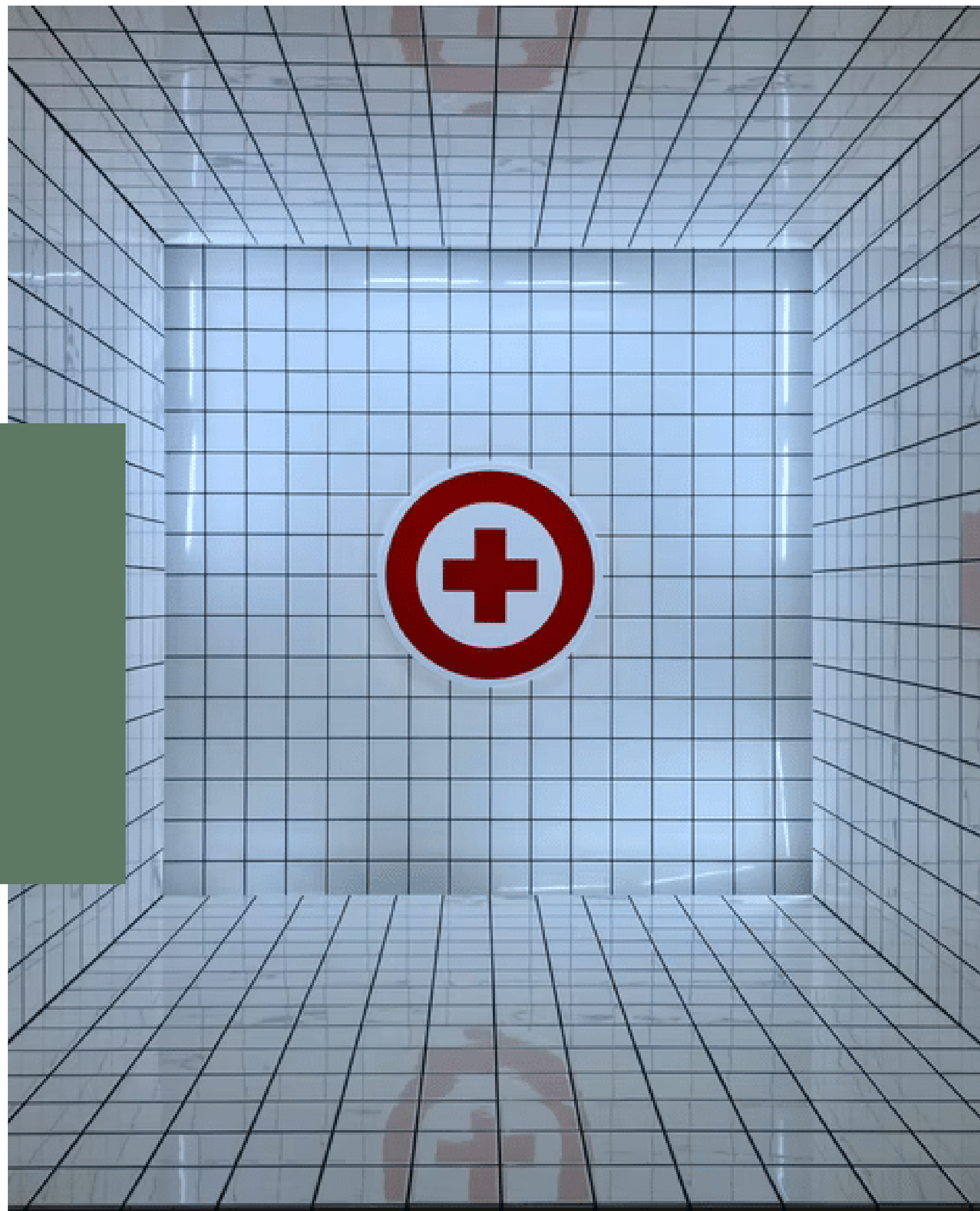


A photograph of a library with dark wood bookshelves filled with books. A wooden ladder is leaning against the shelves on the right. The background is a solid teal color. A white rectangular box is overlaid on the left side of the image, containing the title text in teal. The text is arranged in five lines, centered within the box. The font is a clean, sans-serif typeface.

OVERVIEWS OF LAWS APPLICABLE TO HOSPITAL AND ITS IMPLICATION

At his best, man
is the noblest of
all animals;
separated from
laws and justice
he is the worst



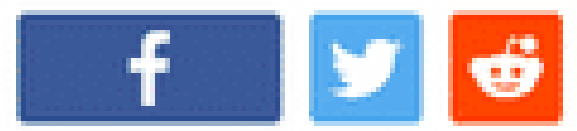


Recent Medical
Negligence cases
became the headline
in the country leading
Newspaper

Home / India / India Others / Supreme Court orders Tamil Nadu to pay Rs 1.7 crore compensation to girl who lost vision

Supreme Court orders Tamil Nadu to pay Rs 1.7 crore compensation to girl who lost vision

The bench found no justification for why the necessary tests were overlooked by the doctors and held them accountable for negligence.



