05 - Medical Waste, Sustainability & Compliance

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From

FOGSI, Food Drugs & Medicosurgical Equipment Committee

Dr.Bhaskar Pal
President
FOGSI

Dr.Suvarna Khadilkar
Secretary General
FOGSI

Dr. Vidya Thobbi
Vice President Incharge
FOGSI

Dr. Asha Jain
Chairperson
FOGSI FDMSEC

Dr. Asha Jain

Editor & Chairperson, FOGSI FDMSE Committee

Message From Dr. Bhaskar Pal

Dr. Bhaskar Pal
President FOGSI-2026

Biomedical waste management is not only about segregation, but also about **understanding what we are generating and how to reduce it responsibly**. The growing volume of waste from OTs and procedure areas makes it important for us to rethink our practices.

This issue draws attention to areas we often do not reflect upon, such as **OT waste segregation, single-use devices, and the concept of a Green OT**. These are not theoretical discussions, but practical concerns that affect both cost and environmental impact.

The question of what can or cannot be reused is especially relevant today, where safety, legality, and affordability have to be balanced carefully. Similarly, improving segregation within the OT itself can significantly reduce unnecessary waste burden.

I hope this issue encourages clinicians to look beyond compliance and move towards **responsible and sustainable practice.**

I appreciate the FDMSE Committee and Dr. Asha Jain for bringing focus to these important aspects.

With best wishes,
Dr Bhaskar Pal
President, FOGSI

Message from Dr Suvarna Khadilkar

Dr. Suvarna Khadilkar
Secretary General FOGSI

Compliance in biomedical waste management is closely linked with **documentation and regulatory awareness**. Many clinics function well in practice, but fall short when it comes to maintaining proper records and meeting statutory requirements.

This issue brings focus to **documentation, avoidable fines, and creating a waste-safe clinic culture**. These aspects are critical, as they directly influence how a clinic performs during inspections and audits.

Proper documentation is not merely a formality; it provides legal protection and reflects the quality of systems in place. Similarly, awareness of common reasons for penalties can help clinics avoid unnecessary financial and administrative burden.

Building a culture where compliance is part of routine practice, rather than a last-minute effort, is essential for long-term sustainability.

I appreciate the efforts of Dr. Asha Jain and the FDMSE Committee in bringing out an issue that is both relevant and practical.

With best wishes,
Dr Suvarna Khadilkar
Secretary General FOGSI

Message From Dr.Vidya Thobbi

Dr.Vidya Thobbi
VP South Zone FOGSI
Incharge FDMSEC

In most healthcare settings, the challenge is not the absence of systems, but the **gap between protocol and actual practice**. Biomedical waste management depends largely on how well the team is trained and how consistently protocols are followed.

This issue rightly highlights **staff training, colour coding, and sharps injury prevention**, which form the backbone of safe waste handling. These are areas where small lapses can lead to significant risk for healthcare workers.

Clear understanding of colour coding and proper handling of sharps are basic, yet frequently compromised. Regular training, supervision, and reinforcement are essential to ensure that these practices become routine.

The articles in this issue provide practical guidance that can be implemented at all levels of care. Strengthening these basics will go a long way in improving overall safety in our clinics and hospitals.

I congratulate Dr. Asha Jain and the FDMSE Committee for addressing these core issues.

Warm regards,
Dr Vidya Thobbi
Vice President Incharge, FOGSI

Dr.Asha Jain
Chairperson
FOGSI FDMSE Committee

FOREWORD

I thank our President **Dr. Bhaskar Pal**, Vice President **Dr. Vidya Thobbi**, and Secretary General **Dr. Suvarna Khadilkar** for their guidance and continued support to the work of the FDMSE Committee.

Biomedical waste management is an area where most of us believe we are compliant, yet small gaps continue to exist in daily practice. These gaps are often not due to lack of knowledge, but due to inconsistency in implementation, supervision, and documentation.

This issue has been designed with a clear focus on **practical aspects that directly affect our clinics**- from segregation in the OT, handling of sharps, and colour coding, to documentation, legal responsibilities, and avoidable penalties. Each article addresses situations that we encounter routinely but may not always handle correctly.

I thank all our authors for contributing their experience and practical insights to this issue:

- Dr. Dr. Prabhdeep Kaur, Dr. Urvashi Barman, Dr. Chitra Pandey, Dr. Vishnupriya KMN, Dr. Geetika Sharma, Dr. Kumudini Jha, Dr. Ginny Gupta, Dr. Sugandha Goel, Dr. Anantha Lakshami P, Dr. V. Padmaja

The **Toolkit and Red Flags sections** have been specifically created for direct use in clinics, with the intention that they can be displayed, followed, and audited.

Our aim is simple- to ensure that biomedical waste management becomes **a routine, reliable system rather than an occasional exercise.**

With warm regards,
Dr Asha Jain
Chairperson, FDMSEC, FOGSI

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1 BMW Rules Doctors Still Break Daily

Author:- Dr Prabhdeep Kaur
MBBS,DGO,DNB,CIMP
CHIEF CONSULTANT
JLNHRC BHILAI

Biomedical waste rules doctors still break daily

A practical reminder for clinics and hospitals on day-to-day biomedical waste compliance- and how small lapses create big risk.

Biomedical waste management is part of safe health-care delivery, not a back-office chore. The World Health Organization describes waste management as a complete chain: segregation at source, safe collection and storage, secure transport, appropriate treatment, and responsible disposal- supported by staff protection and training.

In daily practice, many facilities still repeat the same avoidable errors: mixing waste streams, using the wrong containers, delaying disposal or handover, and skipping documentation. These lapses often occur quietly in busy OPDs, dressing/procedure rooms, and small labs- but their impact is serious: needle-stick injuries, infection risk, environmental contamination, and legal exposure.

Why the WHO approach matters

The WHO framework works because it is practical: treat waste control as a routine part of clinical safety. The core idea is simple- identify hazardous waste at the point of generation, separate it immediately, keep it contained in storage, move it securely, treat it appropriately, and dispose of it without harm to people or the environment.

This matters most in small and medium clinics. The usual problem is not awareness ("waste is dirty") but inconsistency during peak hours, weekends, or staff shortages. WHO guidance repeatedly emphasizes that routine practice, refresher training, and basic infrastructure (bins, liners, signage, storage) often reduce risk more effectively than complex systems alone.

Duties of the occupier (Biomedical Waste Management Rules, 2016)

Under India's Biomedical Waste Management Rules, 2016, the occupier (the person in control of the facility) remains responsible for safe handling of biomedical waste. Outsourcing collection does not outsource accountability.

- Ensure segregation at source with the correct containers available at point-of-use.
- Provide a safe, ventilated, and secured on-site storage area for segregated biomedical waste.
- Train staff (including housekeeping and temporary staff) and supervise day-to-day compliance.
- Handover waste to the authorised operator correctly and document the handover.
- Follow traceability requirements (including barcode-based tracking where applicable) for waste leaving the premises.
- For doctors, biomedical waste compliance is a governance issue: repeated lapses reflect the clinic's systems and leadership, not just housekeeping.

Daily mistakes that recur

- **Mixing waste streams**: soiled items (blood-stained cotton, gauze, gloves, syringe parts) placed in general waste because the nearest bin is "convenient."
- **Unsafe sharps disposal**: needles/sharps put into ordinary bags or overfilled boxes instead of puncture-resistant containers.
- **Poor container discipline**: bins left uncovered or unlabeled; bags/bin liners overfilled.
- **Delayed transfer**: waste kept in clinical areas or handed over late to the authorised waste handler.

Storage, labeling, and traceability

A frequently breached requirement is the 48-hour storage limit for untreated biomedical waste- especially on weekends, public holidays, or when transport is delayed. If storage beyond 48 hours is unavoidable, the occupier must ensure it does not affect human health and must notify the relevant authority with reasons.

WHO guidance reinforces the same principle: store waste away from patient-facing areas, prevent leakage/odour/scavenging/accidental contact, and transport it securely. Traceability makes the chain accountable- bags should be labeled/identifiable, every handover documented, and movement trackable (including barcodes where required).

Why small clinics struggle (and what helps)

Small clinics often rely on informal systems: no written SOPs, limited supervision, no routine audits, and irregular refresher training. In that environment, compliance depends on memory and individual discipline.

What usually improves compliance quickly:

- A simple segregation chart displayed where waste is generated.
- Correct colour-coded bins with liners placed at point-of-use.
- Puncture-proof sharps containers that are not overfilled.
- A secured storage corner away from patient areas.
- A routine, documented handover process.

Medico-legal and reputational consequences

Violations can attract action under the Environment (Protection) Act framework; enforcement summaries indicate penalties may include imprisonment, fines, or both, depending on the violation and legal proceedings. Continued contravention can bring additional penalties.

Beyond legal risk, improper waste handling can trigger staff/neighbor complaints, occupational injuries, contamination, and reputational damage. Visible waste lapses can undermine trust as much as poor sterilisation or record-keeping- so compliance directly affects professional credibility.

Top 10 daily mistakes (quick checklist)

Use this checklist in daily rounds or staff briefings:

1.Mixing general waste with infectious waste.
2.Throwing sharps into ordinary bags.
3.Leaving waste containers unlabeled or uncovered.
4.Overfilling bags and bins.
5.Keeping untreated waste beyond 48 hours.
6.Failing to use barcode or traceability systems where required.
7.Not training new staff in segregation practices.
8.Inadequate supervision of housekeeping staff.
9.Delayed handover to the authorized waste operator.
10.Assuming a small clinic is exempt from strict compliance.

Most failures are not gaps in knowledge- they are gaps in daily discipline.

Making compliance routine

Set up the system so the "right action" is the easiest action:

- Place correct bins and liners where waste is generated (not at the end of the corridor).
- Display a simple segregation chart at eye level.
- Maintain a secured storage area away from patient care spaces.
- Use a fixed, documented handover routine with the authorised operator.

Train and refresh: Give the same basic instruction to new, temporary, and housekeeping staff; refresh it periodically; and correct errors early. Waste handling is only as strong as the people doing it.

For doctors, the message is straightforward: biomedical waste management is part of safe clinical care. A visible, disciplined routine protects staff, patients, the community, and the clinic's reputation.

2 OT Waste Segregation: Where Clinics Fail

Author:- Dr. Urvashi Barman Singh
Prof. & HOD Dept. of OBGY United Institute of Medical Sciences, Prayagraj

Introduction

Biomedical waste (BMW) management is a fundamental component of infection control in healthcare settings, particularly in operation theatres (OTs), where a high volume of infectious and hazardous waste is generated. The **World Health Organization** in its manual Safe Management of Wastes from Health-Care Activities (2nd ed.) emphasizes that improper waste segregation is one of the most critical failures leading to healthcare-associated infections, environmental contamination, and occupational hazards.

In India, biomedical waste management is governed by the **Biomedical Waste Management Rules 2016**, notified by the Ministry of Environment, Forest and Climate Change (MoEFCC), with subsequent amendments (notably 2018). These rules, supported by the **Central Pollution Control Board** guidelines and accreditation standards like **National Accreditation Board for Hospitals & Healthcare Providers**, provide a structured framework for segregation, handling, transport, and disposal of biomedical waste.

