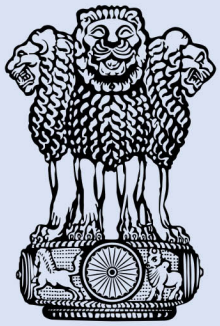

Patient Safety at a Glance

1 st Edition

National Patient Safety Secretariat
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

प्रो.(डॉ.) अतुल गोयल
Prof. (Dr.) Atul Goel
MD (Med.)
स्वास्थ्य सेवा महानिदेशक
DIRECTOR GENERAL OF HEALTH SERVICES

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services

Message

Patient safety is the cornerstone of quality healthcare delivery, requiring constant vigilance, training as well as system strengthening. In alignment with our commitment to fostering an environment of patient safety across healthcare institutions, I am pleased to introduce *Patient Safety at a Glance – 1st Edition*, developed by the Department of Hospital Administration, AIIMS Guwahati in collaboration with National Patient Safety Secretariat of the Directorate General of Health Services.

This book serves as a valuable resource for healthcare professionals providing essential insights into patient safety principles, best practices, and implementation strategies. It covers a wide range of critical topics such as risk management in hospitals, incident reporting, hospital codes, surgical safety, medication safety, infection control, transfusion medicine, and policies for vulnerable patient care. The inclusion of key protocols like the Surgical Safety Checklist, Code Blue protocol, and the management of sharp injuries and blood/body fluid spills makes this publication a inclusive guide for healthcare providers.

I commend the efforts of all contributors towards developing this publication and hope it will serve as a guiding document for health professionals in all medical colleges especially the newer ones and other health institutions thereby improving patient safety outcomes across the country. Let us continue working together to build a safe healthcare system for all.

अतुल गोयल

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Additional Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
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MESSAGE

Every patient who walks into a hospital places their trust in our healthcare system, hoping for care that heals without harm. Patient safety is not just a technical requirement-it is the heart of compassionate, high-quality healthcare. Ensuring that every patient receives safe and effective treatment requires not only strong systems and protocols but also a collective commitment from every healthcare provider.

"Patient Safety at a Glance" is a step toward making this commitment a reality. Developed by AIIMS Guwahati in collaboration with the National Patient Safety Secretariat, this book brings together essential knowledge, best practices, and practical strategies to strengthen patient safety across hospitals and healthcare settings. From preventing medical errors to ensuring clear communication, from managing infections to safeguarding vulnerable patients-this resource is designed to support healthcare professionals in their everyday efforts to make care safer.

True patient safety is built on teamwork, vigilance, and a culture that prioritizes learning and improvement. I deeply appreciate the efforts of everyone who contributed to this important work, and I hope this book serves as a valuable guide for all those dedicated to delivering safer healthcare.

Together, let's continue working toward a future where patient safety is not just a goal, but a way of life.

(Ms. L. S. Changsan)

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(स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक वैधानिक निकाय)
(A statutory body under the aegis of Ministry of Health and Family Welfare, GoI)
Changsari, District-Kamrup, Assam, PIN-781101

MESSAGE

I am pleased to introduce the release of the Patient Safety Manual titled "*Patient Safety at a Glance- 1st Edition*" which is prepared with coordinated efforts of Department of Hospital Administration, AIIMS, Guwahati with inputs from India Patient Safety Network (20 AIIMS, BHU, JIPMER & PGIMER Chandigarh) and National Patient Safety Secretariat, Dte.GHS, MoHFW. We at AIIMS Guwahati, are deeply committed to ensuring the highest standards of care for our patients, and this manual will serve as an important milestone in our ongoing journey towards enhancing healthcare safety and quality.

Patient safety is a cornerstone of modern medical practice, and this manual highlight essential guidelines, protocols, and strategies that are designed to minimize risks and protect the well-being of those entrusted to our care. Through this work, we aim to empower healthcare professionals with the knowledge, tools, and best practices necessary to safeguard patients and improve outcomes.

I would like to extend my heartfelt thanks to all the contributors, authors, and experts who have worked diligently to bring this manual to life. Your efforts will undoubtedly have a lasting impact on the healthcare community and, more importantly, on the lives of countless patients.

At AIIMS Guwahati, we believe that patient safety is not just a goal but a continuous process of learning, adapting, and improving. I hope this manual will serve as a valuable resource for healthcare providers, helping to foster a culture of safety and excellence in medical care.

Executive Director
AIIMS Guwahati

डॉ. एल. स्वास्तिचरण
Dr. L. Swasticharan
Additional Dy. Director General &
Director (EMR)

सत्यमेव जयते

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दिनांक / **Dated**.....

MESSAGE

Ensuring patient safety is a shared responsibility, requiring continuous learning, strong leadership, and system-wide engagement. *Patient Safety at a Glance – 1st Edition* is an important step in our mission to build capacity and strengthen patient safety initiatives in India.

Developed by the AIIMS Guwahati in collaboration with National Patient Safety Secretariat, this book presents a concise yet comprehensive overview of key patient safety concepts, challenges, and solutions. Covering crucial areas such as safety measures in pathology and biochemistry laboratories, radiation oncology, ICU safety, anesthesia safety, and referral protocols, this book provides healthcare professionals with essential guidelines to enhance patient care and prevent adverse events. Special emphasis is placed on policies like verbal communication safety, patient identification, and the protection of vulnerable patients, including elderly individuals and Divyangjan (persons with disabilities).

I extend my heartfelt appreciation to all those who contributed to this initiative and encourage stakeholders across the healthcare ecosystem to actively engage with this resource. Together, let us reaffirm our commitment to safer, high-quality healthcare for all.

(Dr. L Swasticharan)
Head, National Patient Safety Secretariat
Directorate General of Health Services

Preface

Every patient who walks into a hospital carries with them a story—a story of hope, of vulnerability, and of trust. At the heart of healthcare lies a fundamental promise: to heal without harm. Yet, in the complexity of modern medicine, ensuring patient safety remains one of the greatest challenges and responsibilities.

This book, *Patient Safety at a Glance*, is more than a guide; it is a reflection of our collective commitment to making healthcare safer for every individual. It brings together essential protocols, best practices, and insights that aim to strengthen the culture of patient safety across hospitals and healthcare facilities. From medication safety to infection control, from effective communication to emergency response, each chapter is a step toward reducing preventable harm and fostering a system that prioritizes safety at every level.

These pages are not just for doctors or nurses—they are for every healthcare professional who plays a role in patient care. Whether you are a medical student, a hospital administrator, or a frontline worker, this book serves as a practical companion, offering clear, evidence-based strategies that can be applied in real-world scenarios.

True patient safety is not achieved through policies alone—it is built through awareness, vigilance, and a shared responsibility. As you read through this book, we hope it empowers you to take meaningful action, to advocate for safer practices, and to contribute to a healthcare system where trust is never compromised.

Together, let us move towards a future where patient safety is not just a goal, but a way of life.

Dr. Avinash Sunthalia
Deputy Assistant Director General (Patient Safety)
National Patient Safety Secretariat
Directorate General of Health Services

Acknowledgement

The release of the book, "*Patient Safety at a Glance- 1st Edition"* by the National Patient Safety Secretariat, Dte.GHS, MoHFW marks a significant milestone in our ongoing efforts to enhance patient safety and improve the quality of care. This achievement would not have been possible without the support, guidance, and dedication of many individuals who have contributed to the successful completion of this important work.

First and foremost, we express our heartfelt gratitude to Prof. (Dr.) Atul Goel, DGHS, MoHFW, GoI, Ms. L. S. Changsan, IAS, Additional Secretary, MoHFW, GoI, Dr. L. Swasticharan, Addl. DDG, Director EMR, Head, National Patient Safety Secretariat, MoHFW, GoI and the National Patient Safety Secretariat, Dte.GHS, MoHFW, GoI for all the necessary inputs and support in shaping the content of this work.

We would like to express our sincere gratitude to Prof. (Col) Ashok Puranik, Executive Director, AIIMS Guwahati, for his visionary leadership and unwavering commitment to fostering a culture of safety and excellence at our institution. His guidance has been instrumental in the development of this manual and the broader mission of improving healthcare outcomes.

A special acknowledgment goes to the authors, whose tireless efforts, expertise, and dedication have brought this manual to life:

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26. Mr Sita Ram, Assistant Nursing Superintendent, AIIMS Patna

Their collective knowledge and commitment to patient safety have been instrumental in creating a comprehensive and practical resource that will benefit healthcare professionals and patients alike. Each of them has played a key role in ensuring that this manual addresses the complexities of modern healthcare and upholds the highest standards of safety.

We are also deeply grateful to the India Patient Safety Network (20 AIIMS, BHU, JIPMER & PGIMER Chandigarh). Your attention to detail, critical feedback, and collaborative spirit have ensured that this book meets the highest standards of quality:

1. Prof (Dr) Meeta Gupta, Dean Academics, Prof & Head of Dept. Of Obstetrics and Gynecology, AllMS Jammu
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23. Dr. Sunitha, Senior Medical officer, JIPMER

We are also grateful to all the staff, clinicians, and healthcare workers at AIIMS Guwahati, whose dedication to patient care inspires us every day. This manual is a testament to their hard work and an important tool to help them continue delivering safe, effective, and compassionate care.

We acknowledge all the contributors, reviewers, and teams whose behind-the-scenes efforts have made this manual possible. Your contributions are sincerely appreciated.
Finally, we convey our thanks to Dr. Avinash Sunthalia and Dr. Archana Kumari from National Patient Safety Secretariat, Dte.GHS, MoHFW, GoI, whose encouragement and belief make this project a reality- thank you for your kindness and support.

Dr. Biraj Chandra Paul
Assistant Professor
Hospital Administration
AIIMS Guwahati

CONTENTS	PAGE NUMBER

RISK MANAGEMENT PROCESS IN HOSPITAL

Dr. Biraj Chandra Paul
Asst. Prof., Hospital Administration

Risk Assessment:

The risks will be assessed on qualitative two-fold criteria. The two components of risk assessment are (a) the likelihood of occurrence of the risk event and (b) the magnitude of impact if the risk event occurs. The combination of likelihood of occurrence and the magnitude of impact provides the inherent risk level. The likelihood and impact should be rated over a period of 12 to 18 months. The magnitude of impact of an event, should it occur, and the likelihood of the event and its associated consequences, are assessed in the context of the existing controls. Impact and likelihood may be determined using statistical analysis and calculations. Alternatively, where no past data are available, subjective estimates may be made which reflect an employee‘s or group‘s degree of belief that a particular event or outcome will occur.

In determining what constitutes a given level of risk the following scale is to be used for likelihood:

Level	Descriptor
5	Very high likelihood
4	High likelihood
3	Moderate likelihood
2	Low likelihood
1	Very low likelihood

In determining what constitutes a given level of risk the following scale is to be used for impact:

Level	Descriptor
5	Very high impact
4	High impact
3	Moderate impact
2	Low impact
1	Very low impact

Process (for example)	Threats in the process (for example)	Cause(s) of the threats	Impact (On 1 to 5 scale)	Likelihood (On 1 to 5 scale)	Risk score	Threat reduction plan
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Establishment, implementation, certification and maintenance of the quality management system	Systemic non-conformity leading to holding/ withdrawal of certificate of Accreditation/ License					
Quality and Accreditations	Risk associated with infection control, quality of patient care services, physician licensing and credentialing, HMIS documentation and reporting, clinical standards and practices, emergency procedures, clinical audits etc.					
Health & Safety	Risks associated with environment pollution, safety of resources and employees' health and security at health care establishments					
Medical Services/ Patient's healthcare need fulfilment	• Medication error • Surgical error • Other procedures error • Clinical negligence • Documentation error • Injury to patient/ healthcare service provider • Patient fall • Hospital acquired infection • Risks associated with a multidisciplinary					

	approach to acute care, speciality care, diagnostic and investigations and wellness program. This includes risks related to inadequate facilities and inaccurate treatment of an ailment in each of the service areas.					
Service Excellence	• Risks associated with adequate infrastructure to support patient services, patient satisfaction and care for IP, OP Patients and Referred Patients					
Nursing Operations	• Risks related to the adequacy of policies and procedures related to nursing operations and maintaining continuity of care.					
Registration and admission of patients	• Documentation error • Delay • Other error					
Medical records management	• Documentation error • Unauthorized access • Loss or damage • Fire hazard					
Radiology and imaging	• Imaging error • Error in interpretation of images • Documentation error • Drug reaction to					

	patients (e.g. during contrast administration)					
Laboratory	• Test result error • Documentation error • Equipment not calibrated • Vendor evaluation of reagents supplier not done					
Purchase, receipt, issue, inventory control and disposal	• Ineffective purchase: Wrong material (Quality), excess/ short quantity, excess price, delayed delivery • High inventory • Damage, deterioration or pilferage • Stock-out					
Control of outsourced process	• Ambiguity in defining scope of services • Ambiguity in defining commercial terms and conditions • Contract price not realistic • Non-conformity to legal requirements in the contract document					
Housekeeping	• Non-conformity to Bio-Medical Waste Management Rules • Non-compliance to infection control protocols • Inadequate sterilization of facilities like OT, Labour Room, ICU, SNCU, Wards					

Training of staff	• Lack of resources of training • Lack of interest of staff and management					
Maintenance	• Lack of resources for preventive maintenance, calibration and repair • Lack of opportunity to release equipment for preventive maintenance and calibration					
Supply of therapeutic diet	• Patient party does not comply with therapeutic diet advice					
Pharmacy	• Risks associated with operation of pharmacy and delivery of pharmaceutical products to hospital wards/critical care areas and out patients.					
Human Resource	• Risks associated with culture, organisational structure, communication, recruitment, performance management, remuneration, learning & development, retention, Occupational Health & Safety and institutional relations, including supporting systems, processes and procedures.					

Information Technology	• The risk that systemsare inadequately managed or controlled, data integrity, reliability may not be ensured, inadequate HMIS/HIS performance and monitoring, system or network architecture not supporting medium- or long-term business initiatives and strategy, capacity planning not being reviewed on a regular basis resulting in processing failures, risks of data or systems migration or interfaces.					

Risk Evaluation:

Impact and likelihood are combined to produce a level of risk.

Average of the group's score should be determined.

The risk should be classified into three zones based on the combined scores of the group.

• Risks that score within a red zone are considered ―critical‖ and require immediate action plans to close a significant control gap. (Score of 15-25)

• Risks that score within the yellow zone are considered ―cautionary‖ where action steps to develop or enhance existing controls is also needed. (Score of 8 to 12)

• Risks that score within the green zone are considered ―acceptable‖ or in control. (Score of 1-6).

RISK TREATMENT APPROACH:

Likelihood Of Occurrence					
	5	10	15	20	25
	4	8	12	16	20
	3	6	9	12	15
	2	4	6	8	10
	1	2	3	4	5
	Impact of Risk				

RED: Most Critical Need active monitoring

YELLOW: High Impact/ Likelihood Need periodic monitoring

GREEN: Low likelihood & Impact Need Annual Review

Format for Risk Register:

Date of Identification	Risk Title	Risk Description	Possible Cause	Likelihood of Risk (A)	Severity of Risk (B)	Impact Factor (AXB)	Risk Category	Risk Owner
1	2	3	4	5	8	9	10	11

Date of Assessment	Date of Resolve	Residual Risk	Date of Surveillance	Risk Avoidance/Mitigation
12	13	14	15	16

SHARP INJURY PROTOCOL

Dr. Biraj Chandra Paul
Asst. Prof., Hospital Administration

1. Do not panic.
2. Do not put the pricked finger in mouth or squeeze the wound to bleed.
3. Immediately, stop procedure and wash the wound and surrounding skin with soap and running water for 5 minutes.
4. Do not scrub or use bleach, chlorine, alcohol, povidone iodine any antiseptic/chemicals
5. Inform the immediate supervisor in the clinical area and infection control nursing officer.
6. Identify the source details/patient involve so that evaluation for infection can be done.
7. Retain the source or biomedical waste for tracking
8. Report to emergency duty doctor for first aid and counselling. The details will be filled in the needle stick injury register which is available in the Emergency.
9. **If there is exposure on unbroken skin:** Wash the area immediately and do not use any antiseptics
10. **For exposure to eyes:** Irrigate exposed eye immediately with water or normal saline. Sit in a chair, tilt head back and ask a colleague to gently pour water or normal saline over the eye. If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it. Once the eye is cleaned, remove the contact lens and clean them in the normal manner. This will make them safe to wear again. Report to emergency duty doctor immediately.
11. **For exposure to mouth:** Spit fluid out immediately. Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times. Do not use soap or disinfectant in the mouth. Report to emergency duty doctor immediately for further management.
12. The Evaluation for Post Exposure Prophylaxis (PEP) to be done by designated PEP I/C at Integrated Counselling and Testing Centre (ICTC)/ Emergency Doctor, preferably within 2 hours but certainly within 72 hours. Further counselling, investigation, treatment and follow up shall be done as per need.

FORM I

[(see Rule 4(o), 5(i) and 15 (2)]

ACCIDENT REPORTING

1. Date and time of accident:
2. Type of accident:
3. Sequence of events leading to accident:
4. Has the Authority been informed immediately?
5. The type of waste involved in accident:
6. Assessment of the effects of the accident on human health and the environment:
7. Emergency measures taken
8. Steps taken to alleviate the effects of accident:
9. Steps taken to prevent the recurrence of such an accident: ……
10. Does the facility have an Emergency Control Policy? If yes give details:

Date ..... Signature .....

Place.....

Designation.....

(Reporting format from Biomedical Waste Management Rule 2016 and its amendments thereof. Needle stick injury cases have to be reported as minor incident)

REGISTER FORMAT FOR NEEDLE STICK INJURY

Name & designation of health care worker	Department/Unit	Date & time of Needle stick/ sharp injury	Site of injury	Nature of injury (Prick/ cut/ laceration/ splash of fluid/ others	Source (if available) (HIV/ HBV/ HCV/Unknown)
1	**2**	**3**	**4**	**5**	**6**

Action taken on exposed site	HBV Vaccination Status (vaccinated/ partially vaccinated/ not vaccinated)	ART PEP (1st dose given/ indicated/ not indicated	Name & Signature of attending doctor
7	8	9	10

SPILL MANAGEMENT

(Spill of blood/ body fluids)

General recommendations:

1. Small spills (<10 ml) should be managed with one step procedure. Wearing heavy duty gloves contamination should be wiped up with an absorbable material soaked in freshly prepared 1% sodium hypochlorite solution.

2. Large spills: (>10 ml)

- Cordon off the area.
- Appropriate personal protective equipment (PPE) should be worn for cleaning up a blood/ body fluid spill.
- Heavy duty gloves should be worn during cleaning and disinfecting procedures.
- If the possibility of splashing exists, the worker should wear a face mask and goggles.
- Gown, boots/ protective shoe covers should be worn.
- The blood/ body spill area must be cleaned of obvious organic material. The organic material should be first removed and be discarded it in a yellow-coloured biomedical polythene bag.
- After removing organic material, the area should be covered with absorbable material such as paper or cloth and 1% freshly prepared sodium hypochlorite solution is poured over the spread and left for 10-15 minutes, then wipe and discard the material in a yellow coloured biomedical polythene bag.
- After disinfection, thorough cleaning of the floor with soap and water is necessary.
- The treated area should be cleaned and allow it to dry.
- Incident reporting to be done
- **SPILLAGE KIT:** The kit contains PPE (Mask, Cap, Shoe cover/ Gum boots, Heavy duty gloves, disposable gown and goggles), yellow-coloured biomedical polythene bag, absorbable materials (paper/waste cloth/duster), freshly prepared 1% sodium hypochlorite solution, cleaning up scoop and scrapper, caution board.

INCIDENT REPORTING

Dr. Biraj Chandra Paul,
Asst. Prof., Dept. Of Hospital Administration,
Lalit Kumar

I. Introduction:

Incident reporting systems are vital for identifying, analysing, and mitigating risks within healthcare settings. They help in maintaining patient safety, complying with regulatory requirements, and fostering a culture of continuous improvement. A robust incident reporting mechanisms not only enhances the overall quality of care, patient safety and patient satisfaction level in the hospital but also reduces the chances of litigations against the hospital.

Moreover, incident reporting system also constitutes an important aspect for obtaining accreditation from any reputable agency such as the National Accreditation Board for Hospitals & Healthcare Providers (NABH) or Joint Commission International (JCI).

II. Common incidents leading to patient harm in hospital:

1. **Wrong identification of patient** during change of care of patients, during administration of drugs, for any procedures etc. It can lead to catastrophic adverse effects, such as wrong-site surgery.
2. **Ineffective communication** during handing over and taking over of patients by doctors and nursing officers.
3. **Medication errors:** Half of the avoidable harm in health care is related to medication error.
4. **Surgical errors:** Despite awareness of adverse effects, surgical errors continue to occur at a high rate with most of the resultant adverse events occurring pre- and post-surgery.
5. **Health care-associated infections:** Health care-associated infections result in increased length of stay in the hospital, morbidity to patients, increased antimicrobial resistance, and added financial burden on patients and his families.
6. **Patient falls:** Patient falls are the most frequent adverse events in hospitals and more than one third of these incidents result in injury.
7. **Venous thromboembolism:** Venous thromboembolism is a highly burdensome and preventable cause of patient harm, which contributes to one third of the complications attributed to hospitalization.
8. **Pressure ulcers:** They develop from pressure to particular parts of the body over an extended period. Pressure ulcers affect more than 1 in 10 adult patients admitted to hospitals. This can be prevented with appropriate assessment and care.
9. **Unsafe transfusion practices:** Unneeded blood transfusions and unsafe blood transfusion methods put patients at the risk of serious adverse transfusion reactions and transfusion-transmissible infections.

10. **Unsafe injection practices:** Patients, as well as healthcare workers, are put in danger of both infectious and non-infectious adverse events due to unsafe injection practices. [1]

III. Important Definitions:

Incident: An event or occurrence that may cause or causes an interruption or a crisis. In safety, an incident of workplace illness or injury.

Incident reporting: Collecting and analysing information about an event that could have harmed or did harm a patient in a health-care setting.

Patient safety: The reduction of risk of unnecessary harm associated with health care to an acceptable minimum.

Near miss: An incident that did not reach the patient. WHO defines a near miss as ―an error that has the potential to cause an adverse event (patient harm) but fails to do so because of chance or because it is intercepted‖ [2]. According to the Institute of Medicine, a near miss is ―an act of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation‖ [3]. ―An error caught before reaching the patient‖ is another definition [4].

Adverse event: An incident in which a patient is harmed. Serious Adverse Events include:

- Major Hemolytic transfusion reactions
- Serious adverse drug even and medication errors,
- Major discrepancies between preoperative and postoperative diagnoses
- Adverse events during moderate or deep sedation and anesthesia use

Sentinel Event: An ―adverse event that should never be allowed to happen‖, is usually unexpected and involving a patient death or serious physical or psychological injury to a patient. [5]

A sentinel event is a patient safety event (not primarily related to the natural course of a patient‘s illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).

An event can also be considered sentinel event even if the outcome was not death, permanent harm, severe temporary harm and intervention required to sustain life.

Such events are called "sentinel" because they signal the need for immediate investigation and response. [6]

Sentinel Event as an unanticipated death or Major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. The event is one of the following:

i. an unanticipated death, including, but not limited to,

a. death that is unrelated to the natural course of the patient‘s illness or underlying condition

b. death of a full-term infant; and

c. suicide;

ii. wrong-site, wrong-procedure, wrong-patient surgery;

iii. transmission of a chronic or fatal disease or illness as a result of infusing blood or blood products or transplanting contaminated organs or tissues;

iv. infant abduction or an infant sent home with the wrong parents; and

v. rape, workplace violence such as assault or homicide of a patient, staff member, practitioner, medical student, trainee, visitor, or vendor while on hospital property.

The Quality Assurance Department screens the sentinel event and completes a root cause analysis, CAPA and follow up.

IV. Protocols for Incident Reporting

1. **Comprehensive Reporting Mechanism**: Hospital to establish a comprehensive incident reporting mechanism. This system should be user-friendly and accessible to all staff members, allowing them to report incidents easily and without fear of reprisal.
2. **Standardized Reporting Forms**: The use of standardized reporting forms is essential for consistency and accuracy in documenting incidents. Hospital may implement digital forms that can be integrated with the hospital's electronic health records (EHR) system to streamline data collection and analysis.
3. **Timely Reporting and Follow-Up:** Hospitals must ensure that incidents are reported within a specified timeframe, typically within 24 hours of occurrence. Additionally, there should be a clear process for follow-up actions and corrective measures.
4. **Incident Classification and Severity Assessment:** Effective incident reporting systems should include classification and severity assessment protocols. It is recommended to categorize incidents based on their impact and severity, which helps in prioritizing responses and resource allocation.
5. **Root Cause Analysis (RCA):** Performing Root Cause Analysis (RCA) is a critical component of incident management. Hospital to conduct RCA for the incidents to identify underlying causes and prevent recurrence. The findings from RCA should be used to implement preventive measures and improve processes.
6. **Staff Training and Education:** Regular training and education are crucial for maintaining an effective incident reporting system.
7. **Patient and Family Communication:** There should be transparent communication with patients and their families regarding incidents. Hospitals should inform patients and families about incidents that affect their care and the steps being taken to address them.
8. The entries must be clear and legible and if possible, in block capitals. All sections should be completed. Facts only should be reported, not opinion. In the event of litigation, the form could be requested for disclosure and therefore should be accurate and factual. A severity grading of this incident should be made. Any factors that could have led up to the incident should be determined and completed in the relevant section. These could be lack of signage of a wet floor, lack of training, alcohol abuse by the patient, low staffing levels, illegible documentation etc.

V. Process of Incident Reporting:

Categories of incidence: Generally incident occurrences fall into two categories:

1. Indirect patient care and
2. Direct patient care.

Examples of incidents relating to Indirect Patient care are inclusive of the following but not limited to:

1) Fire
2) Security
3) Violence & Aggression
4) Environmental

Examples of Direct Patient care are inclusive of the following but not limited to:

1) Drug Error & Adverse Clinical Event
2) Failure/Incorrect Diagnosis
3) Incorrect Reporting
4) Any non-compliance to standard procedure
5) Unexpected death

Any employee identifying /experiencing the incident, or the employee to whom the incident is first reported, shall be responsible for initiating the Incident Report.

This should be brought to the attention of the person in-charge at that time without delay. It is acceptable for staff to submit an incident report form on behalf of another member of staff who is unable to complete the form personally. Contracted staff also shall complete and submit an incident report for any incidents.

With regards to an adverse incident, the immediate safety and well-being of the patient, staff member or visitor affected or involved must be ensured with remedial first aid or emergency. In the case of a medication incident where the patient has been given the wrong drug / dosage, the treating doctor must formally review the patient‘s condition and the results of any examination recorded in the patient‘s case sheet. If possible, where an adverse incident has occurred involving plant, machinery, equipment or furniture and fittings, label it for the attention of the Medical Superintendent / Deputy Medical Superintendent but do not alter it in any way until it has been seen by them except to move it to a safe place if it is causing a hazard to others. If the incident is rated as major or catastrophic the _scene‘ must not be altered. It may be advisable to check other pieces of similar equipment and label them as unsafe if necessary until they are able to be checked for safety. If the incident involves a medical device, it must be quarantined.

Time Frame for Reporting an Incident

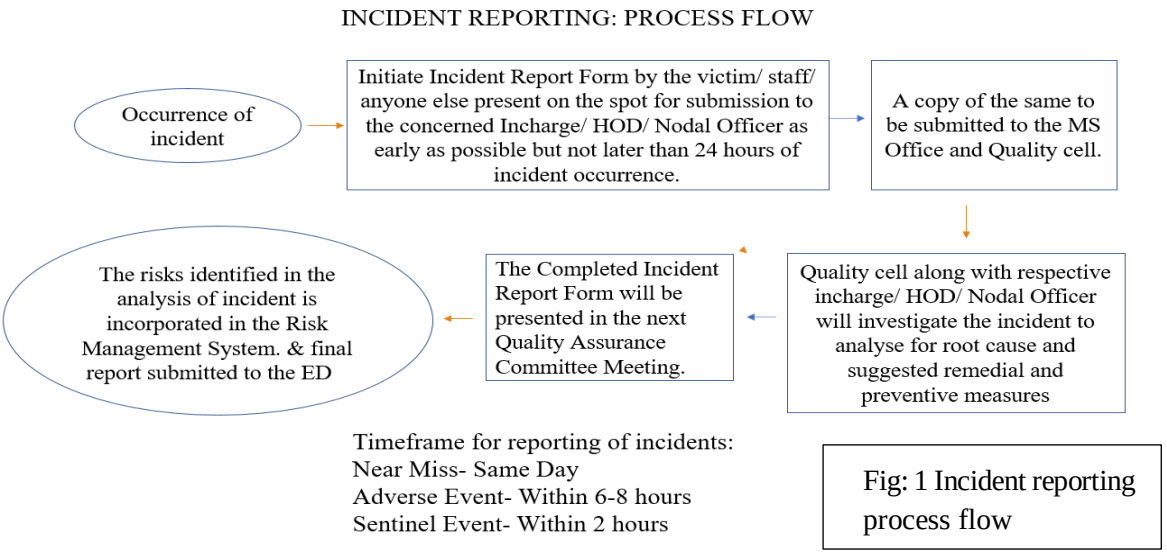
Near Miss Event	Adverse Event	Sentinel Event
Same Day May be in the next morning	Same Day Within 6-8 hours	Immediate Within 2 hours

- The event, whether sentinel, adverse or near miss, must be reported at the earliest so that investigation/ action can be without delay. If delay is likely, an interim report may be given on telephone followed by detailed written report.

- The report must be passed up the channel without any undue delay at any level so as to reach the MS Office, the Safety Officer and the Quality Team at the earliest possible

- Investigation into an Incident: – The investigation team must go into details of the cause and mode of occurrence of the incident, without any distinction whether it is a near miss event or sentinel event. A root cause analysis carried out scientifically should bring out the weak links including the circumstances of the occurrence.
- Once the entire sequence of happening, cause and mode are identified proper corrective measures to be taken to prevent its recurrence in future. Punishment of individual may become necessary in some situation; however, victimization of any individual should never be the goal of such investigation.
- The report must include, in addition to the recommended measures, the responsibility for implementation by name/ designation and the time frame required for effect.
- The process review and evaluation must go on until satisfactory results have been achieved as expected.
- Risk analysis shall be done with the incident reports for its proper mitigation plan in a risk matrix of 25.
- An investigation report must include both the immediate causes and the underlying causes. The report should also include the remedial measures needed to address both the immediate and the underlying cause.
- However, investigation of an event of purely on technical nature such as fire may be carried out by a team comprising of Fire Safety Officer, Security Officer lead by Hospital Administrator.
- After studying the inquiry report, Quality & Safety Committee should submit the same to the Medical Superintendent, along with its views/ comments, including the following details:

1. RCA of the incident
2. Was it system failure or human failure?
3. The exact mode of occurrence
4. Was it first occurrence or repetitive event?
5. Remedial measures to eliminate root cause and recurrence
6. Action to be taken against any individual responsible for the accident/ incident
7. Time frame and the official responsible for implementation of remedial measures



Timeframe for reporting of incidents:
Near Miss- Same Day
Adverse Event- Within 6-8 hours
Sentinel Event- Within 2 hours

Fig: 1 Incident reporting process flow

Format for Reporting of Sentinel/ Adverse/ Near-Miss Events		
Name of the area:	Date:	Time
1	Reporting of Sentinel/ Adverse/ Near-Miss Event:	By victim/ staff/ anyone else present on the spot
2	Particulars of the person reporting: Name/ designation/ department/ phone number:	
3	Brief Description of the Event:	
4	Place of Occurrence:	
5	Date & time of occurrence:	
6	Details of the victim, if any: Name/ Age/ sex: Patient/ Public/ Staff: If staff, then the department Address:	
7	Injuries/ losses sustained:	
8	Condition of the victim:	
9	Immediate and underlying Cause of the event:	
10	Details of the event: (Please attach separate sheet if required)	
11	Reporting to:	

	Designation of the official: Copy to MS & Quality Cell	
Date/ Time:	Name & Signature:	
To be filled by Quality Cell after investigation		
12	RCA:	
13	Corrective Action:	
14	Preventive Action:	
15	Action Plan, responsibility & timeline & follow up monitoring:	
16	Likelihood of Occurrence: 1/2/3/4/5	
17	Impact: 1/2/3/4/5	
18	Risk Scoring:	
19	Risk Mitigation Plan:	

Conclusion:

By implementing comprehensive reporting mechanisms, standardized forms, timely follow-ups, and effective root cause analyses, healthcare facilities can enhance patient safety, improve quality of care, and demonstrate their commitment to excellence. The ultimate goal is to implement system improvements that reduce the frequency of adverse events, mitigate their effects, and possibly prevent the occurrence of events altogether.

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HOSPITAL CODES Dr. B. C. Paul, Dept. of Hospital Administration				
Code	Description	Primary Response	Secondary Response	Follow Up
Code Red	Fire	R-Rescue patients A-Activate Code Red, inform Fire Safety Officer/Security Officer/ Electrical Engineer/MS/DMS C- Contain the fire E-Extinguish or evacuate the area	Attempt to extinguish the fire P-Pull the pin A-Aim the nozzle at base of fire S-Squeeze the handle S- Sweep from side to side Fire not controlled- Call Fire Brigade & Evacuate	Return to normal duty after deactivation of code as per direction. Document as appropriate
Code Blue	Cardio Pulmonary Arrest	Activate Code Blue. Notify response team: Emergency Doctor/Emergency Nursing Officer/ECG Technician/ Consultant or SR Cardiology/ Consultant or SR Anesthesiology & Critical Care/DNS/DMS. Get a crash Cart	Keep the person calm. Check pulse and breathing. Initiate CPR if necessary by qualified staff	Return to normal duties as directed upon code blue all clear.
Code Pink	A newborn/ infant/child is missing or is known to have been abducted/kidnapped	Activate Code Pink. Inform the child's name and looks and mention location carry out accountability check. Inform Security Officer/DMS/NS/MS	Monitor & seal all exits for anyone attempting to leave the hospital premises	Return to normal duties once code is called off. Document appropriately
Code Orange	External disaster like (Accident with mass casualty, Natural Calamity, Epidemics, Bomb blasts/terrorist activities)	Activate Code Orange: Report to Security Officer/NS/DMS/ Disaster response team	Coordination with command nucleus and continue care of existing patients	Return to normal duties when code is deactivated. Document as appropriate
Purple	Security Alert	Activate Code Purple. Inform Security Officer/DMS/MS/NS/Police	Respond immediately/ investigate/ rescue	Return to normal duties when code is deactivated. Document as appropriate
HAZMAT	Hazardous spill which is likely to cause unknown effects, injury, illness or harm to the environment	Call helpline number for HAZMAT. Secure the area, use PPE and go eye wash area. Don't allow people to step in the area	Assist those who have been contaminated. Take them to emergency for evaluation and management.	Return to normal duties as directed. Prevent future spillage. Document appropriately.

CODE BLUE PROTOCOL

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Definition

A 'Code Blue' event denotes a critical emergency within the hospital setting, wherein a patient experiences a sudden cardiopulmonary arrest, necessitating immediate activation of the _Code Blue‘ team for Cardiopulmonary Resuscitation (CPR) and Advanced Life Support (ALS) measures. It involves mobilising medical personnel to perform CPR and advanced resuscitation interventions on-site within hospital premises.

Aim

To establish a standardised, systematic, and highly effective protocol for responding to a cardiopulmonary arrest within the institute. This protocol ensures optimal patient outcomes by prioritising prompt identification of life threatening emergencies, immediate activation of the _Code Blue‘ team, rapid mobilization to the event site, comprehensive documentation of the resuscitation process, and effective communication with the patient's family.

Goals

Immediate identification of cardiopulmonary arrest and prompt activation of the Code Blue team.

Deliver high-quality CPR and initiate advanced life support protocols.

Minimise interruptions in chest compressions to enhance survival rates.

Ensure rapid defibrillation for shockable arrhythmias (ventricular fibrillation, pulseless ventricular tachycardia).

Achieve Return of Spontaneous Circulation (ROSC).

Manage the post-resuscitation phase safely and effectively.

Mobilise a highly skilled and coordinated resuscitation team (Code Blue team) without delay.

Activation:

When to Activate: Code Blue should be initiated instantly when a patient is found unresponsive, pulseless, or exhibiting signs of agonal breathing or inadequate respiration.

Who Can Activate: Any healthcare provider (physician, nurse, or allied health professional) within the Department‘s / Institute.

How to Activate: Clearly announce _Code Blue‘ either vocally or through the centralized announcement system, specifying the exact location of the patient within the Department / Institute. Simultaneously, employing the designated communication channels (intercom, phone system, WhatsApp) to alert the entire Code Blue team.

Green Corridor: Ensure a clear and unobstructed pathway for the _Code Blue‘ team to expedite their arrival at the incident location without delay.

Principles:

Do No More Harm:

Prioritize patient safety and minimize potential harm to both patients and healthcare providers.

Check Responsiveness:

Confirm patient unresponsiveness and absence of a carotid pulse.

High-Quality Chest Compressions:

Initiate chest compressions immediately, ensuring adequate depth (5-6 cm) and a compression rate of 100-120 per minute.

Effective Ventilation:

Utilize a bag-valve-mask or an advanced airway device to ensure adequate oxygenation and ventilation, avoiding hyperventilation.

Early Defibrillation:

Apply an Automated External Defibrillator (AED) or manual defibrillator without delay for shockable rhythms, adhering to defibrillation protocols.

Advanced Resuscitation Techniques:

Involve advanced airway management, establishment of intravenous (IV) or intraosseous (IO) access, administration of resuscitation drugs, and adherence to Advanced Cardiac Life Support (ACLS) guidelines.

Compression-Ventilation Ratio:

Maintain a ratio of 30:2 for compressions to ventilations if no advanced airway is in place; otherwise, continue uninterrupted chest compressions with asynchronous ventilations (one breath every 6 seconds).

Minimal Interruptions:

Minimize pauses in chest compressions to enhance perfusion and prioritize essential interventions.

Code Blue Team Composition and Roles

Team Leader:

A senior physician who coordinates the resuscitation effort, makes critical clinical decisions, directs team members, and communicates with the patient‘s family.

Doctors (Airway and Breathing Management):

Doctor A (Airway Management): Ensures airway patency, cervical spine stabilization, and performs endotracheal intubation if required.

Doctor B (Breathing Management): Evaluates respiratory efforts, checks oxygen saturation, verifies correct placement of the endotracheal tube, and inserts an intercostal drainage (ICD) tube if indicated.

Six Nurses with Specific Roles:

Two Nurses for Chest Compressions: Alternate every 2 minutes to provide high-quality chest compressions without interruptions.

Nurse A (Airway Assistant): Prepares airway equipment and assists Doctor A in securing the airway.

Nurse C (Circulation Manager): Establishes IV/IO access, administers resuscitative medications, and monitors vital signs.

Nurse D (Drug Trolley Operator): Prepares and provides airway instruments to Nurse A and hands over medications to Nurse C following ACLS algorithms.

Nurse T (Documentation and Timekeeper): Meticulously records the timeline of events, drugs administered, defibrillation attempts, and monitors intervals for rhythm checks and other interventions.

Support Staff: Security to cordon off the designated area, Hospital-attendants and house-keeping staff to carry on with their pre-allotted respective work.

CPR Documentation

A designated nurse ensures meticulous and comprehensive documentation throughout the resuscitation process, including the time of _Code Blue‘ activation, all clinical interventions performed, drugs administered, defibrillation shocks delivered, patient responses, and final outcomes. The team leader is responsible for completing the patient‘s medical record, including presenting complaints, clinical assessment, interventions undertaken, outcomes, and planned disposition.

Briefing:

The team leader or an appointed member provides clear, compassionate and transparent communication to the patient‘s next of kin or attendants regarding the patient‘s condition, the

resuscitation measures being employed, and the anticipated prognosis. This should be done while offering emotional support and maintaining professionalism.

Team Debriefing:

Following the conclusion of a _Code Blue‘ event, a structured debriefing session is conducted with all involved team members to evaluate the resuscitation process, assess the team‘s performance, identify any procedural gaps, and discuss areas for improvement. The session also provides an opportunity for psychological support and motivation to the team.

Post-Resuscitation Care:

If ROSC Achieved:

Continue comprehensive monitoring of the patient‘s hemodynamic status, respiratory function, and neurological assessment.

Transfer the patient to the Intensive Care Unit (ICU) or another higher level of care for specialized post-resuscitation management.

Implement strategies to stabilize haemodynamic, provide respiratory support, and maintain normothermia to prevent secondary brain injury.

If ROSC Not Achieved:

The team leader must assess the situation and, if appropriate, decide to discontinue resuscitation efforts based on the patient's clinical status and prognosis.

Ensure sensitive communication and counselling for the family regarding the patient's condition and the cessation of resuscitation efforts.

Complete all required documentation, including the death certificate if applicable, and follow institutional protocols for post-mortem care and handling.

This Code Blue protocol should be periodically reviewed and updated to incorporate new evidence-based guidelines and recommendations for cardiopulmonary resuscitation to ensure optimal patient care and outcomes.