By: [Express News Service](#) | New Delhi |
Updated: July 2, 2015 7:56:02 am



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LIVE BLOG

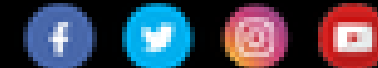
Assembly Elections 2021 Live Updates: Amid case surge, EC wants strict action for flouting Covid protocols

17 mins ago

Coronavirus India Live Updates: India records 3.49 lakh new Covid cases, 2,767 deaths

20 mins ago

Mann Ki Baat Live Updates: PM Narendra Modi to address nation at 11 am today amid



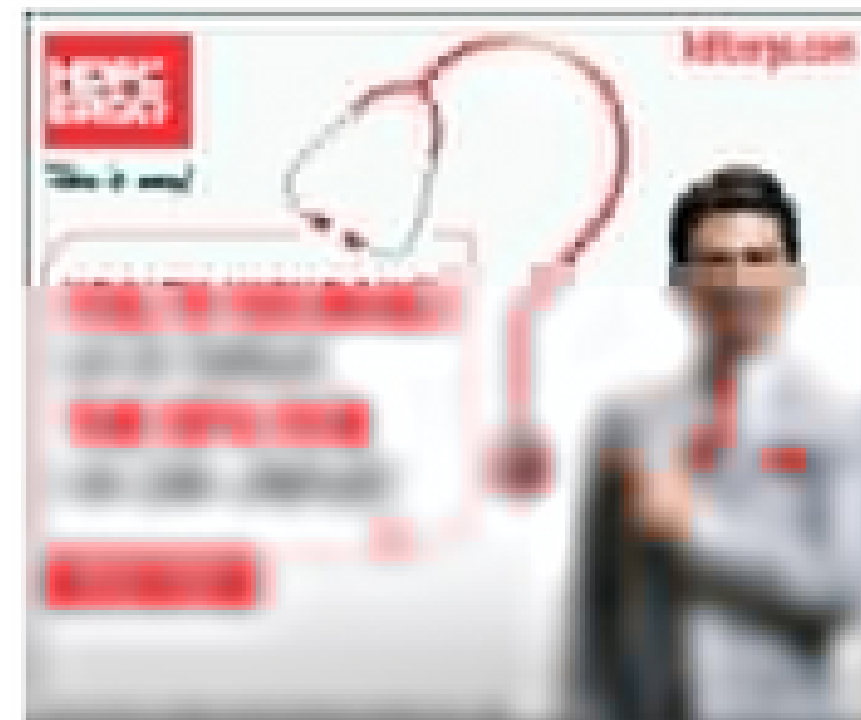
Home > India News

INDIA

Medical negligence, sub-standard drugs caused Chhattisgarh sterilisation tragedy: Panel

Distribution of sub-standard and poison-contaminated medicines besides 'medical negligence' led to the death of 13 women Chhattisgarh's Bilaspur district.

hidden | August 26, 2015 21:42:15 IST



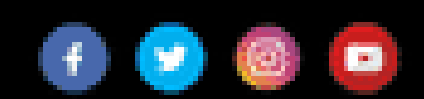
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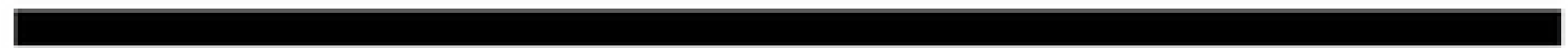
Home > India News

INDIA

SC to AMRI hospital: Pay Rs 5.96 cr to NRI doctor for negligence

The National Consumer Dispute Redressal Commission (NCDRC) in 2011 had awarded Rs 1.73 crore to the doctor whose wife Anuradha Saha died in 1998 following faulty treatment.

hidden | October 25, 2013 07:48:25 IST



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Healthcare industry is growing rapidly
but the core ingredients such as

“

Care, Compassion, Empathy
Trustworthiness and ethical
considerations are loosing
their fabric”

Modern Hospital Is A Matrix Organization

“an amalgam of social, architectural and technological advancements”