Despite clear regulatory frameworks, many clinics- especially small and medium setups- continue to demonstrate significant lapses in OT waste segregation. This article critically examines where clinics fail, why these failures occur, and how they can be addressed.

Scope of OT Waste Segregation

OT waste segregation encompasses the entire lifecycle of waste management:

- **Generation** (during surgical procedures)
- **Segregation at source** (immediate disposal into color-coded bins)
- **Collection and storage**
- **Transportation and treatment**

Waste generated in OTs includes:

- Infectious waste (blood-soaked materials, tissues)
- Sharps (needles, blades)

- Plastic disposables (IV tubing, catheters)
- Glassware and metallic implants
- Chemical and pharmaceutical waste

According to WHO and CPCB, segregation at the **point of generation** is the single most important step in biomedical waste management.

Standard Segregation System in India

The BMW Rules 2016 simplified waste segregation into four color-coded categories:

- **Yellow:** Human and animal anatomical waste, soiled waste, microbiological waste
- **Red:** Contaminated recyclable plastic waste
- **White** (translucent): Sharps including metals (puncture-proof containers)
- **Blue:** Glassware and metallic implants

Failure to follow this classification leads to mixing of waste streams, increasing treatment complexity and health risks.

Where Clinics Fail

1. Failure at Source Segregation

The most critical and common failure is improper segregation at the point of waste generation.

- Mixing infectious and non-infectious waste
- Disposal of blood-soaked materials in general waste bins
- Incorrect placement of sharps

WHO clearly states that once waste is mixed, it is considered entirely hazardous, increasing both risk and cost.

2. Knowledge and Training Deficits

Studies, including those by Datta et al., highlight that lack of awareness among healthcare workers is a major contributor to poor compliance.

- Staff unaware of updated BMW Rules
- Inadequate training of housekeeping personnel
- No structured induction for new staff

Even in NABH-accredited setups, periodic training is often inconsistent or poorly documented.

3. Improper Use of Color-Coded Bins

Despite availability, misuse of bins is frequent:

- Yellow and red bins used interchangeably
- Sharps disposed in plastic bags instead of puncture-proof containers
- Overfilled bins leading to spillage

CPCB guidelines emphasize that bins should not be filled beyond 75% capacity—yet this is commonly ignored.

4. Sharps Mismanagement

Sharps handling remains one of the most dangerous areas of failure.

- Recapping of needles (contraindicated)
- Absence of needle destroyers
- Improper disposal into non-designated bins

This significantly increases the risk of needle-stick injuries and transmission of infections like hepatitis B, hepatitis C, and HIV.

5. Infrastructure Limitations

Many clinics lack adequate infrastructure:

- Insufficient number of bins in OTs
- Lack of foot-operated bins
- Absence of clear labeling or color coding
- No dedicated temporary storage area

BMW Rules mandate proper infrastructure, but compliance is often partial.

6. Lack of Monitoring and Auditing

A major systemic failure is absence of supervision:

- No infection control committee or BMW officer
- Lack of periodic audits
- No documentation or reporting system

NABH guidelines stress continuous monitoring, but smaller clinics rarely implement structured audits.

7. Behavioral and Cultural Issues

Human factors significantly influence compliance:

- Casual attitude toward waste management
- Perception that segregation is “not a priority”
- Time pressure during surgeries

Waste segregation is often viewed as a secondary task rather than an integral part of patient care.

8. Over-Reliance on Housekeeping Staff

Segregation responsibility is often wrongly shifted:

- Surgeons and nurses assume housekeeping will sort waste later
- Housekeeping staff lack training and authority

WHO clearly states that segregation must be done by the **person generating the waste**, not by downstream handlers.

9. Improper Liquid Waste Disposal

Liquid waste handling is often neglected:

- Direct disposal into drains without disinfection
- Mixing chemical waste with general wastewater

CPCB guidelines mandate pre-treatment of liquid waste, which is frequently overlooked.

10. Documentation and Legal Non-Compliance

Poor record-keeping is another area of failure:

- No tracking of waste generation
- Missing manifests and records
- Non-compliance with reporting requirements

BMW Rules require strict documentation, and violations can lead to legal penalties.

Consequences of Poor OT Waste Segregation

1. Increased Infection Risk

Improper segregation contributes to hospital-acquired infections and cross-contamination.

2. Occupational Hazards

Healthcare workers are exposed to sharps injuries and infectious materials.

3. Environmental Pollution

Improper disposal contaminates soil, water, and air, affecting public health.

4. Increased Financial Burden

Mixing general waste with biomedical waste increases treatment costs significantly.

5. Legal Repercussions

Non-compliance with BMW Rules can result in:

- Fines and penalties
- Closure of healthcare facilities
- Loss of accreditation

Bridging the Gap: Recommendations

1. Regular Training Programs

- Conduct periodic CME sessions
- Include all staff categories
- Use practical demonstrations

2. Strengthening Infrastructure

- Ensure adequate availability of bins
- Use clear labeling and signage
- Maintain puncture-proof sharps containers

3. Strict Enforcement of Segregation

- Segregation at point of generation
- Avoid overfilling of bins
- Immediate disposal of sharps

4. Monitoring and Audits

- Establish infection control committees
- Conduct regular audits
- Implement corrective actions

5. Behavioral Change Strategies

- Promote accountability
- Encourage reporting of errors
- Foster a culture of safety

6. Compliance with CPCB and NABH Guidelines

- Follow national standards strictly
- Maintain proper documentation
- Ensure tie-up with authorized waste disposal agencies

Conclusion

OT waste segregation is a critical yet often neglected aspect of healthcare delivery. While regulatory frameworks such as the BMW Rules 2016, CPCB guidelines, and WHO recommendations provide clear directions, the gap lies in implementation- particularly in clinics with limited resources and oversight.

Failures in OT waste segregation are multifactorial, involving deficiencies in training, infrastructure, monitoring, and behavioral attitudes. Addressing these gaps requires a comprehensive approach that integrates education, accountability, and system strengthening.

Ultimately, proper waste segregation is not merely a regulatory obligation- it is an ethical responsibility toward patients, healthcare workers, and the environment. Strengthening these practices will significantly enhance infection control, occupational safety, and sustainability in healthcare systems.

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3 Sharps Injuries: Prevention Is Cheaper Than Treatment

Author:- Dr. Chitra Pandey
M.D., FICOG
Director & Consultant (OBS. & GYNAE)
Harsh Hospital, Prayagraj
Secretory ISOPARB Prayagraj

Introduction

Sharp injuries are caused by needles, syringes with needles, scalpels, blades, broken ampules or other articles that could cause wounds or punctures to personnel handling them. Percutaneous injuries to healthcare workers from needlesticks and other sharps carry significant risks of transmitting blood borne pathogens. In hospitals, clinics, laboratories and other healthcare settings such incidents can lead to significant psychological stress, repeated laboratory Investigations, post exposure prophylaxis, loss of productivity and substantial financial burden for healthcare institutions and affected individuals. The cost associated with managing a single exposure incident is often far greater than the investment required for preventive strategies. Therefore, emphasizing prevention is not only an economical approach but also a crucial step towards ensuring a safer healthcare environment.

Magnitude Of The Problem

CDC estimates 385,000 sharps injuries annually among hospital-based healthcare personnel (>1000 injuries/day). About half of the sharp injuries go unreported. (Ref-1)

Global pooled prevalence of needlestick injuries among healthcare workers was 44.5% (Bouya et al 2020)

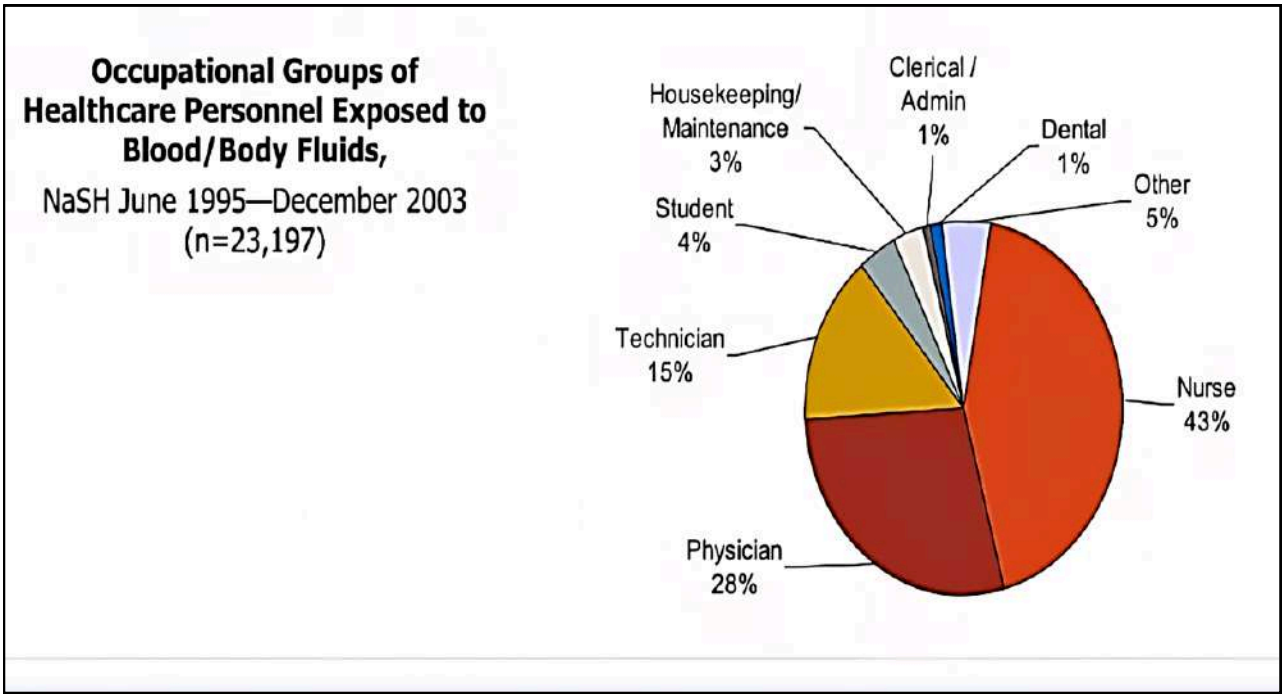
Six devices account for78% of all injuries

- Disposable syringes 30%
- Suture needles 20%
- Winged – steel needles 12%
- Intravenous catheter stylets 5%
- Phlebotomy needles 3%
- Scalpels 8%