SAFE SURGICAL CARE-WHO SURGICAL SAFETY CHECKLIST

Dr Sumanjit S Boro[2]
Dr Ankur Khandelwal

A) Introduction:

-The World Health Organization established The Safe Surgery Saves Lives programme to reduce the number of surgical deaths across the globe.

-The programme aims to cultivate political commitment and clinical will to implement safety issues, including inadequate anaesthetic safety practices, avoidable surgical infection and poor communication among team members.

-The programme resulted in significant reductions in complication and death rates in diverse hospitals and settings and with improvements in compliance with basic standards of care

B) How to run the checklist:

-A single person must be made responsible for performing the safety checks on the list. The checklist coordinator will often be a circulating nurse, but it can be any clinician participating in the operation.

-The checklist is divided into three parts: the period before induction of anaesthesia, the period after induction and before surgical incision, and the period during or immediately after wound closure but before removing the patient from the operating room. Each part corresponds to a specific time period in the normal flow of the procedure.

-The checklist coordinator confirms that the team has completed its tasks before it proceeds onward.

a) Before induction of anaesthesia:

To confirm the safety of the proceeding, all the steps of the checklist are completed before induction of anaesthesia.

Each step is elaborated in detail below.

-Has the patient confirmed his/her identity, site, procedure and consent?

The patient‘s identity, the type of procedure planned, the site of surgery and consent for the surgery are verbally confirmed by the checklist coordinator. A guardian or a family member can give this confirmation in case of children or incapacitated patients. If a guardian or family member is unavailable or if this step is skipped, such as in an emergency, the team should understand why and all be in agreement before proceeding.

-Is the site marked?

-The checklist coordinator confirms that the site of surgery has been marked by the operating surgeon (usually with a permanent felt-tip marker) in cases involving laterality (a left or right distinction) or multiple structures or levels (e.g. a particular finger, toe, skin lesion, vertebra)

-Is the anaesthesia machine and medication check complete?

The Checklist coordinator confirms this step by asking the anaesthetist about the anaesthesia safety check, understood to be a formal inspection of the anaesthetic equipment, breathing circuit, medications and patient's anaesthetic risk before each case.

-Is the pulse oximeter on the patient and functioning?

-The proper placement of the pulse oximeter and its correct function has been confirmed by the checklist coordinator. A few points to be kept in mind are- pulse oximetry reading should be visible to the operating team, and an audible system to be used to alert the team to the patient's pulse rate and oxygen saturation. In dire situations (to save life and limb), this step can be ignored upon agreement from the team members of the operating team.

-Does the patient have a known allergy?

The checklist coordinator should ask whether the patient has a known allergy and, if so, what it is. If the anaesthetist is unaware of it and the coordinator knows it, this information should be communicated to the anaesthetist.

-Does the patient have a difficult airway/aspiration risk?

The coordinator will confirm with the anaesthetist about the possibility of a difficult airway and if it yes, the induction of anaesthesia should begin only when the anaesthetist confirms that he or she has adequate equipment and assistance present at the bedside.

-Does the patient have a risk of >500 ml blood loss (7 ml/kg in children)?

-The coordinator will confirm the possibility of more than half a litre of blood loss during the surgery to ensure recognition and preparation for this critical event from the anaesthesia team. The anaesthetist and surgeon should discuss the blood loss before the surgery begins and with the availability of fluids or blood for resuscitation if more blood loss is expected.

b) Before skin incision:

-Confirm all team members have introduced themselves by name and role

Each person in the operation room is to introduce himself or herself by name and role. It may be possible that the team members are already familiar with each other, but new members or staff that have rotated into the operating room since the last operation should introduce themselves, including students or other personnel.

-Confirm the patient's name, procedure and where the incision will be made

The checklist coordinator will confirm the name of the patient, the surgery to be performed, the site of surgery and, where appropriate, the positioning of the patient to avoid operating on the wrong patient or the wrong site. An awake patient himself can also confirm this.

-Has antibiotic prophylaxis been given in the last 60 minutes?

The checklist coordinator will ask the team whether prophylactic antibiotics were given during the previous 60 minutes and usually the anaesthetist provide the verbal confirmation. If the duration is more than 60 minutes, redosing may be considered and if prophylactic antibiotics are not considered appropriate (e.g. cases without a skin incision, contaminated cases in which antibiotics are given for treatment), the ―not applicable‖ box may be checked once the team verbally confirms this. All these are to reduce the surgical infection rate.

-Anticipated critical events

The checklist coordinator enquired from the anaesthetist, surgeon and nursing staff regarding the possibility of any anticipated critical events. The coordinator asks each team member the specified question loud and clear.

-To surgeon: what are the critical or non-routine steps? How long will the case take? What is the anticipated blood loss?

The idea behind is to inform all team members of any steps that put the patient at risk for rapid blood loss, injury or other major morbidity. This may be an opportunity to review surgical steps, requirements of special equipment, implants or preparations.

-To anaesthetist: are there any patient-specific concerns?

If there are possibility of major blood loss, haemodynamic instability or other major morbidity during the surgery, a member of the anaesthesia team should review out loud the specific plans and concerns for resuscitation—in particular, the intention to use blood products and any complicating patient characteristics or co-morbidities (such as cardiac or pulmonary disease, arrhythmias, blood disorders, etc).

-To the nursing team: has sterility (including indicator results) been confirmed? Are there equipment issues or any concerns?

The scrub nurse/ technologist who is in charge of setting up the equipment should verbally confirm that sterilization is perfect and sterility indicators are verified. If there is any discrepancy between the expected and actual indicator results, should be informed to all the concerned team members before the surgical incision.

-Is essential imaging displayed?

The coordinator should ask the operating surgeon if imaging is needed before placing the first skin incision and if it is yes, the coordinator should verbally confirm that the essential imaging is in the room and prominently displayed for use during the operation. Imaging is one of the critical components for proper planning and conduct of the surgeries.

c) Before the patient leaves the operation room:

-Nurse verbally confirms the name of the procedure:

There is always a possibility that the procedure may have changed or expanded during the time of surgery, the Checklist coordinator should confirm with the surgeon and the team exactly what procedure was done.

-Completion of instrument, sponge and needle counts

The scrub or circulating nurse verbally confirms the completeness of the final instrument, needle, gauze and sponge counts. In case of any mismatch, the team should be alerted so that appropriate steps can be taken (such as examining the drapes, garbage and wound or, if need be, obtaining radiographic images).

-Specimen labelling (read specimen labels aloud, including patient name):

The circulating staff should confirm the correct labelling of any specimens obtained during the procedure by reading out loud the patients name, correct orientations, description of the specimens and if any specific thongs need to be mentioned. Faulty labelling can lead to disastrous outcome.

-Whether there are any equipment problems to be addressed:

If any faulty/defective instruments are identified during the course of the surgery, they should be prevented from being recycled back into the room before the problem has been addressed. The coordinator must ensure that equipment problems arising during a case are identified by the team.

-Surgeon, anaesthetist and nurse review the key concerns for recovery and management of this patient

The post-operative recovery and management plan should be reviewed by the surgeon, anaesthetist and nurse focusing in particular on intraoperative or anaesthetic issues that might affect the patient. Those events which are not evident to all during the surgery and poses threat to the patient during recovery are especially pertinent to all. The idea behind this step is the efficient and appropriate transfer of critical information to the entire team.

With this final step, the WHO Checklist is completed. The Checklist to be placed in the patient record.

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HAI SURVEILLANCE PLAN AT AIIMS GUWHATI

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Introduction:

HAI-An infection occurring in a patient in a hospital or other healthcare facility in whom the infection was not present or incubating at the time of admission. This includes infection acquired in the hospital but appearing after discharge and also occupational infection among staff of the facility.

- Any infection developing in a patient after two calendar days can be labelled as Healthcare-associated infections.

- Hospital Acquired Infection (HAI) surveillance is a system that monitors the HAIs in a hospital.

- The HAI surveillance cycle consists of _data collection—data analysis—data interpretation—data dissemination'.

Objective of HAI surveillance:

- To obtain endemic/ baseline HAI rate and information on type of HAI.
- To compare HAI rates within different wards/ areas of the hospital and among other hospitals.
- To identify the problem area, based on which root cause analysis is conducted to find out the breakdowns in infection control measures followed by which corrective measures will be implemented.
- To identify impending outbreaks and to prevent them.
- To monitor and evaluate the effect of infection control interventions.
- To provide timely feedback to the clinicians; thus reinforcing them to adopt best practices**.**

Areas of HAI surveillance

1. High Dependency Units (HDU)
2. All Intensive Care Unit (ICU, NICU, PICU)
3. Post Operative wards of each surgical department
4. All surgical OPDs (for follow up of post discharge surgical site infections)

Surveillance planned to be done for following major HAIs at our institute.

1. Catheter Associated Urinary Tract Infections (CAUTI)
2. Central Line Associated Blood Stream Infections (CLABSI)
3. Ventilator Associated Pneumonia (VAP)

4. Surgical Site Infections (SSI)

Method of HAI Surveillance

Active surveillance/ Laboratory based Ward liaison surveillance method which is considered as the best method for surveillance.

The ICNs will collect information on all new admissions and existing admissions with device (urinary catheter, central line, ventilator) and/or those who underwent surgeries. They also will prospectively check the laboratory investigations to confirm a diagnosis.

The definitions related to HAI surveillance and the protocol for data collection and analysis (including proformas for surveillance) are adopted from the National Health Safety Network (NHSN)-CDC guidelines for HAI surveillance

The data is collected on monthly basis from each area of surveillance under following heads:

a. Data collection for Identification of HAI

b. Data collection for calculation of denominator values

Data collection& Data Analysis

- The patients admitted in respective surveillance area will be daily monitored for development of HAIs of interest.
- The demographic and clinical details will be collected by the ICNs in the standardized proforma for data collection pre-approved by the HICC, AIIMS Guwahati.
- The ICNs also check Lab reports for these patients simultaneously and correlates with clinical findings.
- The surveillance will be continued till 15 days of admission or till discharge/ death of the patients.
- The ICNs also will monitor patients undergoing major surgeries on daily basis in their respective ward for the development of post-operative infection till their discharge/ death.
- The monitoring for SSI is done for 30/ 90 days depending upon the type of surgery the patient had undergone (Performa prepared by HICC, AIIMS Guwahati)
- The patients which are discharged will be followed up in the respective surgical OPD at the time of their follow up visit using a separate proforma (Performa prepared by HICC, AIIMS Guwahati)
- At the end of month, all the proformas will be submitted to Infection Control Officer, who then will analyse them to diagnose the HAIs as per case definitions given by CDC.

Data Analysis-Calculation for Denominator Values

ICNs also collect following data during their rounds to the hospital at the fixed time. The data will be collected using Denominator Form (Daily Appraisal Form) as prepared by HICC, AIIMS Guwahati

- Patient days = Number of patients admitted daily in each area of surveillance.
- Device days = Number of patients with devices in the respective areas per day.
- Monthly catheter (Foley's) days
- Monthly central line days
- Monthly ventilator days
- Number of surgeries performed in each OT.
- This data will be summed up at the end of each month so as to be used as denominator data for calculation of Device utilization ratios and Rates of HAIs.
- Similarly, total number of surgeries performed will be calculated at the end of every month as a denominator data to enable calculation of SSI

Calculations Of HAI Rates

- The standard CDC/ NSHN definition of HAIs is followed.

The incidence of CAUTI, CLABSI and VAP are calculated for 1000 device days and the prevalence of SSI is calculated for 100 surgeries done.

The formulae for calculation are given below.

HAI Infection Rates	Formulae
CLABSI Rate	No. of CLABSI cases/ Total no. of central line days X 1000
CAUTI Rate	No. of CAUTI cases/ Total no. of catheter days X 1000
VAP Rate	No. of VAP cases/ Total no. of ventilator days x1000
SSI Rate	No. of SSI/ No. of surgeries done X 100
DUR (Device Utilization Ratio)	No. of device (Foley's catheter/ central line/ ventilator) days /No. of patient days

Data Interpretation:

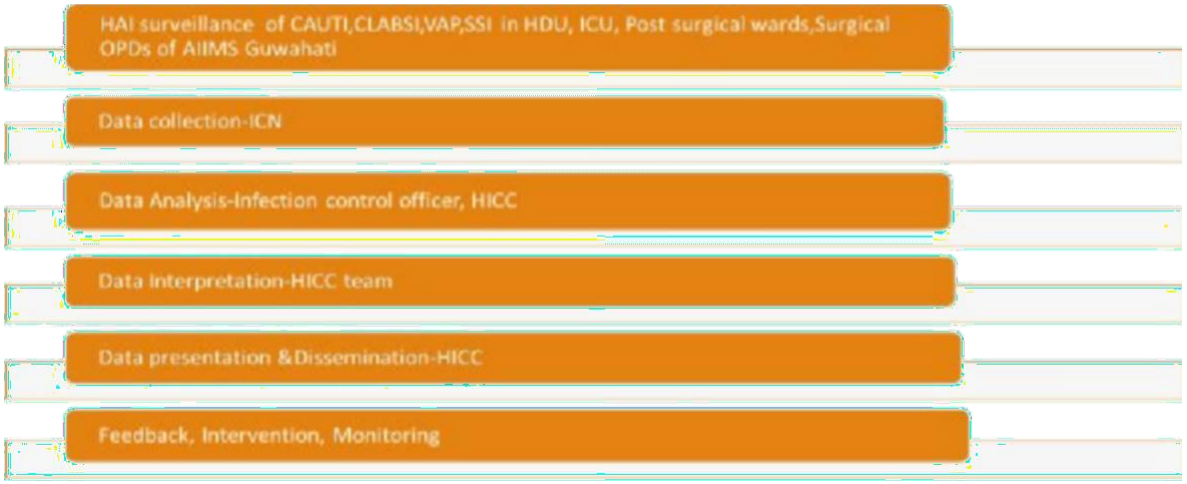
The data is analysed using Microsoft Excel to generate a monthly report of HAI rate of AIIMS Guwahati

Monthly HAI Surveillance report is used for:

- Comparison between two consecutive months, or
- Between different ICUs for the same month, or
- To observe the trend of HAIs over a specified period of time.
- To compare the HAIs rates of the hospital with that of CDC/NSHN HAI rate (75% percentile).

- The monthly HAI surveillance report will be shared with all clinical departments as well as with the Director, Medical Superintendent and the Nursing Principal via email and printed copy.
- The rates will be presented in HICC meetings and discussed among the concerned members.
- The interventions will be planned for each ICU/ward on the basis of the HAI rates.
- Further monitoring for any changes in the rates will be done by ICT followed by feedback to the respective department.
- Monitoring will be done by Process surveillance with key indicator like Hand Hygiene audit, Bundle care audit

Overview of HAI Surveillance:



Conclusion:

The implementation of robust HAI surveillance methods is crucial for enhancing patient safety and improving healthcare outcomes. By systematically monitoring and analysing infection data, hospitals can identify trends, detect outbreaks early, and implement targeted interventions to reduce infection rates.

Moreover, continuous education and training of healthcare staff on infection prevention practices are essential to sustain the effectiveness of surveillance programs

In conclusion, a well-structured HAI surveillance system not only helps in mitigating the risks associated with healthcare-associated infections but also fosters a culture of safety and quality within the healthcare setting. Ongoing evaluation and adaptation of surveillance strategies are necessary to address emerging challenges and to maintain high standards of patient care.

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SAFETY MEASURES IN A PATHOLOGY LABORATORY

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The safety measures which will be enumerated here aim at delivering precise, accurate and timely pathology reports to the patients and/or clinicians.

Table 1 summarizes various measures to reduce or minimize errors in the Pathology laboratory at various stages of sample processing.

Table 1: Measures to minimize errors in the Pathology laboratory

Measures to reduce pre-analytic errors	Measures to reduce analytic errors	Measures to reduce post-analytic errors
• Standard requisition forms • Proper patient preparation • Standard sample collection procedures including barcoding, using good quality vacutainers • Timely transportation of samples to laboratory • Barcode readers for receiving samples in laboratory • Adequate checks before starting sample processing • Facilities for proper storage of samples	• Proper validation and verification of equipments during installation • Adequate daily and periodic maintenance and calibration of analyzers • Daily multilevel internal quality controls • Standard operating procedures for sample processing in analyzers, manual processing for staining smears, coagulation studies, body fluid processing and other investigations which require use of manual techniques • Proper preparation and storage of reagents • Adequate maintenance/calibration of accessory equipments like pipettes, incubators, water bath • Proper inventory management with FIFO (First in first out) for the reagents as per receiving and expiry dates	• Proper correlation of findings with clinical details before validating reports • Delta checks • Generating electronic reports with integration of Laboratory and Hospital Information Systems • Matching the patient identification with the data generated before validation • Providing electronically generated reports and abolishing the practice of hand-written reports • Report generated within predefined turnaround time • Critical alerts are intimated immediately to clinical staff • Calculating laboratory specific reference ranges for parameters for whom universal standard reference range is

	• Confirming parameters like low platelet count with manual count	not applicable, e.g. calculating reference ranges for PT/APTT/TT/Fibrinogen and establishing Mean PT for calculating INR with every change of reagent lots

The following salient points are adopted from document number 112 (issue no.4, issue date 11.02.19 amended on 26.04.19) of the National Accreditation Board for Testing and Calibration Laboratories (NABL) applicable to a Pathology laboratory.

1. The Medical laboratory must produce relevant evidence of legal identification.
2. As per the latest Notification issued by Ministry of Health & Family Welfare (MoHFW) dated 18th May, 2018 notifying Clinical Establishment (Central Government) Amendment Rules, 2018, all laboratories are required to comply with it as applicable regarding the laboratory personnel.
3. The Laboratory Director / designee shall also fulfill the other requirements of ISO 15189:2012.
4. Quality Manager / designee shall be trained in 4-days Quality Management as per ISO 15189. She / He should be a full-time employee.
5. For referred tests, the referral laboratory has to be NABL accredited.
6. The following minimum retention period of records is recommended for ensuring quality service and patient care.

Hematology (CBC)	1 week
Histopathology Reports, Block & Slides	10 years
Cytopathology Reports, Blocks & Slides	5 years
Flowcytometry / Immunophenotyping data	10 years
Electrophoretogram / Immunofixation	10 years
Hemoglobin HPLC data	10 years
Molecular testing gel images, Real time PCR raw data (genetic diseases and cancer)	10 years
Cytogenetics, FISH images	10 years
Coagulation calibration / standard graph	Lot changeover

Raw data & LJ chart of daily values of internal quality control / raw data of EQA	1 year or till the next assessment whichever is later

7. The laboratory shall incorporate salient quality indicators for monitoring its performance. Some examples are: sample collection and identification, transportation and processing, analysis and reporting of results, turnaround time, complaints, equipment downtime, uncertainty of measurements, performance in Proficiency Testing (PT) / External Quality Assurance (EQA) scheme.
8. The laboratory shall have adequate space for efficient functioning, a pleasant ambience and conditions to avoid cross contamination. The laboratory shall have effective separation for incompatible activities.
9. Calibration requirements: The nominal maximum periods between successive calibrations of general equipment are illustrated below. All automated instruments such as cell counters, automated analyzers, automated coagulometers and ELISA readers shall be calibrated by manufacturer at least once a year and
   be verified for calibration after preventive maintenance. Automated Hematology analyzers shall be calibrated using _calibrators' that have traceability to standard reference material or methods.

Item	**Recommended maximum period between successive Calibration**	**Procedure and comments for calibration verification**
Autoclaves	One year	Calibration of pressure gauge and temperature by thermal mapping.
Balances and Scales	One year	In addition, balances with in-built calibration facility must be verified using calibrated weights for calibration once a day before use.
Biological safety cabinet	One year	Calibration of manometer, particle count and air flow also to be checked once in a year. For checking the functioning of UV light colony count to be performed once in 15 days.
Laminar Flow	One year	For horizontal laminar flow where sterile work is being done like media preparation, at least one blood agar media plate shall be used once in 15 days and there should be no growth.

Centrifuge	One year	Tachometer (contact / non-contact type) or Stroboscope. Calibrate temperature using PRT (Platinum resistance thermometer) with digital indicator and timing devices (by a stopwatch) in specialized high speed (> 10000 rpm) centrifuges.
Piston- operated volumetric apparatus, pipettes and dispensers	Initial manufacturer's certificate at the time of purchase and calibration checks every one year thereafter	i) In-house gravimetric checks: Repeat at least 10 times volume delivery and weighing. (The laboratory may refer ISO 8655-6:2002 for guidance). ii) Adjustable devices: take readings at several settings of volume. iii) In-house verification of pipette calibration: Volumes less than 100µl should be checked with balances of appropriate sensitivity / resolution.
Thermometers	One year	Calibration of master thermometer at required temperature for other thermometers in laboratory verification by using calibrated thermometer at 2-3 points covering entire range.

10. For the purpose of recording estimates of uncertainty of measurement imprecision should be documented as k X %CV. k is the coverage factor and at 95% confidence interval it equals to ±1.96 approximated to ±2, so the uncertainty of measurement could be set as:
    a. Coefficient of Variation (%CV)
    b. The uncertainty of measurement would be: ± 1.96 x %CV approximated to ± 2 X %CV

    It is recommended that a minimum of six months internal QC data should be used to calculate routine imprecision, to be updated annually where possible.
11. The laboratory shall follow national, state and local guidelines for BMW handling and disposal**.**

12. Identification by name and / or signatures of the person authorizing release shall be included in the test report in accordance with Cl.5.8.3 of ISO 15189:2012.
13. Results generated by manual tests or by an automated analyzer shall be communicated to the customers / users through a computerized or paper-based information system which manages workflow, quality and audit trail for the samples processed in the laboratory.
14. Storage of examined specimen: The examined specimens can be stored for re-examination and / or additional tests for the period and temperature as specified below:
    a. Complete Blood Counts: <24 hours at 2-8^{0}C
    b. Coagulation test: <4 hours at room temperature
    c. Fluids for cytology – 24 hours at 2-8^{0}C
    d. Cytology slides – 5 years
    e. Blood samples for karyotyping – 6 days at 2-8^{0}C
    f. Fixed cell suspensions – 5 years at -20^{0}C

The storage requirements for the samples which are retained for longer period are as follows:

- ✓ Plasma can be stored at or below -20^{0}C for 1 week and -80^{0}C for up to 1 year.
- ✓ For PT up to 24 hours if samples are maintained between 18 - 24^{0}C and for heparin monitoring it shall be within an hour.
- ✓ Hemoglobin electrophoresis and HPLC: (Hemolysate) 1 week at 2-8^{0}C or longer below -20^{0}C
- ✓ Bone Marrow aspiration slides: 5 years
- ✓ Bone Marrow biopsy: 10 years

15. Internal quality control is necessary to ensure precision and repeatability. For this the laboratory shall use stable controls procured from commercial sources. The data should be plotted on control charts (L.J. charts). Laboratory shall use 2 levels of controls at least once a day. The 24X7 laboratory shall use these controls every 12 hours interval. Laboratory must use a control to check dipstick quality every day. Laboratory shall cross check dipstick with manual methods every 6 months and records to be kept.
16. Split sample testing by different person must be performed once every 3 months for tests like urine analysis, semen analysis, stool examination etc.
17. When a repeat specimen for Histopathology from a patient is received, all previous slides must be reviewed if possible and reflected in the final report.
18. Frozen section results must be compared with the final assessment and both results must be reflected in the final report.
19. Immunohistochemistry: Verification of antibodies every 6 months is a good practice. However, the laboratory is advised to have a daily record of positive controls when the antibodies are used.
20. Minimum of three color immunophenotyping shall be done for immunophenotyping of hematolymphoid neoplasms and for CD4 cell counts.
21. For CD34+ stem cell enumeration appropriately conjugated Class II or Class III anti-CD34 monoclonal antibodies should be used.

22. Flow Cytometry assessment of HLA-B27 shall be done with at least two different antibody clones of defined specificity for HLA-B27.
23. Recommended conditions for sample collection, transport and storage for conventional cytogenetic analysis are tabulated below

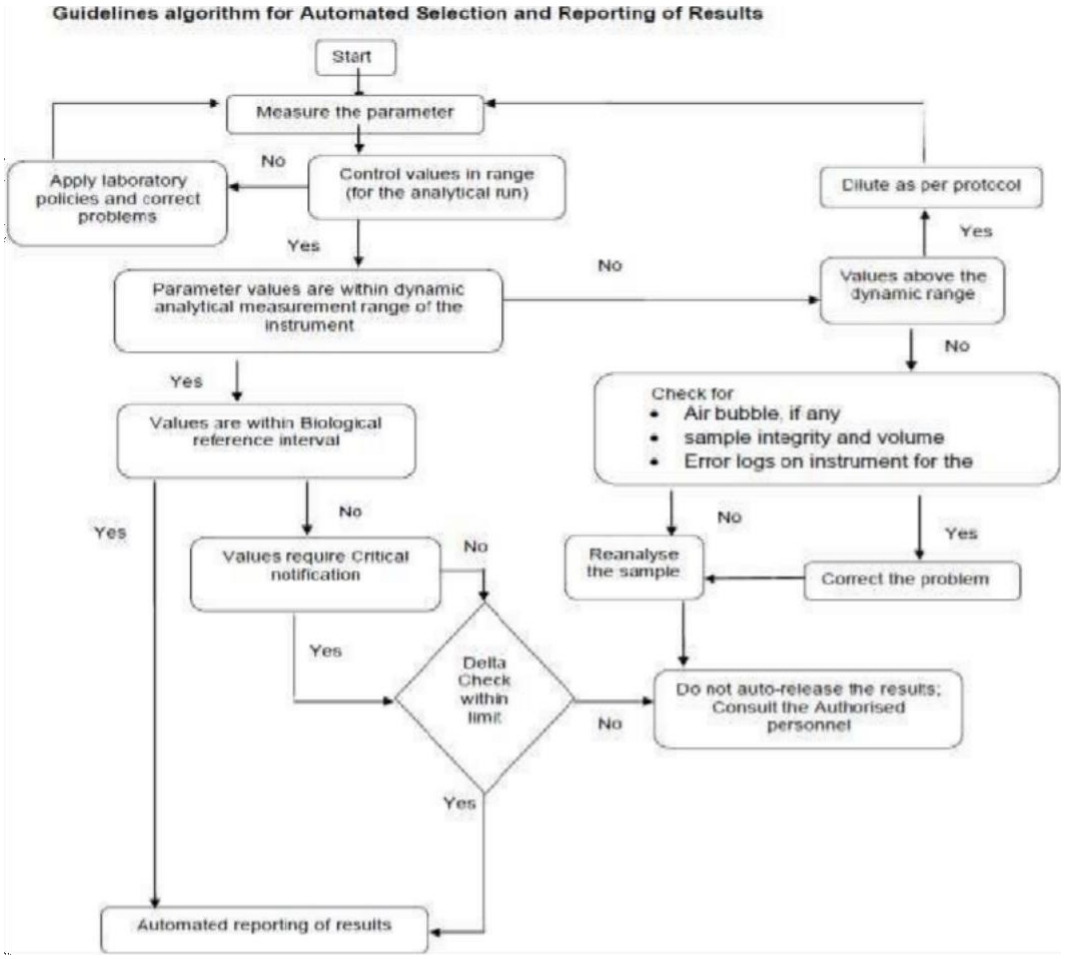
Tissue	**Sample volume**	**Container**	**Mode of collection**	**Transport / Storage**
Whole blood / Cord blood / Bone marrow	Minimum 2- 3 ml	Sterile green top sodium heparin vacutainer	When using a vacutainer use an evacuated tube system to collect the blood. If using an ordinary syringe and a vacutainer, use a transfer device following the same order of draw in case of multiple tubes. Sterility must be maintained	Sample to be transported at room temperature and should be processed as soon as possible. In case of delay, sample to be stored either in an air-conditioned room (22-25^{0}C) or on the door shelf of the refrigerator
Chorionic villus	10-15mg	Sterile 15 ml centrifuge tube or 1.5 ml Eppendorf tube containing sterile transport medium	Sterility must be maintained	Sample to be transported at room temperature and should be processed as soon as possible. In case of delay in processing, the villi samples to be cleaned and

				placed along with culture medium (in a sterile petri dish) inside a carbon dioxide incubator. When immediate cleaning is not possible and storage period is longer, sample should be placed on the door shelf of the refrigerator
Products of conception (POC)	20-30mg	Sterile 50 ml centrifuge tube with sterile saline with few drops of antibiotic or transport medium	Sterility must be maintained	Sample to be transported at room temperature and should be processed as soon as possible. If immediate processing is not possible the sample to be stored on the door shelf of the refrigerator
Other solid tissue Including tumours and skin	4 – 5 pieces, 2-4 mm^2 Punch biopsy of skin must include dermis. Lesional and nonlesional skin shall be	Sterile 50 ml Centrifuge tube or 1.5 ml eppendorf Tube containing sterile saline	Sterility must be maintained	Sample to be transported at room temperature and should be processed as soon as possible. In case of delay in

	kept in separately marked containers	with few drops of antibiotic or transport medium		processing, the samples to be cleaned and placed along with culture medium (in a sterile petri dish) inside a carbon dioxide incubator. When immediate cleaning is not possible and storage period is longer, sample should be placed either in an air-conditioned room (22-25^{0}C) or on the door shelf of the refrigerator
Amniotic fluid	10-15 ml	Two sterile 15- or 50-ml centrifuge tubes	Sterility must be maintained	Sample to be transported at room temperature
Fine needle aspirates / Pleural or other fluids	5-10 ml	Sterile 50 ml Centrifuge tube	Sterility must be maintained	Sample to be transported at room temperature and should be processed as soon as possible. In case of delay, sample to be stored either in an air-conditioned room (22-25^{0}C) or on the door shelf of the

				refrigerator

24. Blood for DNA analysis can be stored at room temperature for up to 24 hours or at 2 to 8°C for up to 72 hours prior to DNA extraction. For RNA studies, extraction shall begin within 4 hours. If extraction is not possible immediately, sample shall be collected in a tube containing an RNA stabilizing additive. Alternatively, the buffy coat can be removed and stored in Trizol reagent at -70°C or lower.
25. Lot verification or parallel testing of controls: The new QC lots may be verified against the old lot by
    running them parallel for CBC and coagulation controls.
26. Lot verification or parallel testing of reagents:
    a. CD4 / CD8 Assay: A minimum of 2 patient samples (One normal and one abnormal sample) or QC should be run in parallel when antibody lot numbers, reagent lot numbers or reagent kits, such as true count, lot numbers are changed.
    b. CBC Analyzer Reagents: Material of known value may include patient samples or controls – minimum of 2 patient samples.
    c. Coagulation Reagents: Parallel testing of new lots of PT reagents also includes verifying the reference range, geometric mean and programming the correct ISI (international Sensitivity Index) into the coagulation analyzer. Parallel testing of APTT reagents should be conducted well in advance of the expiration of the old reagent.
    d. Semi quantitative Tests Urine analyzer strips: A minimum of 2 patient samples are run in parallel on both the old and the new lots (The samples should demonstrate varying results across the range for different strip analytes).
27. Guidelines for following Order of Draw:
    a. Blood culture tube
    b. Coagulation tube (e.g. blue closure) – To be the 1st tube when blood culture is not being collected
    c. Serum tube with or without clot activator, with or without gel (e.g. red closure)
    d. Heparin tube with or without gel plasma separator (e.g. green closure)
    e. EDTA (e.g. lavender closure)
    f. Tube with glycolysis inhibitor
28. EQAS (External Quality Assessment Scheme) is designed to provide the external proficiency testing services so as to enable laboratories to compare themselves with peer groups and thus be able to asses themselves primarily on the issue of accuracy. For using EQAS to achieve acceptable quality; the pre-analytical, analytical and post-analytical factors should be taken into account.



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MEDICATION SAFETY-STATUTORY & LEGAL REQUIREMENTS, DISPOSAL OF DISCARDED/ EXPIRED DRUGS, SURVEILLANCE SYSTEM OF ADR, NATIONAL PHARMACOVIGILANCE PROGRAMME, HIGH ALERT DRUGS, NARCOTICS AND LOOK ALIKE & SOUND ALIKE DRUGS POLICY.

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Dr. Biraj Paul

What is drug:

Section 3(b) of The Drugs and Cosmetics Act-1940 defines a drug as ―

i). All medicine for internal or external use in human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes

(ii) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals,

(iii) All substances intended for use as components of a drug including empty gelatin capsules; and (iv) Such devices* intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals‖

Medication Safety-Statutory & legal requirements:

Regulation of drugs and persons with legal status to handle the same in India falls under the below mentioned acts and rules

A. D & C Act, 1940 And rules 1945
B. New Drugs and clinical trial rules-2019
C. Medical devise rules 2017
D. The Pharmacy act 1948
E. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
F. The Narcotic Drugs and Psychotropic Substances Act, 1985
G. Cosmetic rules 2020
H. Trade names: Trade and Merchandise act, 1958
I. Drug price control order 1995:
J. National essential medicine list 2022

Different authorities to implement:

1. National pharmaceutical pricing authority (to enforce DPCO)
2. Central drugs standard control organization
3. PvPI, IPC Ghaziabad: for ADR monitoring

4. MvPI: Materiovigilance Program of India: To monitor adverse events related to medical devices.
5. FSSAI: Dietary supplements and nuturaceuticals

Schedules of D & C act-1940	**Details**
E(1)	List of poisonous substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine
F	REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK AND / OR FOR PREPARATION OF BLOOD COMPONENTS
F(i)	Part-I: Vaccines Part II: Antisera PART III- DIAGNOSTIC ANTIGENS
F(II)	Standards for surgical dressings
SCHEDULE F (III)	STANDARDS FOR UMBILICAL TAPES
SCHEDULE FF	Standards for ophthalmic preparations
G	It is dangerous to take this medicine except under medical supervision
H	Prescription drugs
H1	The supply of H1 drugs shall be recorded in a separate registrar the time of supply giving the name and address of the prescriber, name of the patient, name of the drug, quantity supplied and such records should be maintained for a period of 3 years and should be open to inspection. These drugs also have specific labelling requirements [GSR 588 (E)]
L-I	GOOD LABORATORY PRACTICES AND REQUIREMENTS OF PREMISES AND EQUIPMENTS
M	GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR PHARMACEUTICAL PRODUCTS
X	List of narcotic and psychotropic substances. Can‘t be purchased as OTC without a valid prescription of registered medical practitioner
N	Minimum requirements for establishment of a pharmacy
P	Contains regulations regarding life period and storage of different drugs
P1	Pack sizes

G	Label: ―Caution: It is dangerous to take this drug except under medica; supervision‖

Disposal of discarded/ expired drugs,

For near expiry drugs:

a. **In individual departments: Senior nursing officer/NO assigned**
   Responsibility:
   i. To evaluate the expiry dates of medicines
   ii. Maintain register
   iii. Looking for any changes/sedimentation
   iv. Inform about near expiry drugs to central store minimum three Months before expiry
   v. Transport to central pharmacy the near expiry drugs
   vi. Maintaining separate area for near expired drugs
   vii. Maintaining separate labelled area for expired drugs.
b. **In central pharmacy: Officer in-charge, Pharmacy**
   i. Take back of near expiry drugs to central pharmacy
   ii. Verification
   iii. Evaluation for any sedimentation and changes
   iv. Informing other departments where there is a possible need
   v. Central pharmacy will relocate to other departments where there is a need.

Disposal of expired drugs:

Responsibility:

1. **Departmental SNO:**
   i. Maintain registrar of all expired/near expiry drugs and convey the same information to central pharmacy.
   ii. Maintenance of separate near expiry drug storage box/storage area with labelled site.
   iii. To maintain separate expired medicines in a different and labelled site/storage box.
   iv. Handing over/delivery of the same to central pharmacy.

Central pharmacy:

1. Collection/receipt of expired drugs from all departments.
2. Make list of expired medicines.
3. To store the same in a separate marked room/Separate storage box with label ―Expired drugs: Not to be used).
4. The storage of expired medicines is under the incharge central pharmacy.
5. The store area should be verifiable by Drugs and therapeutics committee.
6. The list of expired medicine will be communicated to the drugs and therapeutics committee by the officer in-charge
7. After approval of D & TC committee, the same will be communicated to MS office.

8. After approval from MS, the same list will be communicated to incharge, biomedical waste disposal.
9. Transport of expired medicines should be in pilfer proof containers/box/yellow bag or as required by the BMW guidelines.

Drugs and therapeutic committee:

1. Granting approval of the list of expired drugs for further action and handing over to i/c biomedical waste disposal.
2. D & TC committee will assess the list of expired drugs and will note down the reasons of expiry.
3. D & TC committee will review the list of expired medicines at least every quarterly.

Biomedical waste criteria:

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
Yellow	Expired or Discarded Medicines (Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.)	Yellow coloured non chlorinated plastic bags	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
Blue	Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Puncture proof and leak proof boxes or containers with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

Others as per relevant as per BMW

Reference:

a. SOP AIIMS Raipur
b. Guidelines on safe disposal of expired drugs, WHO
c. UP NHM Pharmacy dept SOP
d. DHSM SOP for pharmacy
e. Advisory, Expired medicine, DHS ODISHA
f. Guidelines for biomedical waste management at health care facilities, Assam, May 2023.

Surveillance system of ADR, National Pharmacovigilance programme,

In case of any drug related adverse event, the same should be reported to the ―ADR monitoring centre (AMC)‖. The approved MvPI (Materiovigilance program of India) reporting site is also located in the same office.

The AMC evaluates the case and do causality assessment of the same. The details of which is sent to the Pharmacovigilance program of India (PvPI), IPC Ghaziabad (Through Vigiflow software) for further action. IPC does quality assessment of the report and the same is conveyed to Uppsala monitoring centre global ADR database for global actions and maintenance of ADR database.

The details of the ADR is also conveyed to the Drugs and therapeutics committee. If necessary, The drugs and therapeutics committee and the Pharmacovigilance committee either can intimate the regional office of CDSCO for regulatory sampling and quality control.

In case of any medical devise related adverse event, the same needs to be reported to the MvPI office. The details of the reports are sent to the MvPI for further action.

High Alert Drugs:

These drugs can cause significant harms in case of wrong administration and consequences can be devastating. These medications require special safeguard and safe strategies are needed to be implemented at every step where there is a possibility of error starting from storage, ordering, preparation, administration and monitoring (1). Few of the strategies

1. Limiting access
2. Storage area of HAM to be clearly demarcated and separate
3. Extra label/HAM stickers
4. Extra layer of safety: barcode verification
5. Automated alerts
6. Double checks (automated or manual)
7. Incorporation of technology: CPOE,
8. Error: Report and prompt remedial action, development of S.O.P.
9. Each incident to be reported and analyzed: Gap analysis, Root cause analysis and remedial measures. S.O.P. to be made on all high alert drugs for safe practices.

A list of high alert medicines can be found in the ISMP website (1). Specific steps to address the issues may be taken help of ―The national guidelines on high alert medicines‖ by Ministry of health Singapore (2).

Narcotics:

The Narcotic Drugs and Psychotropic Substances Act, 1985 govern the different steps in usage of narcotics and controlled drugs in hospital and hospital pharmacy.

1. Storage:
   a. To be stored in securely locked cabinet both in Pharmacy and user departments to avoid theft or misuse.
   b. Each vial/unit of narcotic once used should be documented at patient care level with proper patient identification.
2. Physician order of narcotic and controlled substances:
   a. Only by registered medical practitioner.
   b. In case of verbal order (generally not encouraged), the same needs to be confirmed by the RMP within next 12 hours.
3. RNO/ANS/SNO:
   a. Empty ampoules have to be discarded as per BMW protocol and the same needs to be documented in the ―narcotic consumption record‖ book.
   b. Unused narcotics may be returned to the central pharmacy by Nursing officer, however, the same should be witnessed and signed by two licensed staff (RMO/NO/Pharmacist).
   c. To record each administration and responsible for discard the unused portion, the same needs to be documented in the narcotic consumption record.
   d. Nursing superintendent to keep proper documentation in each case.
   e. Narcotic consumption record to be kept in a special dedicated ―Narcotic consumption record‖ by respective nursing superintendent/SNO
4. Hospital pharmacy:
   a. Procurement officer: To keep all detailed track record of all procurements, storage and distribution.
   b. Disposal of expired NDPS drugs is responsibility of hospital pharmacy and should be done as per provisions of NDPS act -1985 and BMW guidelines.
   c. Employee training and sensitization of relevant stakeholders in NDPS-1985 is responsibility of hospital pharmacy.
5. Narcotic drug officer is entitled to monitor the use of NDPS drugs.
6. MIBR (Missed Broken Information Report): To be mandatorily filled in case of recovery of any missing ampoule: For all stakeholders (3).
7. Elicit activity by employee: Will be seriously liable, if found to possess, sale or divert controlled substances and will be handled as per provisions of the NDPS act-1985.

For further details please refer to NDPS-1985 and its amendments.

Look alike & Sound alike drugs policy:

LASA drugs are important causes of medication error, which can be attributed to look-alike (orthographic) or sound alike (phonetic) properties. Look alike may be due to size, shape, color, packaging similarity etc. Sound alike drugs share same phonetics. LASA drugs can be

either between brands, between branded and generic, and among different generics and also can happen with traditional and contemporary medicines. The resultant confusion can mislead any stakeholder in drug administration or the patient him/herself.