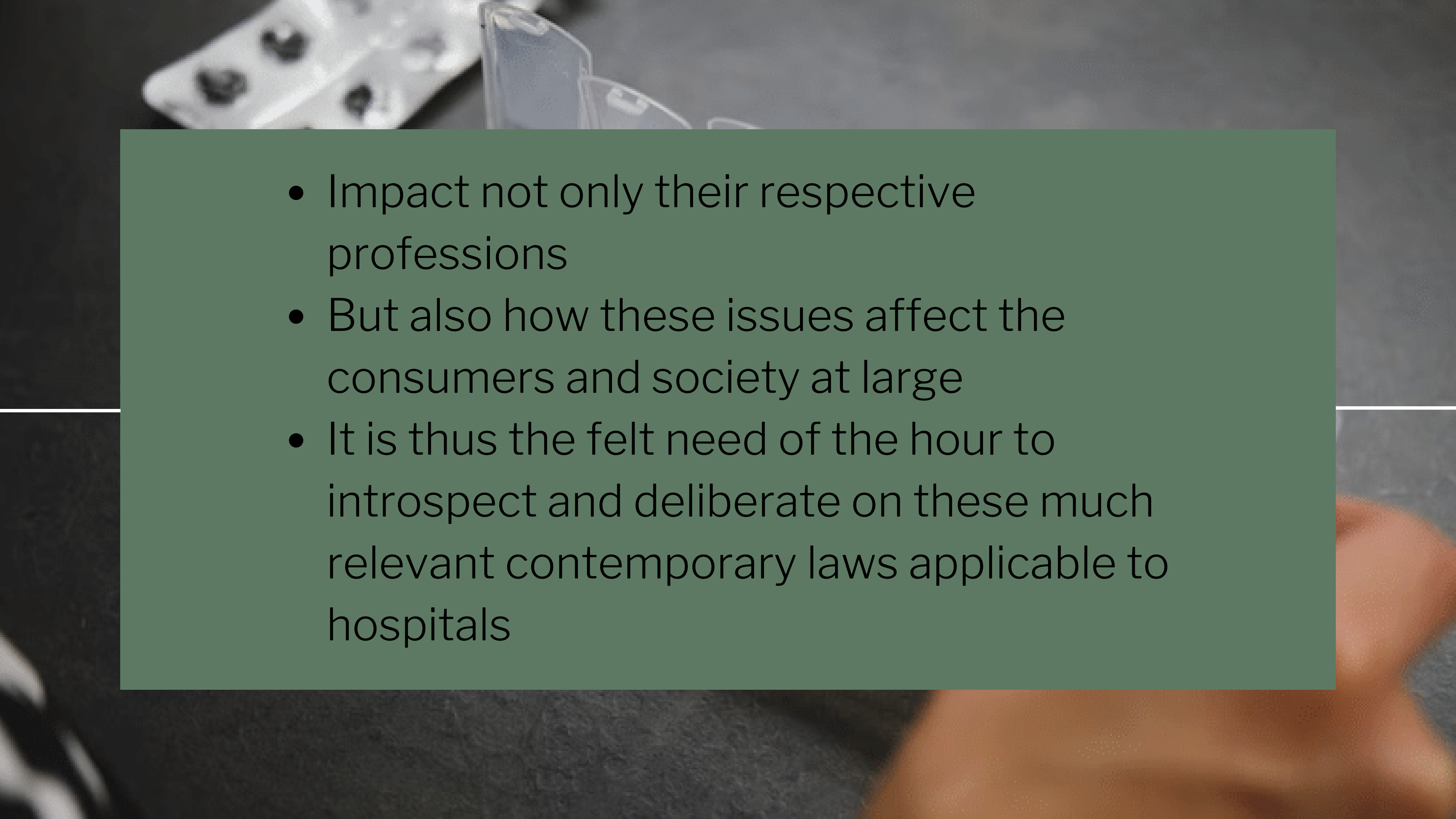
We live in a well-informed society

“ where patients, relatives, and others are inclined to questions= healthcare providers and hospitals when medical outcomes are not acceptable”



- Today, there are legal and ethical dilemmas associated with delivery of healthcare
- It is imperative for healthcare professionals to be well conversant with law and ethics- the pillars of healthcare ecosystem
- Healthcare professionals need to be concerned about how law and ethics



- 
- Impact not only their respective professions
 - But also how these issues affect the consumers and society at large
 - It is thus the felt need of the hour to introspect and deliberate on these much relevant contemporary laws applicable to hospitals

Earliest known code of laws of health practices



- Code of Hammurabi (2000BC)
- Hippocratic Oath (450BC)
- General Medical Council 1857 In England
- Bombay Medical Act (1880) (1914)
- Madras Medical Registration Act (1914)
- Indian Medical Court Act (1933)



Laws applicable to Hospitals

“

- Several laws imposed by the competent authority
- Non-compliance may lead to punishment
- Monetary fine or imprisonment or both
- There are about 156 Laws applicable to hospitals
- Some important one are elucidated here

Laws applicable for Hospitals

Laws related to:

- Commissioning of Hospitals
- Governing the conduct of professionals
- Governing the employees
- Governing the management of patients
- Governing the Hos. Premises and environmental protection
- Governing the drug storage and safe medication





Laws related to commissioning of Hospital

“

These are the laws to ensure that hospital facilities are

- Constructed after due clearance, sanction and registration
- Essential infrastructure facilities is made
- Safe for those using facilities
- Caters for the type and volume of workload anticipated

Laws related to commissioning of Hospitals

Nursing home registration Act	1953
Government Building Act	1899
Clinical Establishment Bill	2010
The Registration Act	1908
Radiation protection certificate for radiology dept from BARC	1971
Atomic Energy(safe disposal of radioactive waste) rules	1987
Lift Act	1942
Electric Rules	1956
Fire safety Rules	1987