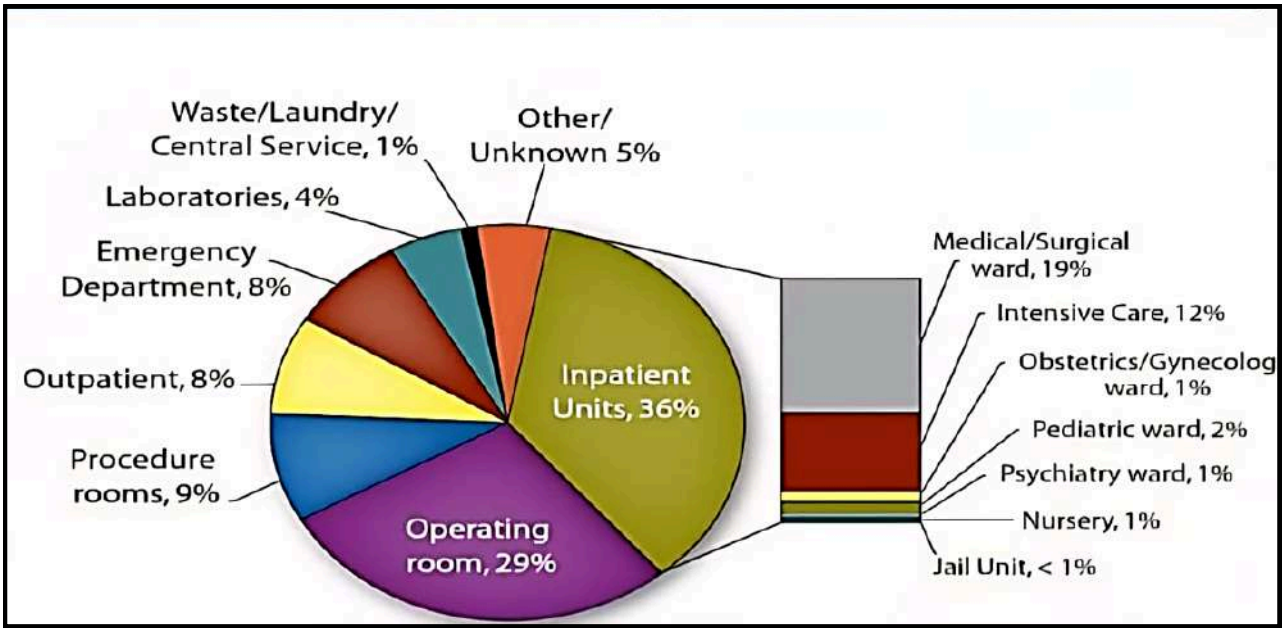
Sharp Injuries In Surgical Settings

- There is significant increase in sharp injuries in surgical settings. Injuries in nonsurgical settings are 31.6% less in comparison to operation room. (Ref-2)
- 30% of the estimated needle sticks and other sharp related injuries occur in operation room.
- Of these 6-16% are self- inflicted while passing suture needles.

- Sutures are the most frequent cause of percutaneous injury – 43.4%.
- Second most frequent cause is scalpel blades-17%



PLACES OF SHARP INJURIES IN HEALTHCARE SEETTING



Infections Caused By Sharp Injuries

Percutaneous injuries from needlesticks and other sharps carry significant risks of transmitting more than 20 bloodborne pathogens including HBV, HCV and HIV for health care workers worldwide. The attributable fractions for exposure to HBV, HCV and HIV are 37%, 39% and 4.4% respectively. These bloodborne infections have serious consequences including long term illness, disability and death.

Other pathogens which can be transmitted by sharp injuries are those Causing tuberculosis, diphtheria, herpes, malaria, Ebola Plague and Epstein-barr infection.

Risk Of Seroconversion Due To Sharp Injury From A Known Positive Source

VIRUS	RISK
HBV	6-30% (If injured person is not hepatitis-B Vaccinated)
HCV	2%
HIV	3%

Work Practices Which Increase The Risk Of Sharp Injuries

- Recapping needles (most important)
- Performing activities involving needles and sharps in hurry.
- Handling and passing needles and sharps after use
- Failing to dispose of used needles properly in puncture-resistant sharps containers.
- Poor healthcare waste management practices
- Ignoring Universal work precautions
- Overworked and tired hospital staff working in suboptimal conditions e.g. giving injectables in poor light.

Prevention Of Sharp Injuries

Approximately 64% of sharp injuries are preventable. Core safety procedures include following measures.

Eliminate Or Reduce Unnecessary Sharp / Needle Use

- Use needle free IV delivery system
- Use alternate routes for medication delivery and specimen collection when available.
- Use alternative cutting methods: Electro surgery
- Alternative suture devices should be used as blunt suture needles, stapling devices, adhesive strips, glues.
- Use blunt rather than sharp retractors.
- Scalpels with safety blades should be preferred.
- Use devices with safety features engineered to prevent sharp injuries

No Recapping

Recapping is single most important cause of needle-stick injuries responsible for 25-30% of cases. If the procedure necessitates reusing a needle multiple times on the same patient (as in giving local anaesthesia) recap the needle between steps using one handed technique or a fixed device that enables one handed recapping. (Ref-3)

Neutral Zone

Neutral zone technique (e.g. a tray) should be adopted for passing sharps and suture needles between perioperative team members. Ideal device for a neutral zone should be large enough to hold sharps which is not easily tipped over.

Double Gloving During All Surgical Procedures

Double gloving decreases the risk of glove perforation reducing the risk of bloodborne pathogens transmission and risk of break injury. It also decreases surgical site infection.

Handle With Care

If multiple sharps are to be used procedure tray or work area should be organized in a manner so that sharp is always pointed away from the operator. If the sharp is reusable, its place should be determined in advance for safe handling after use.

Sharps should never be carried without a tray. Sharp boxes should always be covered

Immediate Disposal 0f Sharps

Sharps should be disposed of immediately after use in the designated, puncture resistant, colour coded and labelled container. Sharp containers should be placed close to the point of use and maintained in an upright position. (Ref-3)

Container Maintenance

Fixed sharp containers should not be fitted higher than 1.4 meter. Sharp containers should be replaced when three quarter full. If a sharp container is overfilled, a new container should be obtained and protruding devices should be removed with forceps or tongs.

Sharps should never be disposed of in to regular garbage.

Employers Responsibility

Training

Ensure all staff receives regular education on bloodborne pathogens and safe handling procedures.

Policies and procedures for sharp safety processes and practises should be developed and Perioperative team members should participate in a variety of quality improvement activities.

Vaccination

Ensure all health workers are vaccinated against hepatitis B (Ref-4)

Post Exposure Plan

Healthcare facilities must establish a written exposure control plan Including reporting, Evaluation and treatment of needle stick or sharp injuries immediately.

Management Of Sharp Injuries

Establish category of exposure

Categories Of Exposure

MILD EXPOSURE: Mucous membrane/nonintact skin with small volume as a superficial wound with low calibre needle, contact with eyes or mucous membrane, subcutaneous injections with a low calibre needle.

MODERATE EXPOSURE: Mucous membrane/non intact skin with large volumes or percutaneous superficial exposure with solid needles e.g. a cut or needle stick injury penetrating gloves.

SEVERE EXPOSURE: Percutaneous exposure with large volumes e.g. an accident with a high calibre needle visibly contaminated with blood, a deep wound, an accident with material that has been previously been used intravenously or intra-arterially.

Occupational Exposure Protocol

1.Crisis management- Remain calm

2. Dispose the sharp appropriately

3. First aid- Wash and irrigate the site

4. Report to the Infection control team

5. Get evaluated for PEP and baseline testing for HIV, HCV, HbsAg

6. PEP should be started within 2 hrs of exposure and not later than 72 hrs.
(Ref-5)

7. PEP must be taken for 4 weeks

8. Follow up HIV testing at 6 weeks,3 months and 6 months

9. Follow up counselling and care.

10. Documentation and recording of exposure

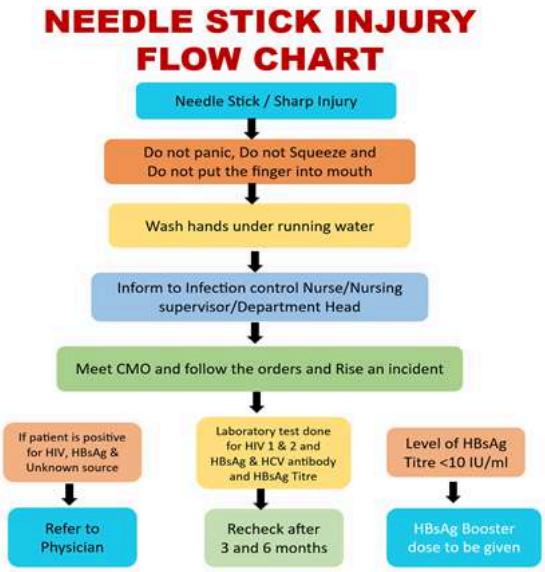
Management Of Exposed Site-First Aid

SKIN – Wash and rinse with soap and water. Do not squeeze to bleed it

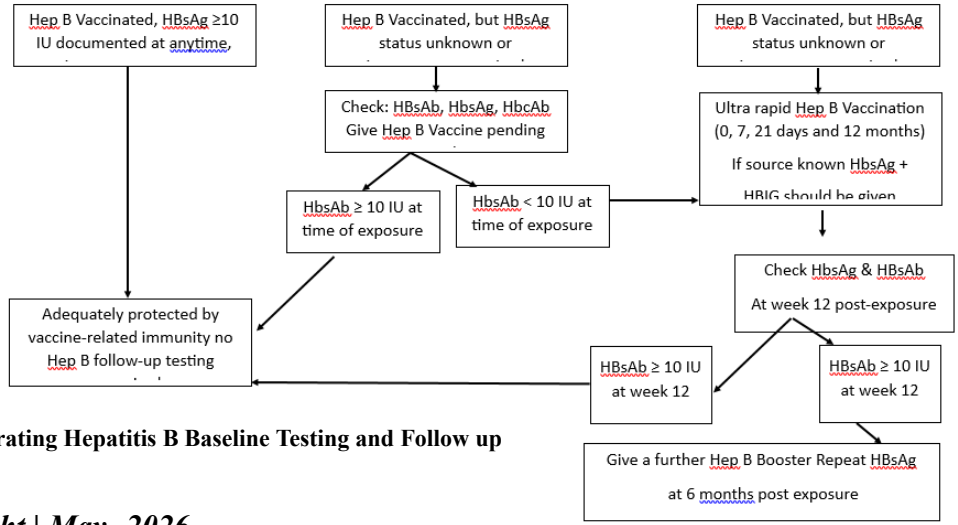
MUCOUS MEMBRANE – Flush exposed membrane with water

EYE – Irrigate with clean water, saline or sterile eye irrigant

MOUTH – Do not swallow, spit fluid immediately, rinse the mouth repeatedly with cold water