Medication use id a multistep process (4) with major steps being

1. Prescribing
2. Transcribing and documenting,
3. Dispensing,
4. Administering and
5. Monitoring.

Step	**Causes of increased probability of LASA**	**Outcome**
Prescribing	Poor handwriting, Abbreviations, Selection of medicine falling in LASA category, verbal order,	Overdosing, under-dosing, inappropriate dosing, inappropriate medications. Outcomes may be worse among patients with risk factors e.g. extremes of age and frailty, organ dysfunction, LASA involving high alert drugs can be particularly dangerous, dependent patients (e.g in ICU, extremes of age), narrow therapeutic index medicines, .
Transcribing and documenting	Poor handwriting, Abbreviations, transcribing verbal order.	
Dispensing	Similar appearance, No colour coding	
Administering	Failure to double check, unclear instructions on administration,	
Monitoring	Failure to monitor after drug administration.	

The different stakeholders in prevention of LASA associated medication error ranges from drug regulators, manufacturers, hospital procurement department, healthcare workers, patient and family. Other parallel stakeholders are organizations involved in the field of medication safety e.g. WHO (5), ISMP (6) and policy makers.

Strategies to address LASA(5)(6):

The strategies may target hospital pharmacy, healthcare workers, patients or as a whole hospital itself. There is a major role of regulators also. These LASA errors may occur at any stage e.g. prescribing, transcribing, dispensing, administering and monitoring.

A. Procurement:

1. Use of failure mode and effects analysis before adding new products to inventory.
2. Any new products are received by pharmacy, identify the possibility of LASA.
3. In case of confusing brand names or possibility of LASA, may consider buying other manufacturers.

B. Prescribing:

1. Avoid drug name abbreviations
2. Electronic prescription may be preferred

3. Write both Brand and generic name (In case of possibility of LASA)
4. Limit verbal or telephonic order to emergencies. In that case read back the order in using a phonotic alphabet (E.g. A for Assam).
5. Use of generic names to avoid confusion in brand names
6. Write legibly while prescribing and transcribing
7. Clear legible handwriting

C. Dispensing:

1. Dispensing When verifying a medication order, ensure that the prescribed medication, dose, dosage form, route of administration, and indication for use make sense in the context of the patient‘s condition. If the drug‘s indication is not clearly stated within the order, and the patient‘s condition or diagnosis does not support the drug‘s intended use, clarify the medication with the prescriber.
2. Adoption of methods to avoid distraction while dispensing and administering medicines.
3. Double checks
4. Technology based solutions like CPOE or bar-coded dispensing

D. Medicine storage:

1. Attach clear labels with Tall man lettering: Example:
   amloDIPINE
   amioDARONE
   In case TML is not possible (e.g. vaccines and immunoglobulins for a particular disease), the trade name on the label could differentiate the two products.
2. Labelling that indicates possible LASA confusion can also help to identify medicines for which TML cannot be applied
3. During storage: separate storage for identified LASA pairs.
4. Other strategies with limited utility: Colour coding (especially used in anaesthesia)

E. LASA list

1. Promotion of LASA reporting culture and near misses
2. Developing and updating LASA list regularly
3. List of confused drug names (by ISMP)

F. Education

a. **Healthcare professionals:** Should be educated in TML and other strategies to avoid medication error as a result of LASA.

b. **Patients:**
   1. Educate about the drugs
   2. Double checks
   3. Teach about TML
   4. Patient can also complain about LASA.
   5. As per education and IQ and cognitive status/Legal representatives.

Reference:

1. highAlert2018-Acute-Final.pdf [Internet]. [cited 2024 Sep 3]. Available from: https://www.ismp.org/sites/default/files/attachments/2018-08/highAlert2018-Acute-Final.pdf

2. national-guidelines-on-high-alert-medications.pdf [Internet]. [cited 2024 Sep 3]. Available from: https://www.moh.gov.sg/docs/librariesprovider4/default-document-library/national-guidelines-on-high-alert-medications.pdf

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4. Vogenberg FR, Benjamin D. The Medication-Use Process and the Importance of Mastering Fundamentals. P T. 2011 Oct;36(10):651–2.

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SAFE CHILDBIRTH PRACTICE GUIDELINES

Dr. Himangshu Malakar,
Dr. Bandana Bharali,
Dr. Anamika Chaudhary

CONTENTS

1. Introduction

Recent WHO guidelines emphasize safe childbirth practices to enhance maternal and neonatal outcomes worldwide. This abstract explores key recommendations for healthcare providers, focusing on evidence-based interventions. Essential components include skilled birth attendance, promoting timely referrals, and ensuring hygienic conditions to prevent infections. Additionally, the guidelines stress the importance of continuous monitoring of maternal and fetal well-being during labor, utilizing partograph charts to track progress and identify deviations promptly.

The abstract underscores the significance of respectful maternity care, advocating for women's autonomy and informed decision-making throughout the childbirth process. It highlights the implementation of non-pharmacological pain management strategies and the judicious use of interventions like oxytocin for labor augmentation. Furthermore, the guidelines emphasize the role of postnatal care in preventing complications and promoting breastfeeding.

In conclusion, adherence to WHO's safe childbirth practices is crucial for reducing maternal and neonatal mortality rates globally. By integrating these recommendations into healthcare systems, countries can strive towards achieving sustainable development goals related to maternal and child health, ensuring safer childbirth experiences for women and their infants.

How to practice safe childbirth:

Childbirth is a complex process and it is very important to remember to not miss out on crucial steps. The WHO has formulated certain checklists to help health-care workers ensure that essential birth practices are performed at critical moments during childbirth for every delivery, every time. While it is not possible to list on a single checklist all practices that are required at each birth, the Checklist does list a core set of practices that have been proven to reduce harm to mothers and new-borns.

The four sections, or pause points, are specific points in time when birth attendants should ―check‖ that they have completed essential birth practices. These pause points allow birth attendants to make their ―checks‖ at times when they can protect the mother and new-born

against dangerous complications, but the pause points also take place when it is convenient for birth attendants to take the time to perform the checks.

THE 4 PAUSE POINTS:

1. On admission-
2. Just before pushing (or before Caesarean)
3. Soon after birth (within one hour)
4. Before discharge

***On admission*:**

- To detect and treat complications that she may already have
- To prepare her (and her companion) for labour and delivery
- To educate her (and her companion) about danger signs for which she should call for help
- Takes obstetric, medical and surgical history
- Assesses gestational age correctly -Assesses gestational age through either LMP or Fundal height or USG (previous or present is available)
- Records fetal heart rate – Fetoscope / stethoscope / doppler
- Records mother's BP and temperature

Just before or during pushing/ caesarean:

- To detect and treat complications that can occur during labour
- To prepare for routine events and possible crisis situations that may occur after birth.
- All caesarean should be classified as per modified Robsons criteria
- Provider ensures six _cleans' while conducting delivery -Sterile gloves , cord clamp , betadine solution ,sterile cutting edge (blade/scissors)
- Performs episiotomy only when indicated with the use of appropriate local anaesthetic.
- Provider allows spontaneous delivery of head by flexing it and giving perineal support, manage cord round the neck, assists delivery of shoulders and body.
- Delivers the baby on mother's abdomen
- AMTSL – Active management of third stage of labour.
- Ensures immediate drying, and assess breathing
- Performs delayed cord clamping and cutting unless indicated otherwise.
- Ensures early initiation of breastfeeding within 1 hour of birth.
- Assesses the new-born for any congenital anomalies
- Weighs the baby and administer Vitamin K

Soon after birth (within one hour):

- To detect and treat complications that can occur after delivery
- To educate the mother (and her companion) about danger signs for which she should call for help.

- Assesses uterine tone and bleeding per vaginum regularly
- Identifies shock by signs and symptoms (pulse > 110 per minute, systolic BP < 90 mmHg, cold clammy skin, respiratory rate > 30 per minute, altered sensorium and scanty urine output < 30 ml per hour)
- Ensures availability of wide bore cannulas (No. 14/16), IV infusion sets and fluids and containers for collection of blood for haemoglobin, blood grouping and cross matching
- Shouts for help, follows ABC approach, monitors vitals, elevates the foot end and keeps the woman warm
- Starts IV infusions, collects blood for Hb and grouping and cross matching, catheterizes the bladder and monitors I/O, gives oxygen at the rate of 6-8 litres per minute .
- Identifies specific cause of PPH .
- Newborn resuscitation

Before discharge:

- To be sure that the mother and newborn are healthy before discharge
- Follow-up has been arranged
- Family planning options have been discussed and offered to the mother (and her companion)
- Education on danger signs to look out for, both in the mother and her baby, has been given in case immediate skilled care is needed.

The WHO checklists are attached to the case files of all the mothers so that it is followed at all the pause points irrespective of the location.
Refer annexure I for WHO checklists.

SAFE BIRTH SUPPLIES-

Supplies required to safely and hygienically manage the process of labour and delivery.

- Ensures sterile/ HLD delivery tray is available
- Ensures functional items for newborn care and resuscitation
- Ensure availability of uterotonic agents - IM/IV oxytocin (preferred), misoprostol
- Designated new born corner is present
- Ensures functional items for newborn care and resuscitation
- Switches radiant warmer _on' 30 min. before childbirth

GENERAL SUPPLIES AND EQUIPMENT

Power Supply
Clean Water
Soap or Alcohol Hand Rub
Disinfectant
Autoclave
Clean Gloves

Stethoscope
Thermometer
Blood Pressure Instrument
Partograph
Fetoscope/Doppler

SUPPLIES IN THE DELIVERY ROOM

Suction Machine
Mucus Extractor
Neonatal Bag and Mask
Oxygen Cylinder/Concentrator
Baby Scale
Needle/Syringe
Urine Dip Sticks
Sterilized Blade/Scissor
Cord Tie/Clamp
Clean Pads for Mother
Clean Towel

MEDICATIONS/INJECTIONS/DRIPS

Bag of IV Fluids
Injectable Oxytocin
Injectable Magnesium Sulphate
Antibiotics for Mother
Antibiotics for Infant
Antihypertensives

Labour room is maintained as per SOP of LaQshya.
(Refer to SOP of Department of Obstetrics and Gynaecology)

Annexure

CHECK-1 On Admission	
Does Mother need referral? o Yes, organized o No	Refer to HRU/Higher centre if any of following danger signs are present, mention reasons and given treatment on transfer note: o Vaginal bleeding o Severe abdominal pain o High fever o History of heart disease or other major illness o Severe headache or blurred vision o Difficulty in breathing o Convulsions
Partograph started? o Yes o No: will start when 4cm	Start when cervix "4 cm, then cervix should dilate *1 cm/hr - Every 30 min: Plot maternal pulse, contractions, FHR and colour of amniotic fluid - Every 4 hours: Plot temperature, blood pressure, and cervical dilation in cm
NO OXYTOCIN/ other uterotonics for unnecessary induction/ augmentation of labor	
Does Mother need -Antibiotics? o Yes, given o No	Give antibiotics to Mother if: o Mother's temperature 38°C (*100.5°F) o Foul-smelling vaginal discharge. o Rupture of membranes > 12 hrs without labour or >18 hrs with labour o Labour >24 hrs or obstructed labour o Rupture of membranes <37 weeks of gestation
Inj Magnesium Sulphate? o YES, given	Give first dose of inj. magnesium sulphate and refer immediately to FRU/Higher centre OR give full dose (loading and then maintenance) if at FRU if: Mother has systolic BP *160 or diastolic *110 with +3 proteinuria OR BP systolic 140 or diastolic *90 with proteinuria trace to +2 along with any of: Presence of any symptom like: o Severe headache o Pain in upper abdomen o Oliguria[<400ml urine in 24hr] o Blurring of vision. o Difficulty in breathing. o Convulsions

<table>
<tr><td>Corticosteroid

o Yes, given
o No</td><td colspan="2">Give corticosteroids in antenatal period (between 24 t to 34. weeks) to mothers if:

o True pre-term labour
o Conditions that lead to imminent delivery like APH, Preterm Premature ROM, Severe PE/E Dose: Inj. Dexamethasone 6 mg IM 12 hourly - total 4 doses</td></tr>
<tr><td>HIV status of the mother:

o Positive
o Negative

o Follow universal precautions</td><td colspan="2">If HIV+ and in labour:

o If mother is on ART, continue same
o If not on ART, start ART
o If ART is not available, refer immediately after delivery to ICTC/ART Centre/Link ART Centre for further HIV management
If HIV status unknown:

o Recommend HIV testing</td></tr>
<tr><td colspan="3">Encouraged birth companion to be present during labour, at birth and till discharge: Yes No</td></tr>
<tr><td colspan="3">Are soap, soap, water, gloves available?

o Yes, I will wash hands and wear gloves for each vaginal exam
o No, supplies arranged.</td></tr>
<tr><td>o Confirm if mother or companion will call for help during labour if needed</td><td>Explain to call for help if there is:

o Bleeding
o Severe abdominal pain
o Difficulty in breathing
o Severe headache or blurring vision
o Urge to push
o Can‘t empty bladder every 2 hours</td><td>Counsel Mother and birth companion on:

o Support to cope up with labour pains.
o No bath/oil for baby
o No pre lacteal feed
o Initiate breastfeeding in half an hour.
o Cloth and wrap the baby.</td></tr>
</table>

Name of the Provider: Date:
Signature:

CHECK-2 Just Before and During Birth (or C Section)

Does Mother need: o Antibiotics? o Yes, given o No	Give Antibiotics to mother if any of the following are present: o Mother temperature 38^{oC} or 105.5^{o}F o Foul smelling vaginal discharge o Rupture of membrane >18 hours with labour o Labour >24 hours or obstructed labour now o Caesarean section
• Inj. Magnesium sulphate? o Yes, given o No	Give first dose of inj. magnesium sulphate and refer immediately to FRU/Higher centre OR give full dose (loading and then maintenance) if at FRU if: Mother has systolic BP >160 or diastolic >110 with +3 proteinuria OR BP systolic >140 or diastolic >90 with proteinuria trace to +2 along with any of : o Presence of any symptom like: Severe headache Blurring of vision Difficulty in breathing Pain in upper abdomen Oliguria (passing <400 ml urine in 24 hrs). o Convulsions
o Skilled assistant identified and ready to help at birth if needed	
Confirm essential supplies are at bedside/labour room: For Mother o Gloves o Soap and clean water o Oxytocin 10 units in syringe o Pads for mother	Prepare to care for mother immediately after birth of baby (AMTSL)* o Confirm single baby only (rule out multiple babies) o Give inj. oxytocin 10 units IM within 1 minute o Do controlled cord traction to deliver placenta o Massage uterus after placenta is delivered, check for completeness (all Cotyledons and Membranes)
For Baby o Two clean dry, warm towels o Sterile scissors/blade to cut cord o Mucus extractor o Cord ligature o Bag-and-mask	Prepare to care for baby immediately after birth . o Dry baby, wrap, and keep warm, give Vit. K, start breastfeeding o If not breathing: clear airway and stimulate o If still not breathing: -Cut cord -Ventilate with bag-and-mask - Call for help (Paediatrician/SNCU/NBSU/F-IMNCI trained doctor if available)

Name of the Provider: Date:
Signature:

CHECK -3 Soon After Birth (Within 1 hour)	
ls Mother bleeding abnormally? o Yes, shout for help, refer if needed or treat if facilities available o No	If bleeding $500 ml, or 1 pad soaked in <5 min: o Call for help, massage uterus, start oxygen, start IV fluids, start oxytocin drip 20 units in 500 ml of RL@40-60 drops/min, treat cause o If placenta not delivered or Or completely retained: give IM or IV Oxytocin, stabilize and refer to FRU/Higher centre o If placenta is incomplete: remove if any visible pieces, and refer immediately to FRU/ higher centre
Does Mother need: Antibiotics? o Yes, given o No	Give antibiotics to mother if manual removal of placenta is performed, or if mother's temperature *38°C ("100.5°F) and any of: o Chills o Foul-smelling vaginal discharge o Rupture of membranes >18 hrs during labour o Labour was >24 hours
Inj. Magnesium sulphate? o Yes, given o No	Give first dose of inj. magnesium sulphate and refer immediately to FRU/Higher centre OR give full dose (loading and then maintenance) if at FRU if Mother has systolic BP >160 or diastolic >1 10 with +3 proteinuria OR BP systolic >140 or diastolic >90 with proteinuria trace to +2 along with any of: o Presence of any symptom like: Severe headache Blurring of vision Difficulty in breathing Pain in upper abdomen Oliguria (passing <400 ml urine in 24 hrs) o Convulsions
Does Baby need: Antibiotics? o Yes, given o No	Give baby antibiotics if antibiotics were given to mother, or if baby has any of: o Breathing too fast (>60/min) or too slow (<30/min) o Chest in-drawing, grunting o Convulsions o Looks sick (lethargic or irritable) o Too cold (baby's temp <36"C and not rising after warming) o Too hot (baby's temp >38"C) o Excessive crying

Referral?

- Yes, organized
- No

efer baby to NBSU/SNCU/FRU higher centre if:

- Any of the above (antibiotics indications)
- Baby looks yellow, pale or bluish

Special care and monitoring? ○ Yes, organized ○ No	Arrange special care/monitoring for baby if any of the following is present: ○ Preterm baby ○ Birth weight <2500 g ○ Needs antibiotics ○ Required resuscitation
Syrup Nevirapine ○ Yes, given and will continue up to 6 weeks ○ NO	Give if mother is HIV+: ○ If mother has received >24 weeks of ART, give syrup Nevirapine to baby for 6 weeks ○ If mother has received <24 weeks of ART or mother is not on ART, give syrup Nevirapine to baby for 12 weeks

- Started breastfeeding. Explain that colostrum feeding is important for baby.
- Started skin-to-skin contact (if mother and baby well) and KMC in pre-term and low-birth weight babies
- Explain the danger signs and confirm mother/companion will call for help if danger signs present.

Name of the Provider: Date:
Signature:

<table>
<tr><td colspan="2">CHECK-4 Before Discharge</td></tr>
<tr><td>Is Mother's bleeding controlled?

○ Yes
○ No, treat, observe and refer to FRU higher centre if needed</td><td></td></tr>
<tr><td>Does mother need antibiotics?

○ Yes, give and delay discharge
○ No</td><td>Give antibiotics to mother if mother has temperature 38ºC or 100.5ºF with any of :

○ Chills
○ Foul smelling vaginal discharge
○ Lower abdominal tenderness</td></tr>
<tr><td>Does baby need antibiotics?

○ Yes, give, delay discharge and refer to FRU/ higher centre
○ No</td><td>Give baby antibiotics if baby has any of:

○ Breathing too fast (>60Vmin) or too slow (<30imin)
○ Chest in-drawing, grunting
○ Convulsions
○ Looks sick (lethargic or irritable)
○ Too cold (baby's temp <36ºC and not rising after warming)
○ Too hot (baby's temp >38ºC)
○ Stopped breastfeeding
○ Umbilical redness extending to skin or draining pus</td></tr>
<tr><td colspan="2">Is baby feeding well?

○ Yes, encourage mother for exclusive breastfeeding for 6 months
○ No, help mother, delay discharge; refer to NBSU/ SNCU/ Higher centre if needed</td></tr>
<tr><td colspan="2">○ Discuss and offer family planning options to mother
○ Confirm post-delivery stay at facility for 48 hours in normal delivery and 7 days in C-section cases
○ Explain the danger signs and confirm mother/companion will seek help/ come back if danger signs are present after discharge
○ Arrange transport to home and follow-up for mother and baby</td></tr>
<tr><td colspan="2">Thank mother for availing services from you</td></tr>
<tr><td colspan="2">DANGER SIGNS</td></tr>
<tr><td>Mother has any of:

○ Excessive bleeding</td><td>Baby has any of:

○ Fast/difficulty breathing</td></tr>
</table>

○ Severe abdominal pain ○ Severe headache or visual disturbance ○ Breathing difficulty ○ Fever or chills ○ Difficulty emptying bladder ○ Foul smelling vaginal discharge	○ Fever ○ Unusually cold ○ Stops feeding well ○ Less activity than normal ○ Whole body becomes yellow

CONCLUSION

This guideline aims for respectful maternal care and safe childbirth and recovery in the post-natal period.

ACKNOWLEDGEMENT

1. WHO SAFE CHILDBIRTH CHECKLIST
2. NATIONAL HEALTH MISSION SAFE CHILDBIRTH CHECKLIST.

Name of the Provider: Date:
Signature:

ROLE OF DEPARTMENT OF TRANSFUSION MEDICINE AND BLOODCENTRE IN PATIENT SAFETY

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Dept of Transfusion Medicine and Blood Centre, AIIMS, Guwahati

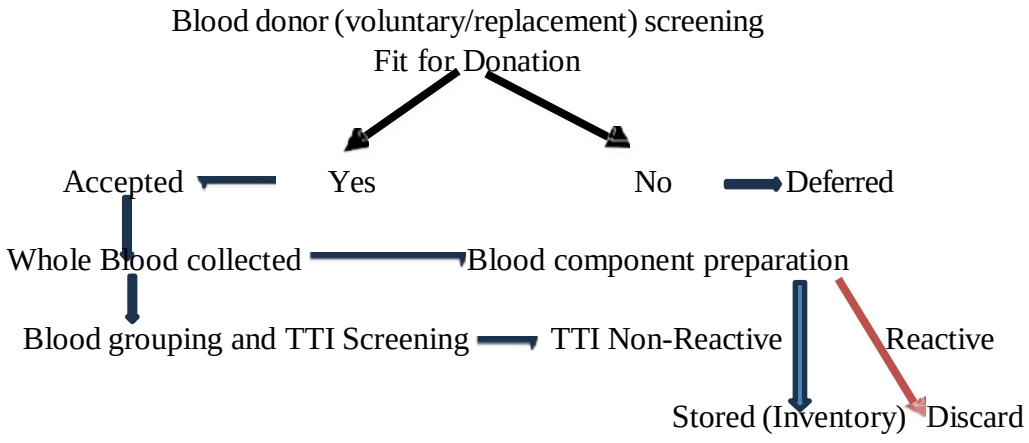
Introduction:

The Department of Transfusion Medicine and Blood Centre is committed to providing patients with safe and timely blood and blood components and accurate results of the tests ordered by various departments. The Blood Centre makes every effort to ensure an adequate inventory of all blood groups and components to meet the needs of the patients. Serologically compatible blood and components are provided to the patients after pre-transfusion testing as per the standard protocol.

The transfusion service has four sections: namely, donor complex, blood component separation unit, transfusion transmitted infection screening laboratory and blood group serology laboratory. The essential processes include donor selection, blood collection, component preparation, screening for transfusion-transmitted infections, blood grouping and crossmatching. Immunohematological tests like blood grouping, direct antiglobulin test (DAT) , indirect antiglobulin test (IAT), antibody identification for transfusion reactions (alloimmunization), hemolytic disease of newborns and autoimmune disorders are performed.

The future scope of our Blood Centre includes apheresis technology involving donor procedures such as single donor platelets collection, donor leukapheresis (including granulocytapheresis, peripheral stem cell collection, lymphocyte collection) and patient related procedures like therapeutic leukapheresis, red cell exchange, therapeutic plasma exchange. Necessary infrastructure will be developed to meet the requirement of special blood components such as peripheral blood stem cell, irradiated components etc. This informative manual on transfusion safety is designed to disseminate knowledge about safe blood transfusion practices to all medical personnel involved in arranging blood or component transfusion to the patients.

FLOW CHART OF FUNCTIONS OF BLOOD CENTRE



PART A. Quality Management System (QMS)

Quality management

1.1. General requirements

- Each blood establishment should develop and maintain a Quality System that is based on Good Manufacturing Practices.
- Quality should be recognised as being the responsibility of all persons involved in the processes of the blood establishment, with management ensuring a systematic approach towards quality and the implementation and maintenance of a Quality System.
- Attainment of this quality objective is the responsibility of senior management. It requires the participation and commitment both of staff in many different departments and at all levels within the organisation and of the organisation‘s suppliers and distributors. To achieve this quality objective reliably there should be a comprehensively designed and correctly implemented quality system incorporating good practice and quality risk management.
- The basic concepts of quality management, good practice and quality risk management are interrelated. They are described here in order to emphasise their relationships and fundamental importance to the preparation of blood and blood components.
- The requirements for implementing a quality system also apply to hospital blood banks.

1.2. Quality system

- Quality management is a wide-ranging concept covering all matters that individually or collectively influence the quality of blood and blood components. It is the sum total of the organised arrangements made with the objective of ensuring that blood components are of the quality required for their intended use. Quality management therefore incorporates good practice.
- The Quality System encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, processing and testing, storage, distribution, quality control, blood component recall, and external auditing, contract management, non-conformance and self-inspection.
- The Quality System should ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications of Good Practice and comply with appropriate regulations.
- The quality system should be designed to assure the quality and safety of prepared blood and blood components, as well as ensure donor and staff safety and patient service. This strategy requires the development of clear policies, objectives and responsibilities. It also requires implementation by means of quality planning, quality control, quality assurance and quality improvement to ensure the quality and safety of blood and blood components, and to provide good patient care
- Senior management has the responsibility to ensure that an effective quality system is in place and resourced adequately, and that roles and responsibilities are defined, communicated and implemented throughout the Blood Centre

- Senior management should establish a quality policy that describes the overall intentions and direction of the blood centre/hospital transfusion services (hereinafter referred to as _organisation‘) related to quality. They should also ensure quality system management and good practice governance through management review to ensure its continuing suitability and effectiveness.
- The quality system should be defined and documented. A quality manual or equivalent document should be established and contain a description of the quality system (including management responsibilities).
- All blood establishments and hospital blood centres should be supported by a quality assurance function (whether internal or related) for fulfilling quality assurance. Their function should be involved in all quality-related matters, and should review and approve all appropriate quality-related documents. An independent function with responsibility for quality assurance should be established.
- All procedures, premises and equipment that have an influence on the quality and safety of blood and blood components should be validated and qualified before introduction and should be re-validated and re-qualified at regular intervals, as determined as a result of these activities.
- A general policy regarding qualification of facilities and equipment as well as validation of processes, automated systems and laboratory tests should be in place. The formal objective of validation is to ensure compliance with the intended use and regulatory requirements.
- A formal change control system should be in place to plan, evaluate and document all changes that may affect the quality, traceability, availability or effect of components, or the safety of components, donors or patients. The potential impact of the proposed change should be evaluated, and the degree of revalidation or additional testing, qualification and validation needed should be determined.
- A formal system for the handling of deviations and non-conformances should be in place. An appropriate level of root-cause analysis should be applied during the investigation of deviations, suspected product defects, and other problems. This strategy can be determined using quality risk management principles. If the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing them. Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system-based errors or problems have not been overlooked, if present. Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed in accordance with quality risk management principles.
- Management should review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.
- There should be periodic management review to monitor the quality system, effectiveness and its operations, with the involvement of senior management, and to identify opportunities for continual improvement of blood and blood component processes.

- Product quality reviews should be conducted with the objective of verifying the consistency of the existing process and the appropriateness of current specifications in order to highlight trends and to identify component and process improvements.

- A product quality review may also be considered as an instrument for surveying the overall quality status of a blood component and its preparation processes, including the collection. Such a review should normally be conducted annually and should be documented. It may include: review of starting materials; critical in-process controls; quality control and quality monitoring; all changes; qualification status of equipment; technical agreements and contracts; all significant deviations and non-conformances, and the effectiveness of the corrective actions implemented; findings of internal and external audits and inspections, and the effectiveness of the corrective actions implemented; complaints and recalls; donor acceptance criteria; donor deferrals; look-back cases.

1.3. Good Laboratory practice

- Good practice is the part of quality management that ensures that blood and blood components are produced and controlled consistently to the quality standards appropriate to their intended use. Good practice is concerned with collection, processing, testing, release and storage and quality control. The basic requirements are:
- All processes are defined clearly and reviewed systematically in the light of experience and shown to be capable of consistently delivering blood and blood components of the required quality and complying with their specifications. This strategy ensures that:

1. Critical steps and significant changes to the process are validated;
2. All requirements are provided including: appropriately qualified and trained personnel; adequate premises and space; suitable equipment and services; correct materials, containers and labels; approved procedures and instructions; suitable storage and transport; instructions and procedures written in an instructional form in clear and unambiguous language, and are applicable specifically to the facilities; operators are trained to carry out procedures correctly; documentation which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the blood or blood component was as expected; any significant deviations are fully recorded and investigated; records of preparation (including distribution) that enable the complete traceability of a blood unit; the distribution of the blood and blood components minimises any risk to their quality; availability of recall system to recall any blood or blood component (including those prepared using a batch of critical materials that have been distributed or issued);
3. Complaints about blood and blood components are examined, the causes of quality defects investigated, and appropriate measures taken in respect of the defective blood components to prevent reoccurrence.

- Quality control is the part of good practice that is concerned with sampling, specifications and testing, as well as with the organisation, documentation and release procedures which ensure that materials are not released for use in preparation, and blood and blood components are not released for distribution, until their quality has been judged to be satisfactory and that the necessary and relevant tests have been carried out. The basic requirements are:

1. Adequate facilities, trained personnel and approved procedures are available for sampling, inspecting/testing starting materials, packaging materials, intermediate components and finished blood and blood components and, if appropriate, for monitoring environmental conditions;
2. Samples of starting materials, packaging materials, and intermediate and finished blood components are taken by approved personnel and methods;
3. Test methods are validated;
4. Records are made, manually and/or by recording instruments, which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out. Any deviations are recorded and investigated fully;
5. The finished blood and blood components comply with the specifications and are correctly labelled;
6. records are made of the results of inspection, and that testing of materials, intermediate and finished blood and blood components are formally assessed against specifications;
7. no blood or blood components are released for distribution that do not comply with the requirements of the relevant authorisations.

- Quality reviews of all blood and blood components (including export-only blood components) should be conducted with the objective of continuously verifying the consistency of the existing process and the appropriateness of current specifications for both starting materials and finished blood components to highlight any trends and to identify product and process improvements.

1.4. Quality risk management

- Quality risk management is the part of the quality system that ensures that the process performance and quality monitoring and review systems are based on risk. Appropriate statistical tools should be used (where appropriate) in the assessment of ongoing process capability.
- The quality system should ensure that processes are in place to ensure the control of outsourced activities and quality of purchased materials. These processes should incorporate the principles of quality risk management and systematically ensure that:
    - the evaluation of the risk to quality is based on scientific knowledge, experience with the process and, ultimately, is connected to protection of the donor and patient;
    - the level of effort, formality and documentation of the quality risk management process is commensurate with the level of risk.

1.5. Change control

Change control procedures should ensure that sufficient supporting data are generated to demonstrate that the revised process results in a blood component of the desired quality, consistent with the approved specifications. Supporting data, e.g., copies of documents, should be reviewed to confirm that the impact of the change has been demonstrated prior to final approval. Written procedures should be in place to describe the actions to be taken if a planned change is proposed for a starting material, blood component specification, process, equipment, environment (or site), product range, method of production or testing or any other change that may affect donor safety, blood component quality or reproducibility of the

process. Changes should be authorised and approved by the responsible persons or relevant functional personnel in accordance with the blood establishment‘s quality system. Following implementation, where appropriate, an evaluation of the effectiveness of change should be carried out to confirm that the change has been successful. Some changes may require notification to, or licence amendment from, a national regulatory authority.

1.6. Deviations

- Blood components deviating from required standards shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician
- There should be a defined procedure for the release of non-standard blood and blood components under a planned non-conformance system. The decision for such release should be clearly documented and authorised by a designated person, and traceability should be ensured.
- There should be systems in place to ensure that deviations, adverse events, adverse reactions and non-conformances are documented, carefully investigated for causative factors of any defect and, where necessary, followed up by the implementation of corrective actions to prevent recurrence.
- The corrective and preventive action (CAPA) system should ensure that existing component nonconformity or quality problems are corrected and that recurrence of the problem is prevented.
- Deviations from established procedures should be avoided as much as possible and should be documented and explained. Any errors, accidents or significant deviations that may affect the quality or safety of blood and blood components should be fully recorded and investigated in order to identify systematic problems that require corrective action. Appropriate CAPAs should be defined and implemented.
- Investigations relating to serious deficiencies, significant deviations and serious component defects should include an assessment of component impact, including a review and evaluation of relevant operational documentation and an assessment of deviations from specified procedures.
- There should be procedures for notifying responsible management in a timely manner of deficiencies, deviations or non-compliance with regulatory commitments (e.g. in submissions and responses to regulatory inspections), component or product defects, or testing errors and related actions (quality-related complaints, recalls, regulatory actions, etc.).

- Senior management and the Responsible Person should be notified in a timely manner of serious deficiencies, significant deviations and serious component or product defects, and adequate resources should be made available for their timely resolution.

- A regular review of all significant deviations or non-conformances should be conducted, including their related investigations, to verify the effectiveness of the CAPAs taken.

1.7. Complaints

- All complaints and other information, including serious adverse reactions and serious adverse events that may suggest that defective blood components have been issued, should be documented, carefully investigated for causative factors of the defect and , where necessary, followed up by recall and the implementation of corrective actions

  to prevent recurrence. Procedures should be in place to ensure that the Competent Authorities are notified, as appropriate, of serious adverse reactions or serious adverse events in accordance with regulatory requirements.
- A person should be designated as responsible for handling complaints and deciding the measures to be taken.
- All the decisions and measures taken as a result of a complaint should be recorded. Complaint records should be reviewed regularly for any indication of specific or recurring problems requiring attention and the possible recall of distributed blood and blood components.
- The competent authorities should be informed in cases of complaints resulting from possible faulty processing, component deterioration or any other serious quality problems, including the detection of falsification.

1.8. Recall

- There should be personnel authorised within the blood establishment to assess the need for blood and blood component recalls and to initiate and co-ordinate the necessary actions.
- An effective recall procedure should be in place, including a description of the responsibilities and actions to be taken. This should include notification of the Competent Authority.
- Actions should be taken within pre-defined periods of time and should include tracing all relevant blood components and, where applicable, should include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.
- Recall operations should be capable of being initiated promptly and at any time. In certain cases, recall operations may need to be initiated to protect public health prior to establishing the root cause(s) and full extent of the quality defect.
- The persons authorised to initiate and co-ordinate the recall actions should normally be independent of the commercial management within the organisation. If they do not

include the senior management and the Responsible Person (blood establishment), the latter should be made aware of any recall operation.

- Recalled blood components or products should be identified and stored separately in a secure area while awaiting a decision on their fate.
- The progress of the recall process should be recorded and a final report issued, including reconciliation of the delivered and recovered quantities of the blood and blood components or products.
- The effectiveness of the arrangements for recalls should be regularly evaluated.

1.9. Corrective and preventive actions

- A system to ensure corrective and preventive actions for blood component nonconformity and quality problems should be in place.
- Data should be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.
- Deviations with the potential to affect quality should be investigated and the investigation and its conclusions should be documented, including all the original details. The validity and extent of all reported quality defects should be assessed in accordance with quality risk management principles in order to support decisions regarding the degree of investigation and action taken. Where appropriate, corrective actions should be taken. The potential impact of the source of the deviation on other components or results should also be considered and preventive action should be taken to eliminate the root cause of the deviation and thereby avoid recurrences.
- As part of periodic quality system reviews, an assessment should be made of whether CAPAs or any revalidation should be undertaken. The reasons for such corrective actions should be documented. Agreed CAPAs should be completed in a timely and effective manner. There should be procedures for the ongoing management and review of these actions and the effectiveness of these procedures should be verified during self-inspection.

1.10. Self-inspection, audits and improvements

- Self-inspection or audit systems should be in place for all elements of operations to verify compliance with the standards. They should be carried out regularly by trained and competent persons, in an independent way, and according to approved procedures.
- All results should be documented and appropriate corrective and preventive actions should be taken in a timely and effective manner.

2.0 Personnel

- Personnel should be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of blood and blood components and be trained and assessed to be competent to perform their tasks.
- The organisation should have an adequate number of personnel with the necessary qualifications and experience. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

- There should be an organisation chart in which the relationships between key personnel are clearly shown in the managerial hierarchy.
- All personnel should have up-to-date and clearly defined job descriptions, which clearly set out their tasks and responsibilities. Responsibility for processing management and quality assurance should be assigned to different individuals, and who function independently. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of good practice.
- All personnel should receive initial and continued training appropriate to their specific tasks. Training programs should be in place and should ensure that personnel have relevant knowledge in Good Practice. Training records should be maintained
- The contents of training programs should be periodically assessed and the competence of personnel evaluated regularly.
- Only persons who are authorised by defined procedures and documented as such shall be involved in the collection, processing, testing and distribution processes, including quality control and quality assurance.
- There should be written safety and hygiene instructions in place, adapted to the activities to be carried out, and in compliance to relevant national law.
- Visitors or untrained personnel should, preferably, not be taken into the processing and laboratory areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.
- It is the organisation‘s responsibility to provide instructions on hygiene and health conditions that can be of relevance to the quality of blood components (e.g. during collection) and to ensure that staff report relevant health problems. These procedures should be understood and followed in a strict way by all staff members whose duties take them into the processing and laboratory areas. Personnel should be instructed when and how to wash their hands.
- Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the preparation of blood components. Medical examinations should be carried out when necessary to assure fitness for work and personal health. There should be instructions ensuring that health conditions that can be of relevance to the quality of blood and blood components are reported by the personnel.
- There should be a written policy outlining the requirements for wearing of protective garments in the different areas. The requirements should be appropriate to the activities to be carried out.
- Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the processing, testing and storage areas should be prohibited. In general, any unhygienic practice within the preparation areas or in any other area where the blood or blood components might be adversely affected should be forbidden.

3. Premises

3.1. General

- Premises including mobile sites should be located, constructed, adapted and maintained to suit the activities to be carried out. They should enable work to proceed in a logical unidirectional sequence so as to minimize the risk of errors, and should allow for effective cleaning and maintenance in order to minimize the risk of contamination.
- Lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect (directly or indirectly) blood components during their processing and storage, or the accurate functioning of equipment.
- Premises should be designed and equipped as per the regulatory requirements laid by DCA, NACO, AABB and WHO guidelines so as to minimise compromise of blood components quality and maximum work activity.
- Steps should be taken to prevent the entry of unauthorised people. Areas for processing, laboratory testing, storage and quality control should not be used as a right of way by personnel who do not work in them.
- Temperature and humidity of the preparation areas should be defined according to the operations undertaken within them and taking into account the external environment.

3.2. Blood donor area

- There should be an area for confidential personal interviews with, and assessment of, individuals to assess their eligibility to donate. This area should be separated from all processing areas.
- Premises should satisfy requirements for the health and safety of both the staff (including those of mobile teams) and the donors concerned with due regard to relevant legislation or regulations.

3.3. Blood collection area

- Blood collection should be carried out in an area intended for the safe withdrawal of blood from donors that is appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation. This area should be organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.
- Before premises are accepted for mobile donor sessions, their suitability should be assessed against the following criteria: sufficient size to allow proper operation and ensure donor privacy; safety for staff and donors; the presence of ventilation, electrical supply, lighting, ancillary facilities; reliable communication, interim blood storage and transport
- The arrangement of the collection room and procedures should ensure that blood is collected in a safe and clean environment to minimise the risk of errors and microbial contamination. Consideration should be given to the arrangement of donor beds and the handling of bags, samples and labels.

3.4. Blood testing and processing areas

- There should be a dedicated laboratory area for testing that is separate from the blood-donor and blood-component processing area, with access restricted to authorised personnel, and should be used only for the intended purpose.
- Laboratories should be designed to suit the operations to be carried out in them. Sufficient space should be given to avoid mix-ups and cross-contamination. There should be adequate suitable storage space for samples and records.
- Special provisions may be necessary to protect sensitive instruments from vibration, electrical interference, humidity and extremes of temperature.

3.5. Storage area

- Storage areas of appropriate standards and sufficient capacity should provide for appropriately secure and segregated storage of different categories of blood and blood components and materials, including quarantine and released materials as well as units of blood or blood components collected under special criteria (e.g. autologous donation). Access should be restricted to authorised persons.
- Provisions should be in place in the event of equipment failure or power failure in the main
- Storage areas should be designed or adapted to ensure good storage conditions. In particulars, they should be clean and dry and maintained within predefined temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored. An alarm system should alert users in a timely manner to any excursion outside predefined limits.
- If quarantine status is ensured by storage in separate areas, these areas should be marked clearly and their access restricted to authorised personnel. Any system replacing the physical quarantine (e.g. computerised system) should provide equivalent security.
- Segregated areas should be allocated and identified appropriately for storage of rejected, discarded, recalled or returned materials, or blood and blood components.
- Printed packaging materials (including sets of labels, e.g. donation identifier or irradiation labels) should be stored safely and in a secure manner.

3.6. Ancillary areas

- Staff rest and refreshment areas should be separate from other rooms.
- Facilities for changing clothes and for washing and toilet purposes should be readily accessible and appropriate for the number of users. Toilets should not directly open to preparation areas.