Laws related to commissioning of hospitals- Implications



- Prior sanctions not obtained
- Stay on construction
- Financial Loss
- Litigation
- Timely facilities not available
- Design not followed as per std.
- Design doesn't follow function
- Ergonomically very poor
- Staff and patient dissatisfaction

**Laws related
to the
governing
the conduct
of
professionals**





- These regulations are to ensure the staff employed in the hospitals are
- Well qualified and trained
- Credentials are verifiable from councils
- Privileges- based on their level of competence
- Perform in accordance with standard code of conduct and ethics

Laws related to governing the conduct of professionals

- | | |
|---|------|
| 1. Indian Medical Council Act | 1956 |
| 2. Indian medical council (professional conduct, etiquette, and ethics) regulations | 2002 |
| 3. Indian Nursing council Act | 1947 |
| 4. Dental council of India regulations | 2006 |
| 5. Rehabilitation Council of India (Amendment) Act | 2007 |



Laws related to the governing the conduct of professionals- Implications



- Any Professional misconduct
- Soliciting any gift/ commission /bonus
- Inquiry
- Disciplinary actions
- Temporary/Permanent
- Removal from medical council registration
- Liable to be tried in any court/ forum
- Civil/ Criminal court
- Consumer redressal Forum

Laws related to Hospital Employees

1.ESI Act	1848
2.Employees provident fund	1952
3.Child Labour Act	1948
4.Minimum Wages Act	1948
5.Maternity Benefit(Amendment) Act	
6.Workmen's Compensation(Amendment) Act	2008 2009
7.Indian Trade Union Act	1926
8.Persons with Disabilities Act	1955

- Laws are for setting standards and norms for
- Conduct of medical practice
- Prevention of unfair practices
- Control of epidemics
- Management of
- Emergencies
- MLC
- Dying declaration
- Autopsy





Governing the management of patients

To safeguard wellness

- | | |
|--|------|
| 1. Drugs and magic remedies (objectionable) advertisements Act | 1954 |
| 2. PC & PNDT Act and Rules | 1994 |
| 3. MTP Act and rules | 1997 |
| 4. Transplantation of human organ Act and Rules | 1994 |
| 5. Birth and death marriage registration act | 1886 |
| 6. The Mental Health Act | 1987 |



Governing the Hospital Premises and environmental protection



1. Biomedical waste Management handling rules	2016
2. The Noise Pollution(Regulation & Control) (Amendment) Rules	2010
3. Rules regarding the safe discharge of effluents in the public sewers/ drains	1007
4. The Air (Prevention & Control of pollution) Rules	1982
5. Environment protection Act and Role	1086
6. Environment protection Act	1996

Governing the drug storage and safe medication

- Laws to control usage of drugs
- Blood and blood products
- Prevent misuse of dangerous drugs
- Regulate the sale of the drugs
- Prevent adulteration of drugs
- Provide punitive action against the offenders

Governing the conduct of professionals Practices

- Laws of contract
- Law of Tort
- Consumer Protection Act
- Doctor Protection Act



Governing the drug storage and safe medication



- Drugs and cosmetic Act & Rules 2005
- Pharmacy Act 1948
- Narcotics and psychotropic substance Act 1985
- Adulteration and sale of drugs (IPC Sec 274)

Recent Changes In Laws



- BMW Rules and Regulation
- AERB Guidelines- ELORA
- PCPNDT Act
- Transplantation of HOA
- Clinical Establishment Act
- Maternity benefit Act
- Reproductive rights (Surrogacy)
- Mental Health Act

BMW Guidelines- Essential Changes

1998

- Occupiers with more than 1000 beds require to obtain authorization.
- Operators duties absent
- Biomedical waste divided in 10 categories
- Rules restricted to HCEs for more than 1000 beds
- No format for annual report
- Schedule 1,2,3,4,5.

2016

- Every occupier generating BMW including health camp or AYUSH requires to obtain authorization.
- Duties of operator listed
- Biomedical waste divided in 4 categories
- Treatment and disposal of BMW made mandatory for all HECs
- A format for annual report appended with the rules
- Change of schedule 1,2,3,4.

Bio-Medical Waste Management Rules, 2010

Human/ Animal Anatomical Waste, Soiled Waste, Expired Medicines, Chemical Waste, Body Clinical Waste

Contaminated Waste (recyclable) like plastic bag, bottle, pipes or container

Bio-Medical Waste Management Rules, 2010

Scalpels, Blades, Needles, Syringes including
Sharp Metal

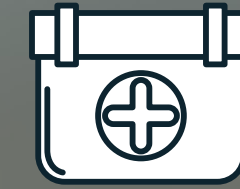
Broken Glassware or Metallic
Body Implan

Which of the following is true about Bio medical waste management rules 2016?

- Bio-medical waste is classified in to 4 categories based on treatment options.
- These rules apply specifically hospitals only.