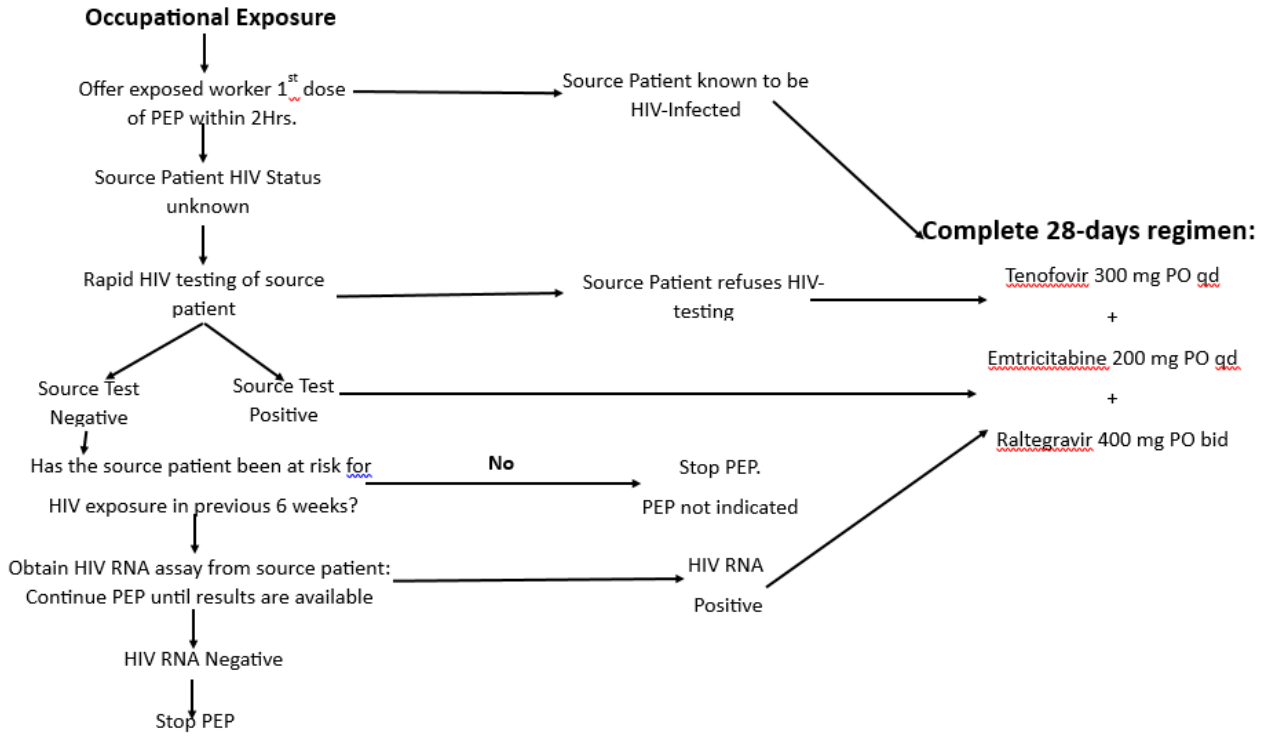


Post Exposure Prophylaxis And Follow Up Of Hepatitis - B



Flowchart illustrating Hepatitis B Baseline Testing and Follow up

Post Exposure Prophylaxis And Follow Up Of HIV



Post Exposure Prophylaxis For Hepatitis C

There is no Known effective PEP exists for hepatitis C. Testing should occur within 48 hours of exposure and guidelines for management and treatment of hepatitis C should be followed.

Conclusion/Take Home Messages

- Sharp injuries are serious yet preventable with physical, psychological, professional and financial consequences.
- Treatment after exposure is often costly, stressful and prolonged. It involves immediate medical care, laboratory testing, follow up and emotional stress.
- In comparison, preventive measures such as training, vaccination, safety engineered devices and proper disposal system are simple, practical and far less expensive.
- Cost of post exposure laboratory investigations, PEP and follow up can be 10 -15 times higher than the cost of preventive measures.
- Investing in prevention protects healthcare workers, reduces institutional costs and promotes a safe working environment and it is a moral and professional obligation of all healthcare institution.

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4 Single-Use Devices: What Can Be Reused Legally?

Author:-Dr Vishnupriya KMN,
Professor and Unit head
affiliated to Dept of OBGYN,
St Johns medical college, Bangalore

Co-Author:-Dr Madhva Prasad,
Associate professor affiliated to Dept of OBGYN, St Johns medical college, Bangalore

Introduction

In today's world, control of costs, reduction of medical waste and improving sustainability are measurable goals in clinical practice. On the other hand, medical legal accountability and patient safety are non-compromisable. These seemingly contrasting viewpoints get tested when the context of single-use devices (SUDs) come into discussion. In many maternity clinics and gynecological operation theatres, there is a common phenomenon of reuse of medical devices, which are as such sold as SUDs. Quite often, we hear medical device representatives using the term **"This is actually single use according to FDA, but it will last for 13-15 cases depending on surgeon usage."** How we deal with such a scenario is the crux of this article. Shedding some light on the sparse information available on this niche matter is the purpose of this article.

A recent newspaper article titled "Why India must end the reuse of single use medical devices" is a case in point [1]

Understanding Single-Use Devices (SUDs)

A single-use device is defined as a medical device intended by the manufacturer to be used once on a single patient and then discarded. This intent is clearly mentioned on the product label- often as "single use," "do not reuse," or with a symbol indicating the same.

The key point many practitioners miss is this: the "single-use" label is not merely advisory- it is a regulatory declaration by the manufacturer. It implies that the device has not been validated for cleaning, disinfection, or sterilization for reuse. Therefore, any reuse shifts responsibility from the manufacturer to the healthcare provider. In gynecology, common examples include suction cannulas, disposable speculums, laparoscopic trocars, harmonic scalpel tips, and hysteroscopy accessories, to name a few.

In a hypothetical scenario where an insurance company wants to find fault with a surgeon for a surgical mishap, the burden of proving that it was indeed the first use of an SUD, would lie on the shoulders of the healthcare provider. Even a 2nd usage of an SUD would constitute violation of medical rules. [2]

The western perspective on reuse of devices.

In the United kingdom, clear recommendations exist regarding the re-use of Single use devices. The re-manufacturer, prior to placing their device on the market or allowing it to be used for services, should ensure that relevant criteria under appropriate medical directives are used. The CE mark on their product should conform to the relevant directives available.

Compliance regulatory standard EN ISO14971 and ISO 13485 are explicity for remanufacture of single use devices. [3]

Elsewhere in the world, the term "reprocessing" is used instead of "remanufacturing".

For ensuring that there is smooth success of the reprocessing, elements of design, reverse logistics and intrinsic system enablers should be instituted.

- Design - The initial design of the product itself is executed in such a way that the usage of Single use devices is minimized apriori.
- Reverse logistics - The logistics of a Singe Use device is executed in such a way that the parts that are dismantled etc can be utilized as valuable products and materials in different repurposed ways, and can be recirculated.
- Intrinsic system enablers - There must be policies in place for enabling above mentioned practices.

Harmonic Shears which are minimally invasive instrumentsused in a variety of Gynecological procedures have been reportedly successfully remanufactued to meet all regulatory standards [4]

Indian perspective on reuse of devices.

The CDSCO has no mention about the routine reuse of SUDs. As per the medical devices rules 2017, if an SUD is utilized after its single use, the liability of all subsequent actions lies on the hand of the healthcare provider team. [5]

Once a device labeled for single use is reused, it effectively becomes a “reprocessed device,” and the liability shifts to the user or institution.

NABH standards are clearer from a quality and safety perspective. [6] They require:

- Strict adherence to manufacturer instructions
- Validation of sterilization processes
- Documentation and traceability of devices used on patients

However, the terms "reuse", "reprocess", "remanufacture" do not appear in the latest NABH guideline.

The Ethical–Legal–Practical Trichotomy

In real-world Indian practice, there is a trichotomy between the ethical perspective, the legal perspective and the practical issues.

Ethically, a treating team is expected to prioritize patient safety and informed consent. Reusing a device not meant for reuse- without disclosure- is a form of ethical misconduct. However, whether existing evidence that reprocessed devices actually have not posed any harm to the patients can be used as a justification is not clear. [7]

Legally, if an adverse event occurs (infection, injury, device failure), the clinician or institution bears responsibility. Courts are bound to look into whether standard guidelines were followed. “Common practice” is not a defensible argument if it is in contravention to existing written guidelines.

Practically, the Indian resourceful “jugaadu” mentality of most practitioners, which is desirable in many situations, leads to the undesirable issue of repeated reuse of medical equipment. So, even if it is not documentable anywhere, the actual number of uses of a SUD should be monitored.

Risks of Reusing Single-Use Devices and monitoring them

The risks are not theoretical- they are well documented and relevant to gynecology.

Infection is the most immediate concern. Many SUDs have narrow lumens, textured surfaces, or materials that cannot withstand repeated sterilization. Inadequate cleaning can lead to biofilm formation, making sterilization ineffective.

Device failure is another significant risk. Repeated use can cause micro-cracks, loss of insulation (especially in electrosurgical instruments), or reduced mechanical integrity. A reused trocar or cannula failing during a procedure is not uncommon. [8]

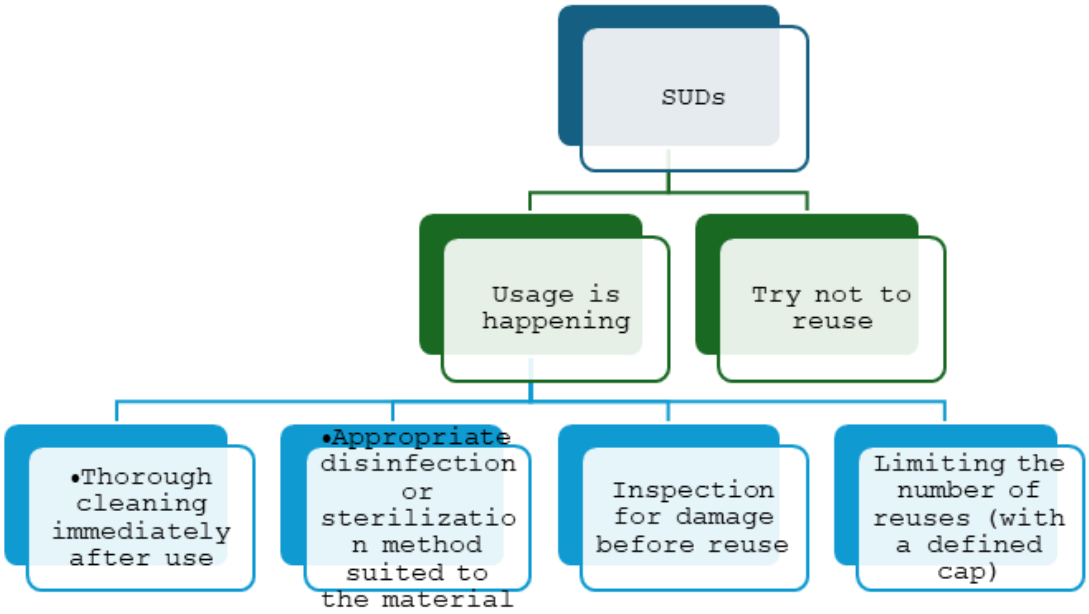
Chemical residue and material degradation can also occur when devices are exposed to sterilizing agents they were not designed for.

Materialovigilance – the way forward

In line with pharmacovigilance practices, a “materialovigilance” program has been instituted. This program has the unique objective of ensuring that no patient is harmed because of the malfunctioning of a medical device or equipment. It has now been mandatory for all doctors to report issues of malfunctioning of medical devices. As a corollary, aninvestigatory authority may ask a question “Is this a Single use device being reused inappropriately?” These discussions are notwithstanding the fact that the reporting portal of the materialovigilance program has been showing very few “hits”, indicating either reluctance to report or difficulties in the materialovigilance platform. [8]

Where Practice Commonly Goes Wrong and what can be done better

Practical issue	Possible solution
Difficult to clearly identify which are SUDs and which are not	Maintenance of separate inventory and storing locations
Autoclaving as a standard method of sterilization	Clear documentation of which method of sterilization for which type of SUD.
Lack of information to patient that an SUD is being used	Protocols regarding transparency and disclosure to patients about such issues
Following “experiences” and “popular practice”	Written validated protocols
Doctor tries to manage everything	Specific experts for specific things atleast for initializing and guiding.