3.7. Waste disposal area

- An area should be designated for the safe disposal of waste, disposable items used during collection, processing and testing, and for rejected blood or blood components.
- Special procedures should be defined for potentially contaminated waste disposal.

4. Equipment and materials

4.1. General requirements

- All equipment should be identified, qualified, calibrated and maintained to suit its intended purpose. Operating instructions should be available and appropriate records kept.
- Equipment should be selected to minimise any hazard to donors, personnel or blood components.
- All validated processes should use qualified equipment. Qualification results should be documented. Regular maintenance and calibration should be carried out and documented according to established procedures. The maintenance status of each item of equipment should be available.
- All critical equipment should have regular, planned maintenance, taking into consideration manufacturer‘s instructions, to detect or prevent avoidable errors and keep the equipment in its optimum functional state. The maintenance intervals and actions should be determined for each item of equipment.
- New and repaired equipment should meet qualification requirements when installed and should be authorised before use.
- All modifications, enhancements or additions to validated systems and equipment should be managed through the change control procedure of the blood establishment. The effect of each change to the system or equipment, as well as its impact on quality and safety, should be determined to identify the extent of revalidation required.
- Instructions for use, maintenance, servicing, cleaning and sanitation should be available.
- Procedures should be available for each type of equipment that detail the action to be taken if malfunctions or failures occur.
- Only reagents and materials from approved suppliers that meet the documented requirements and specifications should be used. Critical materials should be released by a person qualified to perform this task.
- Manufacturers of sterile materials (e.g. blood bag systems, anticoagulant solutions) should provide a certificate of release for each batch. The blood establishment should define acceptance criteria for such certificates in writing, and should include at least the name of the material, manufacturer, compliance with relevant requirements (e.g. pharmacopoeias or regulations for medical devices) and confirmation that the materials are sterile and pyrogen-free.
- Status of materials (quarantined, released, rejected) should be indicated clearly.
- Materials and reagents should be stored under the conditions established by the manufacturer and in an orderly manner that permits segregation by batch and lot as well as stock rotation.
- Storage and use of materials should follow the _first-expiring first-out‘ principle (i.e. the material that expires first should be used first).
- Inventory records should be retained for a period acceptable to and agreed with the Competent Authority.
- Equipment and material inventory records should be kept as a means to build up a history for a processed component to facilitate recalls.

- Repair and maintenance operations should not present any hazard to the donor, staff or quality of the blood and blood components.
- Equipment should be designed or selected so that it can be thoroughly cleaned (and where necessary decontaminated). This should be performed according to detailed and written procedures. It should be stored only in a clean and dry condition.
- Washing/cleaning solutions and equipment should be chosen and used so that they are not sources of contamination.
- Parts of equipment and materials that come into contact with blood and blood components should not react with, add to or absorb from the blood or blood component to such an extent that they affect the quality of the component and thus present any hazard.
- Balances and measuring equipment of an appropriate range and precision should be available. Equipment for measuring, weighing, recording and control should be calibrated and checked at defined intervals using appropriate methods. Adequate records of such tests should be maintained, including the values obtained prior to any adjustment. Calibration reports should include the accuracy of any testing equipment and traceability to a national or international standard. The report and/or calibration certificate should be reviewed and signed to show acceptance of the document. Any failed calibrations will require mention of non-conformance to allow investigation of the potential impact.
- Defective equipment should be labelled clearly as such and, if possible, removed from preparation areas.
- If computerised systems are used, software, hardware and back-up procedures should be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software should be protected against unauthorised use or unauthorised changes. The back-up procedure should prevent loss of or damage to data at expected and unexpected down-times or function failures

4.3 Qualification and validation

General principles

- Facilities and equipment need to be qualified prior to implementation. Systems, processes and tests should be validated, which involves wider consideration beyond the facilities and equipment used.
- The principles of qualification and validation are applicable to the preparation, distribution and issuance of blood components. It is a requirement of good practice that blood establishments and hospital blood banks control the critical aspects of their operations throughout the life cycle of the blood components and the associated processes. Any planned changes to the facilities, equipment, utilities and processes should be formally documented and the impact on the quality of blood components should be validated.
- A quality risk management approach, consisting of a systematic process for the assessment, control, communication and review of risks to quality across the life cycle of the blood component, should be applied. As part of a quality risk management system, decisions on the scope and extent of qualification and validation should be based on a justified and documented risk assessment of the facilities, equipment, utilities and processes.

- Data supporting qualification and/or validation studies which were obtained from sources outside of the blood establishment own quality system may be used provided were in place throughout the acquisition of such data.
- Qualification and validation activities should only be performed by suitably trained personnel who follow approved procedures and report as defined in the blood establishment quality system. There should be appropriate quality oversight over the whole validation life cycle.
- The key elements of the site qualification and validation programme should be clearly defined and documented in a validation master plan (VMP) or equivalent document.

Documentation

- Good documentation practices are important to support knowledge management throughout the product life cycle. Validation protocols should be prepared which specify how qualification and validation should be performed and which define the critical systems, attributes and parameters and the associated acceptance criteria
  .
- All documents generated during qualification and validation should be approved and authorised by appropriate personnel as defined in the quality system.
- Qualification documents may be combined together, where appropriate, e.g. Design Qualification (DQ), installation qualification (IQ) operational qualification (OQ),
- The review and conclusions of the validation should be reported and the results obtained summarised against the acceptance criteria. Any subsequent changes to acceptance criteria should be scientifically justified and a final recommendation made as to the outcome of the validation.

Requalification:

- Equipment, facilities and systems should be evaluated at an appropriate frequency to confirm that they remain in a state of control. Where requalification is necessary and performed over a specific time period, the period should be justified and the criteria for evaluation defined. Furthermore, the possibility of small changes over time should be assessed.

Process validation

- The requirements and principles outlined in this section are applicable to the preparation, distribution and issuance of blood components. They cover the initial validation of new processes and subsequent validation of modified processes or site transfers for maintaining the validated state (ongoing process verification). It is implicit in this section that a robust product development process is in place to enable successful process validation.
- Processes should be shown to be robust and ensure consistent blood component quality prior to their distribution and routine clinical use. Processes should undergo a prospective validation programme, wherever possible.
- Process validation should establish whether all quality attributes and process parameters, which are considered important for ensuring the validated state and acceptable blood component quality, can be consistently met by the process. A

critical quality attribute (CQA) is a physical, chemical, biological or microbiological property of characteristic that should be within an approved limit, range or distribution to ensure the desired component quality. A critical process parameter (CPP) is a process parameter whose variability has an impact on a CQA and which therefore should be monitored or controlled to ensure the process produces the desired quality. The basis by which process parameters and quality attributes were identified as being critical or non-critical should be clearly documented, taking into account the results of any risk assessment activities.

- A process validation protocol should be prepared which defines the CPPs, CQAs and the associated acceptance criteria, which should be based on development data or documented process knowledge. Ongoing process verification should be conducted under an approved protocol or equivalent documents and a corresponding report should be prepared to document the results obtained. Statistical tools should be used, where appropriate, to support any conclusions with regard to the variability and capability of a given process and to ensure a state of control.
- The following items are essential to maintain a validated state:
  i. calibration and monitoring;
  ii. preventive maintenance;
  iii. training and competency;
  iv. supplier requalification;
  v. periodic review;
  vi. performance monitoring;
  vii. system retirement.
- Maintenance of the validated status of the blood components should be documented in the product quality review. Incremental changes over time should also be considered and the need for any additional actions, e.g. enhanced sampling, should be assessed.
- All analytical test methods used in qualification or validation exercises should be validated with an appropriate detection and quantification limit, where necessary
- Where microbial testing of blood components is carried out, the method should be validated taking into consideration the eventual interference of residues with the analysis (e.g. antibiotics for the recovery of microorganisms).

5. Documentation

5.1. General principles

- Good documentation constitutes an essential part of the quality system and is key to operating in compliance with good practice requirements. Various types of documents and media used should be defined fully in the quality management system of the organisation. There are two primary types of documentation used to manage and record good practice compliance: instructions (directions, requirements) and records/reports.
- Documentation may exist in various forms: paper-based, electronic or photographic. The main objective of the system of documentation used should be to establish, control, monitor and record all activities that directly or indirectly impact on all aspects of the quality and safety of blood and blood components as well as any derived medicinal products.

5.2. Required good practice documentation

- Documents setting out specifications, procedures and records covering each activity undertaken by a blood establishment should be in place and kept up-to-date
- Instructions include:
    - Specifications describe in detail the requirements to which the blood and blood components or materials used or obtained during preparation and distribution should conform.
    - Testing instructions detail all the starting materials, equipment and computerised systems (if any) to be used and specify all sampling and testing instructions. If applied, in-process controls should be specified, together with their acceptance criteria.
    - Procedures (otherwise known as standard operating procedures or SOPs) give directions for performing certain operations.
    - Protocols give instructions for performing certain discreet operations, and may record the outcome (e.g. qualification and validation protocols).
    - Technical agreements are agreed between contract givers and acceptors for outsourced activities.
- Records/reports
    - Records provide evidence of various actions taken to demonstrate compliance with instructions, e.g., activities, events, investigations and, in the case of processed blood and blood components, a history of each unit (including its distribution). Records include the raw data that are used to generate other records. For electronic records, designated users should define which data are to be used as raw data. All data on which quality decisions are based should be defined as _raw data‘.
- Certificates of analysis provide a summary of testing results on samples of reagents, products or materials, together with the evaluation for compliance with a stated specification.
- Reports document the carrying out of particular exercises, projects or investigations, together with results, conclusions and recommendations.
- Components should be labelled in accordance with legal requirements

5.3. Control of documentation

- A document control system, defined in a written procedure, should be established for the review, revision history and archiving of documents, including SOPs. Appropriate controls for electronic documents, such as templates, forms and master documents, should be implemented. Appropriate controls should be in place to ensure the integrity of the record throughout the retention period.
- Documents containing instructions should be approved, signed and dated by appropriate and authorised persons. Documents should have unambiguous content and be uniquely identifiable. The effective date should be defined.
- Documents within the quality management system should be regularly reviewed and kept up to date. All significant changes to documents should be acted upon promptly, and should be reviewed, dated and signed by a person authorised to undertake this task.

- The record system should ensure continuous documentation of the procedures performed from the blood donor to the recipient. That is, each significant step should be recorded in a manner that permits a component or procedure to be traced, in either direction, from the first step to final use/disposal.
- Any alteration made to the entry on a document should be signed and dated; the alteration should permit reading of the original information. Where appropriate, the reason for the alteration should be recorded.

5.4. Retention of documents

- It should be clearly defined which record is related to each activity and where this record is located. Secure controls should be in place to ensure the integrity of the record throughout the retention period. These controls should be validated, if appropriate.
- Records should be retained for a period according to local, national requirements, as appropriate.
- Traceability data (that allow tracing from donor to recipient and vice versa) should be retained according to local, national or regional regulatory requirements, as appropriate.
- Documentation regarding investigations into serious adverse events and serious adverse reactions should be retained for a minimum of 15 years.
- Quality system documentation and associated records should be retained for a minimum of 10 years.
- For other types of documentation, the retention period should be defined for 5 years .
- There should be appropriately authorised and dated specifications for starting and packaging materials, as well as finished blood and blood components.

5.5. Labelling

- At all stages of the preparation, labelling should identify the individual components and their nature clearly. The label on an intermediate component should be done as per Drugs & Cosmetics Act Guidelines

5.6. Others

- Written criteria and procedures for release and rejection should be available.
- Records should be maintained of the distribution of blood components to assure traceability of any unit and to facilitate recall, if necessary.
- There should be written policies, procedures, protocols, reports and the associated records of actions taken or conclusions reached (if appropriate) for the following issues:
- validation and qualification of processes, equipment and systems;
- equipment assembly and calibration;
- maintenance, cleaning and sanitation;
- personnel matters, including signature lists, training in good practice and technical matters, clothing and hygiene, and verification of the effectiveness of training;
- environmental monitoring;
- pest control;
- complaints;

- recalls;
- returns;
- change control;
- investigations of deviations and non-conformances;
- audits of compliance with internal quality/good practice;
- summaries of records, where appropriate (e.g., review of the quality of blood components);
- supplier qualification and audits.
- Records should be kept for major or critical analytical testing, processing equipment and areas where blood components have been processed. They should be used to record in chronological order (as appropriate) any use of the area, equipment/method, calibrations, maintenance, cleaning or repair operations

6.0 Blood Donor Selection and Deferral

Every effort is made to provide Blood and components by the transfusion services to the patients irrespective of replacement donation. For planned / elective surgeries, blood

donation may be made well in advance, at least 72 hours prior to the surgery. The patient‘s relatives should be instructed to donate the required quantity of blood.

6.1 Guidelines for referring the donor to Blood Centre:

- Timing of blood donation: 9.00 AM to 5.00 PM from Monday to Friday and 9.00 AM to 12.30 PM on Saturday. Blood donation is closed on Sundays and Gazetted Holidays.
- On certain days when voluntary blood donation camps are held (Expected collection more than 50 units) most of the staff from the bleeding section will be deputed to camp, hence bleeding at the Blood Centre will be either restricted or closed.
- Only relatives and friends of the patients who voluntarily agree; and voluntary donors will be accepted for blood donation. Paid donation is strictly prohibited and punishable by the law.
- Certain categories of donors called Captive or Coerced donors, such as servants working in a household, subordinates, donors having multiple sex partners, jail inmates, drug abusers or long-term medication (except few) are not safe donors and therefore should be discouraged.
- Before referring the blood donor to the blood Centre, ensure that the donor is in good health, free from chronic ailments, not on medication and in the age group of 18 to 65 years (Ideally 20-50 years). Minimum weight more than 45 Kgs (Ideally-50 Kgs.) Donors will be bled only if found fit after thorough questionnaire, required physical examination with investigations conducted at the blood centre. Details of donor selection criteria can be obtained from the Blood centre.
- Donors can donate blood irrespective of their ABO/Rh groups. Blood group specific compatible blood will be provided to the patients. In some cases, Group specific donations are required particularly in Rh Negatives, Bombay blood group, etc.
- When the donors are sent to the blood centre for donation, they must be given a donation slip containing the name of the patient, hospital number, Unit/Ward/OPD for whom the donation is to be made and the number of units to be collected.

- After blood donation, a blood donation slip will be given indicating the donation number which should be retained, in the patient file. This blood donation number is ―NON-TRANSFERABLE‖.

6.2. Referral of Plateletpheresis donors:

- Single donor apheresis platelets (SDP) are prepared by the use of Cell Separators or apheresis machines.
- While every effort will be made to arrange voluntary donors for plateletpheresis, the primary responsibility, however, for arranging suitable donors rests with the Relatives / Consultant in charge of the case.
- Timing for Apheresis: Donors should be sent before 10.30 AM for evaluation or screening with the special request after informing the Blood center. Apheresis screening or procedure will not be performed routinely on Sundays and Gazetted Holidays. If found fit, then the donor collection will be conducted.
- All efforts are made to provide Blood and components by the transfusion services to the patients irrespective of replacement donation. For planned / elective surgeries, blood donation may be made well in advance, at least 72 hours prior the surgery. The patient‘s relatives should be instructed to donate required quantity of blood.
- In case of adverse donor reactions or problems with kit or equipment, the apheresis procedure may have to be abandoned and components may have to be discarded
- Plateletpheresis Donor Screening
- Plateletpheresis donors should be ABO and Rh matched and they are pre-screened for transfusion transmitted infections before the procedure.
- When donors are referred to the blood center for evaluation, they should bring a request containing the name, hospital number, diagnosis, blood group and platelet count of the patient.
- ABO and Rh matched and TTI screened plateletpheresis donors will be kept reserved for the procedure. Repeat TTI screening is required if the duration between screening and apheresis procedure is more than 7 days.
- Donors apart from being fit for whole blood donation, should not be on aspirin or any Anti-platelet aggregation medication and should have Platelet counts more than 1.5lakh/cumm with normal complete blood count.

6.3 Donor eligibility

- Procedures for safe identification of donors, suitability interview, and eligibility assessment should be implemented and maintained. They should take place immediately before each donation and comply with the legal requirements
- There should be secure and unique identification, as well as recording of the contact details, of donors. Robust mechanisms should link donors to each of their donations.
- Upon arrival at the blood establishment, donors should provide evidence of their identity. All donors should undergo a systematic screening process to assess their suitability.
- Only healthy persons with an acceptable medical history can be accepted as donors of blood or blood components.

- The selection process should include assessment of each donor carried out by a suitably qualified individual who has been trained to use accepted guidelines and who works under the responsibility of a physician. This assessment involves an interview, a questionnaire and further direct questions, if necessary.
- The questionnaire should be designed to elicit information relevant to the medical history, general health and other known or probable risk factors related to the donor. It should be designed to be understandable by the donor and given to all donors each time they attend. On completion, it should be signed by the donor.
- Relevant acceptance/deferral criteria should be in place at the blood establishment to control acceptance and deferral of donors.
- The donor interview should be conducted in such a way as to ensure confidentiality.
- The confidential interview should be conducted by staff specifically trained to ask further direct questions to supplement the information in the questionnaire. The person who carries out the assessment should certify that the relevant questions have been asked.
- Records of suitability and final assessment of donors should be signed by a qualified healthcare professional.
- Records should be kept for each activity associated with the selection of the donor. The record should reflect the decision to accept the donor by taking into consideration the medical history, history of deferral, donor interview and results of the physical examination. Rejection of a donor and the reason for deferral should be recorded. A system should be in place to ensure that the donor is prevented from making future donations during a permanent or temporary deferral period.
- Donors should be instructed to inform the blood establishment about any relevant information that was not previously disclosed or if signs or symptoms occur after a donation. This scenario indicates that the donation may have been infectious or that any other information not disclosed during the health screening may render prior donations unsuitable for transfusion.
- Procedures should be in place to ensure that any abnormal findings arising from the donor selection process are properly reviewed by a qualified healthcare professional and that appropriate action is taken.

7.0 Collection of blood and blood components

- The procedure for blood collection should be designed to ensure that the identity of the donor is verified and recorded securely, and that the link between the donor and blood, blood components and blood samples is established clearly.
- Donor identity should be confirmed before each critical step in the process but, at the very least, before donor selection and immediately prior to venipuncture.
- A system of unique donation numbers should be used to identify each donor and the related donation and all of its associated components, samples and records, as well as to link each one to each of the others.
- During or following the donation, all records, blood bags and laboratory samples should be checked for the issued donation number. Donation number labels that have not been used should be discarded using a controlled procedure.
- Systems of sterile blood bags used for the collection of blood and blood components and their processing should be CE-marked or comply with equivalent standards if the

blood and blood components are collected in another jurisdiction. The batch number of the bag should be traceable for each blood component.

- All handling of materials and reagents, such as receipt and quarantine, sampling, storage, labelling, processing, packaging and transport, should be done in accordance with written procedures or instructions and, if necessary, recorded.
- Only reagents and materials from approved suppliers that meet documented requirements and specifications should be used.
- The arrangement of the blood collection should ensure that blood is collected in a safe environment. Consideration should be given to the arrangement of donor beds and the handling of donations, samples and labels. Blood collection procedures should be designed to minimize errors and avoid any risk of microbial contamination of the donation as well as mix-up of samples.
- Maximum amount of sterility should be maintained while blood collection process. Before venipuncture, a check should be made to ensure that the collection system to be used is not damaged or contaminated, and that it is appropriate for the intended collection. Abnormal moisture or discoloration could suggest a defect.
  - Appropriate procedures for hand disinfection and personal hygiene should be in place, and should be performed by personnel before each donation.
  - The skin at the venipuncture site should be free from lesions, including eczema.
  - The venepuncture site should be prepared using a defined and validated disinfection procedure. The antiseptic solution should be allowed to dry completely before venepuncture. The prepared area should not be touched with fingers before needle insertion.
  - The effectiveness of the disinfection procedure should be monitored and corrective action taken where it is indicated to be defective.
  - The expiry date of the disinfectant should be checked. The date of manufacture and the date of opening of in-house disinfectants should be stated on their labels.
- The blood container should be checked after donation for any defect. The integral blood bag collection tubing should be sealed off at the end as close as possible to the blood bag
- SOPs should be in place describing the actions to be taken following an unsuccessful donation. These should specify how to handle already-labelled material and the circumstances under which a repeat venepuncture might be possible.
- Laboratory samples should be taken at the time of donation and be appropriately stored prior to testing.
- The procedure used for the labelling of records, blood bags, and laboratory samples with donation numbers should be designed to avoid any risk of identification error and mix-up.
- After blood collection, blood bags should be handled in a way that maintains the quality of the blood and at a storage temperature and transport temperature appropriate to the requirements for further processing.
- Blood and blood components should be placed in controlled and validated conditions as soon as possible after venipuncture. Donations and samples should be transported to the processing site in accordance with procedures that ensure a constant approved temperature and secure confinement. There should be validation data to demonstrate that the method of transport maintains the blood within the specified temperature

range throughout the period of transportation. Alternatively, portable temperature loggers may be used to record the temperature during transportation of blood to the processing site.

- If a deviation occurs, it should be approved in writing by a competent person. 1623
- Where the blood is not transported by the processing establishment itself, the responsibilities of the transport company should be clearly defined and periodic audits should be conducted to ensure compliance.
- There should be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

8.0 Laboratory testing

- All blood donations should be tested to ensure that they meet specifications and to ensure a high level of safety for the recipient.
- All laboratory testing procedures should be validated before use.
- In addition to the validation of the test system by the manufacturer, an on-site verification of the test system in the laboratory is required prior to its use in routine testing. This validation should demonstrate that:
    - Performance specifications of the system established by the kit manufacturer are met by the laboratory;
    - Laboratory personnel are thoroughly instructed, trained and competent to operate the test system.
- All donation testing activities, handling of donor specimens, sampling, analysis and data processing should be undertaken independently of diagnostic testing of patients.
- Each step of the handling and processing of samples should be described, as should the conditions of pre-analytical treatment of specimens (e.g., centrifugation), storage and transportation (duration, temperature, type of container, storage after testing).
- Upon receipt of samples at the laboratory, positive identification of the samples received against those expected should be carried out.
- There should be data confirming the suitability of any laboratory reagents used in testing of donor samples and blood-component samples
- Testing of blood components should be carried out in accordance with the recommendations of the manufacturers of reagents and test kits (unless an alternative method has been validated before their use) before release of the blood component.
- There should be a reliable process in place for transcribing, collating and interpreting results.
- The quality of the laboratory testing should be assessed regularly by participation in a formal system of proficiency testing, such as an external quality-assurance programme

9.0. Testing for infectious markers

- Testing of donations for infectious agents is a key factor in ensuring that the risk of disease transmission is minimised and that blood components are suitable for their intended purpose.
- Each donation should be tested in conformity with legal requirements. As a minimum blood donors should be tested at each donation for antibodies to HIV-1/HIV-2, for antibodies to HCV, and for HBsAg.

- Additional testing for other agents or markers may be required, taking into account the epidemiological situation in any given region or country and the individual risk of transmitting infectious diseases, in accordance with national legal requirements, where applicable.
- Serological testing should be performed on samples transferred directly into the analyser from the original sample tube or aliquoted in a fully automated environment. Secondary aliquot samples may be used for nucleic acid amplification technique (NAT) testing of mini-pools of individual samples.
- If NAT testing is performed, a thoroughly validated system of labelling/identification of samples, a validated strategy and a validated algorithm to interpret results to individual donations should be in place.
- There should be clearly defined procedures to resolve discrepant results.
- Where blood and blood components have had a single reactive screening test, the original sample should be retested in duplicate according to the Competent Authority requirements. Blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses HIV-1/-2, HCV or HBV should be excluded from therapeutic use. They should be labelled as reactive and should be stored separately in a dedicated environment or destroyed. Appropriate confirmatory testing should take place. In the case of confirmed positive results, appropriate donor management should take place, including the provision of information to the donor and follow-up procedures.
- Appropriate confirmatory testing should take place. In the case of confirmed positive results, appropriate donor management should take place, including the provision of information to the donor and follow-up procedures.
- Screening algorithms should be defined precisely in writing (i.e., SOPs) to deal with initially reactive specimens, and to resolve discrepancies in results after retesting.

10. Blood group serological testing of donors and donations

- Blood group serology testing should include procedures for testing specific groups of donors (e.g. first-time donors, donors with a history of transfusion).
- Each donation should be tested for ABO and RhD blood groups and at least all first-time donors should be tested for clinically significant irregular red cell antibodies. This should not normally apply to plasma for fractionation.
- ABO and RhD blood groups should be verified on each subsequent donation.
- Comparison should be made with the historically determined blood group. If a discrepancy is found, the applicable blood components should not be released until the discrepancy has unequivocally been resolved.
- Donors with a history of transfusions or pregnancy since their last donation should be tested for clinically significant irregular red cell antibodies. If clinically significant red cell antibodies are detected, if applicable, the blood or blood component should be labelled accordingly.
- Only test reagents that have been licensed or evaluated and considered to be suitable by a responsible national authority/competent authority should be used.
- Quality control procedures should be implemented for the equipment, reagents and techniques used for ABO and RhD blood grouping and other blood group antigen

typing as well as detection and identification of alloantibodies. The frequency of the control is dependent on the method used.

11. Component Processing and validation

- All equipment and technical devices should be used in accordance with validated procedures.
- The processing of blood components should be carried out using appropriate and validated procedures, including measures to avoid the risk of contamination and microbial growth in the prepared blood components. Depending on the type of processing and based on a risk assessment, the microbial contamination load on critical equipment, surfaces and the environment of the preparation areas should be monitored.
- The use of closed systems is strongly recommended for all steps in component processing. Open systems may exceptionally be necessary due to local constraints and should be used in an environment specifically designed to minimise the risk of bacterial contamination. When open systems are used, careful attention should be given to the use of aseptic procedures and the premises used should preferably be a grade A environment with a grade B background. A less stringent background may be acceptable if combined with additional safety measures such as preparing the blood component just in time for transfusion as predefined in the specifications, or immediately after preparation applying storage conditions which are unfavourable to microbial growth.
- Validation of freezing processes should consider worst-case scenarios that take into account minimum and maximum loads and positions in the freezer.
- Sterile connecting devices should be used in accordance with a validated procedure. When validated, connections made using sterile connecting devices are regarded as closed-system processing. The resulting weld should be checked for satisfactory alignment and its integrity should be confirmed.

12. Labelling

- At all stages, all containers should be labelled with relevant information on their identity. Labelling should clearly distinguish released from non-released units of blood and blood components.
- The type of label to be used, as well as the labelling methodology, should be defined and established in written SOPs.
- Labels applied to containers, equipment or premises should be clear, unambiguous and in the agreed format of the blood establishment.
- Labelling system for collected blood, intermediate and finished blood components, and samples should unmistakably identify the type of content, and comply with the labelling and traceability legal requirements.
- The label for a finished blood component should comply with the local, national or regional regulatory requirements and contain at least the following information:
    - Unique donation number; there should be traceability through the use of this number to the donor and all records of the processing steps to the final product
    - Product name;

  - Required storage conditions;
  - Expiry date and, where appropriate, time;
  - Date of collection of the donation(s) from which the blood component was prepared and/or the production date and time (where appropriate);
  - ABO and RhD blood group (where appropriate); and
  - Name or other identification of the component preparation site

- Blood Centre shall provide clinical users of blood components with information on their use, composition, and any special conditions that do not appear on the component label.
- For autologous blood and blood components, the label should also comply with additional requirements for autologous donations and should contain also the name and unique identification of the patient as well as the statement ―Autologous Donation‖.

13. Release of blood and blood components

- There should be a safe and secure system to prevent any single blood sample and blood component from being released before all mandatory requirements have been fulfilled. Each blood establishment should be able to demonstrate that each blood or blood component has been formally approved for release by an authorised person. Records should demonstrate that before a blood component has been released, all current declaration forms, relevant medical records, and test results have met all acceptance criteria. If a computerised system is used to release results from the laboratory, an audit trail should indicate who was responsible for their release.
- There should be SOPs that detail the actions and criteria that determine whether the blood or blood component can be released. The release criteria and specifications of blood components should be defined, validated, documented and approved.
- There should be a defined procedure for exceptional release of non-standard blood and blood components under a planned non-conformance system. The decision to allow such release should be documented clearly and traceability should be ensured.
- Before release, blood and blood components should be kept administratively and physically segregated from released blood and blood components. In the absence of a validated computerised system for status control, the label of a unit of blood or blood component should identify the release status.
- There should be a system of administrative and physical quarantine for blood and blood components to ensure that components cannot be released until all mandatory requirements have been met.
- In the event that the final blood component fails to be released due to a confirmed positive test result for infection for an agent, a check should be made to ensure that other components from the same donation and components prepared from previous donations given by the donor have been identified. An immediate update should be made to the donor record.
- In the event that a final component fails release due to a potential impact on patient safety, the donor record should be immediately updated to ensure, where appropriate, that the donor(s) cannot make a further donation.

14. Storage and distribution

- The Quality System of the blood establishment should ensure that, for blood and blood components intended for the manufacture of medicinal products, the requirements for storage and distribution should comply with legal requirements.
- Procedures for storage and distribution should be validated to ensure the quality of blood and blood components during the entire storage period, and to exclude mix-up of blood components. All transportation and storage actions, including receipt of distribution, should be defined by written procedures and specifications.
- Storage conditions should be controlled, monitored and checked. Appropriate alarms should be present and checked regularly; all checks should be recorded. Appropriate actions on alarms should be defined.
- There should be a system to ensure stock rotation involving regular and frequent checks that the system is operating correctly. Blood and blood components beyond their expiry date or shelf-life should be separated from usable stock.
- Before distribution, blood components should be visually inspected.
- Autologous blood and blood components, as well as blood components collected and prepared for specific purposes, should be stored separately.
- Appropriate records of inventory and distribution should be kept.
- Records should be kept of the distribution of blood components between blood establishments, between blood establishments and hospital blood banks and between hospital blood banks. These records should show the date of supply, unique component identifier and name of the blood component, the quantity received or supplied and the name and address of the supplier or consignee.
- Packaging should maintain the integrity and storage temperature of blood and blood components during distribution and transportation.
- Verification of transportation
    - Blood components should be transported in accordance with the defined conditions.
    - It is recognised that verification of transportation may be challenging due to the variable factors involved; however, the different modes of transportation should be clearly defined. Seasonal and other variations should also be considered during verification of transport.
    - Due to the variable conditions expected during transportation, continuous monitoring and recording of any critical environmental conditions to which the blood component may be subjected should be performed, unless otherwise justified.
- Return of blood and blood components into inventories for subsequent reissue should be allowed only if all requirements and procedures relating to quality as laid down by the blood establishment to ensure the integrity of blood components are fulfilled.

15. Blood requisition process (Patient side)

15.1 All blood requisition must have the following information, without which requisition will not be accepted.

a. Name of the patient & Father‘s or Husband‘s Name
b. Hospital Number
c. Location of patient (ward/ bed/OPD unit)
d. Gender
e. Age
f. Haemoglobin, other hematological parameters as required for different blood components.
g. Name of the Consultant & Signature of Resident in charge with date
h. Mobile number of Resident and intercom number of ward. (IMPORTANT)
i. In case of previous transfusions, feedback form with Blood group & Rh type is mandatory.
j. Check the appropriate box to indicate what type of component and number of units to be cross-matched.
k. MSBOS given below may be referred for the number of blood units required.
l. Provide relevant clinical details, such as diagnosis, indication for transfusion, past history of transfusion or reactions, any medications, history of hemolytic disease etc.
m. Check the appropriate box to indicate the priority of the transfusion requirement.
    a. ROUTINE: Blood or component is not required for at least 8 hrs. from the time the requisition is received. In this type, every unit of blood is cross-matched with Coomb‘s test etc. by standard techniques.
    b. URGENT: Blood or component is not required for at least 1 hour from the time requisition is received. In this type, only Immediate Spin cross match is done which does not rule out irregular warm antibodies.
    c. IMMEDIATE: Blood is required in less than 30 minutes from the time sample is received. In this type, no cross matching is performed, only ABO and Rh matched blood is provided. Therefore, this option should be used with utmost care, as the ordering physician will be responsible for the adverse effects. This option is rarely required.
n. The person who draws the sample must affix his/her signature in the label on the sample. Initials are not acceptable. The person signing is attesting that the sample has been drawn from the patient by him / her.
o. Although, every blood sample is potentially infectious, special precautions are taken for HIV, HBsAg, or HCV positive samples. Please indicate in bold letters or use the sticker ―BIO-HAZARD‖ on the top of the requisition form and sample so that person handling the specimen can take additional precautions.

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Guwahati

Department of Transfusion Medicine

Whole Blood/ Blood Component Request Form

Name of the patient (In Capital letters): .....

Age: ..... Body weight: .....(kg) Sex: M( ) F( )

Registration No: ..... Ward: ..... Bed No: .....

Date of Requisition: ___/__/__ Date of Requirement:___/__/__

Clinical Diagnosis: .....

Indication for Transfusion: .....

Blood Group (if known): .....

Hb: ..... Platelet Count: ..... PT/INR: ..... Others.....

History of blood transfusion: Yes( ) No( ) If yes, date of last transfusion: ___/___/__

History of adverse transfusion reaction: Yes( ) No( ) Not known( ) If yes, : __/__/__

History of pregnancy: Yes( ) No( ) Not applicable ( )

Blood component required:

Type	Whole Blood	PRBC	RDP/SDP	FFP	Cryoprecipitate
No. of units (Adult) Paediatric (in mL)					

Modification of blood component if required: Irradiation ☐ Leukoreduction ☐ Washed ☐

Degree of Urgency: Emergency (without crossmatch)* ( ) Urgent** ( ) Routine***( )

[Kindly, Give the consent for uncrossmatched/ immediate spin crossmatched blood unit]

Have you taken blood transfusion consent from the patient: Yes ( ) No ( )

Blood sample Taken by: Name_____ Sign: _____

Date And Time : __/__/__ , ...[AM/PM]

Name and Signature of the Faculty

Contact No of Ward.....

Name and Signature of the SR/JR

NMC Registration No: .....

Contact No:.....

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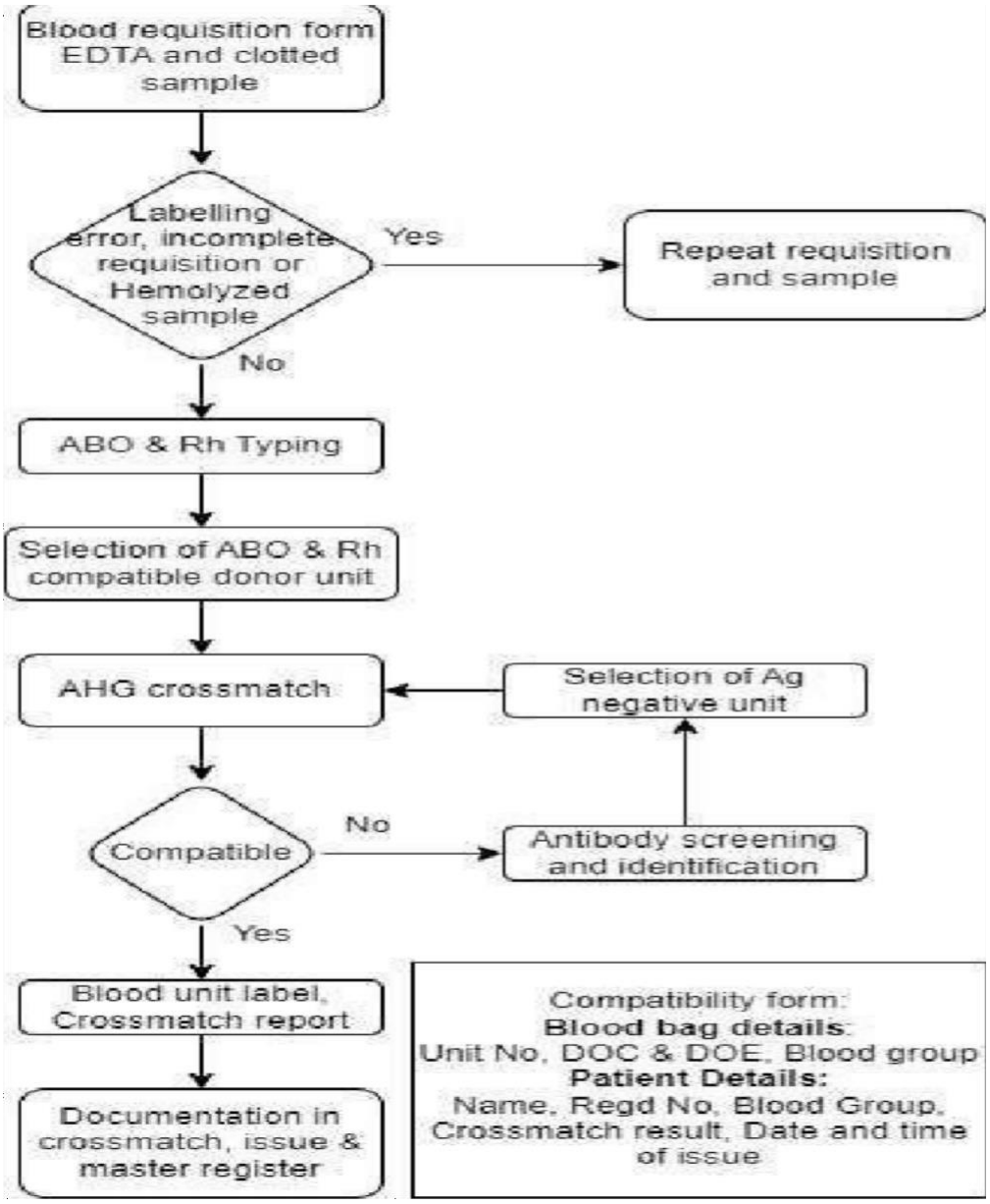


15.2. Requisition for Fresh Frozen Plasma

- Only ABO group specific Fresh frozen plasma is issued.
- There is no need for a cross match.
- The blood center must have a record of the blood group of the patient on HIS. If the record is not available as in case of fresh admission, a specimen for ABO grouping must be sent along with the requisition.
- The components are issued in 1 hour or less after the receiving requisition.
- FFP thawed for more than 4 hrs. is deficient in labile coagulation factors. Therefore, this product should not be asked in advance and stored in a refrigerator in the ward.
- Never refreeze FFP

15.3. Requisition for cryoprecipitate

- Cryoprecipitate is issued irrespective of ABO & Rh of the recipient
- Rest all procedures and storage are similar to FFP

15.4. Requisition for Platelet Concentrate

- The blood centre must have a record of the ABO group before platelets can be issued.
- ABO and Rh-matched Platelets are issued as far as possible subject to availability. There is no need for a blood specimen, provided the record of the group is already done and available on the record.
- Platelets are not always available in stock and therefore additional time may be required for preparation, TTI screening etc.
- Since platelets need to be kept on an agitator and wards do not have proper storage for platelets they should not be ordered in advance. Send the requisition 30 minutes before the transfusion is planned.
- Never keep platelets in Refrigerator

15.5. Requisition of blood and components in special circumstances

1. Non-Group Specific transfusion:

While every effort is made to crossmatch ABO group-specific blood to the patient, non-ABO group-specific blood or components may be issued in cases of emergency due to blood shortages. Contact the blood centre in case any clarification is needed. Compatible blood groups in case of non-ABO group specific transfusion

Patient Group		**Permissible donor groups for FFP**
O		O, A, B AB
A		A, AB
B	B, O	B, AB
AB		AB
Rh-positive	Rh positive, Rh negative	
Rh-negative	Rh-negative	Rh positive/Rh negative

2. Issue of Rh-positive blood to Rh-negative patients and vice versa

Rh-positive blood can therefore be given to Rh-negative patients in life-saving emergencies only certified by the treating physician in consultation with the officer in charge of the Blood Centre. Rh-negative blood can be given to Rh positive patients without much reservation.

16. Receiving samples for blood and components:

1. Sample for cross match (for red cell transfusion only)

2ml EDTA & 5 ml clotted blood sample is required for cross-match of a unit of red cells in adults. Additional sample is required at 1 ml / additional unit. (e. g. for crossmatch of 6 units of blood 10 ml of sample is required. Justification for samples is:

- Forward grouping will be done with EDTA & Reverse grouping and cross matching with plain samples. It may decrease chances of wrong blood in tube incidents.
- We have to keep pretransfusion samples for 7 days for any transfusion reaction workup, for which we have to do DCT both on pre-transfusion and post-transfusion samples.

2. Sample for blood group only

- 2 ml EDTA blood sample is required for ABO grouping and Rh typing.
- The sample must be received in the blood centre by 12 noon one day before to ensure availability of blood for routine transfusions.
- For urgent transfusions, samples must reach the Blood centre at least 2 hours before transfusion.
- In case of immediate transfusion of uncross matched blood, the sample must reach the Blood centre 30 min before transfusion.

3. Sample for FFP, CRYO or PLATELET transfusion

- For fresh / first time transfusions, 2 ml EDTA and 3 ml Clotted sample will be required to determine the blood group.
- For repeat transfusions of these components, there is no need for any blood sample, provided the blood centre has a record of the blood group of the patient or the same may be recorded at ward mentioning previous issue number with date.