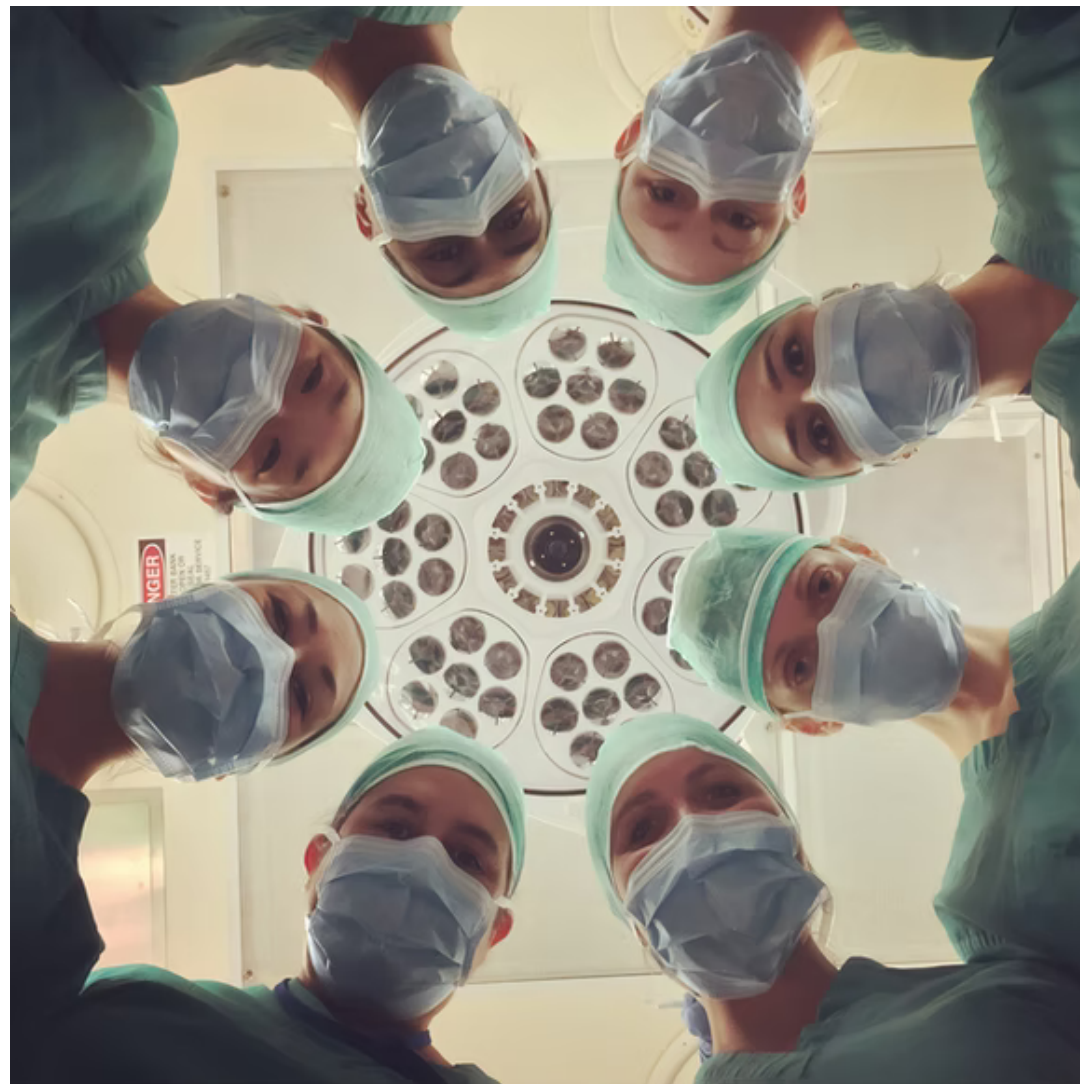
Write a brief note on the salient features of Bio medical waste management rules 2016 and its significance

AERB Guidelines



- eLORA (e-Licensing of Radiation Applications), an e-Governance initiative by AERB, is web-based application for automation of regulatory process for various Radiation Facilities in India.
- The objective of the project is to enhance efficiency and transparency in the regulatory process of AERB.
- The system is aimed at achieving paperless licence of Radiation Facilities

Atomic Energy Regulatory Board(AERB)



- Was constituted in 1983 by government of India
- Carries out certain regulatory and safety functions under the Atomic Energy Act,1962 and Environment Protection Act, 1986, Radiation Protection Rules 2004
- It is the recommendation, research and licensing body in India