Clear documentation and traceability of each used device should be carried out including elements such as

- Number of uses
- Sterilization cycles
- Any observed defects

A periodic audit and infection surveillance to detect any adverse trends should be in place.

"Grey Zone" Devices in Gynecology Practice

Certain devices fall into a grey zone where reuse is common but not clearly regulated.
For example, laparoscopic trocars are often reused after sterilization, though many are labelled as single-use. The loss of insulation, valve integrity and sharpness at entry are all problems.

Suction cannulas and hysteroscopy tubing sets are commonly reused. These have internal surfaces which are difficult to thoroughly clean.

Electrosurgical accessories (like monopolar cables or harmonic scalpel tips) are risky due to insulation failure, which can lead to unintended burns.

Hence, sensibility is needed while dealing with these "grey zone devices".

Moving Toward Safer and Sustainable Practice

A one-stop solution is difficult to offer for such a complex issue. The best solution is a multi-party involvement involving doctors, nurses, CSSD staff, administrators, financial planners, environmentalists and a legal team to identify the best way forward, keeping the natural principles of medical ethics [9] at the forefront.

Conclusion

The issue of single-use devices sits at the cusp of safety, sustainability, and practicality. In the Indian context, where cost constraints are real, a balanced approach is necessary—but that balance cannot come at the cost of patient safety or legal vulnerability. [10]

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5 Colour Coding Confusion in Waste Disposal

Author:-Dr. Geetika Sharma
Fertility expert & Gynaecologist, Umang IVF & Super speciality Hospital, Bilaspur, Chhattisgarh

Introduction

Walk through any busy obstetrics and gynaecology ward in India and you are likely to see the same sight: a yellow bag overflowing with syringes and needles, a red bag containing used paper wrappers, and a general dustbin holding items that belong elsewhere. Colour-coded waste bags exist to protect patients, healthcare workers, and the wider environment. Yet misidentification and misuse of these bags remain among the most persistent and correctable safety failures in our settings.

The Bio-Medical Waste Management (BMWM) Rules, 2016- amended in 2018- provide a clear national framework for segregation, collection, treatment, and disposal of biomedical waste. Despite two decades of regulation and multiple revisions, compliance audits by the Central Pollution Control Board (CPCB) continue to identify segregation at source as the weakest link in the waste management chain. This article explains the colour-coding system, highlights the common errors seen in clinical practice, and provides a simple reference tool for daily use.

Obstetrics and gynaecology units generate a disproportionately high volume of biomedical waste per bed per day- bloodied linen, placental tissue, sharps, infusion sets, and a range of potentially infectious soft waste. Getting segregation right in the OBG context is therefore especially important.

Table 1: National Colour-Coding System at a Glance

Bag Colour	Waste Category	Examples (O&G context)	Regulatory Reference
Yellow	**General/non-hazardous**	Paper, packaging, food waste, non-infected material	*Bio-Medical Waste (Management) Rules 2016, Schedule I*
Red	**Contaminated recyclable**	IV tubing, syringes, catheters, gloves, bags (without sharps)	*BMWM Rules 2016, Category 6*

Bag Colour	Waste Category	Examples (O&G context)	Regulatory Reference
White	**Sharps / Metallic waste**	Needles, scalpels, blades, glass slides	*BMWM Rules 2016, Category 5*
Blue	**Glassware (recyclable)**	Glass vials, bottles, ampules — intact or broken	*BMWM Rules 2016, Category 5*
Black	**Solid waste – general**	Non-clinical solid waste (offices, kitchens), e-waste	*Solid Waste Management Rules 2016*

Note: The white/translucent puncture-proof container (for sharps) is sometimes listed separately from the white bag. In practice, both are designated for metallic waste- needles, blades, and broken glass- and should be treated identically at the point of disposal.

Common Errors in O&G Practice

Several patterns of misuse appear repeatedly across audit reports and peer-reviewed studies. Recognising these is the first step to correcting them.

- Sharps in yellow bags: This is the single most dangerous error. Needles and blades in a soft yellow bag are not visible to the waste handler, who may sustain a needlestick injury while tying, lifting, or transporting the bag. The sharps container is white and rigid- sharps must go directly into it at the point of use.

- Placental waste in red bags: Placental tissue and body fluids are anatomical waste and belong in the yellow bag, not red. The red bag is for contaminated recyclables- items that have come into contact with blood or body fluids but can potentially be recycled after treatment, such as IV tubing and gloves.

- General rubbish in clinical bags: Paper cups, food packaging, and unsoiled wrappers placed in red or yellow bags unnecessarily increase the volume and cost of hazardous waste treatment. A dedicated black or domestic waste bin must be present in every room.

- Expired drugs in the general waste stream: Cytotoxic agents, hormone preparations, and even routine drugs such as antibiotics must not be placed in general waste or drain-flushed. They require separate segregation and return to a licensed pharmaceutical waste handler.

- Ignoring the blue bag for broken glass: Broken glass ampoules and vials are placed in general bins or sharps containers interchangeably in many settings. The blue bag is specifically designated for glass items -intact or broken - and should be kept alongside the sharp’s container at every procedure trolley.

- Overfilling bags: The BMWM Rules stipulate that bags must be tied and labelled when three-quarters full. Overfilled bags split during handling, spilling contents and causing exposure incidents.

The Regulatory Framework: What the Rules Require

The Bio-Medical Waste Management Rules, 2016 (as amended 2018) replaced the earlier 1998 Rules and strengthened several provisions relevant to hospital practice. Key requirements include the following.

- Segregation at source: Every healthcare facility must segregate waste at the point of generation into the prescribed categories. This is a legal obligation on the occupier of the facility.

- Pre-treatment of microbiology and laboratory waste: Before placing in yellow bags, high-risk laboratory waste should be autoclaved or chemically disinfected on-site.

- No mixing of categories: Mixing of categories- even inadvertently- is a violation of the Rules. Inspectors from the State Pollution Control Board are empowered to issue notices and impose penalties.

- Record-keeping:Form 2 of the BMWM Rules requires a daily log of waste generated by category and weight. Monthly returns must be submitted to the CPCB online portal. This is not a back-office function- the clinician-in-charge carries administrative liability.

- Training: The Rules mandate that all healthcare workers handling biomedical waste receive training at the time of joining and at regular intervals thereafter. A single annual lecture does not satisfy this requirement.

- Tie-up with a common biomedical waste treatment facility (CBWTF): Facilities that do not have on-site treatment infrastructure- which includes most clinics and small hospitals- must have a valid, documented agreement with a licensed CBWTF for collection and disposal.

- The WHO has also published guidance emphasising a hierarchy of waste management: reduction at source, reuse where safe, and recycling before disposal. This aligns with the Indian framework but reminds us that the first step is to generate less hazardous waste in the first place- an often-overlooked principle.

Why Does Confusion Persist?

Audit data and qualitative research consistently identify three root causes of poor segregation in Indian hospitals.

Knowledge gaps. Studies in Indian postgraduate settings have found that a significant proportion of nursing and medical staff cannot correctly identify the category corresponding to each bag colour. A cross-sectional study from a tertiary teaching hospital in central India found that only 52% of healthcare workers could correctly classify all five bag categories. Knowledge is the necessary foundation- without it, correct behaviour is impossible.

Infrastructure failures. Even well-informed staff cannot segregate correctly if the right bin or bag is not present at the point of care. A yellow bag alone at a procedure trolley forces an impossible choice. All five categories of receptacle should be available wherever waste is generated.

Supervision and accountability gaps. In many facilities, no one person is designated responsible for auditing waste segregation on the ward. Without accountability, drift is inevitable. The BMWM Rules do designate the occupier of the facility as legally responsible, but operational accountability must be delegated explicitly and monitored.

Practical Guidance for the O&G Clinician

The clinician in charge of a ward, operation theatre, or outpatient clinic need not manage waste personally- but must ensure the system is in place and functioning. The following steps are actionable without significant additional cost.

- Post laminated colour-code charts at every disposal point in the local language and in English. Simple visual reminders reduce errors even among experienced staff. The CPCB website provides approved chart templates free of charge.
- Conduct a monthly five-minute walk-around audit of waste bins on the ward. Look for overfilling, wrong items, and missing containers. Document findings in the biomedical waste register.
- Include biomedical waste in new staff orientation- on day one, not after probation. A ten-minute practical demonstration at the point of care is more effective than a lecture.
- Ensure a written agreement with a licensed CBWTF is current and on file. Check the collection frequency - inadequate collection leads to accumulation, which leads to improvised disposal.
- Review the register quarterly. Sudden changes in waste quantity by category may indicate a segregation failure or a procedural change that has not been communicated.
- For expired or recalled drugs, contact the licensed biomedical or pharmaceutical waste handler. Do not flush hormone preparations or cytotoxic- environmental contamination from drug waste is an emerging regulatory concern in India.

Table 2: Practical Checklist- Ward / Clinic Audit

PRACTICAL CHECKLIST — Waste Segregation Audit (OBG Ward / Clinic)	
□	Colour-coded bags (Yellow / Red / White / Blue / Black) stocked and labelled per BMWM Rules 2016
□	Sharps container (white/translucent, puncture-proof) at every procedure point- not a general bin
□	Yellow bags used only for infected soft waste; never for sharps, glass, or general rubbish

PRACTICAL CHECKLIST — Waste Segregation Audit (OBG Ward / Clinic)	
☐	Red bags designated for contaminated recyclables only; not double-bagged with yellow
☐	Staff orientation completed at joining- not limited to one annual lecture
☐	Separate collection trolleys for each colour category; not mixed during transport within facility
☐	No overfilling- bags sealed and labelled when three-quarters full
☐	Biomedical waste register (Form 2) updated daily; CBS Form II filed monthly with CPCB portal
☐	Expired drugs segregated and returned to vendor or surrendered to licensed hazardous waste handler
☐	Display charts with colour-code guide posted at each disposal point in local language and English

Conclusion

The colour-coding system for biomedical waste is not complicated- it has five categories and a clear national mandate. Yet it remains one of the most reliably mismanaged systems in Indian healthcare. The good news is that the solution requires no new technology and relatively modest resources. What it requires is that each clinician takes ownership of the system within their unit.

A needlestick injury from a misplaced sharp, a complaint from the State Pollution Control Board, or a hepatitis transmission in a waste handler are all preventable consequences of a correctable failure. The BMWM Rules 2016 give us the framework. Our job as clinicians is to make it work in practice- bag by bag, bin by bin, ward by ward.

KEY POINTS FOR PRACTICE

- Yellow = infected soft waste; Red = contaminated recyclables; White = sharps; Blue = glass; Black = general waste
- Sharps must go directly into the rigid white/translucent container- never into a soft bag of any colour
- Placental and anatomical waste belongs in the yellow bag, not the red bag
- All five disposal receptacles must be present at every point of care where waste is generated
- The clinician-in-charge carries legal liability under the BMWM Rules 2016; record-keeping is mandatory
- Training at joining, monthly walk-around audits, and a valid CBWTF tie-up are practical non-negotiables

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6 Clinic Fines You Can Easily Avoid

Author:- Dr. Kumudini Jha
Retired H.O.D, DMCH
Director, A.A.N. Hospital
President, DAOGS

Author:- Dr. Asha Jain
Chairperson FDMSEC & President
Raipur Menopause Society

Introduction

Running a successful healthcare practice or clinical establishment in India is a balancing act. It requires providing excellent patient care while keeping up with everyday administrative, environmental, and clinical regulations. For many practicing doctors, terms like State Pollution Control Board (SPCB), Clinical Establishments Act (CEAct), and National Medical Commission (NMC) can cause unnecessary anxiety.