16.4. Sample for transfusion in neonates

- Serum of the newborn will have ABO antibodies of mother‘s origin passively transferred across the placenta. Therefore, cross matching will be performed using the mother's sample for neonates till the age of 6 months and blood compatible with both neonates and mother will be issued. 5 ml of clotted sample from mother and 2 ml EDTA sample from the new born will be required
- Information required on the mother‘s sample.
    - Name of the patient & Father‘s or husband‘s Name. It should match with the name on the requisition form.
    - Hospital number of the patient matching with that on the requisition form.
    - Name of the test to be performed (Grouping, cross matching)
    - Signature of the resident.
    - Date of collection of samples.
- Samples from newborn should be labeled as ―Baby of mother‘s name with husband‘s name‖ and should be labeled with mother‘s identification, in case sheet is not made for the baby. All labelling should be done at one place.

16.5.Labeling errors

- Labeling errors are potentially life threatening and may result in transfusion of incompatible blood/components.
- Significant labeling errors include the following:
  - Overwriting
  - Correction not authenticated by signature.
  - Wrong or no Hospital No on specimen or requisition
  - Specimens drawn from the wrong patient, this can be avoided by withdrawing the sample into a pre-labeled tube at the bedside, one sample at a time.
  - Name and/or Hospital number on the specimen not matching with name and / or Hospital number on requisition.

Note: The specimen and requisition will be discarded by the blood centre if these types of labeling errors are found. The Resident and/or Nurse will be informed that a new specimen is required.

- Minor labeling errors include the following:
  - Small spelling errors in name
  - No signature of the resident on the requisition.

In such cases, information will be conveyed by phone and unless the concerned resident corrects the error, the specimen and requisition will be rejected and a fresh sample will be required.

17.0. Issue of Blood and Components

1. In case of routine cross matches, if ICT of the patient is negative, blood units will be issued on demand after doing immediate spin technique at Room temperature.
2. In case Blood units are not lifted, they will be stored in the blood centre refrigerator after cross match.
3. At present matched blood is collected from the Blood centre by interns/resident doctors. Relatives or friends of the patients will not be allowed to collect blood units from the blood centre.
4. Interns are required to bring proper details such as Patient name, Hospital number, indication, diagnosis and type of blood components to be taken.
5. The blood centre personnel will enter the details of the blood units, including time and date of issue. The intern/resident doctor will have to confirm details of blood units in the issue register, compatibility form, cross match label and sign in the register and
6. write the name in capital letters before leaving. The intern will have to cross check compatibility and certify, if necessary.
7. Return of unused blood
   1. If the blood is not to be used for any reasons, return it to the blood centre immediately within 30 minutes.
   2. Compatibility forms need to be sent to the Blood bank along with unused blood.
   3. The red cells units will not be accepted if one of the ports is opened. The blood bag should have the labels attached to it which will help to proper identification of units.

8. Blood units should not be stored in the refrigerator in the ward. These refrigerators are not specifically designated, monitored, tested and controlled, as are blood bank fridges. Blood should be collected only 30 minutes in advance before planned transfusion

18. Administration of blood and components

- Check the blood or components before starting the transfusion by two different personnel.
- Consent form must be completely filled up and signed by both the patient/ patients' attendant, and the treating physician.
- The following must be checked:
  - Verify that you have received the required blood or component ordered.
  - Match ABO and Rh group of the patient with the ABO & Rh group of the blood product label. If there is discrepancy, do not start transfusion. Report to the blood centre and Residents in the ward immediately.
  - Check expiration date, unit number and component label.
  - Check the integrity of the unit by applying light pressure to the unit and examine for any leaks.
  - Check the bag for the presence of clots.
  - Compare the blood bag number with the number listed on compatibility report
  - Carefully observe the appearance of the unit.
- Identification of the Patient: This is a very important step before starting the transfusion, as misidentification of the patient is the most common cause of mismatched transfusion and may prove fatal to the patient
  - Compare the patient's name, Hospital number and blood group on the blood bag with the patient's name and Hospital number and blood group on the patient file.
  - If the patient is conscious, confirm the name by having him/her state the name and compare it with the name on the compatibility report.
  - Before starting the transfusion, record the time, temperature of the patient, pulse rate and BP on the patient file. This will be helpful to monitor any changes in the vitals during transfusion.
  - The red cells should not be kept outside if transfusion is delayed. They should be stored at 2 to 4 C (preferably in the blood bank refrigerator, not in the domestic refrigerator/ freezer compartment).

18.1 Administration of red blood cell components:

- Ensure the IV line is patent and Gauge of the needle is adequate to transfuse the blood component. Use a standard blood transfusion set with a filter.
- Examine the red cell bag for clots, abnormal dark purple blue color. Red cells will usually be dark red in color. If anything seems abnormal, check with the blood centre.
- Invert the bag several times to ensure re-suspension of red cells. Follow the administration instructions on the blood bag label.
- Concurrent fluids along with red cell transfusion:
  - Avoid additions of any type of fluid or drug into the blood bag.
  - Only compatible IV solution compatible with blood is isotonic (0.9%) saline and may be used along with red cell transfusion.
  - Do not mix any medication along with the red cell unit. Some drugs can cause hemolysis due to their high pH. 5% dextrose can cause agglutination of red blood

cells. Ringer lactate solution can result in clotting because of its calcium content. If medication were added to the blood component it would be difficult to investigate the cause of the transfusion reaction if there is any.

- Do not mix blood components together, e.g. red cells and platelets before transfusion.

- Start the transfusion slowly for the first 15 minutes and observe the patient. If the clinical status is OK, the remaining unit can be transfused as per the indication. However, check the patient frequently for any significant change in the vitals. Record all vital signs on the case file and compatibility form.
- Change the transfusion set after 4 units of blood.
- Red Cell transfusion should be completed within 4 hours of starting. Beyond 4 hours, there is a risk of bacterial contamination.
- If the transfusion is uneventful, paste one copy of the compatibility form in the case file and return the duly filled ***no reaction form*** to the blood centre.
- If there is any adverse reaction to the transfusions, action to be initiated as per the ―Transfusion reaction management‖ protocol.
- If the blood product is not to be used for any reason, do not store it in the refrigerator in the ward as these refrigerators are not designated for blood storage. Return unused blood bags to the blood centre immediately.
- Discard the empty blood component bag in the Biohazard Waste Container in the Ward, unless the patient has suffered an adverse reaction in that case the bag has to be returned to the blood centre along with the completely filled reaction form and two post-transfusion samples for investigation.

18.2 Administration of Plasma & Cryoprecipitate:

- Follow the general guidelines of identification and inspection of blood components as mentioned in red cell administration.
- Thawed FFP will be clear with yellow straw color. Cryoprecipitate will usually be cloudy.
- Get FFP thawed in the blood centre. Thawing of plasma components:
- Thawing of FFP and Cryo is done at 37° C in a water bath.
- Place the unit in a plastic over wrap so that water in the bath will not contaminate the component.
- The ports of the component bag should not come in contact with the water.
- Squeeze the component intermittently to ensure rapid thawing.
- Generally, thawing of FFP takes 10 to 15 minutes.
- Standard blood administration set is satisfactory for transfusion of plasma components.
- Once thawed, plasma components should not be frozen. They can be kept at 4° C for not more than 24 hrs.

18.3 Cryoprecipitate:

- Cryo can be administered using a 50 ml syringe. After thawing, aspirate all Cryo in a syringe with a needle. A significant amount of Cryo will remain attached to the walls of the plastic containers. Injecting 25 ml of isotonic saline in the bag and rinsing it

thoroughly can rectify this.

- Follow the rest of the procedure as mentioned in Red Cell administration.
- Thawed cryoprecipitate should be stored at 4° C and used within 4 hours.

18.4 Administration of Platelet Products

- General guidelines for patient identification and component inspection are the same as red cell administration.
- A blood administration set issued by the blood centre should be used for platelet transfusion. After platelets are transfused, it is preferred to rinse entrapped platelets from the filter by flowing 50 ml of isotonic saline through it. Platelet concentrates should not be transfused through the set used for transfusing other blood components.
- Transfusion of one random unit of platelets should be completed in 20 minutes due to the risk of bacterial contamination.
- Since platelets need to be stored on agitators, request and collect platelets from the blood centre just before transfusion.
- Rest of the procedure is the same as for red cell administration.

18.5 Use of Filters for the administration of blood and components:

- Routine blood transfusion sets have a filter with a 170µ pore size.
- Micro-aggregate filters: Micro-aggregate filters have a pore size of 40 microns. They allow rapid transfusion of blood and components and at the same time prevent micro-aggregate
- from entering the circulation. They are used in cardiopulmonary bypass surgery.

Leukocyte filters:

Leukocyte filters are used to prevent febrile transfusion reactions and CMV transmission. They are especially useful in multiple transfused patients. There are two types of Leukofilter (Bedside and lab side).

Two units of red cells can be transfused using a single filter. The proper selection of the leukocyte filter should be made, depending on the type of component to be transfused.

18.6 Warming of blood Products:

- Generally, there is no need to warm the unit of red cells before transfusion. Keeping the blood unit at room temperature for 30 minutes will be enough in most cases (the time taken for crossmatching and transportation to the ward). Immediately after issue, the blood unit should be transfused without any waiting period.
- In special circumstances, such as patients with cold agglutinins in the serum, it is important to pre-warm the unit at 37° C before transfusion.
- Special blood warmers may be used for this purpose. Blood should not be warmed in the

Dry Incubator in the laboratory. It is important to keep the patient warm during transfusion.

- Always check for the presence of hemolysis while using a blood warmer

There is no need to warm blood before transfusion except in massive transfusion. (Infusion rate @ 15 ml/Kg body weight/hour in children or @ 50 ml/Kg body weight/hour in adults.)

Blood Component	Storage temperature	Storage period (Life span)	Infusion rate
Packed red cell	2-4^{0}C	42 days	1-2ml/min* 15min Then as much as tolerated
Fresh Frozen plasma	-40^{0}C/ -80^{0}C	1 year	2-5ml/min* 15min Then as much as tolerated
Platelet conc. (RDP/SDP)	20-24^{0}C	5 days	2-5ml/min* 15min Then as much as tolerated
Cryoprecipitate	-40^{0}C/ -80^{0}C	1 year	As rapidly as tolerated
Whole Blood	2-4^{0}C	35 days	1-2ml/min* 15min Then as much as tolerated
Cryoprecipitate	-400C/ -800C	1 year	As rapidly as tolerated
Whole Blood	2-40C	35 days	1-2ml/min* 15min

19. Neonatal and Childhood Transfusions

Pre-transfusion testing for neonates and infants within the first four postnatal months

- Samples from both mother and infant should be obtained for ABO and Rh D typing.
- Investigations on the maternal sample:
    - ABO and Rh D group
    - Screen for the presence of atypical red cell antibodies.
- Investigations on the infant sample:
    - ABO and Rh D: ABO by cell group only (a reverse group would detect passive maternal antibodies).
    - Direct antiglobulin test (DAT)
- In the absence of maternal serum, screen the infant‘s serum for atypical antibodies by an indirect antiglobulin technique (IAT).
- A positive DAT on the neonate‘s red cells or an atypical red cell antibody in maternal or neonatal serum suggests possible hemolytic disease of the newborn (HDN).
- For PRBC Transfusion, unit should be selected such that-

- Adequate hematocrit
- Compatible with baby and mother (Crossmatch with both)
- Rh-Negative mother: Rh Negative unit is selected
- CPDA blood is preferred over SAGM
- 5-7 Days old blood unit
- Leukofiltered
- Irradiated (Must in Intrauterine transfusion)
- CMV negative
- Sickle cell negative

- Single donor apheresis platelets manufactured to neonatal specifications are used.

They should be CMV-negative and ABO RhD identical or compatible with the recipient. A typical dose is 10–20 mL/kg

20. Adverse Transfusion Reaction

Any change in vitals or new-onset signs and symptoms during or after the completion of transfusion should be considered as a transfusion reaction until otherwise proved. Different causes of ATR are as follows:

ACUTE (IMMEDIATE)	DELAYED
IMMUNE TRANSFUSION REACTION	
Acute hemolytic transfusion reaction (AHTR) Febrile nonhemolytic transfusion reaction (FNHTR) Allergic reaction (urticaria/ Anaphylaxis) Transfusion related acute lung injury (TRALI)	Delayed hemolytic transfusion reaction (DHTR) Alloimmunization Post transfusion purpura (PTP) Transfusion associated graft vs host disease (TA-GVHD)
NONIMMUNE TRANSFUSION REACTION	
Transfusion associated circulatory overload (TACO) Nonimmune hemolysis (Physical/chemical) Sepsis (Bacterial contamination)	Iron overload Air embolism

Acute hemolytic transfusion reaction (AHTR) is defined as immune-mediated hemolysis occurring within 24 hours of incompatible blood transfusion.

- Most commonly ABO incompatible; it can also be caused by non-ABO antigens, such as Kell, Kidd, and Duffy, due to- wrong patient sample (Wrong blood in tube) or wrong unit transfused at the bedside to a patient or transfusion of incompatible RBCs (could be ABO incompatible to patient antibodies)
- Approach to AHTR
    a. Stop the transfusion
    b. Maintain IV access

c. Provide good supportive care
d. Contact the transfusion service immediately
e. Return implicated blood bag, tags and attached administration set to blood centre
f. Check for clerical error (i.e. patient identity and the patient identity on RBC unit)
g. Centrifuge post reaction blood sample and examine serum / plasma for hemolysis; if noted, compare with pre-reaction specimen
h. Perform DAT; if positive, compare with pre-reaction specimen DAT
i. Repeat ABO type of the donor unit, pre- and post-transfusion patient sample
j. Repeat antibody screen on the pre- and post-transfusion sample
k. Repeat crossmatch with the pre- and post-transfusion sample
l. If there is evidence of a hemolytic transfusion reaction, additional testing should be performed as needed:
m. Laboratory studies for hemoglobinemia and hemoglobinuria (the free hemoglobin causes both plasma and urine to appear red), decreased serum haptoglobin (very sensitive marker of hemolysis) and increased lactate dehydrogenase
n. Perform coagulation tests for DIC: PT, APTT, fibrinogen, platelet count

o. Maintain good urine output (> 1ml/kg per hour), can use diuretics (furosemide)
p. Treat shock and support cardiac and respiratory function
q. Administer low dose dopamine for hypotension (1 - 5 µg/kg per min)
r. Manage DIC and hemorrhage as clinically indicated

- Preventive measures
  a. Strictly adhere to the protocol to prevent mislabeled and miscollected samples
  b. Bedside sample collection, ask the name before drawing sample, label it there itself
  c. Dual sample policy (Blood grouping at admission, pretransfusion testing sample)
  d. Always perform bedside check before administering blood products
  e. Two persons to check the details of blood unit and patient
  f. Other innovations include barcoding of blood components and patient ID
  g. Educate physicians and nurses regarding transfusion practice

DHTR

- DHTR is defined as Hb either remaining the same or declining after 24 hours of transfusion. The implicated antigens are usually minor antigens like Rh, Kell, Duffy, Kidd, MNS. There are two types of DHTR:
  a. Primary alloimmunization resulting from the incompatibility of Rh, Kell, Duffy, Kidd, and other systems due to blood transfusion, tissue transplantation or pregnancy (First exposure). It mostly presents with mild fever, fall in Hb without jaundice.
  b. Secondary Response is caused by an anamnestic response of the immune system to a foreign red blood cell antigen from previous exposure by pregnancy or previous transfusions. It commonly presents with a fall in Hb, a rise in bilirubin, usually 5-7 days after the transfusion. Very rarely the patient may present with renal failure.Hemolysis is mostly extravascular and less clinically dramatic compared to the acute hemolytic reaction.
- Lab evaluation:
  a. Repeat Blood grouping, Crossmatching
  b. DAT: Positive, might be negative
  c. Antibody screening/ Identification: Positive
  d. For confirmation of hemolysis:
  e. CBC: Fall in Hb, Reticulocytosis, peripheral smear: Anisopokilocytosis,

Polychromatophils with nucleated RBC
f. LDH: Rise
g. LFT: Increase bilirubin
h. Treatment:

- Supportive care
  a. Ag negative blood unit is selected as per the alloantibody identified.
  b. Antibody screening prior to every transfusion.
  c. A transfusion alert card should be issued to the patient.

FNHTR

- A febrile reaction during or following transfusion and where a hemolytic reaction is ruled out.
- FNHTR is most commonly seen with transfusion of red cell components.
- Management
  a. Diagnosing a febrile nonhemolytic transfusion reaction (FNHTR) involves excluding all other options that may present with fever.
  b. If this type of reaction is suspected, the transfusion should be stopped.
  c. A transfusion reaction work-up should be initiated.
  d. If the initial testing is negative, a culture may be ordered to rule out a bacterially-contaminated blood component.
  e. Antibodies involved with these reactions are not routinely identified because of the difficulty in demonstrating their presence in vitro.
  f. Antipyretics, such as acetaminophen, should be administered to the patient and the transfusion can continue once the symptoms subside.
  g. Provision of the leukoreduced blood component in the future transfusion.

TRALI and TACO

- Transfusion-associated cardiac overload (TACO) is due to fluid overload occurring within one to two hours of transfusion.
- Transfusion-related acute lung injury (TRALI) is an acute transfusion reaction that occurs within six hours of transfusion of plasma containing blood components due to the presence of antibodies against HNA or biologic response modifiers (BRM) in donor plasma or patient‘s plasma (reverse TRALI) and it can be life-threatening.

- The clinical definitions of TACO may include evidence of positive fluid balance or cardiogenic involvement, which may manifest as left heart failure, elevated blood pressure, or tachycardia.
- Unfortunately, for both TACO and TRALI, only supportive measures are available, and specific therapies are lacking. Supportive measures for TACO may include diuresis, oxygen, and intubation.
- For TRALI, supportive measures may include oxygen, intubation, and judicious fluid and pressure management to maintain hemodynamics.
- Preventive strategies for TRALI (TRALI mitigation) include
  a. Donor deferral based on antibody screening (anti-HNA and anti-HLA antibodies),
  b. Donor deferral based on the history of pregnancy or history of transfusion
  c. Deferral of all female donors (use of male-only plasma donors).

Transfusion-Associated Graft vs. Host Disease (TAGVHD)

The introduction of immunocompetent lymphocytes into susceptible hosts. The allogeneic lymphocytes engraft, proliferate, and destroy host cells. If performed, marrow study shows hypoplasia, aplastic anemia, or marked hypocellularity with a lymphohistiocytic infiltrate.

Definitive: A clinical syndrome occurring from 2 days to 6 weeks after cessation of transfusion characterized by:

- Characteristic rash: erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and hemorrhagic bullous formation.
- Diarrhea
- Fever
- Hepatomegaly
- Liver dysfunction (i.e., elevated ALT, AST, Alkaline phosphatase, and bilirubin)
- Marrow aplasia
- Pancytopenia

and

Characteristic histological appearance of skin or liver biopsy.

Probable: Meets definitive criteria

EXCEPT

Biopsy negative or not done.

Possible: N/A

Post Transfusion Purpura

Thrombocytopenia usually arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.

Definitive: Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia

and

Thrombocytopenia (i.e., decrease in platelets to less than 20% of pre-transfusion count).

Probable: Alloantibodies in the patient directed against HPA or other platelet specific antigen detected at or after development of thrombocytopenia.

and

Decrease in platelets to levels between 20% and 80% of pre-transfusion count.

Possible: PTP is suspected, but laboratory findings and/or information are not sufficient to meet defined criteria above. For example, the patient has a drop in platelet count to less than 80% of pre-transfusion count but HPA antibodies were not tested or were negative. Other, more specific adverse reaction definitions do not apply.

Unknown

Use this category if the patient experienced transfusion-related symptoms, but the medical event that caused those symptoms could not be classified.

Transfusion-Related Acute Lung Injury (TRALI)

Acute hypoxemia with PaO2/fraction of inspired oxygen [FIO2] ratio of 300 mmHg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion.

Definitive: NO evidence of acute lung injury (ALI) prior to transfusion

and

ALI onset during or within 6 hours of cessation of transfusion

and

Hypoxemia defined by any of these methods:

- PaO2/FIO2 less than or equal to 300 mmHg
- Oxygen saturation less than 90% on room air
- Other clinical evidence

and

Radiographic evidence of bilateral infiltrates

and

No evidence of left atrial hypertension (i.e., circulatory overload)

Probable: N/A

Possible: N/A

Transfusion-Associated Circulatory Overload (TACO)

Infusion volume that cannot be effectively processed by the recipient either due to high rate and/or volume of infusion or an underlying cardiac or pulmonary pathology.

Definitive: New onset or exacerbation of 3 or more of the following within **12 hours** of cessation of transfusion:

(At least 1 of the following from A & B:)

A. Evidence of acute or worsening respiratory distress (dyspnea, tachypnoea, cyanosis and decreased oxygen saturation values in the absence of other specific causes) **and/or**

B. Radiographic or clinical evidence of acute or worsening pulmonary edema (crackles on lung auscultation, orthopnea, cough, a third heart sound and pinkish frothy sputum in severe cases); **or both**

and

- Elevated brain natriuretic peptide (BNP) or NT-pro BNP relevant biomarker
- Evidence of cardiovascular system changes not explained by underlying medical condition (Elevated central venous pressure, evidence of left heart failure including development of tachycardia, hypertension, widened pulse pressure, jugular venous distension, enlarged cardiac silhouette and/or peripheral edema)
- Evidence of fluid overload

Probable: N/A

Possible: N/A

Transfusion-Transmitted Infection (TTI)

A bacteria, parasite, virus, or other potential pathogen transmitted in donated blood to transfusion recipient.

Definitive: Laboratory evidence of a pathogen in the transfusion recipient.

Probable: N/A

Possible: Temporarily associated unexplained clinical illness consistent with infection, but no pathogen is detected in the recipient. Other, more specific adverse reactions are ruled out.

Note: Possible cases cannot meet the definite or probable imputability criteria.

Association for the Advancement of Blood & Biotherapies

Quick Reference Guide

NHSN Hemovigilance Module: Adverse Reaction Definitions

Allergic Reaction

The result of an interaction of an allergen with preformed antibodies. In some instances, infusion of antibodies from an atopic donor may also be involved. It may present with only mucocutaneous signs and symptoms.

Note: Minor allergic reactions (non-severe) do not have to be reported to NHSN.

Definitive: 2 or more of the following occurring during or within 4 hours of cessation of transfusion:

- Conjunctival edema
- Edema of lips, tongue and uvula
- Erythema and edema of the periorbital area
- Generalized flushing
- Hypotension
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Respiratory distress; bronchospasm
- Urticaria (hives)

Probable: ANY 1 of the following occurring during or within 4 hours of cessation of transfusion:

- Conjunctival edema
- Edema of lips, tongue and uvula
- Erythema and edema of the periorbital area
- Localized angioedema
- Maculopapular rash
- Pruritus (itching)
- Urticaria (hives)

Possible: N/A

Transfusion Associated Dyspnea (TAD)

Respiratory distress within 24 hours of cessation of transfusion that does not meet the criteria for TRALI, TACO, or allergic reaction. Respiratory distress should not otherwise be explained by a patient's underlying or pre-existing medical condition.

Definitive: Acute respiratory distress occurring within 24 hours of cessation of transfusion

and

Allergic reaction, TACO, and TRALI definitions are not applicable.

Probable: N/A

Possible: N/A

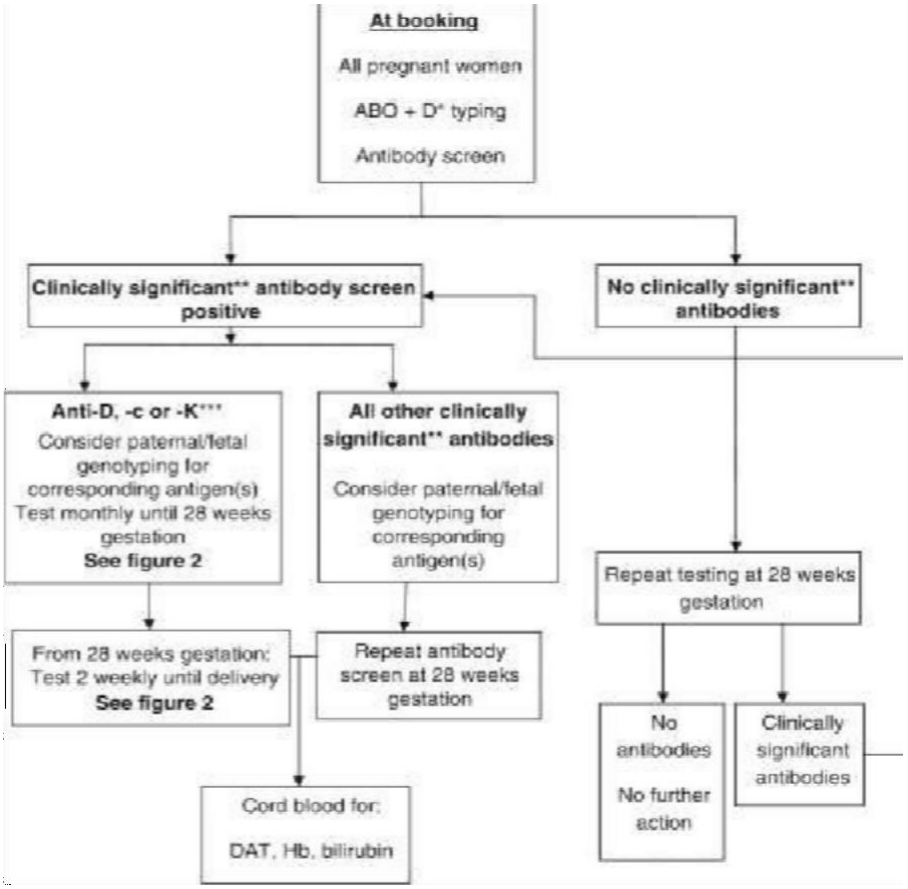
Other

Use this option if the recipient experienced an adverse reaction that is not defined in the Hemovigilance Module Surveillance Protocol (e.g., transfusion-associated acute gut injury (TRAGI), transfusion-associated immunomodulation (TRIM), iron overload, microchimerism, hyperkalemia, thrombosis).

Figure: AABB Reference Guide for classification and severity of Transfusion Reaction

20. ANC OF PREGNANT MOTHER

Flow diagram of receiving samples of ANC patients booked at this hospital



- It is essential that the request form and sample conform to the requirements described in the guidelines on the administration of blood components
- Samples should be dated, labelled and signed by the person taking them, in the presence of the pregnant woman who should, whenever possible, be asked to state her full name and date of birth. Sample labels pre-printed away from the phlebotomy procedure or taken from the notes, e.g. _addressograph' labels, should not be used
- ABO/D typing- A record of the pregnant woman's ABO and D type performed at booking is useful as confirmation of any subsequent testing on another sample taken at the point of need should the woman or her baby require blood transfusion at a later date.
- Maternal D typing is also undertaken to identify D-negative women who require anti-D Ig prophylaxis.If clear-cut positive results are not obtained in D typing, the woman should be classified as D negative until the D status is confirmed.
- All pregnant women found to be D negative should be given written information about their D-negative status and the importance of anti-D Ig prophylaxis. The D

status should be clearly recorded in the notes to inform those responsible for their care of the need to offer prophylactic anti-D Ig (BCSH, 2014) (Grade 1C).

- Screening for red cell antibodies: Maternal antibody screening is undertaken to detect clinically significant antibodies, which might affect the fetus and/or newborn, and to detect antibodies that may cause problems with the provision of compatible blood components for the woman and for the fetus/newborn.
- Antibody identification: When a positive antibody screen is obtained and red cell antibodies are detected, further testing of maternal blood should be undertaken to determine the specificity(ies) and to determine the concentration/strength of antibodies (using titration or a method of quantification) and the likelihood of HDFN.
- Once red cell antibodies have been identified in pregnancy, the identification process should be repeated with each additional sample taken to identify or exclude any additional clinically significant maternal alloantibodies, as women who have developed an alloantibody are at greater risk of developing additional antibodies. This will ensure that all antibodies that have potential to cause HDFN are monitored and will facilitate the timely provision of compatible blood if required for the woman and/or for the baby. The frequency of repeat tests for antibody screening and identification will be determined by the specificity and strength of antibody and whether an intrauterine transfusion (IUT) has been administered.
- Where possible, each sample should be tested in parallel with the previous sample and the results compared to identify significant changes in antibody concentration.
- Antibody titration: Titration is used to assess the concentration of clinically significant red cell antibodies. Careful attention to technique is necessary to minimise the variables in the methodology employed
- Paternal testing: If potentially clinically significant maternal antibodies have been identified, paternal testing should be considered to predict the risk to current and future pregnancies. This may be particularly relevant if non-invasive fetal genotyping is not available for the corresponding red cell antigen (Grade 1B).

Conclusion:

Blood transfusions are essential for many life saving treatments, but they must be administered with caution. By adhering to proper protocols, monitoring for reactions and ensuring continuous staff education, we can minimize the risks and improve patient outcomes in blood transfusion practices.

OPERATION THEATRE INFECTION CONTROL PRACTICES

Dr Sumanjit S Boro
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Aim:

- To outline the standard operating procedures in the operation theatres for infection control and prevention.

Application:

- Applicable to all staff working in the operation theatre as per their roles.

Terms:

- **Asepsis:** Prevention of contamination with microorganisms.
- **Bioburden:** The count of viable microorganisms or contamination level on a surface or object before the sterilization procedure.
- **Biologic Indicator (BI):** A standardized test preparation of bacterial spores used to demonstrate effective sterilizing conditions by providing a defined resistance to a specific sterilization process.
- **Chemical Indicator:** Agents or devices used to monitor or confirm the attainment of one or more parameters for a satisfactory sterilization process, or used in a specific test of the sterilization equipment.
- **Chemisterilant:** Chemical agents with properties that kill all forms of microbial agents, including spores.
- **Cleaning:** Removal of foreign material, including soil or organic materials, from objects or surfaces, normally accomplished using water with detergents or enzymatic products.
- **Clinical Contact Surfaces:** Surfaces likely to be touched by personnel or patients before, during, or after surgery, or that may become soiled during surgery.
- **Contact Time:** The time a disinfectant need to remain wet in direct contact with the surface to effectively kill or deactivate microorganisms.
- **Decontamination:** OSHA defines decontamination as "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles, and the surface or item is rendered safe for handling, use, or disposal."
- **Disinfectant:** A chemical or physical agent that eliminates disease-causing pathogens and other microorganisms but not bacterial spores.
- **Disinfection:** The thermal or chemical destruction of all vegetative forms of microorganisms, except bacterial spores, on inanimate objects.

Cleaning of Surgical Environment:

Surgical site infections (SSIs) are a leading cause of healthcare-associated infections. This is most important, particularly in low and middle-income countries. Ensuring stringent infection prevention and control practices in operating theatres is therefore of utmost importance. Cleaning the surgical environment reduces the risk of exposure to infectious microorganisms for patients and healthcare staff. The responsibility for maintaining a

clean surgical environment lies with the operative staff. The cleaning of the operating environment must be carried out by trained personnel, focusing on both surface cleaning and fogging.

General Outlines:

- Strict hand hygiene should be maintained at all times.
- Appropriate personal protective equipment (PPE) must be worn.
- Sterile bed sheets or drapes should be available for the operating table for every case.
- The operating theatre doors should remain closed at all times, with movements minimized.
- The number of personnel present during surgery should be restricted to the necessary minimum.
- For all patients' standard precautions must be followed, irrespective of their infection status.
- OT personnel should have received appropriate vaccinations, including TT and Hepatitis B.
- Cleaning of horizontal surfaces, particularly high-touch surfaces, should involve a sequence of soap solution mop, water mop, followed by disinfectant mop.
- Ensure the concentration of stock solutions for detergent, germicide, and disinfectant is known and followed.
- Adhere to the manufacturer's instructions for the proper use of disinfectants, including recommended use dilution, material compatibility, storage, shelf-life, and safe use and disposal.
- The 'in use' dilution of the disinfectant, whether for surfaces or the environment, should be freshly prepared daily in a clean container.
- Any leftover solution should be discarded at the end of each use or day.
- Ensure surfaces are adequately wetted with disinfectant during the procedure, allowing a contact time of at least 1 minute.
- Allow surfaces to dry after disinfection.
- Decontaminate mop heads and cleaning cloths regularly to prevent contamination.
- In operating rooms, a fresh mop cloth should be used each time for clinical contact surfaces.
- Floor mops should be changed weekly or whenever soiled, whichever is earlier.

Disinfectants to be used:

- 70% Alcohol
- 0.5% to 1% Sodium hypochlorite (Various concentrations for different purposes)
- 0.5% to 1% Bacillocid special
- Hydrogen Peroxide (11% w/w) and Sliver Nitrate solution (0.01% w/w)

Infection Control Protocols:

General principles for OT cleaning & Disinfection:

- Surfaces must be routinely cleaned first with detergent to remove any foreign and organic matter. Disinfection should follow cleaning. Do not apply disinfectant without cleaning as organic matter such as pus, blood, urine, amniotic fluid, etc. inhibits the action of the disinfectant by protecting microorganisms.

- Spills must be cleaned immediately. Apply a higher concentration of disinfectant (0.05 % to 0.5% Sodium hypochlorite) to the spill, then clean with detergent.
- Disposable or freshly laundered washable cloths or mops should be used with freshly prepared solution for each task.
- OTs must be cleaned daily. This includes furniture, lights, equipment, windowsills, ledges, scrub rooms, and sinks. Thorough cleaning of the entire OT should be done once a week.
- Do dry vacuum cleaning for dry floor cleaning. Brooming is not recommended.
- Wet vacuuming is the preferred method to clean the floors, wet mopping can be done if a wet vacuum is not available.

Collections of water should be dried immediately. Leaking faucets and sinks should be fixed as wet areas encourage microbial growth and can be a source of infection.

Daily cleaning procedure:

***Before start of the first case, at least one hour before*:**

- Damp dust with detergent.
- Disinfect all equipment, furniture, and lights.

Between Cases

- Place soiled towels, drapes, and gowns in a clean laundry bag and send them to laundry.
- Wet linen should be placed in a plastic container so that bacteria do not pass through the moist material.
- Soiled instruments must be placed in disinfectant and then sent to the cleaning area, this prevents occupational hazards to the cleaner.
- Wipe all used equipment, furniture, and lights.
- Move the operating table to one side and wet vacuum or wet mop a 3–4 feet area around the operating site.
- Empty the suction bottle and wash the suction bottle and tubing with detergent– disinfectant. The best is a disposable suction bottle.

Terminal daily cleaning after scheduled cases are over:

- Remove all portable equipment from the room
- Wipe windowsills, overhead lights, equipment, furniture, and waste containers with a cloth soaked in detergent and high-level disinfectant solution.
- Wet vacuum or wet mop the entire floor area.
- Clean and disinfect the wheels.
- Restock unsterile supplies.
- Check levels and dates of all sterile supplies and restock.
- Clean scrub sinks with scouring powder.

Weekly general cleaning procedure

- Remove all portable equipment. Clean lights and fixtures with detergent disinfectant solution and cloth.
- Clean doors hinges and facings and rinse with solution.
- Wipe down the walls with a mop soaked in detergent disinfectant solution.
- Scrub the floor with a floor cleaning machine and disinfectant detergent solution.
- Replace clean portable equipment, clean wheels, and castors by rolling them across a towel saturated with detergent disinfectant.
- Wash and dry all furniture and equipment including
    - Operating room table
    - Suction holders
    - Foot and sitting stools
    - IV stands and all other stands
    - X-ray view boxes
    - All tables
    - Tubing to oxygen tanks
    - Waste containers and buckets
- Clean the air-conditioning grills.
- Empty all shelves, wipe them with detergent–disinfectant, and dry them before replacing the supplies.

Fogging:

Indication of Fogging:

- If any infected case like anthrax, gas gangrene, tetanus, or an open septic wound with laboratory evidence of Clostridium tetani surgery performed in the operation room.
- Before functioning of a newly constructed or renovated or repaired operation room.

Requirements:

1. Fogger Machine
2. Water
3. Hydrogen Peroxide (11% w/v) and Silver Nitrate solution (0.01% w/v)

To undertake Terminal Disinfection before fogging
Calculate the area to be fogged in cubic feet
i.e. Length X Breadth X Height Example: L= 10 ft, B=10 ft & H=10 ft
Then cu. Ft area is 10 X 10 X 10=1000 cu. ft.

General instructions before fogging:

- Remove all the dust from the area where fogging has to be carried out.
- Clean the room thoroughly and mop all the surfaces
- Before starting the fogging process room & all surfaces should be cleaned with disinfectant
- Labels should be put on the door with time of starting & expected time of opening
- Seal the room including windows and ventilators air tight.
- Use adhesive tapes to close the gaps.
- Keep air conditioning switched off.

- Switch on exhaust for 15 minutes prior to starting air conditioning.
- Air conditioning to be started after 1 hour of the procedure.

Precautions to be taken during the process of fogging

- Do not use flammable/non-approved liquids in the fogging machine.
- Do not use a machine without a timer device.
- Never probe into the front nozzle from where the mist comes out.
- Use a funnel to pour the liquid in the machine tank.
- After completion of procedure add some plain water in the empty tank and fogger machine should be started for flushing.

Fogging procedure:

- Measure the area of room to be fogged in cubic feet.
- Disinfectant to be used as per the area size of O.T for allotted time
- For each 1000 cu.ft. (28.3 cu.mt.) space, use the approved high-level disinfectant according to the manufacturer‘s instructions.
- Pour this solution into the fogging machine
- Switch on the machine
- Keep it for 60 minutes
- No neutralization with ammonia is required
- Appropriate use of PPE like gloves, masks, goggles, etc
- Check all the activities are being carried out which were mentioned in the instructions for pre-fogging.
- Mark sure that no person will present in the area or room of fogging apart from the person who is carrying the fogging operation.
- The person who is carrying out the operation should be aware of the fogger machine mechanism and handling of the fogging disinfectant liquid.
- Microbiological Surveillance after Fogging
- Recommended only in case of fogging done after new construction/ renovation/ repair work or after procedures done on septic cases.
- Not indicated in case of fogging being done as a part of terminal cleaning. In such case, the area/room can be used immediately after fogging.
- Surveillance cultures in the form of air sampling by open plate cultures (settle plates) and swabs for isolation of aerobic and anaerobic bacteria should be taken by a trained person.
- Information regarding the same should be provided to the infection control team before fogging.
- The area/room where fogging was performed should not be used until the microbiological surveillance cultures are reported as negative.
- OT/ room/ area can be used only after microbiological surveillance cultures are reported as negative.

Instruments Sterilization

- Preferably use a dedicated, separate autoclave.
- Ensure instruments are thoroughly cleaned before sterilization.
- OT staff, including the sister in charge, should verify the sterilization of items before use.

- Maintain a logbook, recorded by the person responsible for sterilization, and supervised by the sister in charge of OT.

Maintenance of Records

- Maintain records of autoclave use.
- Keep checklists for the cleaning of OT and high-touch objects.
- Document biomedical waste management practices.
- Retain training records of OT staff.
- Keep up-to-date vaccination records for OT staff.

Staff Training:

- Conduct periodic assessments and training sessions for OT personnel through seminars and educational videos. Records of these sessions should be maintained.
- Conduction of awareness drives on special occasions to motivate the hospital staff.

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CODE PINK & CHILD SAFETY

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Child abduction is a terrifying crime of unlawfully removing a minor from their parent or legal guardian. It can be committed by acquaintances or strangers with some strong motives. Code Pink Policy is widely used by various hospitals against this heinous act of child abduction to ensure the safety of the children within the hospital premises.

AIM:

To educate all the staff or Healthcare Professionals regarding Code Pink, and to seek guidance and participation regarding the same

WHAT IS CODE PINK?

Code pink is an emergency code which is used by various hospitals to combat abduction of neonate, infant, or child within hospital premises. It activates **code pink system** which comprises a predefined set of actions for the safeguard of the missing neonate, infant or child.

The entire system of coordination, communications, decisions, and actions followed during such situation is known as code pink system.

The Code pink system comprises

(A) Code pink alarm activation

(B) Code pink response

(C) Demobilization

(D) Post-response.

This policy is applicable for all neonate, infants or children within the hospital premises irrespective of whether they are patients or visitors.

CODE PINK SYSTEM:

A. Code pink alarm activation

After confirmation of missing infant or child, the concerned Nursing Officer will inform to the concerned Faculty/ MS immediately and he/she will also activate Code Pink through Public Address System

The announcement ―CODE PINK‖ will be done three times consecutively with appropriate information like name, age, sex, color of dress and the location from where the child or infant is missing.

(For example, a 3 years old girl named XYZ who was wearing a red colour dress

is missing from the Pediatric ward at 1st floor IPD Block)

Announcement: CODE PINK….3 years old girl, XYZ, red colour dress, Pediatric ward)

In case any child or infant is missing from OPD foyer area, OPD complex area, or from anywhere within the hospital campus, The parent or guardian of child will dial the dedicated Helpline no and will inform about the incident

Information shared:

1. Name, Age, gender, dress colour
2. Time since missing
3. Area of Missing

The Information will be shared with the concerned Nursing Officer on duty to activate Code Pink through Public Address System.

