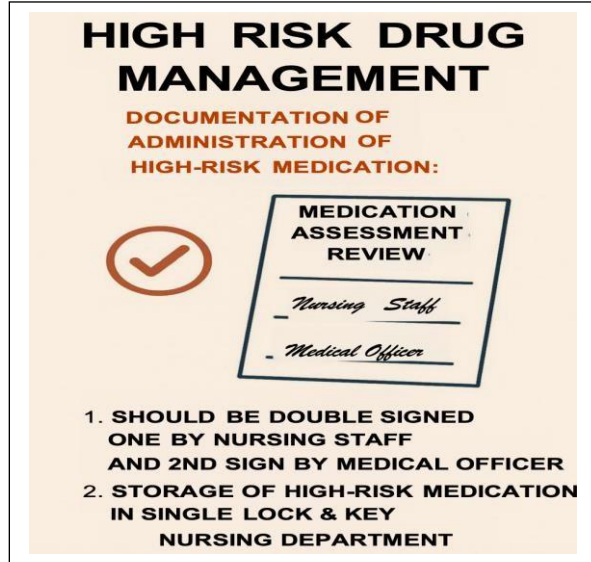
knowledge in this particular evaluation compared to the other healthcare roles, with pharmacists performing moderately well and medical officers showing the greatest opportunity for knowledge improvement among the three professional categories measured.

• **Evaluating The Effectiveness Of Current Safeguards And Barriers To Proper Implementation :-**

We have created posters for both nursing and pharmacy departments that were designed and distributed throughout wards and pharmacy areas to educate healthcare professionals about safety protocols. These visual aids serve as immediate references before dispensing and before/after administering medications, allowing staff to quickly verify proper procedures by simply looking at the posters. This approach aims to prevent protocol deviations by both pharmacy staff and other healthcare professionals, ensuring consistent adherence to critical safety measures for high-risk medications in the future.



(FIGURE -7)



(FIGURE -8)

- **Creating Educational Interventions To Address Knowledge Gaps :-**

Role-Specific Training Programs - Develop targeted education modules customized for each healthcare role, with particular emphasis on medical officers who scored lowest on knowledge assessment.

5. DISCUSSION

This observational study at Indus International Hospital revealed critical insights into high-risk medication handling processes, demonstrating contradictions between policy and practice. [6,7] While individual medication black dot identification compliance was high (95.04%), systemic measures showed significant gaps in both pharmacy (9% of pouches lacking black dots, 8% missing dual signatures) and nursing departments. [8,9] Paradoxically, despite these procedural compliance issues, actual error rates remained remarkably low (4-4.5%), suggesting effective informal safety mechanisms. Knowledge assessment revealed nurses outperforming both pharmacists and medical officers (7.4/10 vs 5.9/10 and 5.4/10 respectively), challenging traditional hierarchical expectations and identifying medical officers as requiring targeted interventions. [10,11] Educational poster implementation represents an initial improvement step, though the disconnect between knowledge levels and compliance rates suggests barriers beyond knowledge deficits.[12,13] Study limitations include the short timeframe at a single institution and reliance on documentation review rather than direct observation, indicating a need for future observational studies exploring barriers to compliance and evaluating targeted interventions for medical officers who demonstrated the greatest knowledge gaps. [14,15]

Pharmacy Error Reduction Strategies:-

- **Visual Identification Systems:** Redesign the black dot system with larger, more visible indicators or distinct color-coding.
- **Workflow Restructuring:** Establish a dedicated high-risk medication verification station.
- **Education Enhancement:** Schedule regular refresher training for pharmacists on high-risk medication policies.

- **Quality Monitoring:** Conduct periodic unannounced audits with immediate feedback mechanisms.

Nursing Error Reduction Strategies:

- **Documentation Enhancement:** Transition to electronic medication administration records with mandatory dual verification fields.
- **Protocol Development:** Create standardized high-risk medication administration protocols with visual aids.
- **Leadership Designation:** Establish dedicated high-risk medication champions on each nursing unit.
- **Practical Training:** Conduct simulation-based training focusing on administration protocols.
- **Environmental Safeguards:** Implement "do not disturb" periods during medication preparation.
- **Accountability Mechanisms:** Develop peer-review processes for high-risk medication handling.

6. Conclusion

This observational study at Indus International Hospital identified notable disparities between high-risk medication handling policies and actual practice, revealing both strengths and areas for improvement.[6,7] Despite high individual medication compliance with black dot identification (95.04%), significant gaps existed in systemic safety measures at both pharmacy and nursing levels.[14,8] Paradoxically, actual error rates remained remarkably low (4-4.5%), suggesting the presence of effective informal safety mechanisms.[15,16] The knowledge assessment highlighted nurses as possessing superior understanding of medication policies compared to pharmacists and medical officers, challenging traditional clinical hierarchies.[10,11] Implementation of educational posters and role-specific training programs, particularly targeting medical officers who demonstrated the lowest knowledge scores, represents a foundational step toward improvement.[12,13] However, the disconnect between knowledge levels and compliance rates indicates that comprehensive interventions must address not only knowledge deficits but also workflow constraints and institutional culture factors.[17,10] This study underscores the need for multifaceted approaches to high-risk medication safety that combine enhanced visual identification systems, workflow restructuring,

documentation improvements, and accountability mechanisms to strengthen patient safety in accordance with WHO's "Medication Without Harm" initiative.[2,17,18]

7. Data Security Protocol

Patient information confidentiality was rigorously maintained during the investigation period and subsequent analysis phase. Research team members utilized the collected data exclusively for scholarly inquiry and advancement of medication safety practices, with no disclosure to unauthorized parties.

8. Conflict of Interests

Authors have no conflict of interests.

9. Authors' Contributions

NG conceptualized the study, developed the protocol, and led the data analysis and interpretation of findings. Data collection and documentation of high-risk medication errors within the pharmacy setting were jointly conducted by NG and DK. The evaluation of collected data and development of error mitigation strategies for both pharmacy and nursing departments were performed collaboratively by DSL and Dr.PKG provided critical input for guideline development, prepared the manuscript, and conducted a comprehensive review of the data analysis and interpretation. All authors have reviewed and endorsed the final version of the manuscript.

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