- However, these regulations are simply designed to maintain public health, medical ethics, and environmental safety. Operating a hospital or an obstetric-gynecologic clinic without knowing these frameworks is a serious legal risk. By understanding exactly what regulators look for, you can implement basic workflows to keep your clinic fully compliant, completely stress-free, and legally secure.

Part 1: Environmental Safety & The Inspector's Checklist

State Pollution Control Boards (SPCBs) act as environmental watchdogs under the Central Pollution Control Board (CPCB). They strictly enforce laws like the Water Act 1974, the Air Act 1981, and the Environment Protection Act 1986.

When inspectors conduct routine or surprise visits, they use a structured checklist focused on physical and electrical safety to eliminate hazardous shock risks or code violations. You do not need to be an engineer to pass; you just need to ensure your maintenance team or local electrician maintains a neat, clean baseline.

Physical and Electrical Infrastructure Requirements:

- **Clear Identification**: Ensure all electrical panels feature highly visible nameplates, clear voltage ratings, and precise circuit ID tags.
- **Unobstructed Access**: Keep the working clearance around electrical panels completely clear of storage boxes, equipment, or furniture.
- **Panel Maintenance:** Keep panel doors, latches, and ventilation openings fully functional and unobstructed. Enclosure gaskets must remain intact, and any unused holes must be plugged to maintain proper Ingress Protection (IP/NEMA) ratings.

- **Paperwork & Labels:** Keep a file with your clinic's basic wiring schematics and updated single-line diagrams. Ensure arc flash labels displaying current dates are visible on main panels.
- **Wiring and Devices:** Regularly check that equipment grounds are secure with no loose connections, fuses are intact, power and control wiring are properly separated, and all DIN rail devices are firmly tied down and labeled. Your installations should meet standard local NEC/IEC or certified panel benchmarks.

Part 2: Avoiding Daily Waste Management Mistakes

The heaviest administrative financial penalties in healthcare settings are triggered by failures in Bio-Medical Waste (BMW) management. Regulatory bodies like state health departments and SPCBs penalize clinics for simple daily routine errors. These are completely avoidable with a little discipline.

- **Never Mix Waste Streams:** This is the most common daily blunder. Throwing biomedical or infectious waste into general domestic waste bins instantly invites severe penalties.
- **Strict Source Segregation:** Train your clinical and housekeeping staff to strictly segregate waste at the point of generation into the mandated color-coded bags: yellow, red, blue, and black.
- **Observe the 48-Hour Rule:** Under the Bio-Medical Waste Management Rules 2016, a clinic cannot store biomedical waste on-site for more than 48 hours unless it has a dedicated, secure cold storage area. Ensure regular collection intervals with your authorized vendor and verify that all waste containers are clearly labeled.
- **Barcoding and Tracking:** Total tracking of biomedical waste movement is legally mandatory. Ensure your BMW collection bags are properly barcoded before they leave your facility.
- **Staff Protection and Incident Reporting:** Provide your waste handlers with appropriate personal protective equipment (PPE). Any accidental needle-stick injuries, chemical spills, or operational accidents must be documented in a logbook and formally reported to authorities within 24 hours.

Part 3: Understanding Environmental Compensation (EC)

If an inspector finds an operational failure, the SPCB can issue an administrative charge called Environmental Compensation (EC) based on the "polluter pays" principle. It is important to know that EC is not a criminal court fine; it is civil compensation for environmental damage. This means you can be ordered to pay it through an administrative order, even if no court case is filed against you.

Under the CPCB Guidelines, Environmental Compensation is calculated using a strict formula:

$$EC = PI \times N \times R \times S \times LF$$

- **PI (Pollution Index):** Determined by your facility category. Large hospitals (more than 50 beds) are classified as Red (score of 80), while small clinics generally fall under the Orange category (score of 50).
- **N (Number of Days):** The exact number of days the violation continued uncorrected. Every day adds to the amount until you achieve full compliance.
- **R (Rupee Factor):** A standardized monetary factor, typically set at ₹250 for biomedical waste violations.
- **S (Scale of Operation):** Based on bed capacity. Small clinics with fewer than 10 beds use a low multiplier of 0.5; 10–50 beds use 1.0; 50–200 beds use 1.5; and facilities with more than 200 beds use 2.0.
- **LF (Location Factor):** Set at 2.0 for metropolitan or ecologically sensitive areas, and 1.0 for other regions.

The Financial Realities of EC:

- **Minimum Thresholds:** The minimum EC starts at ₹5,000 for small clinics and ₹1 Lakh for larger hospitals. For repeat violations, the EC amount automatically doubles each time.
- **Strict Timelines:** Once an EC order is issued, the payment window is very narrow—typically 15 to 30 days. Failing to pay can cause authorities to invoke your bank guarantee or issue a closure order for the clinic.
- **Appeals:** You can appeal an EC order to the National Green Tribunal (NGT) within 30 days. However, the law mandates that you must deposit 75% of the levied EC amount upfront before your appeal can even be heard.
- **Statutory Court Fines:** Separate from administrative EC, actual prosecution in a court of law under the Environment Protection Act 1986 can lead to heavy statutory fines (ranging from ₹10,000 to over ₹1 Lakh per violation), cancellation of your clinical license, or criminal imprisonment for up to 5 years for severe, willful negligence.

Part 4: Fines Under the Clinical Establishments Act (CEAct) & NMC

While environmental bodies look at waste and pollution, your core clinical infrastructure and professional conduct are monitored under the **Clinical Establishments (Registration and Regulation) Act (CEAct)** and the **National Medical Commission (NMC)** rules.

1. Operating Without Registration (CEAct Section 41)

Running a clinic or hospital without a valid registration—or forgetting to renew your provisional or permanent registration on time—carries immediate financial penalties.

- **First Offence:** A fine up to ₹50,000.
- **Second Offence:** A fine up to ₹2 Lakhs.
- **Subsequent Offences:** Penalties extending up to ₹5 Lakhs.
- **Individual Staff Liability:** Any doctor or healthcare professional who knowingly works in an unregistered hospital faces an individual fine of up to ₹25,000.

2. Non-Display of Rate Cards and Fees

Transparency is a key feature of the CEAct. Your facility must clearly display standard charges for consultations, beds, diagnostic tests, surgeries, and emergency procedures. Failing to display these rates openly carries standard progressive non-compliance fines, starting at ₹10,000 for a first oversight and scaling up to ₹50,000 for repeated issues.

3. Refusal to Provide Emergency Stabilization

The CEAct mandates that all registered facilities must immediately evaluate and stabilize patients in an emergency condition (such as acute trauma, sudden cardiac events, or active obstetric emergencies) regardless of the patient's immediate ability to pay. Refusing basic emergency stabilization before arranging a safe referral can result in heavy institutional fines or the immediate cancellation of your hospital’s registration license.

4. Mandatory Data and Stipend Non-Disclosure (NMC Mandate)

The NMC actively penalizes healthcare institutions and teaching hospitals that fail to publish mandatory compliance data on their public websites. In line with recent directives, institutions must openly disclose uniform stipend details for MBBS interns and postgraduates. Failing to upload or maintain this data has resulted in strict monetary penalties of must follow generic drug prescription guidelines and strictly avoid accepting financial cutbacks or kickbacks from diagnostic laboratories or pharmaceutical companies. Violating these rules can lead to individual doctors being suspended from the medical register and the institutional blacklisting of the hospital.

Part 5: The Essential License Checklist

To keep your facility running smoothly, ensure that your administrative office holds and maintains these active legal permits:

1. **Medical Registration Certificates:** Valid registration sheets for all practicing physicians from the NMC or State Medical Council.
2. **Clinical Establishment Certificate:** Active provisional or permanent registration under the CEAct or respective state nursing home acts.
3. **Local Municipal Trade & Health Licenses:** Obtained from your local municipal body or Panchayat to operate a commercial health service, including specific approval for exterior clinic nameplates/signboards.
4. **Fire No-Objection Certificate (Fire NOC):** Mandatory for all indoor facilities, requiring functional fire extinguishers, clear emergency exits, and certified building safety layouts.
5. **SPCB Pollution Clearances:** Valid Consent to Establish (CTE) obtained before building and Consent to Operate (CTO) secured before initiating medical care.
6. **Bio-Medical Waste (BMW) Authorization:** An active SPCB permit backed by a valid, signed contract with an authorized local Common Bio-Medical Waste Treatment Facility (CBWTF).
7. **PC-PNDT Registration:** Absolutely mandatory if your clinic operates an ultrasound scanner. This license is issued by the District Appropriate Authority (Chief Medical Officer) and must be renewed every 5 years.
8. **AERB License to Operate:** Filed through the e-LORA portal for any radiation-emitting equipment, such as diagnostic X-Ray units, CT scanners, or dental OPG machines.
9. **Retail Drug License:** Required under the Drugs and Cosmetics Act only if your facility operates an in-house pharmacy that dispenses medicines directly to patients via a retail counter.

Your 5-Step Daily Strategy for a Penalty-Free Practice

To take the stress out of compliance, build these simple, highly actionable habits into your practice management:

- **Automate Your Renewal Timeline:** Create digital calendar alerts set exactly **90 days before the expiry** of your Clinical Establishment Certificate, SPCB BMW Authorization, Fire NOC, and PC-PNDT registration. This gives you ample time to manage the paperwork.
- **Implement a Visual Rate Directory:** Place a neat, clear, and comprehensive pricing board directly at your reception or billing desk to fulfill the transparency mandates of the CEAct.

- **Conduct a Daily 5-Minute Waste Audit:** Assign a senior nurse or floor manager to walk through the facility once a day to verify that waste streams are properly segregated, bins contain the correct color-coded bags, and no biomedical waste is kept on-site past the 48-hour limit.
- **Keep an Inspection-Ready Binder:** Centralize all active licenses, up-to-date staff council registrations, daily waste manifest sheets, and staff training logs into a single physical folder in the main administrative office. Back this up digitally on a shared drive.
- **Act Swiftly on Legal Notices:** If your clinic ever receives an official show-cause or non-compliance notice, do not panic. Submit a detailed response accompanied by a clear corrective action plan within 7 days. Under environmental rules, a voluntary disclosure of an operational lapse combined with swift correction can often mitigate your liability, reducing potential EC penalties by 25% to 50%.

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7 Green OT: Myth or Possibility?

Author:- Dr Ginny Gupta
MBBS, MD, FICOG
(Ex-PGI Chandigarh)

Green Operation Theatre: Myth or Possibility?

Operation theatres are among the most resource-intensive areas in healthcare, contributing substantially to energy consumption, biomedical waste generation, water usage, and greenhouse gas emissions. In gynecology, high-volume procedures such as cesarean sections, hysterectomies, and laparoscopic surgeries further increase this environmental burden.