B. Code pink response:

- Reinforcing with security guards at all exits of the ward or the place from where the child is missing.
- The main gates of the hospital to be closed to freeze movement in and out.
- In-charges, Nursing Officers and other staff should start search of the missing infant or child in and around the place of missing.
- Searching act should be prompt withholding all routine works, but critical patient care should not be hampered.
- Movement of persons from the respective area shall be restricted.
- CCTV surveillance should be done
- Every suspicious person (carrying gym bag or blanket) is to be frisked
- Vehicle boots/dickey to be checked.

Role of Security staff:

- Locks all exits in and around the ward and place of missing.
- Closes main gates of the hospital
- Immediately activates search of entire facility both interior and exterior.
- Maintaining security in the unit.
- Informs nearby Police station if the missing child is not found.

C. Demobilization

- When code pink incident is resolved, the Security in-charge will announce ―Code pink, all clear‖ three times.
- Employees will resume their routine work.
- Main gates of the Hospital will be opened

D. Post response:

From child perspective

- If the child or infant is found, a quick and thorough physical examination should be done to ensure that the child or infant is well. He or she should then be handed over to the parents
- If the child or infant is found with minor injuries, first aid or treatment should be given immediately. In case the child was an admitted patient, readmission should be done with new Hospital Identification number (CR No.)
- If the child or infant is found with severe injuries or in dead condition, police should be immediately informed. A medico-legal case must be documented.
- If child or infant is not found within sufficient time (1 hour of search), police should be informed.

From Administrative perspective:

- The Security in-charge should prepare a detailed report on the code pink incident and submit it to the Hospital Administrator.
- The report must contain:
  - **Description of Child**
  - **Time of code pink activation**
  - **Details of search activation**
  - **Outcome of code pink**
- The Hospital administrator must analyze the effectiveness of the code pink system and take necessary corrective action to make it more robust.

SUSPICIOUS BEHAVIOURS / CUES

- Unusual movement of bag which indicates someone may be carrying a baby within a bag
- Anyone trying to sneak out of back exit
- Persons who carry large packages, duffel bags or gym bags.
- Abductors are known to search out targeted rooms:
  - Mother‘s room
  - Playrooms
  - Close to staircase
  - Elevators
  - OPD Foyer area

CODE PINK REPORT

DATE……/……/…….

NAME……

AGE…… SEX……. DRESS COLOUR……

PARENT/GUARDIAN……

ADDRESS……

TIME OF CODE PINK ACTIVATION……

SEARCHING DETAILS:

CHILD FOUND

Healthy/ minor injury / major injury / Dead

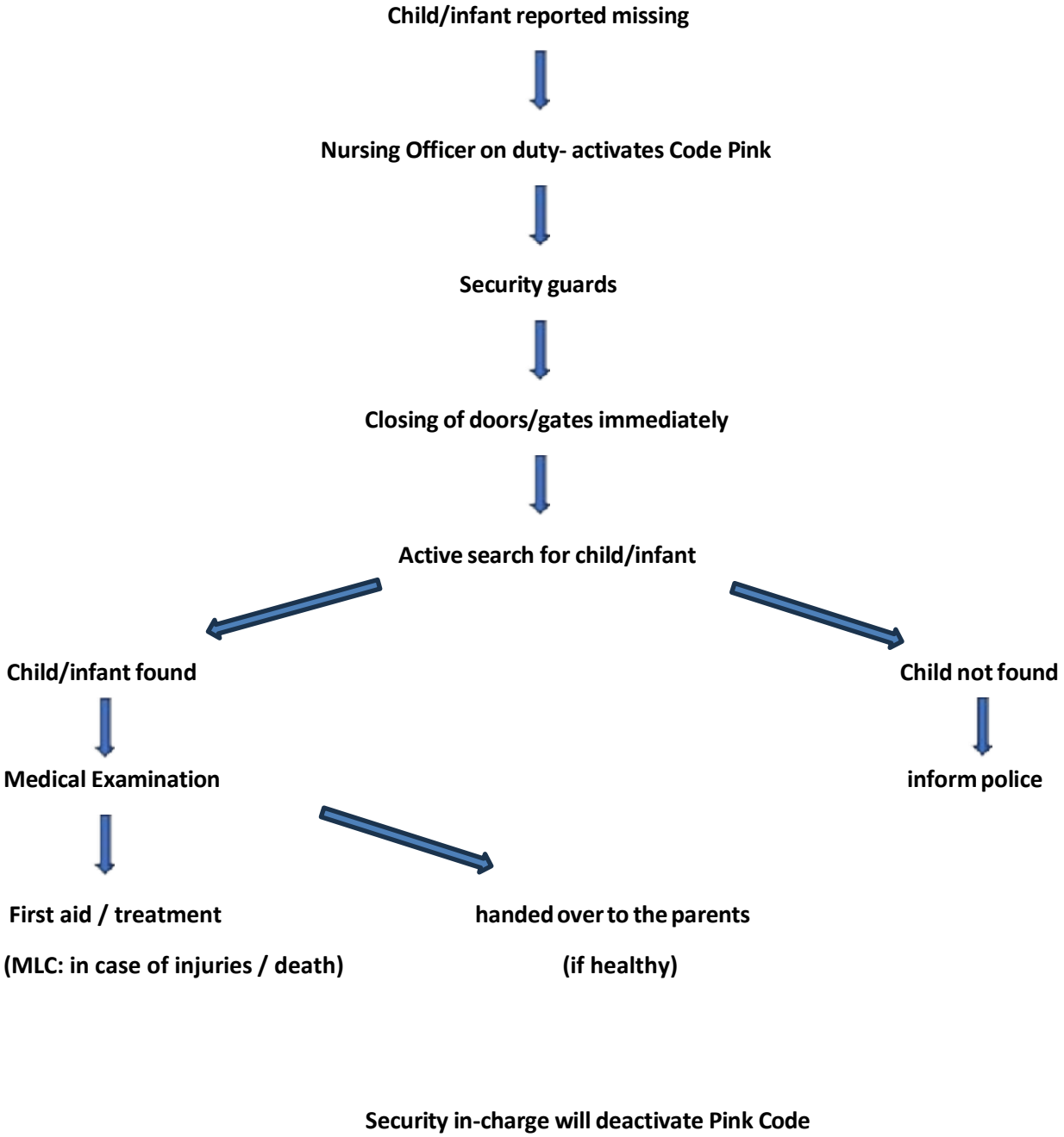
MLC: Yes / No

CHILD NOT FOUND

POLICE INFORMED: Yes / No

SECURITY IN CHARGE

FLOWCHART:


Child/infant reported missing
Nursing Officer on duty- activates Code Pink
Security guards
Closing of doors/gates immediately
Active search for child/infant
Child/infant found
Child not found
Medical Examination
inform police
First aid / treatment
(MLC: in case of injuries / death)
handed over to the parents
(if healthy)
Security in-charge will deactivate Pink Code

CHILD SAFETY

Children are more prone to accidental hazards and health deterioration if proper safety standards and regulations are not followed in the hospital. Child safety policy is an intrinsic part of child health care in the hospital which prevents accidental hazards and health deterioration in children. It is very essential to monitor the functionality and effectiveness of the child safety policy in the hospital. Child safety audit is an essential tool to ensure that hospital follows safety standards and regulations for children which are the part of child safety policy. The audit has a crucial role in implementing safety management strategies that protect children in the hospital. Following is the framework of child safety audit.

Schedule:

AIIMS Guwahati will be conducting child safety audit once in every three months(quarterly)

Who will conduct?

Audit will be conducted by independent clinical department.

What will be done?

Audit will be done using child safety checklist.

Gaps will be identified.

Root cause analysis will be done for the gaps

Action plan prepared for:

Closure of gaps

Responsibility of the concerned

Timeline to resolve gaps

CHILD SAFETY AUDIT CHECKLIST:

S. N	SAFETY MEASURES	YES/NO	REMARKS
01	Does the hospital have a provision of identification band for all infants or children admitted in Pediatric ward or Neonatal ward?		
02	Does the hospital have beds with sliding railings to prevent from falling?		
03	Does the Hospital have a dedicated pediatric ward for assessment, investigation and treatment of admitted patients?		
04	Are the staff trained on management of Adverse Events Following Immunization?		
05	Is drug dosage of the Pediatric patients strictly calculated according to weight of the patient and sometime BSA?		
06	During IV Fluid therapy, is strict intake and output monitoring being done?		

07	**Are the Nursing Officers appointed in neonatal ward well trained in neonatal resuscitation?**		
08	**Is proper hand hygiene maintained while handling neonates and infants?**		
09	**Is Code Pink policy active in the hospital?**		
11	**Are expiry and near expiry (residual life of less than 6 months) drugs stored at a separate place?**		
12	**Does the hospital follow manufacturer's instruction before drug administration?**		
13	**Does the hospital follow one needle, one syringe, one injection policy?**		
15	**Are needles disposed in white colored, translucent, puncture proof container?**		
16	**Are roofs and walls free from fungal growth and plaster chipping?**		
17	**Is there periodic surveillance of false ceiling, railings of staircase etc?**		
18	**Is there any loose wire hanging over wall or roof?**		
19	**Is there any broken glass of window?**		
20	**Are the toys free from sharp edge and glass materials?**		

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Safety measures in a Biochemistry lab

(Dr. Indrajit Nath, Additional Professor, Dr. Chandan Nath, Assistant Professor Dr. Bidyut Bhuyan, Senior Resident)

The practice of medical laboratory science is often associated with risk of accidents and hazards. The laboratory worker is very much at a risk of acquiring transmissible diseases through contact with patients or handling clinical specimens. A poorly designed and overcrowded laboratory has increased possibility of mishaps therefore the laboratory should be maintained by well-trained, dedicated and meticulous staff. Every lab must have an appropriate code of safe lab practice. It's important that all accidents should be promptly reported to the safety officer or lab-in-charge.

HAZARDS IN THE LABORATORY:

- Cuts & Pricks: may result from edges of broken glass wares, edge of knife, scissor, accidental pricking with needle or other sharp instruments etc.
- Burns: may result from substances catching fire, Bunsen burners, spirit lamps, faulty electric circuits, accidental swallowing of corrosive liquids, spillage over skin etc.
- Hazards of Toxic Chemicals: may be due to inhalation of fumes of toxic chemicals, swallowing/ingestion of chemicals during mouth pipetting, skin contact with toxic chemicals etc.
- Infection: may be due to inhalation of aerosols (in air borne droplets) during breakage, spillage, centrifugation, dispensing, pipetting, snap opening of specimen containers, ingestion of pathogens by contaminated food/fingers, needle pricks, cuts, scratches, insect-bites, sores or skin lesions etc.
- Electric Shocks: usually due to ignorance/carelessness caused by faulty electrical circuits, incorrect installation of equipment, touching exposed live wires etc.

SAFETY RULES FOR LABORATORY WORKER AT A GLANCE:

All specimens arriving in the laboratory should be regarded as being potentially pathogenic. It is a very wrong notion to think that only specimens meant for bacteriological investigation are infectious. A specimen of CSF sent for glucose estimation may be a part of the same specimen sent for bacterial meningitis investigation. The same is true of a specimen of blood sent for hemoglobin or packed cell volume measurement which may contain infectious microorganisms. The lab worker, must therefore, observe some "do's" and "don'ts" in order to prevent lab acquired infections. Some of the rules for the lab worker are:

- Should wear protective clothing (lab coats/gowns) over normal clothing; closed shoes and never walk bare foot in lab.
- Specimens and infected materials should be handled with care.
- Should avoid eating, drinking or chewing gum inside lab.
- Refrain from smoking, applying cosmetics in the working zone.
- Avoid pipetting with mouth or licking any gummed labels.

- Protective gloves/plastic aprons should be used while collecting blood sample for hepatitis, AIDS, viral hemorrhagic fever investigations.
- Needles after use should be immediately disposed off in white translucent puncture proof biomedical waste container which are finally incinerated.
- Any cuts, insect bites, open sore or wounds should be covered with water proof adhesive dressing.
- Finger nails should be kept short.
- All infected or contaminated materials should be disinfected before disposal.
- There should be a jar of disinfectant on each bench at start of day's work which must be changed every day.
- In case of spillage, disinfectant solution should be poured to cover the spilled area and left for 15 mins before cleaning up. (To be managed as per spill management protocol).
- Infected glass wares should be disinfected by soaking overnight in hypochlorite solution and cleaning thoroughly under running water.
- Cleaning of all lab benches before closing of lab.
- Thorough hand wash before leaving lab.

MAJOR CAUSES OF LABORATORY HAZARDS :

Dangerous chemicals: Chemicals are usually either directly or incorporated into reagents and stains. These dangerous chemicals include highly flammable ones like alcohols, highly corrosive ones like phenol, sulphuric acid, toxic ones like formaldehyde, carcinogens like benzidine or explosives like picric acid.

To minimize accidents, it is mandatory to label dangerous chemicals with hazard symbols and supply simple instructions for usage and storage. It is also important to label reagents those are prepared from these types of chemicals, it should include nature, strength of the solution, date of preparation, expiry and other safety warnings. It is advisable that the chemicals required for daily usage should be kept in the main lab and others in the store room. Also, they should be periodically checked to detect any kind of leaks, pressure building in the container that may lead to bursting of the container.

Store rooms where these kinds of chemicals/hazardous stocks are stored are designed with adequate ventilation to contain the fire, explosion etc. if unfortunately occurs. Fire extinguisher should be placed just outside the store room. Radioactive substances require proper supervision provided by law.

Flammable chemicals: These chemicals should be stored in fire proof metal boxes at ground level preferably in an outside, cool, locked store. Only small amounts of flammable chemicals should be left inside the lab. A container of flammable liquid should never be opened near an open flame. A bottle of ether should be opened at least 3 meters away from naked flame. "No smoking" sign must be present at these sites and must be strictly enforced.

Corrosive substances: Strong acids like concentrated sulphuric acid, nitric acid; caustic alkalis like sodium hydroxide, potassium hydroxide should be stored at the floor level. Never mouth pipette a corrosive liquid; always use an automatic pipette or dispenser. Eyes must be protected from fumes of corrosive substances. When mixing, acid must be always added slowly to water but never the reverse. Always protective footwear should be worn to protect from accidental stepping while spillage. Acid & alkali burns should be always washed under free stream of running cold water.

Toxic & Irritating chemicals: Toxic chemicals are equally irritating and can cause serious ill health or even death if inhaled, swallowed or touched with bare hands. Some of these chemicals cause irritation of skin/mucosa. Highly toxic chemicals like potassium cyanide should be kept in locked cupboards. Wear protective gloves when handling & wash hands immediately after using a toxic substance. Chemicals such as formaldehyde, ammonia with an irritating or harmful vapor should be used in a fume cupboard or safety cabinet.

Carcinogenic chemicals: These chemicals are capable of causing cancer when inhaled or ingested or when they come in contact with skin. The chance of developing cancer depends on the length & frequency of exposure and concentration of chemical. The carcinogen substance should be stored in a closed container, wear protective gloves and face mask when handling and wash everything after the usage.

Explosive chemicals: An explosive chemical can explode as a result of heat, flame or friction. Chemicals such as picric acid should be stored under water. Never leave these kinds of chemicals in a dry state.

Radioactive chemicals: All areas where radioactive materials are stored must be pasted with caution signs. Traffic in this area should be restricted to essential personnel only. Decontamination of lab equipment, glass ware and work area should be routinely done. Only properly trained persons should be allowed to work with radioactive chemicals and must be regularly monitored to ensure maximum dose of radiation is not exceeded.

SAFETY MEASURES FOR THE VARIOUS LABORATORY HAZARDS:

- **General Safety measures:**

13. Preparation for Laboratory Work

Before beginning any laboratory tasks, ensure you are aware of the following:

• Understand the hazards associated with the lab materials and familiarize yourself with proper handling, storage, and emergency procedures. Always read labels before moving, handling, or opening chemicals, and never use products from unlabeled containers.

• Get to know the agents, processes, and equipment in the lab. If you are uncertain about any procedure, consult with your supervisor before proceeding.

• Know the locations and operation of safety and emergency equipment, such as fire extinguishers, telephones, and emergency exit.

• Be aware of emergency reporting procedures and contact numbers.

14. During Laboratory Work

• Limit lab access to authorized personnel only. Children are not allowed in laboratory environments.

• Avoid smoking, eating, drinking, storing food or beverages, using tobacco, applying cosmetics or lip balm, and handling contact lenses in the lab.

• Secure long hair by tying it back or using other restraints when working with chemicals, biological hazards, or moving machinery.

• Maintain a clean workspace, free from unnecessary chemicals and biological specimens. Do not leave reagent bottles, whether full or empty, on the floor.

• Walk rather than run in the lab.

• Keep exits and passageways unobstructed at all times.

• Report accidents and near-misses to your supervisor immediately.

• Wash your hands thoroughly before leaving the laboratory.

• Treat all human blood and body fluids as if they are potentially infectious.

15. Exiting the Laboratory

• Ensure that all unused materials are returned to their designated storage areas. Clean and decontaminate any equipment or surfaces that may have come into contact with hazardous substances with 75% Ethanol.

• Remove and leave behind protective clothing (such as lab coats and gloves) before exiting the lab.

• **Chemical Safety:**

• ***Handling and storage of various laboratory chemicals:***

Guidelines for storing hazardous chemicals include:

• Limit the number of containers in the lab to only what is necessary.

• Keep glass containers elevated off the floor to avoid accidental collisions with people or equipment.

• Store chemicals away from heat sources and direct sunlight.

• Avoid keeping cartons in the lab; if necessary, store them away from work areas.

• Do not place hazardous liquids or large items on shelves above eye level.

• Promptly dispose of expired or unwanted chemicals.

• ***Disposal of Expired, Contaminated, and Discarded Chemicals***

• Dispose of expired, contaminated, or discarded reagents and chemicals exclusively in yellow bags. (Reference: Biomedical Waste Management Rule and its latest amendments thereof)

• ***Actions to Take in the Event of a Major Chemical Spill***

- Evacuate all non-essential personnel from the affected area immediately.
- Assist anyone who may have been exposed to the spilled chemical.
- If the spilled substance is flammable, extinguish all open flames, turn off the room's gas supply, and disconnect any electrical equipment that might create sparks.
- Avoid inhaling any fumes or vapors from the spilled chemical.
- Secure the area by establishing a barrier around the spill.
- Follow these guidelines for specific types of spills:

  • **Flammable Liquids:** Quickly shut off all potential sources of ignition. If a fire starts, alert everyone nearby and extinguish the flames. If no fire is present, cover the spill with absorbent materials and dispose of them properly.

  • **Corrosive Liquids:** Notify everyone in the vicinity. If vapors are being released, evacuate the area. Do not attempt to clean up the spill unless the liquid is highly diluted; if it is concentrated, flush the area with water.

  • **Corrosive Solids:** Clean up spills using a dustpan and brush, and dispose of the collected material properly.

16. *Precautions for Handling Laboratory Chemicals*

Many chemicals used in healthcare laboratories can be potentially hazardous. Therefore, they should be handled with care, using practices that minimize exposure, in accordance with good laboratory practices (GLP) and proper occupational hygiene standards. Product-specific handling, storage, and disposal instructions should be obtained by maintaining and reviewing the Material Safety Data Sheets (MSDS).

17. Understanding Hazards and Safety Documentation

Lab personnel are encouraged to review the material safety data sheet (MSDS) available online for each chemical and also supplied by the vendor along with the reagents of the Automated analyzer either in hard copy or soft copy format they routinely handle. The MSDS provides detailed information about the properties of a substance, including physical data (such as melting point, boiling point, and flash point), toxicity, health effects, first aid measures, reactivity, storage requirements, disposal instructions, protective equipment, and spill response procedures. It is a crucial tool for ensuring product stewardship and maintaining workplace safety by outlining safe handling practices for both workers and emergency responders.

- **Biosafety:**

- **Spill Decontamination:**

- For small spills of infectious materials, follow one step process of cleaning the area with wet mop dipped in freshly prepared 1 % hypochlorite solution
- For larger spills (greater than 10 ml), secure the area to prevent unauthorized access.
- Wear gloves and appropriate protective clothing, such as a mask and lab coat.
- Cover the spill with disposable towels/ absorbent material.
- Soak the towels/ absorbent material with freshly prepared 1 % sodium hypochlorite solution.
- Leave the disinfectant-soaked towels on the spill for 10-15 minutes before removing and disposing of them.
- Clean the area again and let it air dry.
- Treat the material as you would other infectious waste.
- Dispose of the materials in yellow colored Bio-Medical Waste bags.

• Precautions for Handling Biohazardous Materials:

To minimize exposure to potentially infectious materials, laboratory workers must adhere to the following safety precautions:

- Common diseases transmitted through biohazardous materials, such as blood and body fluids, include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). HBV vaccination shall be taken by all laboratory staff.
- Always wear gloves during phlebotomy procedures (mandatory).
- Use gloves and laboratory coats when performing tests or handling potentially infectious materials. Gloves should not be worn outside the laboratory, and avoid using phones or opening doors with contaminated gloves. Dispose of used gloves with other disposable materials and autoclave them.
- Wash hands immediately after removing gloves.
- Never pipette potentially infectious materials by mouth.
- Remove laboratory coats before leaving the laboratory.
- Eating, drinking, smoking, applying cosmetics, or touching contact lenses is strictly prohibited in the laboratory (mandatory).
- Avoid injuries from sharps. Do not recap needles; instead, dispose of them in a needle destroyer and use puncture-proof containers for all sharps. If injured by a sharp or needle, encourage bleeding, wash the area with soap and water, apply disinfectant and first-aid dressing, and report to the Head for further management as per the Needle Stick Injury policy. Always use sterile disposable needles and syringes for phlebotomy (Fill out the Adverse Incidents Form).
- Treat all materials as potentially infectious, including blood, body fluids (e.g., semen, vaginal secretions, pericardial fluid, etc.), and unfixed tissues, organs, or blood slides.
- Clean the workbench daily with a 0.5% sodium hypochlorite solution.
- Maintain cleanliness and organization in the laboratory. Avoid dirt, dust, clutter, and ensure floors are regularly cleaned with a germicidal solution, especially after any spills of infectious materials.
- Regularly inspect refrigerators and freezers for broken vials or tubes containing infectious agents.
- Limit laboratory access during work activities.
- Dispose of decontaminated materials in BIOHAZARD labeled bags according to BMW Rules.

According to CDC & NIH guidelines, it has been recommended that all specimens from patients should be considered potentially infectious. The approach is referred as "UNIVERSAL

PRECAUTION" and eliminates the need to identify the patients infected with HIV or other blood borne pathogens.

A laboratory worker should consider skin (especially when scratches, cuts, abrasions or other lesions are present) & mucous membranes of nose, mouth and respiratory tract as potential pathways for entry of infectious agents. Needles and other sharp instruments must be carefully handled and properly discarded.

Spilling and splashing of infected materials should be avoided.

An accidental injury such as needle stick injury to the worker with infectious material from a known case of HBV and HIV infection should be immediately reported.

- **Electrical Safety**

Even with circuit breakers in place, it's crucial to follow these precautions:

- Verify that the voltage settings are correct before connecting any instrument to the mains supply.
- Always use sockets with a ground contact (earth) to reduce the risk of electrical shock.
- Ensure that surfaces (floor and bench tops) are dry when operating electrical equipment.
- Avoid placing liquid containers on or near instruments to prevent spills, which could lead to electrical shock or short circuits.
- If liquid spills near the mains input of an instrument, immediately unplug the device.
- All electrical outlets should have grounding connections and require three-pronged plugs.
- Never remove the ground pin from a three-pronged plug.
- Disconnect cords by pulling the plug, not the cord.
- Be familiar with the procedure to cut off the electrical supply to the laboratory in an emergency.
- Maintain clear access to breaker panels, which should be labeled to indicate which equipment they control.
- Ensure all wires are dry before connecting them to circuits.
- Tag and disconnect any defective equipment.
- Discharge all electrical potential before starting repair work on equipment with high voltage power supplies or capacitors.
- Limit the use of extension cords and avoid running them across walkways.
- Use CO_2 or dry chemical fire extinguishers for electrical fires.
- Avoid using extension cords or wires without proper consideration of their safety.
- Conduct electrical audit at least once in a year and do thermal scanning for electrical loads

- **Glassware Safety**

- Use a dustpan and brush to clean up broken glass instead of using your hands.
- Dispose of broken glass in a rigid container according to BMW Rules.
- Everyday stresses like heating and impacts can weaken glassware; handle all glassware with caution.
- Immediately discard any glassware that is chipped, cracked, or star-cracked, as it may not withstand normal use.

- **Equipment Safety**

When acquiring lab equipment, prioritize the following features:

- Equipment that minimizes direct contact with hazardous materials, mechanical, and electrical energy.
- Corrosion-resistant materials that are easy to decontaminate and impervious to liquids.
- Smooth surfaces without sharp edges or burrs.
- Quality certification of the equipment, preventive maintenance
- Site readiness of the equipment including electrical load calculations

To prevent equipment contamination and reduce the risk of malfunctions that might cause leaks, spills, or aerosolized pathogens:

- Review and retain the manufacturer's documentation for reference.
- Operate and maintain equipment according to the manufacturer's guidelines.
- Ensure that all users are adequately trained in the proper setup, usage, and cleaning of the equipment

REPORTING ACCIDENTS:

Any accident in the lab involving personal injuries, even minor ones should be immediately reported to the person-in-charge of the lab. It should be followed by an accident investigation report. The injury report should contain the name of the injured person, time, place & nature of injury. The investigation report should include the information on the injured person, an account of the accident, cause of accident, nature of injury and the actions to be taken to prevent a recurrence.

Most of the accidents are mainly due to 2 reasons:

1. Environmental factors: These include unsafe conditions like inadequate safeguards, use of improper or defective equipment, hazards associated with location or poor housekeeping.
2. Personal factors: These include improper lab attire, lack of skills or knowledge, specific physical or mental conditions and attitude to work.

Safety of Elderly Patients in Hospitals

Dr Divendu Bhushan, Associate Professor & Head, Department of Emergency Medicine, AIIMS Patna

Mr Sita Ram, Assistant Nursing Superintendent, AIIMS Patna

The world's population is ageing fast. In 2020, 1 billion people in the world were aged 60 years or over. That figure will rise to 1.4 billion by 2030, representing one in six people globally. By 2050, the number of people aged 60 years and over will have doubled to reach 2.1 billion. The number of persons aged 80 years or older is expected to triple between 2020 and 2050 to reach 426 million (4)

According to NITI Aayog report, in India, senior citizens, i.e. people aged 60 years and above, currently comprise a little over 10% of the population, translating to about 104 million. Life expectancy in our country is 67.3 years in 2021. The United Nations Population Fund (UNFPA) projects that this population, which will make up 158 million people by 2025, is the one that is ageing at the fastest rate. By 2050, the elderly population is projected to rise to 319 million (19.5% of the total population). Further, the total dependency ratio (ratio of people who are economically dependent on others to the no of people able to provide support), which stood at 56.92 in 2020, is projected to decrease steadily till the 2025 due to the rise in the percentage of the working-age population; but it is expected to rise again to touch 61.22 by 2050.

Government concern about the health of elderly, so in a significant move, the Union Cabinet approved a major expansion of the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) on September 11, 2024. Under this decision, all senior citizens aged 70 and above will receive health coverage, regardless of their income, providing them with free health insurance coverage of up to Rs 5 lakh per family.

Key Areas of Concern

a. OPD Visit:

1. The hospital may provide dedicated registration counter for elderly patients.
2. Lobby should be well lit and light should adequate
3. "May I help you" counter who actively listen to their problem and try to solve on priority. This signage must be in local language too.
4. Many elderly can't walk long in the corridor- so availability of adequate wheel chairs is necessary.
5. Easily accessible lift, drinking area and toilets.
6. Pharmacist at medicine counter to explain proper intake of medicine.
7. Clear instructions when to visit next and red flag signs when they can visit hospital anytime. Many times, physician call patients very frequently for observing blood pressure and sugars. We should avoid this and ask them to make a chart at home and visit we any value deviate much from normal.
8. There should be a separate facility of getting investigations for elderly, physically challenged persons and report collection too.
9. Proper signage must be there at appropriate place, so that it's maximum visible and appreciated by the people.
10. Vaccination: Promote immunizations for preventable diseases, such as influenza and pneumonia
11. The hospital shall run dedicated geriatric clinics with trained/ qualified health care staff.

b. IPD care

Geriatric persons are not just more aged adults. They are fragile and all organs are at their age, so they compromise early in comparison to young persons. There are few areas where we should more emphasise when deal with elderly:

- **Communication Barriers:** Hearing, vision, or cognitive impairments can hinder effective communication. This many times lead to over diagnosis of altered sensorium. Delirium in elderly is important to recognise as it can signify severe sepsis, electrolyte imbalance, and CVA etc.
- **Falls:** Elderly patients are at high risk of falls, leading to fractures and other complications. Elderly and frail are at risk of fracture which is common in hospital setting. Restrain is another risk factor for soft tissue and fractures in elderly in hospital. Training and education for use of toilets to be done.
- **Medication Errors**: Polypharmacy increases the chances of drug interactions and incorrect dosages.
- **Infections**: Prolonged hospital stays and invasive procedures elevate the risk of healthcare-associated infections (HAIs). Elderly are at risk of developing bed sores if care is not taken. In ward patient attendant can be a part of patient care along with nursing.
- **Emotional Well-being:** Anxiety, depression, and feelings of isolation are common among elderly patients.
- **Restrain:** The Restraint Policy NABH serves as a guideline for healthcare institutions to manage patients who may pose a risk to themselves or others. The policy covers the appropriate use of physical, mechanical, or chemical restraints while focusing on minimizing harm and respecting the patient's rights.
  Restraint is only used as a last resort after other de-escalation techniques have failed. NABH emphasizes that patient safety and dignity should be the top priority when implementing any restraint. The policy ensures that healthcare providers have a clear process to follow, ensuring compliance with legal and ethical standards.

- **Use of ID bands:** All elderly patients in the hospital shall have to be considered as vulnerable patients and appropriate preventive measures as per need may be adopted by the hospital. Patient and family education about vulnerability and preventive aspects to be done by the nursing officers. Side rails of bed to be raised. Vulnerable patient ID band to be used.
- **Follow up Tele-Consultation:** Tele-consultation services may be provided for follow up of geriatric patients wherever applicable in order to prevent frequent visits to hospitals (both for OPD and IPD patients)

Policies to Uplift care for Elderly in Hospital

1. **Communication Training**

- **Staff Education:** Conduct workshops on geriatric care and effective communication techniques.
- **Sign Language Interpreter:** Arrange for a sign language interpreter if the patient uses sign language as their primary communication method.
- **Patient-Centred Communication:** Use simple language, visual aids, and ensure interpreters are available if needed.
- **Simple Language:** Use short sentences, avoid medical jargon, and repeat information as needed.
- **Nonverbal Cues:** Use gestures, facial expressions, and body language to reinforce verbal communication.

2. **Environmental Adjustments:**

- **Anti-skid tiles,** call bell system and hand rails in bathrooms and toilets
- **Adequate Lighting**: Ensure rooms and examination areas are well-lit without glare.
- **Large Print Materials**: Provide written materials in large fonts or Braille, depending on the patient's needs.
- **Contrast and Colour Coding**: Use high-contrast colours for signage, instructions, or equipment to make them easier to identify.
- **Family Involvement**: Engage family members in care plans to bridge communication gaps.

3. **Involve Caregivers**

- **Family as Partners**: Engage family members or caregivers to support understanding and decision-making.
- **Behavioural Cues**: Observe input from family about the patient's usual behavior or communication preferences.

4. **Technology-Based Solutions**

- **Video Remote Interpreting (VRI):** Use video interpreting services for patients with hearing loss.
- **Text-to-Speech Apps**: Provide tools that convert text to speech for patients with vision impairments.
- **Cognitive Support Apps**: Use apps that send reminders for medication or appointments.

5. **Staff Training and Sensitization**

- **Empathy Training**: Educate staff on the emotional and physical challenges faced by elderly patients with impairments.
- **Specialized Training**: Conduct workshops on communicating effectively with patients with sensory or cognitive impairments.
- **Cultural Competency**: Understand and respect the cultural and linguistic preferences of elderly patients.
- **Social Workers**: Engage social workers to help coordinate additional resources or caregiver support.

6. **Enhancing Physical Safety**

- **Fall Prevention**: Install non-slip flooring, handrails, and adequate lighting. Conduct fall-risk assessments for all elderly patients upon admission.
- **Assistive Devices**: Escorts, provide wheelchairs, walkers, and other aids as needed.
- **Regular Monitoring**: Increase the frequency of patient rounds, especially at night.
- **Surveillance**: Use CCTV cameras to monitor potential fall-prone areas and respond proactively.
- **Feedback Systems**: Collect patient feedback to identify safety concerns and implement improvements.

7. **Medication Safety**

- **Comprehensive Reviews**: Perform regular medication reconciliation to avoid polypharmacy risks.
- **Clear Labelling**: Ensure medications are clearly labelled with instructions, including pictorial aids if necessary.
- **Education**: Train staff to recognize signs of adverse drug reactions.
- **Evidence based treatment guidelines**: Hospital should adopt standard treatment guidelines from recognised bodies in order to prevent poly pharmacy and maintaining high standard of care.

8. **Infection Control**
- **Hygiene Practices**: Enforce strict hand hygiene protocols among staff, patients, and visitors.
- **Screening and Isolation**: Identify and isolate infections promptly to prevent cross-contamination.
- **Vaccination**: Promote immunizations for preventable diseases, such as influenza and pneumonia.

9. **Promoting Emotional Well-being**
- **Therapeutic Activities**: Offer recreational therapy sessions, including Yoga, music, art, and group activities.
- **Counselling Services**: Provide access to mental health professionals for emotional support.
- **Visitation Policies**: Implement flexible visitation hours to reduce feelings of isolation.

Geriatric and Palliative Medicine (GAP)-ED partnership

The National Programme for the Health Care for the Elderly (NPHCE) is an articulation of the International and national commitments of the Government as envisaged under the UN Convention on the Rights of Persons with Disabilities (UNCRPD), National Policy on Older Persons (NPOP) adopted by the Government of India in 1999 & Section 20 of "The Maintenance and Welfare of Parents and Senior Citizens Act, 2007" dealing with provisions for medical care of Senior Citizen. The primary aim of this is to coordinate care for older adults who are likely to be discharged home.

Ensuring the safety of elderly patients in hospitals is a shared responsibility requiring concerted efforts from all stakeholders. Implementing the proposed strategies can significantly improve the quality of care and outcomes for this vulnerable population.

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RADIATION ONCOLOGY DEPARTMENT

Radiation Oncology is the discipline of human medicine concerned with the generation, conservation and dissemination of knowledge concerning the causes, prevention and treatment of cancer involving special expertise in the **therapeutic applications of ionizing radiation**. Ionizing radiations for clinical use in malignancy can be delivered by two ways: 1) External Beam radiotherapy (EBRT) and 2) Brachytherapy (BT)

The aim of radiotherapy is to deliver accurate and precise dose to the tumor for maximal benefit while minimizing risk of harm to surrounding normal tissues (Figure 1). To achieve this goal of precision and accuracy, following the principles of Quality Assurance (QA) in radiotherapy is of utmost importance. According to International Commission on Radiation Units and measurements (ICRU), the available evidence for certain types of tumors demonstrates that for the goal of achieving eradication of the primary tumor, an accuracy of +/- 5% is required in the delivery of absorbed dose to the target volume.[1]

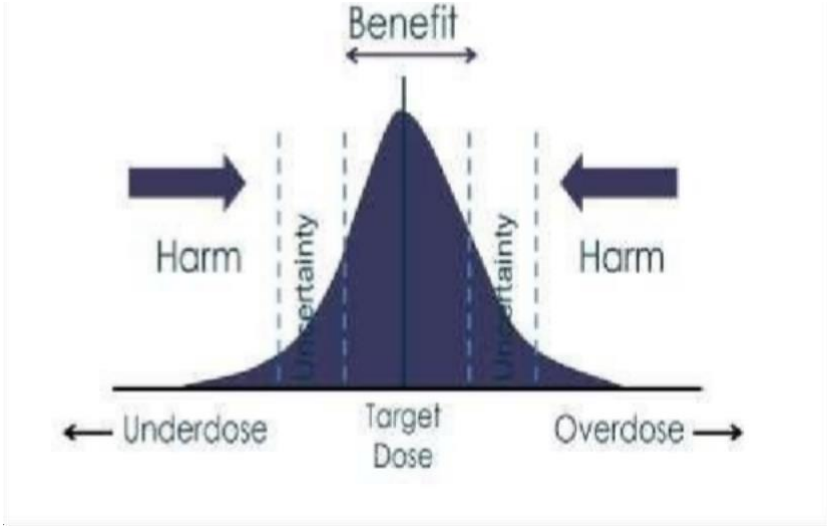

Figure 1: Illustration demonstrating the need for maximizing dose to the target volume and limiting dose to the surrounding tissues—for greater benefits with least harm in radiotherapy treatments

These QA procedures in a radiotherapy department can be classified into two broad headings, viz. a) Machine-specific QA and b) Patient-specific QA

Machine-specific QA: Various mechanical, electrical, dosimetric and radiation safety procedures are performed as parts of machine-specific QA as per international guidelines in a radiotherapy department. The Task Group 142 document from American Association of Physicists in Medicine is the most widely followed for QA of medical Linear Accelerators.[2]

The QA procedures can be divided based on their frequency of performance viz. Daily, Weekly, Monthly and Annually. The most important frequently conducted QA tests are- Photon and Electron Output Constancy, Photon Beam energy Check and Mechanical Check for field size, laser and optical distance indicator (ODI). Additionally, the radiation safety tests include checks for the proper functioning of Door Interlock, Radiation Beam Indicator, CCTV and Last Man Out Switch. Besides, for advanced treatments like Intensity Modulated radiotherapy (IMRT) or Volumetric Modulated Arc therapy (VMAT), specific QA tests for functioning and integrity of Multileaf collimators (MLC) need to be carried out- which include MLC spoke test, Leaf transmission, Interleaf leakage etc. [2]

Annually radiation protection survey is mandatorily done in the radiotherapy department. It is done to check for any leakage radiation around the radiotherapy installation and to make sure that the radiation levels does not exceed the dose limit recommended by the competent authority.[3]

Figure 2: A) Machine-specific QA being conducted by team at Department of Radiation Oncology, AIIMS, Guwahati. B) Radiation protection survey being conducted by an expert in the department with a hand held radiation dosimeter.

Figure 3: The various equipment installed in a Linear Accelerator machine and console for ensuring radiation safety and are parts of Quality Assurance viz. A: Emergency Stop Switchb B: Last Man Out Switch (LMOS), C: CCTV camera unit and D: Two-way audio-visual system.

b) **Patient-specific Quality Assurance**: These procedures are carried out after preparation of treatment plan and before delivery of the finalized plan in the treatment unit for a particular patient.[4] The various commonly conducted patient-specific QA tests are-

Imaging: This is the most important aspect of accurately setting up the patient in the treatment position on the Linac couch. It forms a part of the Image Guided radiotherapy (IGRT) procedure. Figure 4 shows an example of a patient undergoing Cone Beam CT (CBCT) imaging on the Linac couch for accurate treatment positioning. The CBCT scan on couch is matched with the treatment planning CT scan by the IGRT software and any shifts detected in any of the axes (x-, y-, z- axis) can be corrected manually or automatically.

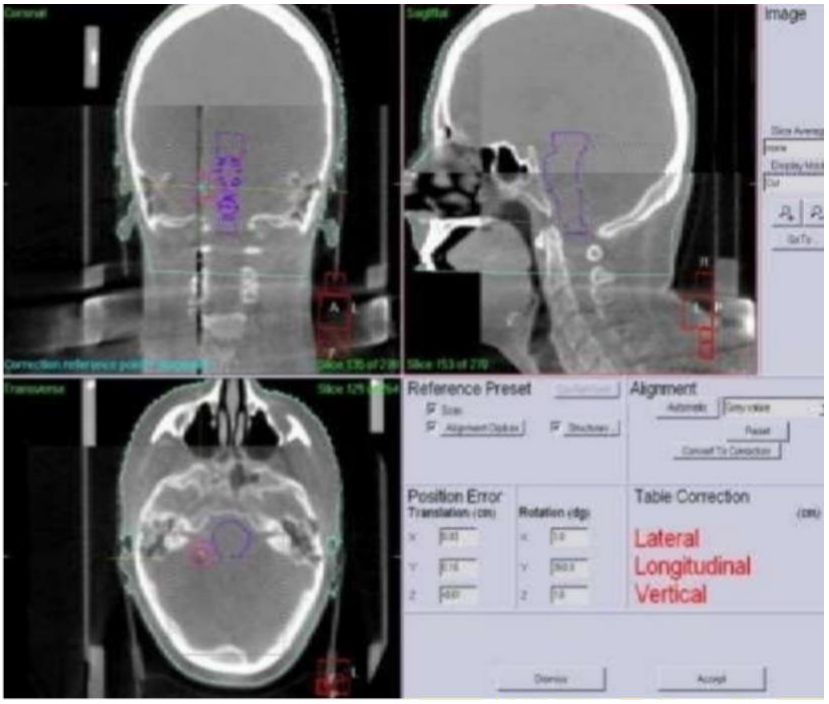

Figure 4: Imaging done before the start of treatment to accurately set-up the patient

Point Dose Check: In this procedure, specially designed phantom with an ionization chamber is used to verify dose to particular point in the phantom corresponding to the treatment plan before actual treatment is done. Most commonly polystyrene slabs with an ionization chamber enclosed within it is used to conduct this procedure.