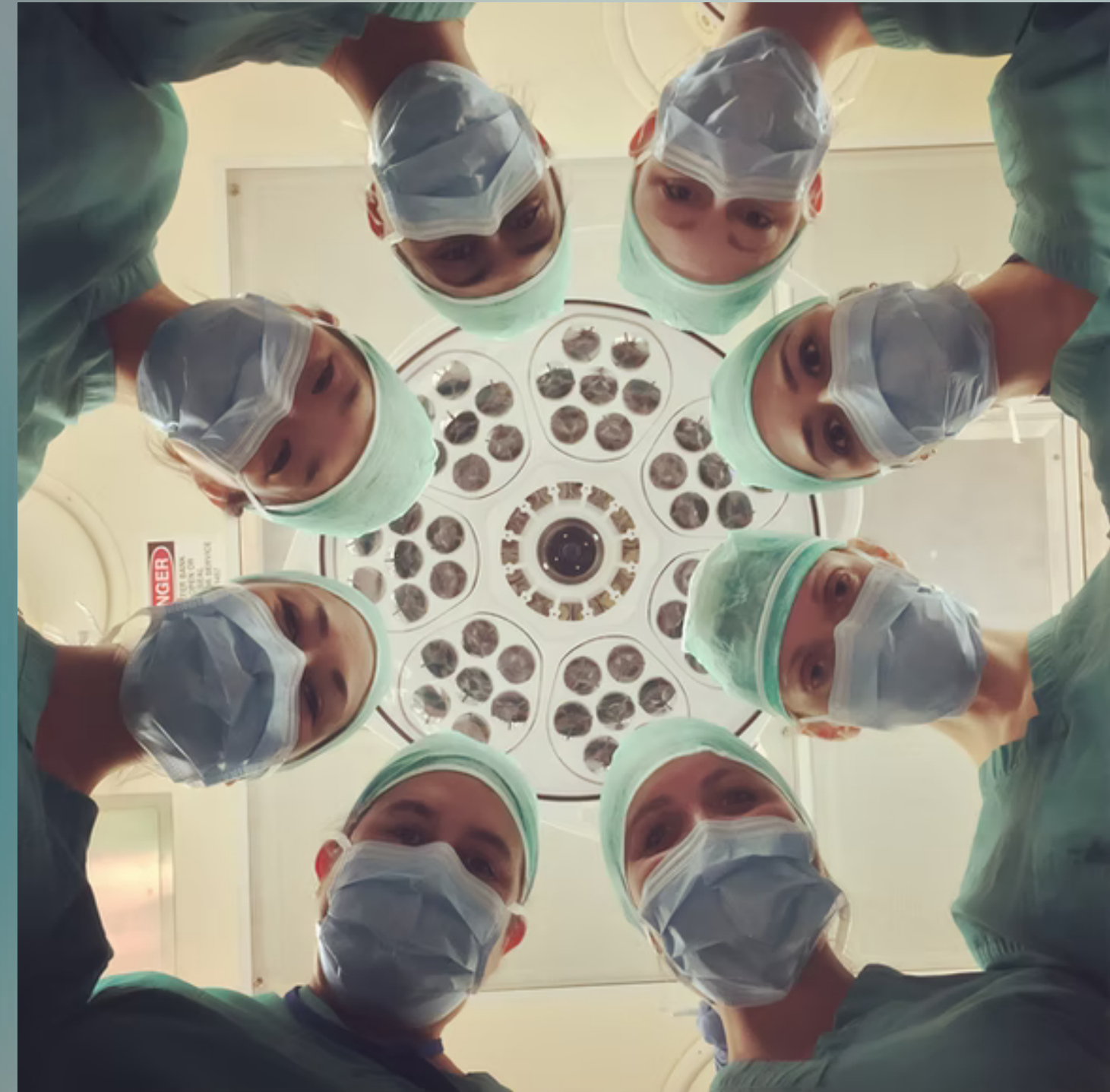
Amendments of PCPNDT Act

- Portability of machine only in the hospital where it is registered.
- Portability outside hospital allowed in a mobile which must be registered with PNDT & equipped with all emergency drugs.
- CT, MRI, PET-CT are also mandatory for registration with PC PNDT Act
- All X Ray Machines should have AERB approval.
- All records to be maintained and preserved for two years or till disposal of the court case whichever is later.



Transplantation of Human Organ and Tissues Rules 2014

- Title changed from “Human Organ” to Transplantation of “ Human Organ and Tissues Rules 2014”.
- Different Forms annexed to the rules for Application, Consent, Authorization & Approval in human Organ and tissue donation.
- Constitution & composition of Brain stem death panel, Authorization Committee.
- Certification of Brain Stem Death described in detail.