The concept of a "Green Operation Theatre" represents a systems-based approach aimed at reducing environmental impact without compromising patient safety or surgical outcomes. Core principles include efficient resource utilization, waste minimization, energy conservation, sustainable procurement, and rational use of consumables.

A major misconception is that sustainable OT practices compromise sterility and infection control. Current evidence indicates that properly sterilized reusable instruments are comparable in safety to disposable alternatives, and appropriate waste segregation may actually reduce contamination risks.

Another common concern is cost. Although certain interventions require initial investment, long-term benefits include reduced waste disposal costs, lower energy consumption, and decreased procurement expenditure- particularly relevant in high-volume gynecological units. Importantly, many sustainable interventions are feasible even in resource-limited settings.

Key components of a Green OT include:

- Waste management: strict segregation of hazardous and non-hazardous waste using color-coded systems, minimizing unnecessary disposables, and promoting safe recycling practices.
- Rational use of consumables: adoption of reusable gowns and drapes, customized surgical trays, and avoidance of unnecessary instrument preparation.
- Energy efficiency: implementation of LED lighting, optimized HVAC systems, motion sensors, and shutdown of idle equipment.

- Sustainable anesthesia practices: preference for low-flow anesthesia, reduction in use of high global-warming-potential agents such as desflurane, and greater utilization of regional anesthesia where clinically appropriate.

- Water conservation and green procurement: efficient autoclave use, leak prevention, selection of minimally packaged products, and avoidance of environmentally hazardous materials.

In gynecology specifically, cesarean sections offer significant opportunities for standardized instrument sets and reduction of drape and packaging waste. Laparoscopic surgery requires attention to disposable instrument use and gas optimization, while gynecologic oncology procedures necessitate balancing sustainability with procedural complexity and patient safety.

Implementation barriers include lack of awareness, resistance to established practices, inadequate institutional policies, and infrastructure constraints. Effective transition requires institutional leadership, staff training, audit systems, and multidisciplinary collaboration among surgeons, anesthesiologists, nursing personnel, infection control teams, and administrators.

From an ethical perspective, the principle of “do no harm” extends beyond individual patient care to environmental stewardship. Environmental degradation contributes indirectly to disease burden, reproductive health issues, and adverse pregnancy outcomes.

The Green Operation Theatre is therefore not an idealistic myth, but an achievable evolution in modern healthcare. Many interventions are practical, cost-effective, and compatible with established surgical safety standards.

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8 Training Staff for Waste Compliance

Author:-Dr. Sugandha Goel, Infertility Specialist and Laparoscopic Surgeon, Director, Kamla Nagar Hospital, Jodhpur.

Co-Author:- Dr. Aakanksha Tiwari, MBBS, DNB (2nd year), Kamla Nagar Hospital, Jodhpur

Introduction

Biomedical waste management is an integral component of modern healthcare delivery, yet it remains an underemphasized domain in many institutions Effective training of healthcare personnel for waste compliance is therefore a cornerstone of infection prevention, occupational safety, and regulatory adherence.

The World Health Organization (WHO) defines healthcare waste as all waste generated from healthcare activities, of which approximately 15% is hazardous and capable of causing infection, toxicity, or injury (1). Poor management of such waste exposes healthcare workers and the public to serious risks, including transmission of blood-borne infections such as hepatitis B, hepatitis C, and HIV(2). These risks underscore the need for structured and continuous staff training.

Regulatory Framework and Need for Compliance

In India, biomedical waste management is governed by the Bio-Medical Waste Management Rules, 2016, which mandate strict protocols for segregation, treatment, transport, and disposal of waste (3). These rules explicitly require healthcare facilities to train all categories of staff involved in waste handling. Training is not optional; it is a statutory obligation tied to institutional licensing and accreditation.

Despite clear regulations, studies reveal a persistent “know-do gap” among healthcare workers, where awareness does not always translate into practice. This gap is often attributable to inadequate or irregular training, lack of supervision, and insufficient institutional emphasis on compliance.

Objectives of Staff Training in Waste Compliance

Training programs should aim to achieve the following:

1. Knowledge Enhancement: Understanding categories of waste, color coding, and associated risks.

2.Skill Development: Proper segregation, use of personal protective equipment (PPE), and safe handling techniques.

3. Behavioral Change: Promoting accountability and adherence to standard operating procedures (SOPs).

4. Risk Mitigation: Reducing occupational hazards such as needle-stick injuries and exposure to infectious materials.

Training should be tailored to different cadres- doctors, nurses, laboratory technicians, sanitation staff, and waste handlers- based on their roles and exposure risks.

Components of an Effective Training Program

A comprehensive training module for biomedical waste compliance should include:

1. Risk Awareness and Infection Control

Staff must be educated on the health hazards associated with improper waste handling, including exposure to pathogens and toxic chemicals. Emphasis on infection prevention and control (IPC) principles is critical(4).

2. Segregation and Color Coding

Segregation at the point of generation is the most crucial step in waste management. Training should reinforce the importance of correct color-coded disposal to prevent cross-contamination and ensure appropriate treatment pathways (5).

3. Use of Personal Protective Equipment (PPE)

Proper use of gloves, masks, gowns, and eye protection must be demonstrated and practiced. Training should also include donning and doffing procedures to minimize contamination (4).

4. Handling, Storage, and Transport

Staff should be trained in safe handling techniques, storage time limits (not exceeding 48 hours for untreated waste), and transportation protocols .

5. Emergency Response and Incident Reporting

Training must include procedures for managing spills, injuries, and exposure incidents, along with mandatory reporting mechanisms (4).

6. Legal and Ethical Responsibilities

Healthcare workers should be made aware of the legal implications of non-compliance, including penalties and institutional liabilities .

Methods of Training Delivery

Training should be continuous and multimodal:

- **Induction Training:** Mandatory for all new employees before they begin clinical duties.
- **Periodic Refresher Courses:** At least annually, to reinforce knowledge and update staff on new guidelines.
- **Hands-on Demonstrations:** Practical sessions on segregation, PPE use, and waste handling in their language.
- **E-learning Modules:** Flexible and scalable training options for large institutions.
- **Audit and Feedback:** Regular monitoring and feedback to ensure compliance and identify gaps.

WHO and international agencies have developed structured training modules covering all aspects of healthcare waste management, which can be adapted locally (6).

Role of Institutional Leadership

Effective waste compliance training requires strong institutional commitment. Hospital administrators must:

- Develop a formal training calendar
- Allocate resources for training materials and trainers
- Maintain records of training sessions and attendance
- Integrate waste management training into quality assurance programs

Documentation of training is essential for regulatory compliance and must be submitted to authorities as part of annual reporting (5).

Impact of Training on Compliance

Evidence suggests that targeted training significantly improves biomedical waste management practices. Structured interventions have been shown to enhance segregation accuracy, reduce hazardous exposure, and improve overall compliance rates (7). Furthermore, training fosters a culture of safety and accountability, which is critical in high-risk healthcare environments.

Challenges and Solutions

Despite its importance, several challenges hinder effective training:

- **High Staff Turnover**: Requires repeated induction training
- **Resource Constraints**: Particularly in low-resource settings
- **Language and Literacy Barriers**: Among sanitation workers
- **Lack of Monitoring**: Leading to poor adherence

Solutions include simplified training materials, use of visual aids, multilingual instruction, and integration of training into routine hospital operations (8,9).

Conclusion

Training staff for waste compliance is not merely a regulatory requirement but a professional and ethical responsibility. As healthcare providers, we must recognize that safe waste management is an extension of patient care.

Continuous education, institutional support, and strict adherence to guidelines are essential to bridge the gap between knowledge and practice.

By investing in robust training programs, healthcare institutions can safeguard their workforce, protect the environment, and uphold the highest standards of clinical governance.

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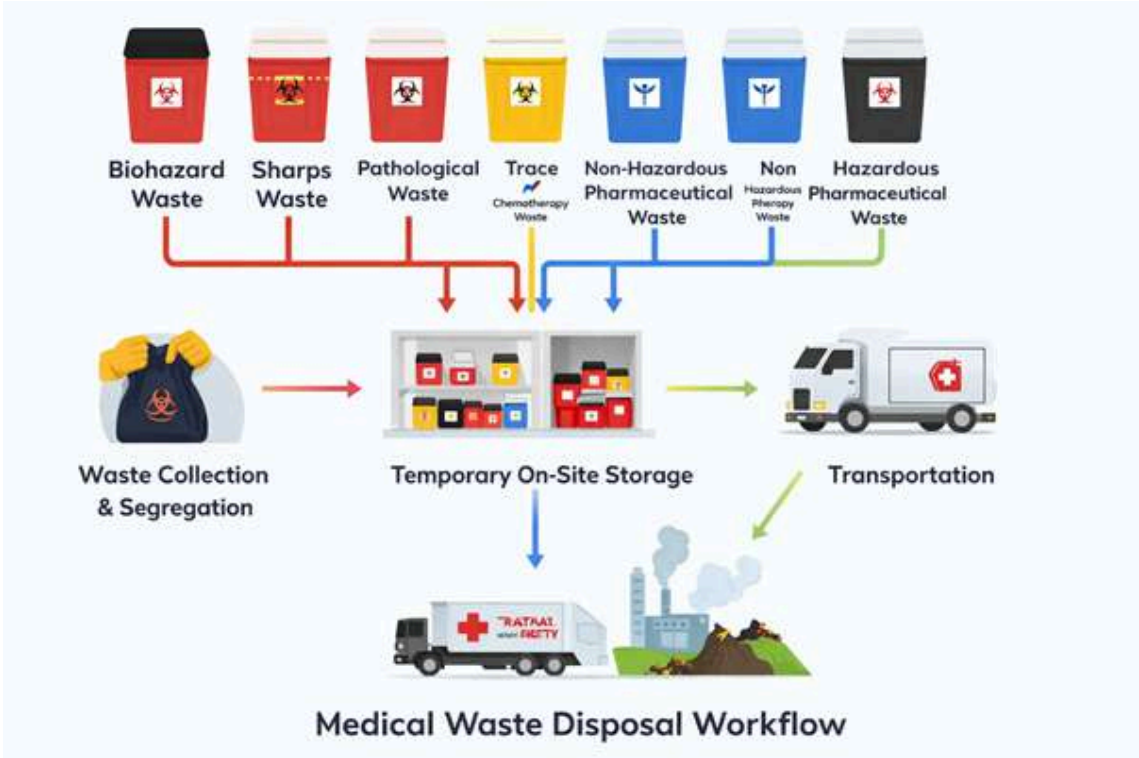
9 Documentation That Protects You

Author:- Dr. Anantha Lakshmi Porla
Professor and Head of the Government Medical College in Vikarabad
Secretary of the Hyderabad Obstetrics and Gynecology Society

Hospitals, clinics, laboratories, and even some industries produce biomedical waste (BMW). To avoid damage, this waste needs to be recognized, separated, and handled carefully. These days, handling biomedical waste is a professional duty for all healthcare personnel, not just a housekeeping chore.

"If it isn't written down, it didn't happen," as the saying goes.
Documentation is therefore crucial. It is required by law, ethics, the environment, and patient safety to document biomedical waste activities. Staff, patients, institutions, waste handlers, and the general public are all protected by accurate records.