Planar/ Volume Dose Check: In this procedure, phantoms with 3-dimensional detector arrays are placed on the Linac couch and a fraction of finalized treatment plan of a particular patient is delivered upon it. The dose data is then compared with the data calculated

in the Treatment Planning System (TPS) for that particular plan of the specific patient and analyzed using Gamma evaluation. The limit for acceptability of the plan uncertainty is set upto +/- 2% and 2 mm.

RADIOLOGICAL PROTECTION: For judicious and beneficial use of ionizing radiation and to prevent any potential harm to patients, the following principles must be adhered to[5]:

- **Justification of Radiation**: The potential benefits of using therapeutic ionizing radiation in a given clinical scenario must outweigh the harms anticipated from it. As shown in Figure 5, the Tumor Control Probability (TCP) curve should be significantly towards the left of the curve for Normal Tissue Complication Probability (NTCP). The ratio of TCP:NTCP is called the Therapeutic ratio and for any particular tumor treatment by radiotherapy, it should always be greater than unity.

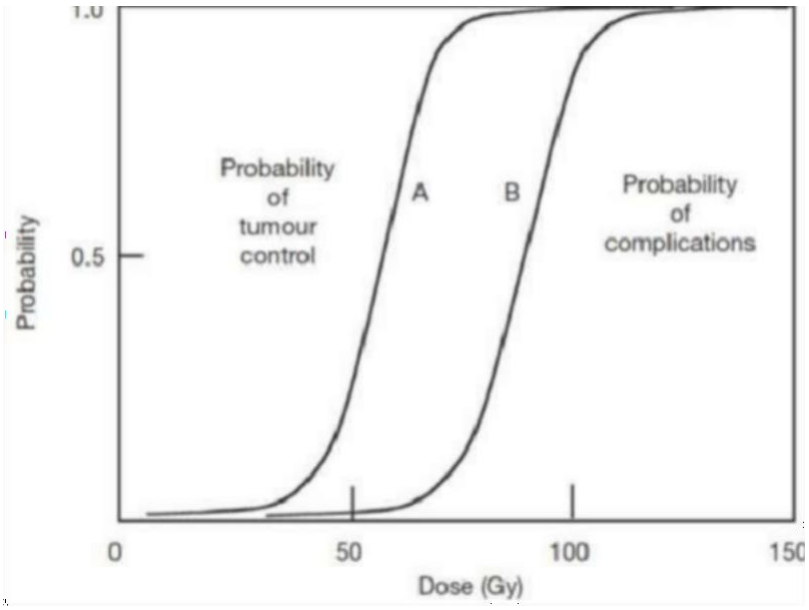

Figure 5: Curves showing the relation of probability (y- axis) of tumor control and probability of normal tissue complications at a particular dose of radiation (x-axis) for a specific tumor type

- **Optimization of Radiation**: It pertains to measures taken to reduce the amount of radiation that a person has received (exposure dose) to as low as reasonably achievable for that particular scenario. In consideration of economic and social factors, there must be an effort to reduce individuals‘ exposure doses and the number of exposed people to **a**s **l**ow **a**s **r**easonably **a**chievable. This is known as the **ALARA** principle.

- **Dose Limitation:** This third principle is an outcome of the earlier two principles and is an objective guide to adhere to the doctrine of ALARA. It refers to the use and implementation of ***Dose Constraints*** for patients in approving treatments and ***Dose limits*** for ensuring safety of radiation workers and general population.
  For a patient undergoing treatment the maximum dose that can be safely delivered to the surrounding normal tissues have been determined from series of data generated by

Emami et al and Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC) studies[6,7]. These are known as dose constraints. They have specified organ wise dose constraints for optimization of radiotherapy plans according to different planning technique and dose fractionations used.

The dose limits or reference levels for general public and radiation workers have been prescribed by various regulatory authorities but in Indian context we follow the limits set by Atomic Energy Regulatory Board as shown in Table 1.[3]

Table 1: Dose limits for various categories of radiation personnel and general public as per AERB.

Dose Limits as per AERB Directive No. 01/2011 dated 27.04.2011			
	Occupational workers	Apprentices and Trainees	General Public
Whole body (Effective dose)	20 mSv/ year averaged over 5 consecutive years ## Must not exceed 30 mSv in any year	6 mSv in a year	1 mSv in a year
Lens of eyes (Equivalent dose)	150 mSv in a year	50 mSv in a year	15 mSv in a year
Skin (Equivalent dose)	500 mSv in a year	150 mSv in a year	50 mSv in a year
Extremities (Hands and Feet) Equivalent dose	500 mSv in a year	150 mSv in a year	---
For pregnant radiation workers, once pregnancy is declared the Equivalent dose limit to embryo/foetus shall be 1 mSv for the remainder the pregnancy			

The following are the three basic factors upon which the radiation dose exposure depends and which can be modified to achieve the dose limits by radiation personnel.[3]

1. **TIME**: Reduce the period of exposure to radiation to reduce the dose received from the source
2. **DISTANCE**: Increase distance from source to decrease exposure rate (Inverse Dquare law)
3. **SHIELDING**: Using large shielding thickness with high atomic number materials eg Lead, Steel, Concrete etc reduces the exposure rate of gamma/X-ray radiation. Also, radiation workers should use an appropriate protection device, as and when necessary.

Use of Safety signages in Radiation Oncology department: As per AERB directive no. 02/2011 under rule 14 (3) of the Atomic Energy (Radiation Protection) Rules, 2004- it is mandatory to identify high risk areas in the department with appropriate safety signages. These signages consist of radiation symbols and warning signs. Figure 6 below demonstrates few of the signages that are routinely put up in radiotherapy installations.

Figure 6: Safety signages to be pasted in the entry door of radiation installations as per AERB

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PATIENT SAFETY PROTOCOL FROM PULMONARY PERSPECTIVE

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"This is the era of Evidence-based Medicine and patient safety should be a priority in healthcare practice."

Effective communication between patient and healthcare team, practising evidence-based medicine, being ethical, constant learning and educating, capacity to deal with adverse events with a problem-solving attitude, and creating safe working environment are the pillars to build the basic foundation of patient safety [1].

From Pulmonary perspective, patient safety measures have to be taken at different levels involving different stakeholders. Actions are needed from patients and their caretakers, treating healthcare team, and administrative authorities.

The respiratory patients can actually behave either as source of infections or vulnerable to the airborne transmissible or droplet infections. The lungs are the most vulnerable organs as they are in direct contact with the environment during the process of respiration. As a result, any deleterious respirable elements (<5μm) in the environment can get access into the lower airways and the lungs via the upper airways. The acutely infected respiratory patients can be infectious to others while talking, coughing, and sneezing. On the contrary, the chronic respiratory patients are prone to harbour lung opportunistic infections from the environment and other infected patients. Patients can follow some very simple day-to-day non-pharmacological practices that can enhance and improve their quality of life. During the recent SARS-CoV-2 pandemic, such non-pharmacological interventions saved many lives worldwide.

I. Actions to be taken by patients

(A). Safety protocol for infectious respiratory patients

These patients should be careful so as not to transmit their infection to other healthy people or chronically ill patients.

1. Patients suffering from seasonal flu or other bacterial infections, preferably should wear a properly fitting clean face mask covering the nose and mouth correctly so that they do not spread the infectious microorganisms (virus and bacteria) to others. 2 ply

cloth mask with increased thread count are non-inferior to surgical or N95 masks [5,6].

2. Such patients should follow the basic talking, coughing, and sneezing etiquettes. They should not shout and talk loudly and cover the nose and mouth with a piece of cloth or their hands or elbows while coughing or sneezing.
3. Patients should also be careful in disposing their infected sputum in proper dedicated disposing area in public places. At home, they can pour boiling water in the sputum container, spit in a bactericidal container or spit on a piece of paper or cloth and burn it immediately.
4. Patients should maintain physical distance of atleast 2 metres (≈ 6 feet), while they are sick and infectious, both at home and work place [7].
5. Patients should maintain proper hand hygiene and be careful enough not to touch or rub their eyes with infected hands. They should wash their hands with soap and water frequently before and after touching objects.
6. Such patients should not share their belongings with others while they are sick, especially food items, cosmetics and beauty accessories (in case of females), comb, pen, etc.
7. Patients should also maintain proper upper airway hygiene by cleaning their nasal cavities, oral cavity, and throat regularly with antiseptic gargles or lukewarm saline water, early morning and preferably after each meal.
8. Such patients may preferably restrict themselves to home till the incubation period of their infection is over.

(B). Safety protocol for chronic respiratory patients

The chronic respiratory patients often have structural lung abnormalities due to which they are prone to harbour opportunistic microorganisms or any other microorganisms very easily in the lungs that lead to periodic exacerbations of their disease. Therefore, such patients should be very particular in following the basic health protocols, especially infection prevention practices in order to improve their quality of life. Such patients should practise the following-

1. Regular use of properly fitting face mask covering nose and mouth correctly, especially while moving outside in public and crowded places and hospital areas.
2. Maintain proper physical distance of atleast 2 metres (≈ 6 feet) from infected people.

3. Maintain proper upper airway hygiene as mentioned in earlier section.
4. Maintain proper hand hygiene by washing with soap and water after touching infected objects.
5. Patients should avoid exposure to triggering factors that may aggravate their adverse lung conditions like organic and inorganic dust, smoke, inhalation of molds and allergens, excessive cold weather, and damp areas.
6. Such patients should maintain a high protein diet to replenish the chronic protein loss through their excessive sputum production (provided liver and kidney functions are normal). They should avoid stale and cold food items.

(C). Precautions to be taken during sputum collection

The respiratory patients should maintain utmost care while coughing up of own sputum for collection to test or discard so as not to cause health hazards to others in the vicinity. During coughing sputum, patients should choose an isolated area, whether indoor or outdoor. If indoor, windows should be wide open to the outside atmosphere, provided there is no one in the vicinity.

II. Role of treating healthcare team

Patient education

The treating team has to be active in properly counselling and educating the patients and caretakers regarding safety measures and ways of dealing with their disease that should include the following-

1. Proper counselling and education of patients regarding airborne infections and necessary precautions to be taken.
2. Avoidance of triggering factors (allergens, irritants, smoke, damp areas, cold exposure, etc) in case of asthmatic and chronic respiratory patients.
3. Proper inhalation techniques and care of drug delivery devices like spacer, nebulizer, etc.
4. Importance of drug compliance or adherence and education on adverse effects of drugs.
5. High protein diet for replenishing the constant protein loss in case of chronic sputum production (provided hepatic and renal functions are normal).
6. Regular use of properly fitting face mask as mentioned in earlier sections.

7. Maintenance of proper upper airway hygiene.
8. Maintenance of a diary or note book for self-monitoring of symptoms and exacerbations.
9. Recognition of red flag signs for health care visit.
10. Teaching family members or caretakers the different airway clearance techniques like postural drainage in case of chronic respiratory patients with structural lung abnormalities.
11. Motivational and psychosocial counselling including options for meditation and vocational training.
12. Emphasize on smoking and tobacco cessation.

III. Role of Administrative Authority

Building proper Health Infrastructure

Ideally there should be a separate department of Infectious Disease management that takes care of all infectious and communicable diseases under one roof. It becomes easier to provide the right infrastructure to handle such cases. Whether outpatient department (OPD) or inpatient department (IPD), infectious and communicable disease patients cannot be managed under centralised air-conditioned system. The following should be kept in mind during building up of infrastructure for such patients-

1. A separate independent hospital or building with proper cross ventilation system (6-12 air changes per hour) in OPD and IPD blocks [1].
2. Separate isolation wards with negative pressure ventilation to manage the infectious patients within incubation period.
3. Provision of intensive care facilities in the IPD block to manage the critically ill patients.
4. Provision of a pulmonary rehabilitation centre in the building to manage the chronic patients, facilitated with a multidisciplinary team comprising of treating physician, physiotherapist, psychiatrist, dietician, and nursing personnel.
5. Virus-laden exhaust air should be treated with HEPA/UV (High-Efficiency Particulate Air Filter/Ultraviolet) equipment, where HEPA filters can capture particles as small as 0.3 microns, while UV light and TEG (triethylene glycol) can kill viruses and bacteria [4].

Challenges

There are various challenges in meeting all necessary requirements in the creation of patient safety environment. These can exist both at community and institutional levels [3]. In the community, social behaviour like lack of talking, coughing, and sneezing etiquettes, indiscriminate spitting habits, addictions of toxic substances, lack of proper health education, etc, special populations like migrants, illiterate tribal and non-tribal communities, people residing in remote underdeveloped areas, high risk centres like old age homes, orphanages, mental asylums, prisons, lack of social support, etc, environmental factors like indoor and outdoor air pollution, are important issues to be dealt with seriously. At institutional level, lack of dedicated infectious disease management hospitals or buildings with proper isolation wards with negative pressure ventilation and intensive care facilities, overcrowding of patients and attendants in hospitals with lack of restricted entries, lack of trained manpower to deal with patient population in a systematic manner, centralised air-conditioned systems in hospitals without facilities of proper cross ventilation, lack of a robust system to segregate infectious and non-infectious patients, etc are matters of serious concern.

Recommendations

1. Enactment of effective legislation

Certain Laws or Acts should be passed and made mandatory by the Central and State Governments like compulsory free elementary education for all citizens of the country, penalisation for non-compliance to safe health practices, enforcement of strict civic rules for good health practices, complete ban of smoking and tobacco in any form, strengthening the pollution control laws of the country, etc. Influenza and pneumococcal vaccinations can be made mandatory for high-risk patients.

2. Utilization of social media

Local languages should be used more while utilizing social media for creating health awareness amongst people residing in remote and distant areas. Patients have to be properly educated in their language on multidisciplinary safe health practices and emphasized on strict compliance to those practices for their health benefit.

3. **Establishment of separate hospitals for infectious disease management**

   There should be separate branch for Infectious Disease management and Government should build separate well-equipped hospitals to handle such diseases. That way it is easier to manage and focus on research related to such diseases.

To conclude, the ancient renowned Greek philosopher and polymath Aristotle propagated the principle of "mens sana in corpore sano" which means "a sound mind in a sound body". Without a healthy body, the mind cannot function properly and in the absence of both, one may lead a miserable and piteous life dependant on others, contributing to the economic burden of the country. Hence, health and thereby patient safety measures should always be a priority for every citizen of a Nation.

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ENHANCING PATIENT SAFETY IN INTENSIVE CARE UNIT (ICU)

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Introduction

Intensive Care Units (ICUs) provide critical care to patients with life-threatening conditions. Ensuring patient safety within these units is paramount. This manuscript outlines key infrastructure, resource, and policy considerations to enhance patient safety in ICUs.

Infrastructure

- **Closed ICU System:** Closed ICUs offer enhanced care coordination, improved clinical outcomes, and optimized resource allocation. Despite challenges, the potential advantages justify further exploration and innovative approaches. As healthcare systems evolve, closed ICUs may become a cornerstone of critical care. [1]

- **Nurse-Patient Ratio: Nurse staffing norms in India are outdated, but NABH recommendations offer practical guidelines. Key nurse-to-patient ratios include 1:6 for general wards, 1:4 for super specialty wards, and 1:1 for ventilator beds in ICUs. A 45% additional staff reserve is recommended to cover leave and work-load fluctuations.**[2]

Resources

- **Trained Staff:** Recruiting and retaining well-trained nursing and paramedical staff is essential for providing competent care and managing complex patient situations.

- **Regular Training:** Ongoing training, including supervised collaborative and hands-on skill sessions, ensures ICU staff are up-to-date with best practices for clinical scenarios. Team-training using curricula like crisis resource management (CRM) and

Team STEPPS enhances skills in Advanced Life Support (ALS), Extra Corporeal Membrane Oxygenations (ECMO), and trauma response. This approach is well-received, promotes clinical learning, and positively impacts staff behaviours.[3]

- **Interprofessional Simulation:** Health-care simulation (HCS) is increasingly used in medical education, especially in critical care, for mastering procedures, improving communication, and enhancing team performance. Evidence shows HCS benefits decision-making, quality improvement, and handling high-risk events. Challenges like cost and logistics are discussed alongside strategies for optimizing its use in critical care training.[4]

Policies

- **Incident Reporting:** An anonymous and online incident or error reporting system encourages staff to report adverse events without fear of retribution, allowing for identification and correction of underlying issues. Negative reports can foster a culture of blame and overlook the systemic factors influencing behaviours within reporting systems. In contrast, nonpunitive language helps identify the root causes of safety concerns more effectively. Reporting systems should prioritize patient outcomes and learn from systemic issues rather than placing blame on individuals.[5]

- **Quality Audits:** Routine audits are essential for monitoring ICU performance metrics such as standardized mortality ratios, readmission rates, and infection rates [e.g., Catheter Related Blood Stream Infections (CRBSI), Ventilator Associated Pneumonia (VAP)]. By tracking these indicators, healthcare teams can identify trends, improve protocols, and ensure adherence to best practices. The audits help to drive continuous improvement, minimize patient risks, and optimize clinical outcomes. [6]

- **Quality Improvement:** Employing a quality improvement approach, such as the Plan-Do-Study-Act (PDSA) cycle, allows for systematic problem-solving and continuous improvement in care quality. [7]

Protocols and Standard Operating Procedures (SOPs)

- **Comprehensive Protocols:** ICUs should have clear written protocols and SOPs for key procedures like admission, discharge, intubation, extubation, daily rounds (FAST HUG BIDS), and weaning. Regular updates are essential to keep them aligned with best practices. Checklists and protocols improve communication and decision-making by organizing care and defining roles, helping manage time constraints.[8]

Infection Control

- **Hand Hygiene:** Adherence to strict hand hygiene practices is essential for preventing the spread of infections. Implementing alcohol-based hand rub dispensers at bedside and promoting hand hygiene education among staff can significantly reduce the risk of healthcare-associated infections (HAIs). A decrease in HAIs was noted following the COVID-19 outbreak, likely linked to improved hand hygiene practices in recent months. This trend highlights that, even amidst a pandemic, hand hygiene compliance by healthcare workers alone can effectively reduce HAIs in hospital settings.[9]

- **Bundle Care:** Implementing bundle care for common HAIs, such as ventilator-associated pneumonia (VAP), central line-associated bloodstream infections (CLABSI), and catheter-associated urinary tract infections (CAUTI), can significantly reduce the incidence of these infections.[10]

Reduction of Complications

- **Procedure Checklists:** Following documented procedure checklists for high-risk procedures, such as pulmonary artery catheter (PAC) insertion and central venous catheter (CVC) insertion, Percutaneous Dilatational Tracheostomy (PDT) can help reduce complications associated with these procedures.
- **Delirium Prevention: The SCCM's Pain Agitation Delirium (PAD) guidelines can be systematically implemented through the evidence-based ABCDEF bundle, encompassing Awakening and Breathing coordination, Choice of sedation, Delirium monitoring and management, Early mobility, and Family engagement. This approach is associated with significant improvements in**

both in-hospital survival and the number of days free of delirium and coma, even when adjusted for patient age, illness severity, and mechanical ventilation. Notably, even partial implementation yields measurable benefits. This initiative complements existing literature, providing a comprehensive framework for large-scale quality improvement across diverse hospital systems.[11,12]

- **Prone Ventilation Bundles:** The COVID-19 pandemic has led to significant morbidity, with 15% of patients developing severe disease requiring ICU admission and mechanical ventilation. Prone ventilation improves oxygenation and survival in patients with severe ARDS. However, it can lead to complications, necessitating trained staff and adherence to protocols. Establishing a dedicated "prone team" and implementing a prone bundle of care, including checklists and training programs, can enhance patient safety and care quality in busy ICUs. [13]

- **Medication and Fluid Administration Errors:** Medication safety is crucial, especially for critically ill patients. Optimizing drug formulations and using system-based solutions can reduce errors throughout the medication process. Hospitals must prioritize technology like Computerized Provider Order Entry (CPOE), smart pumps, and barcode administration to enhance safety. Each ICU should assess its own error risks to implement tailored, multimodal strategies for improvement.[14]

Teamwork and Communication

- **Multidisciplinary Meetings:** Restructuring ICU rounds can significantly improve multidisciplinary collaboration, which is essential for effective patient care and decision-making. The shift towards collaborative care planning, including ad hoc multidisciplinary team meetings (MDTMs), enhances coordination and overall patient outcomes. [15]

- **Team Briefings and Debriefings:** Briefings and debriefings improve teamwork by fostering shared understanding, mutual trust, and effective communication. Implementing them during ICU and ward rounds enhances efficiency by reducing

redundant tasks and organizing care. This strategy benefits both team performance and learning, targeting core competencies like diagnosis, communication, and reasoning. Conducting regular team briefings and debriefings can enhance teamwork, communication, and patient safety. [16]

- **Interprofessional Training:** Providing interprofessional training on communication skills can improve communication among healthcare providers and enhance patient safety.[17]

- **Communication with Relatives:** Effective communication is essential for patient-centered care and shared decision-making throughout a patient‘s healthcare journey, from diagnosis to treatment and discharge. Poor communication can lead to misunderstandings and harm, as seen in a study where 23% of emergency department patients did not receive an explanation of their health problem upon discharge. In 2020, strategies such as health information technology (HIT) and patient access to electronic health records (EHR) were reviewed to enhance patient-provider communication and involve patients in preventing adverse events. Simplified discharge information and the use of interpreters were also highlighted to improve patient understanding and reduce communication errors.[18]

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PATIENT SAFETY IN ANAESTHESIA

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Introduction

In 2002, the World Health Assembly (WHA) recognised insufficient patient safety as a significant issue leading to widespread public health risks across the globe. In response, they passed a resolution (WHA55.18), urging nations to enhance patient safety by improvising the healthcare and monitoring systems. By May 2004, the WHA took a step further, approving the establishment of a global alliance to elevate patient safety efforts. It led to the creation of the World Health Organization's (WHO) Patient Safety Initiative later that year [1]. For the first time, leaders from various agencies, policy-makers, and patient advocacy groups collaborated internationally to address the principle of "First, do no harm" and mitigate the negative impacts of unsafe healthcare. WHO Patient Safety's objective is to support the development of policies and practices that enhance patient safety [2].

In South Asia, the estimated requirement for surgical care is about 4,520 cases annually per 100,000 people [3]. In India, for example, a district with a population of two million must handle approximately 248 surgeries daily. Assuming half of these cases are managed by public healthcare institutions, roughly 124 surgical cases are treated daily. These operations involve interaction between medical devices and the patient‘s sterile tissues or mucous membranes. Despite advancements in technology, infection rates in healthcare settings in developing countries still exceed 25%, which hampers the provision of surgical services due to infections acquired within hospitals. While operating rooms may be available, ensuring the consistent quality of surgical care and adherence to technical protocols remains a substantial challenge in many healthcare systems [3].

A 2004 analysis from 56 countries estimated that between 187 and 281 million major surgeries are performed globally annually, equating to one operation for every 25 people [4]. Although it is challenging to compare surgery outcomes due to varied case types, data from

industrialised countries indicates that significant complications occur in 3–22% of inpatient surgeries, with a death rate ranging from 0.4–0.8% [5,6]. Nearly half of the adverse events were preventable. Meanwhile, developing nations show higher mortality rates, ranging from 5–10%, with anaesthesia-related death rates in some regions of sub-Saharan Africa reaching 1 in 150 surgeries [7]. Postoperative complications and infections also remain significant concerns worldwide [7-10].

Improving surgical safety faces several challenges. First, it is often not considered a significant public health issue, especially in low-income countries where surgery is viewed as costly and thus less of a priority. Second, there is a lack of comprehensive data, making it difficult to evaluate the success or failure of surgical safety efforts. Third, safety protocols, even where they exist, are not consistently applied across different countries. Finally, the inherent complexity of surgical care presents a barrier to widespread improvements in safety standards. Despite advancements in safety and monitoring standards that have significantly reduced preventable deaths and complications in wealthier nations, anaesthesia remains a significant cause of surgical mortality worldwide. About thirty years ago, a healthy individual undergoing general anaesthesia faced a 1 in 5,000 chance of fatal complications [11]. However, thanks to improved knowledge and adherence to fundamental care protocols, this risk has drastically dropped to 1 in 200,000 in more developed countries, representing a forty-fold improvement. Unfortunately, in developing regions, the likelihood of anaesthesia-related deaths remains 100 to 1,000 times higher. For example, avoidable mortality due to anaesthesia in Zimbabwe, Zambia, Malawi, and Togo has been reported as 1 in 3,000, 1,900, 500, and 150 respectively [12-14]. These statistics highlight a persistent and critical absence of safe anaesthesia practices in many parts of the developing world. Anaesthesia patient-safety-related practice and infrastructure, even in developing countries like India and even in teaching institutes, are not as desired [15,16]. Poor anaesthesia services in low-income countries are one of the weakest areas hindering the quality of healthcare and patient safety [17]. Based on the WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives. Geneva: WHO; 2009, Anaesthesia Safety Checklist includes various parameters under different headings [18].

Before Induction of Anaesthesia:

Is an experienced and trained assistant available to help you with induction?

- Yes
- Not applicable

Is the Nil-by-Mouth period adequate?

- Yes
- Not applicable

Is there intravenous access that is functional?

- Yes

Is the patient on a table that can be rapidly tilted into a head-down position in case of sudden hypotension or vomiting?

- Yes

Equipment check:

- If compressed gas will be used, is there enough gas and a reserve oxygen cylinder?
- Are anaesthetic vaporizers connected?
- Is the breathing system that delivers gas to the patient securely and correctly assembled?
- Breathing circuits are clean?
- Is resuscitation equipment present and working?
- Is the defibrillator AED plus manual with ECG check done? Whether battery functioning?
- Is the laryngoscope, tracheal tubes, and suction apparatus ready and clean?
- Needles and syringes are sterile?
- Are the drugs drawn up into labelled syringes?
- Emergency drugs are present in the room (if needed).
- Was the Anaesthesia Workstation self-check test done? Pass or Not
- 20% Intralipid emulsion to be available in need for LAST (Local Anaesthesia Systemic toxicity)
- Injection of Dantrolene Sodium to be made available for cases of Malignant Hyperthermia
- For the Caesarean section OR guidelines, refer to the LAQSHYA guidelines (Labour Room Quality Improvement Initiative) by the National Health Mission, Ministry of Health & Family Welfare, and the Government of India 2017 [19].

Operating Room

Ensure that procedures are established for the correct use of the OR and that all staff are trained to follow them:

- Keep all doors of the OR closed except those required for the passage of equipment, personnel, and the patient.
- Store some sutures and extra equipment in the OR to decrease the need for people to enter and leave the OR during a case.
- The number of people allowed to enter the OR should be kept to a minimum, especially after an operation has started.
- Keep the OR uncluttered and easy to clean.
- Between cases, clean and disinfect the table and instrument surfaces.
- At the end of each day, clean the OR: Start at the top and continue to the floor, including all furniture, overhead equipment, and lights. Use a liquid disinfectant at a dilution mentioned by the manufacturer [20, 3].
- Equipment like anaesthesia machines, monitors, ventilators, infant warmers/baby cribs, etc., or other equipment/furniture. After each procedure/ as and when required, whether used or not in the last 24 hours, damp mopping and drying are followed by disinfection with 70% isopropyl alcohol.
    - The monitor screen should not be mopped with any solvent.
    - Floors, walls, and surfaces: Routine cleaning once every two hours with aldehyde-free high-level disinfectant (HLD) like 70% isopropyl alcohol.
    - Spot cleaning: As required, OT tables, labour beds, and other such surfaces are to be cleaned and disinfected after every use after disinfection with 0.5% chlorine solution.
    - Intensive deep cleaning: Weekly/ Holidays. Level of cleaning/ disinfection (As per Spaulding‘s Classification): Cleaning and intermediate level disinfection by routine cleaning with soap detergent and disinfection with aldehyde-free high-level disinfectant (HLD) like 70% isopropyl alcohol. All equipment and instruments must be cleaned and disinfected with aldehyde-free high-level disinfectants like peracetic acid and autoclaving accept heat-sensitive equipment and instruments [20].
- Sterilize all surgical instruments and supplies afterwards and store them somewhere protected and ready for subsequent use. Every facility should have a

routine sterilisation process that includes means for verifying the sterility of all surgical instruments, devices, and materials. Indicators should be used to determine sterility and checked before equipment is introduced onto the sterile field. Before induction of anaesthesia, the nurse or other person responsible for preparing the surgical trays should confirm the sterility of the instruments by evaluating the sterility indicators and communicating any problems to the surgeon and anaesthetist.

Sponge and instrument counts

- It is essential to Keep track of the materials used in the OR to avoid inadvertent disposal or the potentially disastrous loss of sponges and instruments in the wound.

It is standard practice to count supplies (instruments, needles, and sponges):

- Before beginning the case
- Before final closure
- On completing the procedure

The aim is to ensure that materials are not left behind or lost. Pay special attention to small items and sponges.

Create and make copies of a standard equipment list as a checklist to check equipment set up for the case and then as counts are completed during the case.

When trays are created with instruments for a specific case, such as a caesarean section, a checklist of the instruments included in that tray should also be made for future reference [20].

Leave the OR ready for use in case of emergency

Operative procedure list

An operative procedure list is needed whenever the surgical team will perform several operations in succession. The list is a planned ordering of the cases on a given day.

When preparing the list, elements such as urgency, the patient's age, diabetes, infection, and the procedure length should all be considered.

Operate on ―Clean‖ cases before infected cases since the potential for wound infection increases as the list proceeds.

Also consider other factors when making up the operative list: children, diabetic patients, and patients with multiple co-morbidities (American Society of Anesthesiologists, ASA Physical status III and above) should be operated on early in the day to avoid being subjected to prolonged periods without food.

Ensure that between operations:

- The operating theatre is cleaned. Cleaning should start from the innermost zone to the outermost zone. Morning, evening, after every surgery and as and when required, Damp Mop with detergent and water followed by disinfection with 0.5% chlorine [20]
- Instruments are re-sterilized
- Fresh linen is provided

Clear standard procedures for cleaning and storing operating room equipment are essential; all staff must always follow them.

The probability of wound infection increases in proportion to the number of breaches of the aseptic technique and the length of the procedure. Masks covering the mouth and nose are standard practice [18].

The purpose is to prevent contamination of the patient‘s tissues with microorganisms from the surgical team's upper respiratory tract and to protect the OR staff's mouth and nose from splashes of blood or other fluids from patients during a procedure. Masks significantly reduce contamination of the surgical site, but the association between mask use and surgical infections is less clear [21,22].

Sterile robes are used to prevent bacteria on the skin of surgeons from coming into contact with the patient's tissues and blood and fluids from patients from coming into contact with the skin of the surgical team. Using sterile gloves for surgery is standard practice; however, 8–15% of surgical gloves are torn or punctured during procedures [23-25].

Postoperative care

Does the patient require:

- ICU (Intensive Care Unit)
- HDU (High Dependency Unit)
- Can be discharged to the ward from PACU (Post Anaesthesia Care Unit)

If the patient is restless, something is wrong -

Look for the following reasons in the recovery room:

- Airway obstruction
- Hypoxia
- Haemorrhage: internal & external
- Hypotension and/or hypertension
- Postoperative pain
- Hypothermia, shivering
- Vomiting, aspiration
- Residual narcosis/ Residual neuromuscular blockade
- Falling on the floor

Standards of postoperative anaesthesia care require haemodynamic monitoring.

The most recent revision of the American Society of Anesthesiologists published in 2019, and the guidelines of 2013 are summarised here [26,27]:

I. All patients who have received general, regional, or monitored anaesthesia care shall receive appropriate post-anaesthesia management.

II. A patient transported to the post-anaesthesia care unit (PACU) shall be accompanied by an anaesthesia care team member. During transport, the patient shall be continually evaluated and treated with monitoring and support appropriate to the patient‘s condition.

III. Upon arrival in the PACU, the patient shall be reevaluated, and the anaesthesia care team member accompanying the patient shall provide a verbal report to the responsible PACU nurse.

IV. The patient‘s condition shall be evaluated continually in the PACU. The patient shall be observed and monitored by methods appropriate to the patient‘s medical condition. Particular attention should be given to monitoring oxygenation, ventilation, circulation, level of consciousness, and temperature. During recovery from all anaesthetics, a quantitative method of assessing oxygenation, such as pulse oximetry, shall be employed in the initial recovery phase. *

V. A physician is responsible for the patient's discharge from the PACU.

*Under extenuating circumstances, the responsible anaesthesiologist may waive the requirements marked with an asterisk (*): it is recommended that when this is done, it should be stated (including the reasons) in a note in the patient‘s medical record.

Summary of Recommendations for Patient Assessment and Monitoring in the Postanaesthesia Care Unit:

Various monitoring parameters must be measured, and the patient must be clinically assessed and correlated accordingly. The haemodynamic parameters measured are SpO_2, ECG, NIBP, RR, Temperature, IBP, and $ETCO_2$ (Capnometry).

Other equipment required to shift the patient from OT to ICU/HDU/PACU includes Patient warming devices (Forced air warmer/ Warmer blanket), a shifting trolley with side rest, a transport ventilator with an attached O_2 cylinder, a self-inflating Bag mask with an O_2 insufflation port, and a Multipara Transport monitor.

1. Respiratory: SpO_2 (Pulse oximetry)— Continuous oxygen saturation, airway patency, and respiratory rate should be assessed. Particular attention should be given to monitoring oxygenation and ventilation.
2. Cardiovascular: ECG (Electrocardiography)—Heart rate and blood pressure should be routinely monitored, and electrocardiographic monitors should be immediately available.
3. Neuromuscular: NMT monitoring—Neuromuscular function should be assessed for all patients who received nondepolarizing neuromuscular blocking drugs or have medical conditions associated with neuromuscular dysfunction.
4. Mental Status, Consciousness should be periodically assessed, Usually Glasgow Coma Scale is used.
5. Temperature: Use a temperature probe (e.g., axillary or nasal) to periodically assess the patient's temperature and prevent and treat hypothermia; continuous monitoring is desirable.
6. Pain: Pain should be periodically assessed at rest and in movement.
7. Nausea and Vomiting- Periodic assessment of postoperative nausea and vomiting should be routinely performed.
8. Hydration- Postoperative hydration should be assessed and managed accordingly. Certain procedures may involve significant blood loss and require additional intravenous fluid management.

9. Urine—Urine output should be monitored in all major cases, and urinary voiding assessment should be performed on a case-by-case basis for selected patients or procedures.
10. Drainage and Bleeding—Drainage and bleeding should be assessed periodically [26].

Summary of Recommendations for Discharge [26,27].

1. Patients should be alert and oriented, or their mental status returned to baseline.

2. A minimum mandatory stay is not required.

3. Vital signs should be stable and within acceptable limits.

4. Discharge should occur after patients have met specified criteria.

5. Use of scoring systems may assist in documenting fitness for discharge.

6. The requirement to urinate before discharge and drink and retain clear liquids should not be part of a routine discharge protocol, although these requirements may be appropriate for selected patients.

7. Outpatients should be discharged to a responsible adult who will accompany them home.

8. Outpatients should receive written instructions regarding post-procedure diet, medications, activities, and a telephone number to call in an emergency.

Discharge Scoring Systems:

- **Modified Aldrete Scoring**
- **PADSS (Post Anaesthesia Discharge Scoring System)**

Criteria for the Determination of Discharge Score for Release from the Postanaesthesia Care Unit [28]	
Variable Evaluated	**Score**
Activity Able to move 4 extremities on command	2
Able to move 2 extremities on command	1
Able to move no extremities on command	0

Breathing Able to breathe deeply and cough freely	2
Dyspnea	1
Apnea	0
Circulation Systemic blood pressure <=20% of preanaesthetic level	2
Systemic blood pressure is 20% to 50% of the preanaesthetic level	1
Systemic blood pressure >=50% of the preanaesthetic level	0
Consciousness Fully awake	2
Arousable	1
Not responding	0
Oxygen Saturation (Pulse oximetry) Greater than 92% while breathing room air	2
Needs supplemental oxygen to maintain saturation >90%	1
Less than 90% with supplemental oxygen	0
Modified from Aldrete JA. The Postanaesthesia recovery score was revisited. *J Clin Anesth*. 1995; 7:89–91.	

A score of 9 out of 10 was considered adequate for discharge from the PACU

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REFERRAL OF PATIENT TO OTHER CENTRE

(Inter-facility Transfer of a Patient)

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Department of Hospital Administration

All healthcare facilities should have established procedures for referral of patient in order to maintain continuity of care.

The hospital should have a list of referring facilities with contact number and details services provided by them. This should be readily available in emergency department, OT, ICU, Labour Room etc.

The hospital should also maintain the list of available ambulance services with duty roster of drivers and contact numbers. In case of non-availability of own ambulance service, the hospital should have a plan for making an ambulance available within a defined time frame. Contact details of referral transport/ambulance displayed in the emergency, labour room, OT, ICU etc.

Prior intimation regarding the patient's condition must be shared with the referring facility. The information regarding the case, expected time of arrival and special facilities such as specialist availability, blood, intensive care services may be required, is communicated to the referring facility before shifting the patient.

All patient shall be referred with referral slip having summary of the patient's condition and the treatment given. Referral slip includes demographic details, detail history, examination findings, and management done. Reason for referral should be clearly stated and referral is authorized by competent person.

The hospital staff should confirm the suitability of referral with higher centres to ascertain that case can be managed at higher centre and will not require further referrals.

During referral of patient, the accompanying staff must be appropriate to the clinical condition of the patient.

Patient/family members should be informed and consulted before referral to other hospital. They should be explained about the need and importance of referral, possible adverse consequences to the patient if not referred on time.

A patient can also be transferred for investigations/procedures only. In case of patient referral for diagnostic test/ opinion, back referral policy is to be followed i.e., the patient will be referred back after receiving desired diagnostic test/ opinion.

The hospital should have a mechanism to facilitate the ―appropriate transfer‖ of stable, non-emergent patients who request such a transfer. Stable Patient is transferred to another organization through the ambulance, accompanied by ambulance driver, helper & EMT

The hospital should have a mechanism to facilitate the appropriate transfer of medically unstable patients. In case of transfer of patients in a life-threatening situation (like those who are on ventilator) to another organization, a doctor / ACLS Trained Staffs accompanies the

patient. The ambulance driver helper, male nurse (Trained in BCLS and / or ACLS), or doctor accompany during the transfer.

No patient should be denied resuscitation and first aid. Patient should be referred only after initial stabilization and following the safe transfer policy. As far as possible, all the transfers should be done using Institute‘s ambulances.

A register for referred patients is to be maintained in the hospital.

In case of a referral received from a hospital where no care was provided (including basic resuscitation and first aid/ registration), it needs to be notified to the concerned authorities with all details. All the patients referred from periphery and other institutes are promptly treated at the hospital if the services to be provided are within the scope pf the hospital.

Standard/Uniform referral IN and referral OUT format should be used for each referral. It should be signed and stamped by individual doctors. No generic stamp should be used.

Terminally ill patient/ brain dead/ gasping patient should not be referred to any other hospital unless there is consideration for an organ transplant that too after counselling.

Facility conducts referral audit on monthly basis

Every quarter, the referral policy is to be reviewed after gap analysis.