Transplantation of Human Organ and Tissues Rules 2014

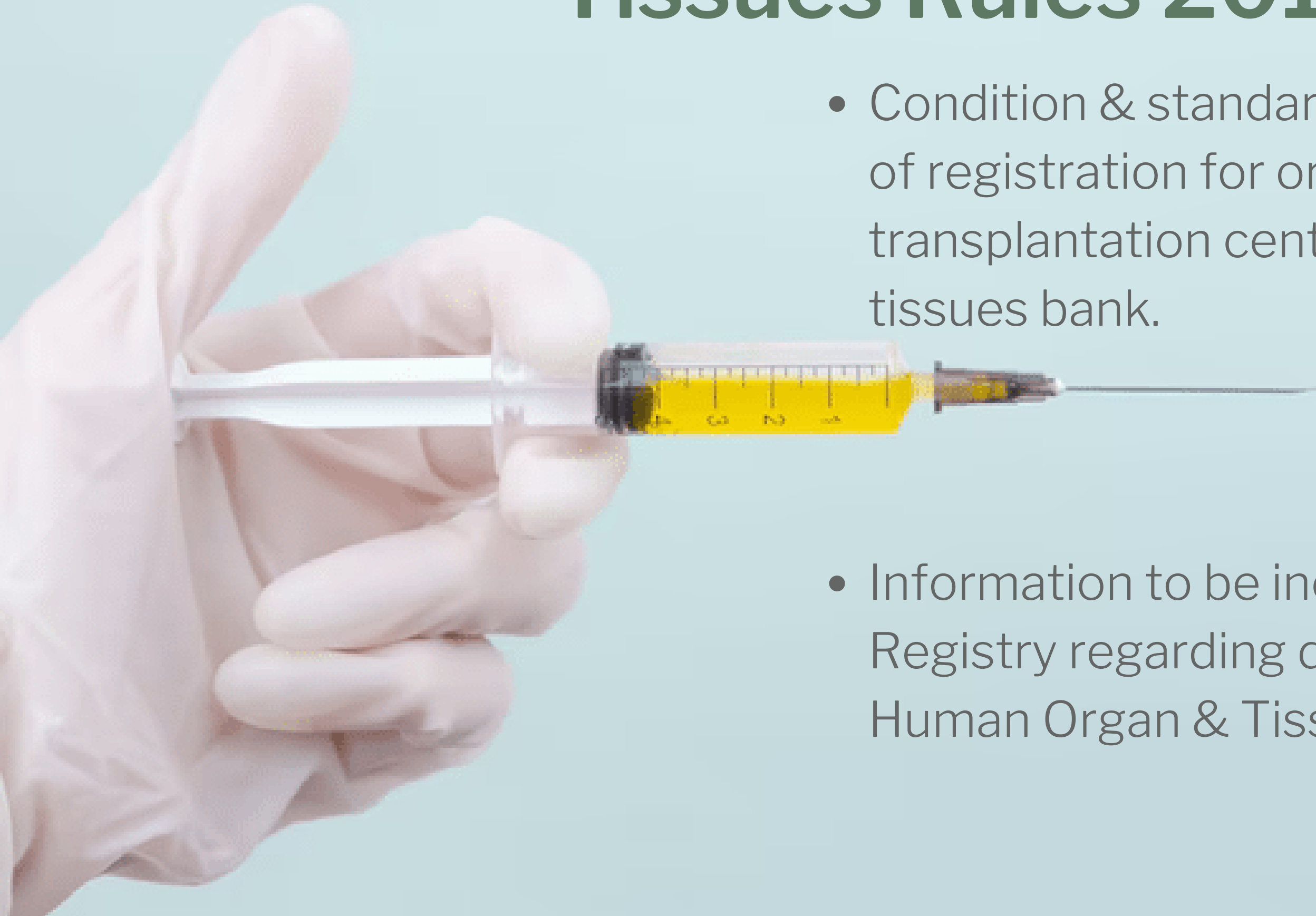
✓ Process of verification of Live donation has been described in detail

✓ Education Qualification of specialist carrying out retrieval and transplant of organ and tissues has been described.

✓ Qualification and role of Transplant coordinator clarified.

✓ Manner of establishing National Organ & Tissues Network explained

Transplantation of Human Organ and Tissues Rules 2014



- Condition & standards for grant of certificate of registration for organ on tissue transplantation centre , retrieval centre and tissues bank.
- Information to be included in National Registry regarding donor & recipients of Human Organ & Tissues

Amendments in Clinical establishment Act 2012



- Clinical Establishment rules 2012 (Rule 9)
- Registration and continuation of clinical establishment
- Hospital should display the scope of services and rate charges for each service.
- Rates for procedures/ services to be charges as determined and issued by central government
- Compliance to STG
- Maintenance and provision of EMR/HER.
- Maintain of information and statics in accordance with all applicable laws.

Some More
Examples of
Non
Conformity and
Implications



Impact of Not Following Laid Down Norms For Fire Safety

Police here on Tuesday arrested for employees for Hospital X, including its superintendent a day after a devastating fire on its premises killed 20 patient



Media Reports- Adverse Publicity

This is a joke. The hospital didn't follow any fire safety norms. The hospital even not qualifies the norms and never got the clearance from fire department. The owner of Hospital should be arres....

Impact of Not Following Laid Down Hota

Police Filed 1000 page plus charge sheet on Monday in the Kidney Racket that was busted at Hospital Y on July 14, when a transplant was stopped in Mid-way

A total of 14 people, including five doctors, were arrested during the course of probe while the patient, aged 54, died last month after getting interim bail.