Every healthcare facility in India is required by the Biomedical Waste Management Rules to manage waste in a way that protects people and the environment. Documentation serves as evidence that these regulations are being adhered to.



Medical Waste Disposal Workflow

Documentation Requirements

1. Records of Waste Segregation

Keep track of the waste produced by every department. For each category, use the appropriate color-coded bags. Perform audits every day to verify the accuracy of segregation. Keep logs and checklists for compliance.

2. Register of Sharps Injuries

- Note the time, date, and kind of sharp that was used.

1. Record the location of the injury and the specifics of the exposure.
2. Keep track of prophylaxis, follow-up, and immediate treatment.

Guards against occupational exposure claims for employees and organizations.

3.Records of Collection and Handover

- Take note of the type and amount of waste.
- Note the transport information, the time of collection, and the handler's name and signature.
- Save the Common Biomedical Waste Treatment Facility (CBWTF) receipts.

4.Tracking Logs and Barcoding

- Track waste bags from the point of origin to disposal using barcode systems.

Records of Training

- Keep track of schedules, orientation records, competency evaluations, and attendance sheets.
- One of the most frequent inspection failures is missing training documentation.

5.Reports on Spills and Accidents

- Keep track of the type of spill, the affected area, the individuals involved, the corrective measures, the disinfection, and the preventative measures.
- Converts mishaps into teaching moments.

6.Logs of Storage Area Monitoring

- Keep track of storage area conditions to guarantee compliance and safety. Regulatory and Authorization Documents
- Maintain pollution control board permits and approvals. Reports for the Year
- Provide annual reports on the production and disposal of biomedical waste.

Advantages of Documentation

- Legal Protection: Prevents fines and demonstrates adherence to the law.
- Safety & Accountability: By making clear what waste is managed, it safeguards employees and handlers.
- Support for Accreditation: Assists in fulfilling NABH and other requirements.
- Environmental Responsibility: Prevents pollution by ensuring waste is treated safely.
- Traceability: Establishes an unambiguous path from generation to disposal.
- Audit Readiness: Ensures compliance and streamlines inspections.
- Penalty Prevention: Lowers the possibility of closure or harm to one's reputation.

Dangers of Inadequate Documentation

- Penalties and fines imposed by authorities.
- Failures in accreditation.
- Notices about pollution control.
- Claims for occupational health.
- In medical-legal cases, the defense is weak.
- A decline in public and regulatory trust.

To conclude

Effective documentation serves as a safeguard. It demonstrates compliance with regulations, safeguards employees, promotes accreditation, and guarantees proper disposal of waste. Conversely, inadequate documentation increases the risk of penalties, legal issues, and reputational harm.

Robust records foster safety and trust. Inadequate documentation compromises credibility and compliance.

10 Creating a Waste-Safe Clinic Culture

Author:- Dr. Padmaja Veeramachaneni
Designation: MBBS, MD- OBG
City: Vijayawada

In modern healthcare, medical waste management is often viewed as a chore. A true waste-safe culture integrates safety into the daily rhythm of the clinic, protecting staff, patients, and the environment.

The Problem with Compliance-Only Mindsets:

Most clinics fall into the trap of "passive compliance." The common mistakes include:
Delegation decay: Thinking waste management is the responsibility of the "cleaning staff" only.
Convenience over safety: Placing the wrong waste in the nearest bin to save a few seconds.
Audit-panic: Periodic spikes in vigilance that vanish as soon as the inspection ends.

When waste management is treated as a secondary concern, the risk of needle-stick injuries and cross-contamination skyrockets. Safety is not a set of rules; it is a clinical habit.

Leadership: The Consultant's Role

The clinic owner or lead consultant sets the "safety tone." If leadership ignores the condition of sharps bins or uses improper disposal methods for convenience, the staff will mirror that behavior.

Leadership must shift from being "inspectors" to being "mentors." By actively involving the team in the design of the waste-flow process and treating waste safety with the same clinical rigor as a surgical procedure, the staff perceives it as an essential part of high-quality care rather than an administrative burden.

Behavioral Nudges and Practical Integration

To build a sustainable culture, we allmust reduce the friction between "doing it right" and "doing it fast." Use behavioral nudges:

- **Strategic Signage**: Use of color-coded signs directly at eye level above bins. Use icons rather than long text.

- **The Proximity Rule**: Ensuring sharps containers are within reach of the point of use. If a clinician has to walk across the room with a used needle, the risk of injury increases exponentially.

- **Incentives over Penalties**: Rather than punishing errors, celebrate "Safety Wins." Recognize staff members who catch a segregation error before it enters the disposal chain.

Waste Category :

Only 15% of all medical waste is considered “hazardous waste” which may be infectious or toxic, whereas 85% of the hospital generated waste is general and non-hazardous waste, comprising food containers, packaging, and medical supplies (i.e., gloves and masks, among others) used in the screening process for patients without contagious diseases.

So having a poster like this very clearly helps the whole team aware of the correct disposing of waste

Practical Handling Tips

Infectious (Yellow) : Keep the lid closed when not in active use.

Sharps (Puncture-proof): Never overfill; seal at 3/4 capacity.

General/Recyclable: Place these away from clinical zones to prevent mixing.

Infection Control and Patient Communication

Waste safety is an extension of infection control. If waste is not managed, pathogens linger in the clinical environment. Furthermore, patient awareness matters. When patients see a clinic that is visibly meticulous about waste, it reinforces their trust in the practice’s standards of hygiene.

Avoid "clinical-looking" bins in waiting areas, but ensure that any patient-facing waste is clearly marked.

If a patient asks why you are segregating waste, view it as a teaching moment: "We separate our waste to ensure the highest safety standards for our community." This simple sentence builds confidence and brand value.

Sustainability and Safety: The Combined Model

Sustainability is often viewed as an "extra," but it is deeply linked to safety. Over-segregating or generating excessive waste increases the volume of hazardous materials that require complex, high-energy processing.

Reduce: Audit your inventory. Do you really need to unwrap three separate items for a minor procedure?

Reuse/Recycle:Ensure non-contaminated paper or cardboard is diverted from the infectious waste stream.

Efficiency: Smaller, more frequent collections are safer than stockpiling large quantities of infectious waste.

Shift from plastic to cloth bags.

From disposable gowns to cloths caps and gowns , which can be washed and autoclaved
Replace shoes caps with Laboratory or OT only shoes
Use Qr codes intead of paper instructions
Promote e presciptions
Check Shelf life and prevent expiry related waste
Energy conservation : install LED lighting and motion sensors to activate or tuen off ceiling lights
Turn off computers , Monitors , non essential equipment when not in use
Purchase energy efficient equipment

Legal and Safety Implications

In India, the **Bio-Medical Waste Management Rules** are clear. Non-compliance can lead to the suspension of a clinic's registration or heavy penalties under the Environmental Protection Act. More importantly, the legal liability of a needle-stick injury resulting from poor waste management falls directly on the clinic owner. Protecting staff is not just an ethical duty; it is a legal necessity for business continuity.

Take-Home Points for Your Practice to ensure sustainable , responsible health care

1. Stop treating it as a chore: Waste management is a clinical procedure, like hand-washing or sterilization.

2. Optimize the flow: Place bins exactly where the clinical action happens to make the "right" choice the "easiest" choice.

3. Lead by example:If the consultant ignores safety protocols, the entire team will.

4. Engage the team: Conduct brief, monthly "safety huddles" to discuss one improvement in your waste workflow.

5. Simplify, don't complicate: Use visual aids, keep bins accessible, and keep the disposal process consistent.

By integrating waste management into the very fabric of your clinic's culture, you do more than avoid a fine—you create a safer, more professional environment that your staff will be proud to work in and your patients will instinctively trust.

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APPENDIX

TOOLKIT

Medical Waste, Sustainability & Compliance – Clinic-Ready Toolkit

1. Ensure biomedical waste is segregated **at the point of generation** and not later.
2. Maintain **strict adherence to the 4-colour coding system** as per BMW Rules 2016.
3. Do not store biomedical waste beyond **48 hours under any circumstances**.
4. Use **labelled, barcoded bags and containers** for all categories of waste.
5. Place **puncture-proof containers for sharps** at every procedure point.
6. Never recap needles and ensure **immediate disposal after use**.
7. Display **clear colour coding charts** in OT, labour room, and OPD areas.
8. Train all staff, including housekeeping, at **regular intervals with documentation.**
9. Maintain a **Biomedical Waste Register updated daily without gaps.**
10. Ensure tie-up with an **authorised biomedical waste disposal agency.**
11. Keep **spill management kits readily available and accessible.**
12. Vaccinate all staff against **Hepatitis B and Tetanus as per protocol.**
13. Audit waste practices **monthly with corrective action documentation.**
14. Avoid mixing general waste with biomedical waste to **reduce disposal costs.**
15. Use **closed bins with foot-operated lids** in all clinical areas.
16. Maintain **incident reporting for sharps injuries and exposure events.**
17. Display **contact details of waste disposal agency and emergency numbers.**
18. Ensure **proper storage area with restricted access for biomedical waste.**
19. Do not reuse single-use devices unless **specifically permitted and documented**.
20. Conduct **mock inspections periodically to ensure readiness.**

B. RED FLAGS

20 Common Traps in Biomedical Waste Management

1. Mixing infected waste with general waste to reduce disposal cost.
2. Incorrect disposal of gloves, IV sets, and plastics in wrong colour bags.
3. Absence of sharps containers at point of use.
4. Recapping needles after procedures.
5. Overfilled waste bags leading to spillage and contamination.
6. Lack of staff awareness about colour coding.
7. No documentation of staff training.
8. Failure to maintain daily biomedical waste records.
9. Storage of waste beyond 48 hours.
10. Missing or incorrect labelling of waste bags.
11. No barcoding where mandated.
12. Using open bins instead of closed, foot-operated bins.
13. Absence of spill management protocols.
14. No reporting system for needle-stick injuries.
15. Reuse of single-use devices without policy or documentation.
16. No formal agreement with authorised waste disposal agency.
17. Ignoring minor violations until inspection notice is received.
18. Lack of supervision in OT waste segregation.
19. No periodic audit of waste management practices.
20. Treating compliance as a formality rather than a system.

C. FDMSEC COMMITTEE RECOMMENDATIONS

- Every clinic must implement **strict segregation at source without exception.**
- Colour coding compliance should be **non-negotiable across all clinical areas.**
- Biomedical waste management must be **included in routine clinical audits.**
- Staff training should be **structured, repeated, and documented.**
- Sharps injury prevention must be **treated as a priority safety indicator.**
- Documentation should be **complete, updated, and inspection-ready at all times.**
- Clinics must be aware of **legal provisions and potential penalties.**
- Waste generation should be **reviewed periodically to reduce unnecessary burden.**
- Sustainability practices such as **waste reduction and rational use of disposables** should be encouraged.
- Leadership by consultants is essential to **build a culture of compliance and safety.**

05 - Medical Waste, Sustainability & Compliance

FDMSEC Insights | May-2026

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President
FOGSI

Dr.Suvarna Khadilkar
Secretary General
FOGSI

Dr. Vidya Thobbi
Vice President Incharge
FOGSI

Dr. Asha Jain
Chairperson
FOGSI FDMSEC

Dr. Asha Jain

Editor & Chairperson, FOGSI FDMSE Committee