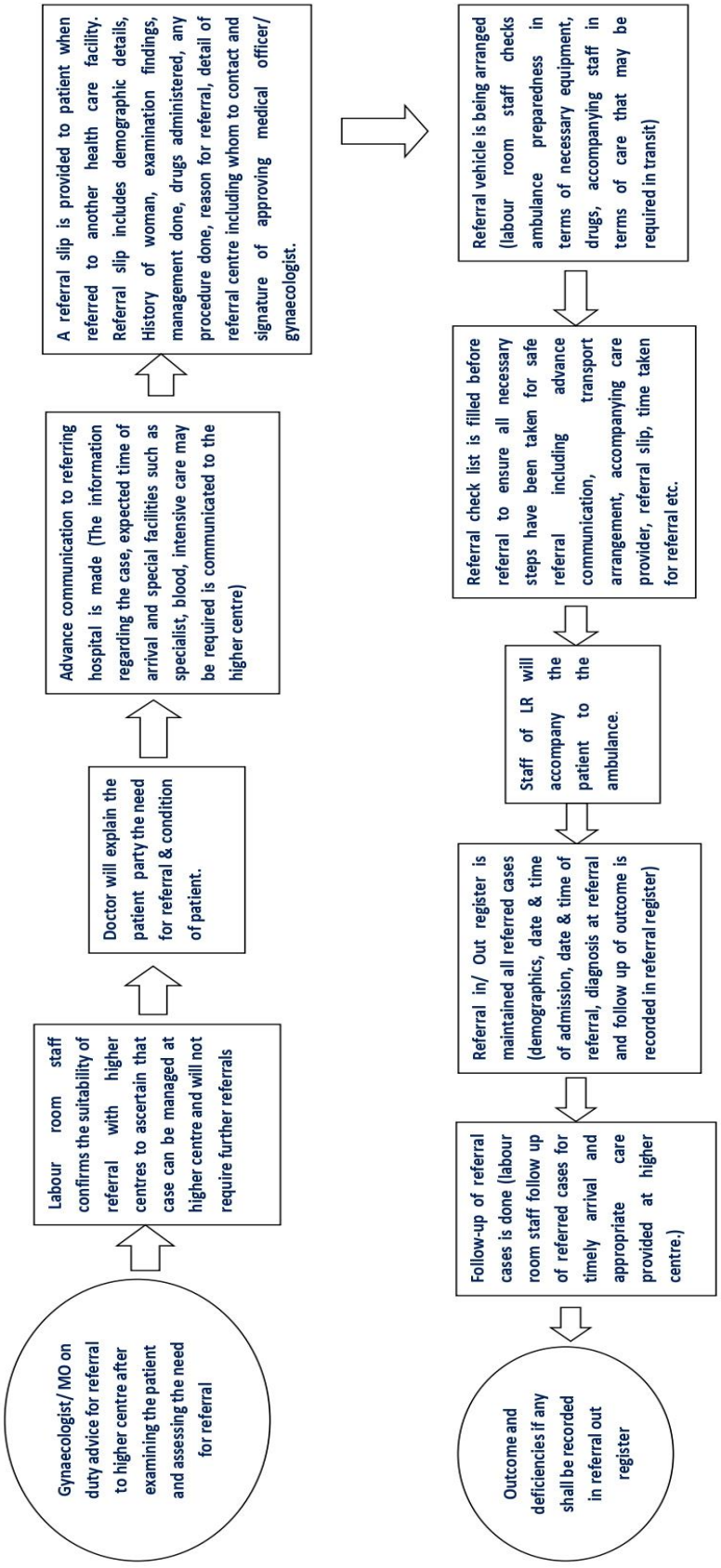
To ensure that all hospital staff are trained to use referral protocols

Review availability of referral protocols and facilitated their development in case of non-availability

Referral checklist				
SN	**Criteria**	**Complete**	**Incomplete**	**Remarks**
1	Name of Facility:			
2	Block:			
3	District:			
4	Name and signature of service provider:			
5	Phone No.			
6	Name of patient			
7	W/o or D/o of patient			
8	Age			
9	MCTS No.			
10	Date of Admission			
11	Time of Admission			
12	Date of Referral			
13	Time of Referral			
14	Date of Delivery			
15	Time of Delivery			
16	Delivery/ Referral outcome			
17	Reason for referral			Please write reason
18	Facility name (referred to)			
19	Treatment given			
20	Procedure performed			Please provide details if performed
21	Referral Note/Slip with demographic details of patient, examination findings, management done, drug administered, reason for referral, any procedure done, details of referral centre and signature of MO			

22	Advance communication detail of referral centre including whom to contact			
23	Referral vehicle is being arranged			
24	Time taken for referral			
25	Ambulance preparedness-necessary equipment, drugs, accompanying staff			
26	Accompanying care provider			
27	Referral out register is maintained: Demographics, date S time of admission, date S time of referral, diagnosis at referral and follow up of outcome is recorded in referral register			
28	Follow up done: labour room staff follow up of referred cases for timely arrival and appropriate care provided at higher centre			

REFERRAL PATHWAY



VERBAL COMMUNICATION

1. Purpose:

To reduce the risk of errors resulting from misinterpreted verbal orders and test results by improving the effectiveness of communication among care providers.

2. Scope:

All Patient Care Areas

3. Policy:

Verbal communication of orders and all test results should be limited to situations where immediate written or electronic communication is not feasible.

3.1 Specific Information:

• The receiver of the verbal order writes down the complete order, and then reads it back to the sender. The sender then confirms/verifies the accuracy of the order.

• Verbal orders and test results are immediately written by the individual receiving the order or result in the patient file

• The verbal order or test result is read back verbatim to the prescriber for verification of accuracy.

• Repeating the order or test result back to the prescriber without writing it first is not acceptable.

• If read-back in emergent situations {such as a Code Blue (for cardiac arrest) in the Emergency Department or in the operating room} would or could jeopardize the care of the patient, a "repeat back" is acceptable.

• The read-back applies to all telephonic/verbal orders and test results (both normal and abnormal values).

• Verbal orders are entered into the patient's medical record with the date, time, name, and titles of the people sending and receiving the order/result, and signed and dated by the individual receiving the order.

• Verbal inpatient orders are reviewed and countersigned by the prescriber or another physician member of the team caring for the patient as soon as possible, but no later than upon completion of the Medical Record. Verbal orders should be ratified within 24 hours by the Ordering Consultant.

• Only approved abbreviations are used in the documentation of verbal orders.

• There is no exception to the list of verbal order of medication.

• Verbal Medication Orders should be written in progress note by the staff nurse or duty medical officer.

- Elements included in a verbal medication order are:

a. Date, time;

b. Name of patient;

c. Drug name (brand or generic);

d. Dosage form (e.g., tablets, capsules, inhalants, etc.);

e. Exact strength or concentration;

f. Dose, frequency, and route;

g. Quantity and/or duration;

h. Name of prescriber;

i. Name and title of individual receiving the order.

- The content of verbal medication orders is clearly communicated.

a. The name of the medication is confirmed by spelling, if necessary, for clarity.

b. In order to avoid confusion with spoken numbers, a dose such as 50 mg is dictated as "fifty milligrams...five zero milligrams" to distinguish from what could be heard as "fifteen milligrams". When writing the verbal order, the dose may be written in numerical format.

c. Route and frequency are provided without abbreviations (i.e., "1 tab tid") and are verbally communicated as, "Take/give one tablet orally three times daily." When writing the verbal order, use standard approved abbreviations.

VULNERABLE PATIENTS POLICY

Dr. Biraj Chandra Paul
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1. Definition of vulnerable patient:

Vulnerable patients are those who are or may be unable to protect and care for themselves from substantial damage or exploitation, or who require additional care.

As a result, there are possible dangers (physical or mental) connected with vulnerable patient during their hospitalization, which the hospital may foresee in order to provide appropriate preventive care.

2. Purpose of vulnerable patient policy in hospital:

To identify vulnerable patient and to prevent them against any harm or exploitation during their stay in the hospital and to provide them a safe and secure environment.

3. Scope:

The vulnerable patient policy is applicable in all patient care areas of the hospital

4. Policy:

The vulnerable patients shall be kept in safe and secure environment to minimize the risk of any harm or abuse.

Staff must be taught to care for vulnerable groups, and all care providers must be made aware of the risks they face.

All vulnerable patients shall be identified by the nursing staff during admission and orange coloured identification band shall be secured as per the patient identification policy of the hospital.

4.1 Vulnerable Patients are:

1. All patients aged 65 years of age and above
2. All patients aged 12 years of age and below
2. Patients with pregnancy and in the post-natal care

3 Patients with limited physical mobility- Specially those who cannot perform their daily necessary activities of living i.e. going to the bathroom, eating etc.

4 Patients with impaired mental function

5 Comatose patients

6 An unconscious female patient left alone or unattended. Survivors of sexual assault.

7 Patients on wheel chairs, trolleys, with walking and hearing aids

8 Patients with impaired communication or language problems

9 Patient with impaired bladder function

4.2 For providing care to the vulnerable patients:

The hospital should provide a safe and secure environment:

1. Beds should be provided with side rails and lockable wheels.
2. The nursing staff should visit frequently and keep the patients and their families informed about the patient care area and safety measures.
3. All vulnerable patients must be admitted and treated in wards where such facilities are provided.
4. Patients falling into the above categories are encouraged to be admitted to the hospital with an attendant. If the patient does not have an attendant, the hospital may arrange for one.
5. Patients with mental illness must be accompanied by their legal guardian during admission in the hospital.
6. The Hospital may take measure to prevent new born theft, sweeping and baby fall by providing CCTV cameras in all key areas, 24X7 Security Guard arrangement, providing window grills, frequent rounds by nursing staff and encouraging one attendant to accompany the patient at all times. The hospital shall also provide identification tag for both mother and baby.

4.3 PROCEDURE:

Care of Vulnerable Patients:

1. Prompt attention and service shall be provided while minimizing waiting times in OPD & diagnostics for vulnerable patients.

2. It is important to identify elderly patients who struggle with walking or are confined to bed, and ensure they receive assistance to visit a doctor or be admitted to the hospital. The

staff will alert the ward boys when they encounter such patients, and they will arrange for transportation in a wheelchair.

3. Patients with physical disabilities should be given access to a wheelchair or trolley within the hospital.
4. All patients falling in the vulnerable group shall be screened for special assistance needs during hospitalization.
5. Nursing Assessment for vulnerable patients shall be done on admission and reassessment to be done depending on progress of patient status or any change of care level.
6. Depending on the vulnerable aspect, each patient will be provided with actions and support to ensure that care and safety aspects are addressed.
7. Vulnerable patients will not be left alone at any given time.
8. A female attendant shall attend female patients for their physical interventions such as bathing and toilet.
9. All minors shall be admitted along with an attendant approved by the family.
10. Any special requests made by the patient/family will be respected.
11. A list of vulnerable patients is generated in the daily census and informed to the Nursing In charge
12. Regular monitoring will be ensured by supervisory staff to ensure the safety and security of vulnerable patients.
13. Vulnerable patients must have side railings on their beds to guarantee their safety.
14. There shall be one responsible bystander always with the patient.
15. The patient's condition and dietary and health-related activities will be communicated to the relatives.
16. Counselling facility for mentally challenged patients shall be provided.
17. Mentally challenged patients shall be provided special attention by the allotted nursing officer.
18. The nursing staff and the attendees shall show maximum tolerance and patience while dealing with these patients.
19. Attendants/relatives shall be encouraged to be with them whenever advisable.
20. Special cares should be taken by the treating doctor or the attending nurse/technician to explain things related to the disease and treatment carefully and patiently.

21. In case informed consent needs to be obtained while treating a child or mentally challenged patient, it shall be ensured that consent is obtained from the persons directly related to the patient like father, mother, brothers or sisters.

22. Everything about the proposed procedure / treatments shall be informed along with possibilities of likely complications that may arise.

23. Installation of CCTV cameras in all key areas, 24X7 Security Guard arrangement, providing window grills, frequent rounds by nursing staff and encouraging one attendant to accompany the patient at all times to prevent new born theft, sweeping and baby fall. The hospital also provides identification tag for both mother and baby to prevent the same

24. Medical measures like screening and prevention for hypoxia, hypothermia, bed sores, pain management should be done. Restorative care, and judicious use of medications, may be practiced.

Other measures:

- Wearing Safety Belt during transportation on a wheelchair or stretcher.
- Availability of Comfortable environment to vulnerable patients.
- Consent for Restraint from family member.
- Restraint Monitoring (2 hourly).
- Pressure ulcer preventive care provided to the bedridden patient and fall risk assessment.
- Anti-skid Mat outside the washroom and dry surface
- Anti-skid tiles in toilet
- Toilets for Divyangjan

POLICY & PROCEDURE FOR IDENTIFICATION OF PATIENTS

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This document shall provide guidelines for the hospital to identify patient correctly during hospitalization. This policy will be applicable throughout whole hospital.

Identification of patient correctly is the first pillar of International Patient Safety Goal for Hospital, National Patient Safety Goal and also an important component of WHO Patient Safety Solution & Surgical Safety Checklist. In order to identify patient correctly always use two identifiers; it can be Name and Unique Hospital Identification Number (UHID)/Date of Birth (DOB)/Central Registration Number (CR No.) for both Inpatient (IPD) and Outpatient (OPD) Department cases. For unknown/ comatose patient brought in Emergency Department, identify patient as unknown 1 or 2. Never use room number and bed number for identification of patient.

The identification of patient must preferably be in active communication (spoken words) rather than passive communication (gesture/ head nodding etc.)

The identification of patient must done prior to commencing any procedure without any interruption and it must be repeated before any procedure.

1. **POLICY OBJECTIVE:**
   - 1.1 To correctly identify patients to prevent medication errors, transfusion errors, testing errors, wrong person procedures, and the discharge of infants to the wrong families.
   - 1.2 To ensure that patients are properly identified prior to any care, treatment or services taking place in the hospital e.g., correctly identify patients during inter-departmental transfer, during change in care level of patients and during any procedures.

2. **EXCEPTIONS:**
   - 2.1 Patients unable to provide identifying information e.g., hermodynamically unstable, comatose, unconscious, psychiatric disorders and unknown patients.
   - 2.2 Small infants and patients with a disease process, injury, or treatment that prevents safe placement of Identification (ID) band on any extremity
   - 2.3 Due to non-availability of supply of patient ID band from Hospital Stores due to any reason.

3. PROCEDURES:

3.1 Identifying a Patient with ID Band

- The hospital staff must ensure that all inpatients must wear an ID band at all times during the stay in the hospital.
- The patient‘s ID must be confirmed by the staff before administering any medication or carrying out any intervention or procedure.
- At least two identifiers (e.g., patient‘s full name and UHID number/ Central Registration number) must be used to verify patient‘s ID.
- If the patient is found to have no ID band, neither medication should be administered, nor should any procedure or intervention be performed without any confirmation from the Head of the Department.
- In cases in which patient‘s ID band is torn or rubbed or has been removed, for any reason, it is the responsibility of the staff to ensure that it should be replaced without any delay.
- Procedures Requiring Correct Identification of Patients:

  The list below is not exclusive, patient should be identified before:

  I. Consultation in OPD
  II. Admission of patient
  III. Blood Sampling
  IV. Blood Transfusion
  V. Collecting of patient body fluid samples
  VI. Confirmation before declaration of death
  VII. Administration of any Medications
  VIII. Surgical intervention and any invasive procedure
  IX. Transport/ transfer of patient
  X. Inter-hospital and inter-departmental transfer of patient
  XI. X-ray and other imaging procedures
  XII. Transferring baby to family

3.2 Placement of Patient’s ID Band:

The ID band shall be put as follows:

i. First choice right wrist
ii. Second choice left wrist
iii. Third choice ankles, right or left
iv. Patients who are at risk of or likely to remove their ID band should ideally have two ID bands in place, one on the wrist and the second on the ankle. The ID band shall only be removed when the discharge procedure is complete. One additional identical ID band may be kept in the patient‘s file.

3.3 Types of Identification Bands

- There are different colours of bands as per the category under which the patient falls. The different colours of bands are:
  • White Band – Universal band, mandatory to be worn by all patients admitted to the hospital.
  • Yellow Band – For patients who have allergies or any history of allergy
  • Orange Band – For patients who need extra attention or care and/or patients who are above 65 or below 14 years of age and have potential to fall (vulnerable patients).
  • Pink and Blue band – Identification for new-born babies, pink is for girls and blue is for boys.

3.4 Process of patient identification using name and UHID/ CR No.:

Verify patient to their ID band

⇩

Confirm stated patient‘s first and last name are an exact match to the patient‘s name on the ID band

⇩

Check UHID Number/ CR Number on the patient‘s ID band.

⇩

Confirm the UHID/ CR. No. is an exact match to the UHID/ CR No. on the patient‘s file

Verifying patient ID is defined as matching the patient to the ID band. Confirmation of patient ID required the use of two available patient identifiers (i.e., name both first and last name, UHID/ CR No. number/DOB/Age). Matching the patient to the ID band could only be done by asking the patient his or her name and matching the UHID/ CR No from the file to the ID band attached to the patient‘s wrist. Various other parameters to be identified, such as:

• Method of patient verification

• Colour of ID band used

• Identification details on the band

• Legibility of identification details

• Presence of core identifiers on the band

• Verbal confirmation of patient‘s name

• Identification checks before transfer to procedure room

• Type of procedure

• Double identification before medication

• Double identification before procedure

3.5 The identification band must include the following:

1. **Patient's full name**
2. **UHID/ CR No./ IP No.**
3. **Age/ Sex**
4. **Ward**
5. **Blood Group**
6. **Consultant's name**

3.6 In rare events of the patient being unknown, the identification band should state:

1. **Emergency No.**
2. **UHID/ CR No./ IP No.**
3. **Gender**
4. **Approximate Age**
5. **Ward or Location**

As more information becomes available the identification band must be updated.

3.7 Unknown/ unconscious patients:

For unknown and unconscious patients (such as trauma patients), identification is made by emergency staff until a unique identification has been made. For unknown/ comatose patient brought in Emergency Department, identify patient as unknown 1 or 2.

3.8 Theatre/ Sedated Patients:

Patient identification is confirmed by theatre staff prior to being anaesthetized. A member of this team identifies the patient prior to the medical/ surgical exposure. Identification to be done on patient‘s arrival in the pre-operative area and again in the operative room. Always use WHO Surgical Safety Checklist for surgical cases and honestly perform Sign In, Time Out and Sign Out procedure.

3.9 Identification of patient in the OPD and OPD sample collection area:

Patient who visits OPD/ Sample collection area are identified by full name and age/date of birth verbally and match with the document like OPD slip/requisition slip for sample collection. No identification band in OPD

3.10 Transfer between patient care areas like wards, ICU etc.:

It is not uncommon that beds are shared with attendants of patient or interchanging the beds by patient themselves and if without any confirmation injections or intravenous line is secured to them, it can be a disastrous situation for the hospital. Hence while going to the patient‘s room
/ bed always check the room/ bed number then ask the patient his full name, age/DOB and cross check from the case file.

Patient who are transferred from one patient care area to another should have their ID band checked as part of their admission/ transfer process. If details are incorrect/ missing they must be given a new ID band with the correct details and the old one must be removed, an incident form must be completed. Do not write over the old ID band.

3.11 Blood Transfusion:

The bedside check is vital to prevent transfusion error.

Two practitioners are responsible for correct identification of patient

a) Check verbally
b) Check ID band

If it is not sure-DO NOT give blood until patient has an accurate ID band

3.12 Maternity: (As per hospital policy)

Mother‘s ID band must include all details as per policy

Baby‘s ID band:

Two ID band should be applied to two separate baby limbs and checked daily.

Information to be read:

First ID band:

Mother‘s name of the baby

UHID No. of mother

Date & mode of Delivery

Second ID band:

Baby‘s gender followed by mother‘s full name

Baby‘s UHID number

Date & Time of Birth

The mother confirms the details with the nursing officer. Following delivery, the ID band is applied to the baby‘s ankle.

On discharge the nurse removes the First ID band and the details checked with the mother. The second ID band is left with the baby to be removed by mother at home.

No baby is found without wearing an ID band even at discharge.

However, four identity bands which are exactly identical with the following information may be used for identification of baby:

Name of the mother (preferably)/ father:

Sex of the baby:

Date & Time of Birth:

Mother‘s UHID/ CR. No.:

One band each, may be secured around the left ankle and left wrist of the baby, one band may be tied around the left ankle of the mother and the fourth may be preserved by the hospital.

3.13 Psychiatric Ward: All patient in the psychiatric ward may be identified by ID band secured above the left ankle and the left wrist. One additional identical ID band may be kept in the patient file.

3.14 Patient who does not wear ID band:

There are some situations where a patient may not wear ID band:

- The patient refuses to wear the ID band
- The patient is allergic/having skin irritation
- The patient removes the ID band

The patient should be informed of the potential risk of not wearing the ID band. This discussion and the reason for not wearing the ID band must be documented in the patient record. In case, of history of allergy to the material of the ID band alternate methods may be used for identification of patient as per hospital policy.

The ID band should be made of water proof material which can be removed only by tearing/ cutting once secured.

NEEDLE STICK INJURY AND POST EXPOSURE PROPHYLAXIS

By:

Dr. Annu Gupta

Dr. Md. Jamil

Post Exposure Prophylaxis (PEP)

"Post exposure prophylaxis" (PEP) refers to the comprehensive management given to minimize the risk of infection following potential exposure to blood-borne pathogens (HIV, HBV, HCV).

This includes:[1]

1. First aid
2. Counselling
3. Risk assessment
4. Relevant laboratory investigations based on informed consent of the source and exposed person.
5. Depending on the risk assessment, the provision of short term (4 weeks) of antiretroviral drugs
6. Follow up and support

"Exposure" which may place an Health care worker (HCW) at risk of blood-borne infection is as follows:

1. Per cutaneous injury (e.g. needle-stick or cut with a sharp instrument).
2. Contact with the mucous membranes of the eye or mouth.
3. Contact with non-intact skin (particularly if the exposed skin is chapped, abraded, or afflicted with dermatitis).
4. Contact with intact skin when the duration of contact is prolonged (e.g. several minutes or more) with blood or other potentially infectious body fluids.

Potentially infectious body fluids are:

- Blood
- Semen
- Vaginal Secretion
- Cerebrospinal fluid
- Synovial, pleural, peritoneal, pericardial fluid
- Amniotic fluid
- Other body fluids contaminated with visible blood

Risk of transmission of infection:

The risk of transmission of HIV infection following Needle Stick Exposure is around 0.3% and after mucous membrane splash to eye, oro-nasal is around 0.09%. For transmission of HBV is 6-30% and for HCV is 1-1.8% following the needle-stick exposure.[2]

Management after potential exposure with infectious body fluids:

Step 1: Management of Exposure Site: FIRST AID

a. After percutaneous Injury: If the skin is broken after a needle-stick or sharp instrument immediately wash the wound and surrounding skin with water and soap, and rinse**. Do not scrub. Do not use antiseptics or skin washes (bleach, chlorine, alcohol, betadine).**

b. **After a splash of blood or body fluids:**

i. To unbroken skin:

- Wash the area immediately
- Do not use antiseptics

ii. For the eye:

- Irrigate exposed eye immediately with water or normal saline.
- Sit in a chair, tilt head back and ask a colleague to gently pour water or normal saline over the eye.
- If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it.
- Once the eye is cleaned, remove the contact lens and clean them in the normal manner. This will make them safe to wear again.
- Do not use soap or disinfectant on the eye.

iii. For mouth:

- Spit fluid out immediately.
- Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times.
- Do not use soap or disinfectant in the mouth.

Dos and Don'ts for the Exposed individual	
Dos	**Don'ts**
Stay calm	Do not panic
Remove gloves, if appropriate	Do not place the pricked finger into the mouth
Wash exposed site thoroughly with running water and soap	Do not squeeze blood from wound
Irrigate thoroughly with water, if splashes have gone into eyes and mouth	Do not use bleach, alcohol, iodine, antiseptic, detergent etc.
Consult the designated physician/ personnel immediately as per institutional guidelines, for management of occupational exposure	

Step 2: Establish eligibility for PEP

Eligibility for PEP is determined by:

a. Source HIV status: Assessment for eligibility should be based on the HIV status of the source whenever possible and may include consideration of background prevalence and local epidemiological patterns.

b. Type and severity of exposure: Exposures that may warrant HIV PEP include:

- Type of body fluids: blood, bloodstained saliva, breast milk, genital secretions and cerebrospinal, amniotic, peritoneal, synovial, pericardial or pleural fluid. While these fluids carry a high risk of HIV infection, this list is not exhaustive. All cases should be assessed clinically, and health workers should make decisions as to whether the actual exposure constitutes a significant risk.

- Types of exposure:
    - Mucous membrane: sexual exposure; splashes to eye, nose, or oral cavity
    - Parenteral exposures: an accident with a high calibre needle (>18 G) visibly contaminated with blood
    - A deep wound (haemorrhagic wound and/or very painful); transmission of a significant volume of blood
    - An accident with material that has previously been used intravenously or intra-arterially

Exposures that do not require HIV PEP include:

- When the exposed individual is already HIV positive
- When the source is established to be HIV negative
- Exposures to bodily fluids that do not pose a significant risk, i.e., tears, non-blood-stained saliva, urine, and sweat
- Exposure to intact skin (unless abraded or inflicted with dermatitis)

*Ascertainment of source HIV status may be difficult in some settings. In settings with high background HIV prevalence or where the source is known to be at high risk for HIV infection, all exposure may be considered for post-exposure prophylaxis. PEP initiation should never be delayed due to unavailability of the source's HIV test results.

Step 3: Counselling for PEP

For an informed consent, exposed persons (clients) should receive appropriate information about what PEP is and the risk and benefits of PEP. It should be clear that PEP is not mandatory. The client should understand details of window period, baseline test, drugs that are used, their safety and efficacy and issues related to these drugs during pregnancy and breast-feeding.

He/she should be counselled on safe sexual practices till both baseline and 3 months HIV test are found to be negative.

Psychological support: Many people will feel anxious after exposure. Every exposed person needs to be informed about the risks and the measures that can be taken. This will help to relieve part of the anxiety, but some may require further specialized psychological support.

Step 4: Laboratory evaluation

HIV, HBV and HCV testing of exposed person should be done as early as possible. The decision whether to test for HIV or not should be based on the informed consent of the exposed person. A positive HIV status at baseline indicates need for referral to HIV care and treatment.

Step 5: Prescribing PEP

- Timing of PEP: As post-exposure prophylaxis (PEP) for HIV has its greatest effect if begun within 2 hours of exposure, it is essential to act immediately. There is little benefit if >72 hours have lapsed but PEP can still be used if the health care worker presents after 72 hours of exposure. The prophylaxis
- needs to be continued for 28 days.
- A 28-day prescription of antiretroviral drugs should be provided for HIV post-exposure prophylaxis following initial risk assessment.
- Report exposure immediately to appropriate authority. Never delay the start of therapy due to debate over regimen. In cases with exposure from person on ART, start available three drug regimens and seek opinion after that. In case of highly treatment experienced source, initiate first dose as per guidelines and expert opinion should be sought.

Step 6: Follow-up

Enhanced adherence counselling is recommended for individuals initiating HIV post exposure prophylaxis.

Follow-up client at 7 days, 14 days, 28 days and 12 weeks after starting PEP.

Follow-up HIV testing at 4 weeks, if negative, test again at 12 weeks after which test as per risk category.

Assess for and manage adverse effects due to PEP.

Monitor for acute sero-conversion illness, within 3-6 weeks after exposure. If suspected, refer to treatment services.

Assessment of the exposed individual:

- The exposed individual should have confidential counselling and assessment by an experience physician.
- The exposed individual should be assessed for pre-existing HIV infection intended for people who are HIV negative at the time of their potential exposure to HIV.
- Exposed individuals who are known or discovered to be HIV positive should not receive PEP. They should be offered counselling and information on prevention of transmission and referred to clinical and laboratory assessment to determine eligibility for antiretroviral therapy (ART).
- Besides the medical assessment, counselling exposed HCP is essential to allay fear and start PEP (if required) at the earliest.

Counselling for PEP:

- Exposed persons (clients) should receive appropriate information about what PEP is about and the risk and benefits of PEP in order to provide informed consent.
- It should be clear that PEP is not mandatory.
- Informed Consent.
- Psychological support: Many people will feel anxious after exposure. Every exposed person needs to be informed about the risks and the measures that can be taken. This will help to relieve part of the anxiety, but some may require further specialized psychological support.
- Documentation on record is essential. Special leave from work should be considered for a period of time e.g. 2 weeks (initially) then, as required based on assessment of the exposed person‘s mental state, side effects and requirements.

PEP Prescription:

PEP must be initiated as soon as possible, preferably within 2 hours

Exposed person	Preferred regimen for PEP	Alternate regimen (if preferred regimen is not available or contra-indicated)
Adults and adolescents (≥ 10 years old and ≥ 30 kg body weight)	Tenofovir (300 mg) + Lamivudine (300 mg) + Dolutegravir (50mg) (one tablet OD)	Tenofovir (300 mg) + Lamivudine (300 mg) (FDC – one tablet OD) + Lopinavir (200mg)/Ritonavir (50mg) (two tablets BD) or Tenofovir (300 mg) + Lamivudine (300 mg) +

		Efavirenz (600mg) (one tablet OD)
Children (weight ≥20 Kg and age ≥6 years	Zidovudine + Lamivudine (dosage as per weight band)** + Dolutegravir (50mg) (one tablet OD)	If Hb <9 gm/dl: Abacavir + Lamivudine (dosage as per weight band) + Dolutegravir (50mg) (one tablet OD) or Zidovudine + Lamivudine + Lopinavir/ Ritonavir (dosage as per weight band) **
Children (weight <20 Kg or age 6< years)	Zidovudine + Lamivudine + Lopinavir/ Ritonavir (dosage as per weight band) **	If Hb <9 gm/dl: Abacavir + Lamivudine + Lopinavir/ Ritonavir (dosage as per weight band) **

Availability of PEP drugs:
PEP drugs are required on an urgent basis after accidental exposure and should be available and accessible round the clock. In all cases, the first dose of PEP should be offered as soon as possible, preferably within 2 hours, once the decision to give PEP is made. The PEP regimen should be made available from ARV drug stocks, in emergency ward, with proper documentation. A regular check should be made for expiry of drugs with replacement of short expiry drugs.

Documentation:
PEP cases should be documented in accidental exposure form (including consent form) and PEP register and reporting of drug consumption should be done.

Prophylaxis for Hepatitis B Virus

Pre-Exposure Prophylaxis for Hepatitis B Virus

Routine vaccination against HBV is mandatory for the HCW since they are at higher risk of exposure to HBV infection than the general population as they are more likely to come in contact with blood, body fluids or sharps. After 1-2 months of completion of three dose Hepatitis B vaccination series, HCW should be tested for anti-HBs titres. A seroprotective level of anti-HBs after completion of a vaccination series is defined as anti-HBs ≥10 mlU/mL; a response < 10 mlU/mL is inadequate and is not a reliable indicator of protection.

Post-Exposure Prophylaxis For Hepatitis B Virus

If the source is KNOWN or SHOWN to be positive for Hepatitis B surface antigen (HBsAg), the level of exposed HCW anti-HBsAg antibodies titre is important.

1. If the injured HCW is immunized (anti-HBs antibodies > 10 IU/mL), whether from vaccination or past infection they are protected, and there is no need for Hepatitis B immunoglobulin after a potential or confirmed exposure to Hepatitis B.

2. If the HCW is unimmunized or a non-responder (did not seroconvert to the vaccine) or has antibody levels to HBsAg less than 10 IU/mL), and sustains a needle-stick injury from a patient with evidence of chronic HBV (HBs Ag positive), ***they should be given HBIG (hepatitis B hyperimmune globulin) 0.06ml/kg as soon as possible, preferably within 24 hours and should simultaneously start/reinitiate the course of HBV immunization with three- dose of hepatitis B vaccine at a different site for unimmunized/previously unfinished second hepatitis B series.*** The second and third doses should be separated by at least 2 months interval. If the HCW has had two series of the HBV vaccine and was still a non-responder, they should receive a second dose of HBIG, 1 month after the first dose. Following completion of 3 dose vaccination series, the level of immunity (antibodies to surface antigen i.e. anti-HBs titres) should be checked 1-2 months later. Those whose anti-HBs titres are <10mIU/ml should complete a second 3- dose vaccine series or be evaluated for HBs Ag positivity. If HBsAg is positive after exposure, the person should be counselled regarding the modes of prevention of HBV transmission to others and to seek treatment for HBV.

Post exposure prophylaxis for percutaneous or per mucosal exposure to hepatitis B virus

Vaccination/Serostatus	Source HBs- Antigen positive	Source HBs- Antigen negative	Source unknown
Unvaccinated	Hepatitis B immunoglobulin(HBIG) single dose and initiate vaccination	Initiate Vaccination	Initiate Vaccination
Responder to vaccine/Protected	No treatment	No treatment	No treatment
Non responder After one series (3-dose) of vaccination	HBIG single dose and initiate revaccination	No treatment	If source known to be high-risk: treat as if source were HBsAg-positive (HBIG single dose and initiate revaccination)
Non responder After 2 series (6 doses) of vaccination	HBIG two doses (separated by 1 month)	No treatment	If source known to be high-risk: (treat as if source were HBsAg-positive) HBIG single dose and initiate revaccination

Antibody response unknown	Test exposed person for anti-HBs: If ≥10 mIU/mL: no treatment If <10 mIU/mL: HBIG single dose and vaccine booster	No treatment	Test exposed person for anti-HBs If ≥10 mIU/mL: no treatment If <10 mIU/mL: initiate revaccination

Exposure to hepatitis C virus:

Hepatitis C virus infection may lead to development chronic liver disease in majority of cases if not treated. Depending on whether active viral replication is occurring for Hepatitis C, the risk of transmission after a sharps injury from an HCV infected person varies from 1-1.8%. No post exposure therapy is available for hepatitis C, but seroconversion (if any) must be documented. ***The exposed HCW should be retested for HCV antibodies at 3 and 6 months with monitoring of clinical signs and symptoms***. Preferably the exposed HCW should be under the care of a hepatologist/physician so that HCV infection if happens is detected at the earliest (Liver enzymes monitored and in case these increase that may indicate infection) and treatment for HCV can be instituted. Standard precautions and other infection control practices should be followed. For any occupational exposure to blood borne pathogens, counselling and appropriate clinical and serological follow-up must be provided.

ANNEXURE I

PROFORMA
Needle Stick Injury And PEP
AIIMS Guwahati

Date:_____ **Registration No_____**

Doctor's detail who has examined the patient:
Name_____
Designation_____

Nodal Officer for PEP & NSI:
XXXXXXXXXXXXXXX
Department of XXXXXXXXX
AIIMS Guwahati
Contact Number: +91-XXXXXXXXXX

PLEASE DON'T GIVE THIS PROFORMA TO THE PATIENT

KEEP THIS FILLED UP PROFORMA IN THE FOLDER

This Proforma to be filled up for all cases of needle stick Injury or other Injury occurred inside the hospital that having the potential of infection transmission

Patient's Detail:

Name:.....

Age ..... Sex.....

Designation:.....

Contact number:.....

Department where posted.....

Signature.....

Exposure History Details

1. Date and Time of the Exposure:.....
2. Place of exposure (Department, Ward, ICU etc):.....
3. Time since exposure to reporting: .....
4. Type of Contact:.....
   a) Penetrating wound b) Abrasion c) Mucosal Exposure d) Intact skin
   e) Other (specify).....
5. In case of injury with instrument, specify the instrument:
   a) Hollow Needle b) Solid Needle c) Scalpel or other surgical Blade
   d) Other Specify:.....
6. Purpose of sharp item used……
7. When did injury occurred?
   a. Before the use of instrument b. During the use c. After the use of instrument.
8. Source of Potential Infectious Material:.....
   a) Blood b) Blood Mixed Body fluid c) Blood stained instrument or material
   d) Body Fluid e) Unknown f) Other Specify.....

Injury Details

1. Site of the injury:.....
2. Type of injury:.....
3. Circumstances that causes injury……..

Vaccination status

(Of the exposed patient)
Hepatitis B Vaccination (*Tick mark the appropriate statement*):

a) Vaccination completed and titre is known to be more than 10 units
b) Vaccination completed but titre is not known.
c) Incomplete Vaccination.
d) Not Vaccinated
e) Not know whether vaccinated or not.

Source Patient Details

a) Source patient **Known / Unknown**
b) Source from (department, ward etc).....
c) If source patient is known then complete the details of the source patient *(Tick mark the appropriate result)*:

a) HBsAg- Reactive/ Non-Reactive/ Unknown.
b) Anti HCV- Reactive/ Non-Reactive/ Unknown.
c) HIV I&II- Reactive/ Non-Reactive/ Unknown.

Viral Marker Report of Exposed Patient

a) HBsAg- Reactive/ Non Reactive/ Unknown.
b) Anti HCV- Reactive/ Non Reactive/ Unknown.
c) ICTC- Reactive/ Non Reactive/ Unknown.

A. HIV Exposure Code- A. EC1. B. EC2. C. EC3

B. HIV Source Code- A. HIV SC1. B. HIV SC2. C. HIV SC unknown

TREATMENT

(Tick Mark the appropriate Points)

(Kindly consult the PROTOCOL BOOK for appropriate treatment option)

a) First Aid with counselling
b) Injection Tetanus Toxoid
c) Hepatitis B Immunoglobulin with First dose of Hepatitis B Vaccination
d) Hepatitis B Immunoglobulin with Booster dose of Hepatitis B Vaccination
e) PEP for HIV given
f) Others (specify).....

Follow Up

A. Person taking PEP for HIV:

Week 2 and 4: LFT, Complete blood count, RBS, KFT.....
Week 6: HIV-Ab.....
Month 3: HIV-Ab, Anti HCV, HBsAg.....
Month 6: HIV-Ab, Anti HCV, HBsAg.....

B. Person not taking PEP for HIV:

Week 2 and 4: Clinical Monitoring.....
Week 6: HIV-Ab.....
Month 3: HIV-Ab, Anti HCV, HBsAg.....
Month 6: HIV-Ab, Anti HCV, HBsAg.....

Any Drug Reactions or Adverse Reaction:

.....

.....

.....

.....

.....

.....

Consent for Post Exposure Prophylaxis

I …….…….. s/d/w of .....a resident of ….....hereby declare that I voluntarily give my consent to get the PEP for hepatitis B/ hepatitis C/ HIV after understating the nature of injury I suffered and the possibility of transmission of hepatitis B, hepatitis C and HIV infection.

I have been informed in the language I understand about the nature of the injury I suffered and the possibility for transmission of hepatitis B, hepatitis C and HIV infection. I also understand the limitation of the post exposure prophylaxis in the prevention of the above mentioned infections and also the side effect and expected complication of the treatment. I also understand the need of regular follow up and I agreed that I will comply with the follow up schedule.

_____ _____ _____

Name of Subject Date Signature of Subject

We have witnessed that the patient signed the above form in the presence of his/her free will after fully having understood its contents.

_____ _____

Name and signature of the person who has explained the details to the patient.

_____ _____ _____

Name of Witness Date Signature of Witness

References :

1. Adapted from National AIDS Control Organization (2021). National Operational Guidelines for ART services, 2021.New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.
2. King KC, Strony R. Needlestick. [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK493147/
3. Post-exposure Prophylaxis after Hepatitis C Occupational Exposure in the Interferon-free Era

DIVYANGJAN SAFETY

Dr Amit Kumar Mallik
Assistant Professor, Department of Rehabilitation Medicine
AIIMS Guwahati

1. Salient features for Divyangjan Friendly hospital:

- All entry door should be sliding/folding type
- Entrance width >=(3 ft) without any step or raiser on it
- Handle height should be approximately 2 ft from the floor
- Lever lock system should be used at accessible height
- Visibility should be very good in both day and night
- Flooring should be even and non-slippery
- At least 5 ft turning space for wheel chair should be kept near all entry points in all the wards
- The layout of ward should be such that the bed should not be in a corner of a wall, at least 3ft should be provided for a wheelchair from the side of the wall for access and there should be large enough space for transfer by a wheelchair user, or for a helper to assist in the transfer
- The bed should be at a height from the ground that permits wheel chair turning under the bed, a minimum 3ft width should be kept in front and any other furniture
- The max. and min. height of bed-shelf should be between 1.5 ft-4ft
- Ramps should be there in all buildings with proper signages to reach there and it should have hand rail to grab on and the width of ramp should be minimum 3ft with slope of (1: 20- 1: 12)
- In toilets and bathrooms, the basin should be installed at a height and position for convenient access with appropriate knee clearance and foot clearance space and the mirror height should also be as to permit its use
- Grab rails should be at a height and position that allows for easy gripping, should have call buttons or other signals devices at a height and position easily reached in an emergency
- Toilet compartments should have enough floor space for wheelchair users to enter and exit (1500 x 1500 mm), toilet bowl should be of a type (e.g. wall-hung) and in such a position as to permit easy approach by wheelchair users
- The seat of the toilet bowl should be at the correct height (16-20 inch)
- Western Commode compartments should have support rails preferably upward folding at a position and height of 26-28 inch from the floor

2. Pre-requisite for implementation:

- Commitment from top leaders
- Engagement from regulatory authority- The Department of Empowerment of Persons with Disabilities (DEPwD)-President, Secretary, under-secretary, director etc
- Financial assistant and fund allocation system-

Implementing Agencies:

- Departments of the State Governments / Union Territories.
- Autonomous Bodies / Statutory Bodies / Public Sector Undertakings set up by the Central / State Governments / UT including Central / State Universities.
- National Institutes /CRCs / DDRCs / RCs / Outreach Centres under MSJ&E.
- Organizations registered under Societies Registration Act. 1860, or Indian Trusts Act, 1882 or Companies Act, 1956.
- Central / State recognized Sports Bodies & Federations

Sugamya Bharat Yojna under Scheme for Implementation of Persons with Disabilities Act (SIPDA) assist to implement it.

3. Barriers to implementation of Divyangjan safety norms in hospital:

- Absence of Rehabilitation medicine department in most of the medical institutions
- Lack of pro-active implementing agencies
- Lack of awareness in medical fraternity and general public regarding these facilities

4. Conclusion:

Laws and facilities available in present time are many, but ultimately implementation depends on pro-activity and awareness.

5. Recommendations:

- In all medical institution there should be one Rehabilitation Medicine department, which can be nodal center for implement present schemes
- There should be one nodal officer from the Rehabilitation Medicine department who will be taking care of these scheme implementation
- To reach at ground level there should be a team which acts up to community level