Hospital have been burnt..



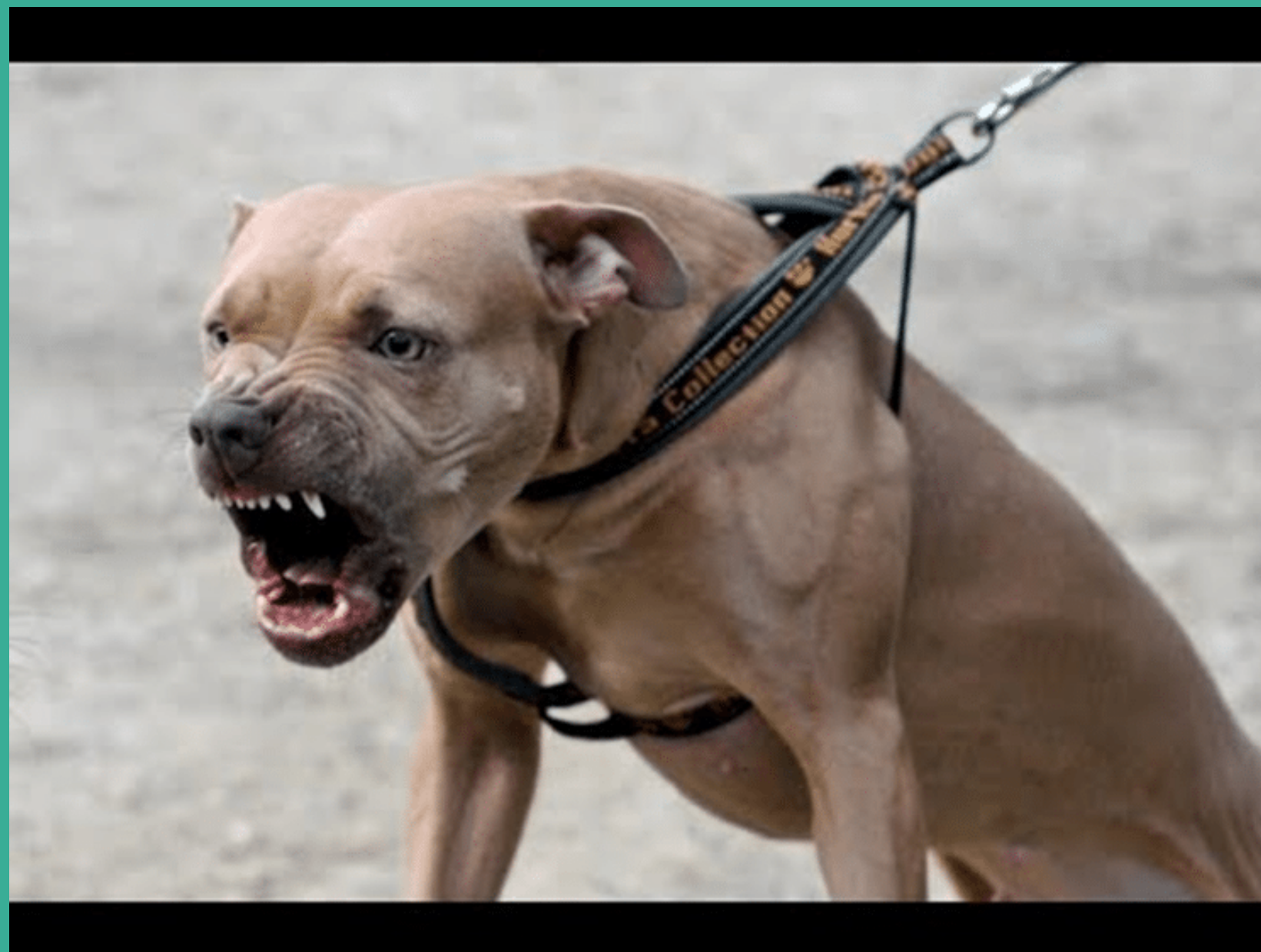
Would
this be
you and
me



Would this be your regular staff?



Your Official Spokespersons?



THE OVERALL IMPLICATION

- Adverse Publicity
- Loss Of Image
- Deteriorate Hospital Patient & Doctor
Patient relationship
- Vandalism and Loss of Property
- Violence against Staff
- Repeated and long standing court cases
- Punitive Actions
- Financial
- Imprisonment



Take Home Message

- Be Aware of the Laws and regulations that govern Hospital and Patient Care Services
- Remember that these are for the safety of the hospital, patient, staff, community and the environment.
- They are not there to harass you but to facilitate your functioning
- Ensure their Implementation
- Understand the implications for non conformity

**ALSO
REMEMBER**



- IGNORANCE IS NOT BLISS and can land the hospitals and health care providers in trouble
- PREVENTION IS ALWAYS BETTER THEN CURE

Law is blind



Thank
You