

PD233: Design of Biomedical Devices and Systems

(Lecture 2 - Bioethics)

Dr. Manish Arora

CPDM, IISc

Course Website:

<http://cpdm.iisc.ac.in/utsaah/courses/>

Ireland votes by landslide to legalise abortion

Leo Varadkar vows legal terminations by end of year after huge vote for change

- Ireland to start abortion law reform after historic vote
- Share your reaction to Ireland's abortion referendum



NEWS

No going back: The two sides in Argentina's abortion debate

By Katy Watson
BBC South America correspondent, Buenos Aires

7 August 2018



Argentina abortion vote



The green kerchief is worn by pro-choice activists of all ages

It is the middle of winter in Buenos Aires, but a spring-like green has blossomed in the city in recent months.

Top Stories

US to sanction Russia over Skripal attack

Ex-spy Sergei Skripal and his daughter fell ill after being poisoned by a nerve agent in the UK.

2 hours ago

Women break records in US election

3 hours ago

New Mexico kids 'trained to attack schools'

3 hours ago

ADVERTISEMENT

Features



The Barcelona jihadists and the hunt for a second gang



[Home](#) » [Opinion](#)

Mental Healthcare Act: A paradigm shift

It is laudable that the Mental Healthcare Act has had cross-party support, with both the UPA and NDA governments helping it along

Last Published: Wed, Dec 27 2017, 07:24 AM IST

✉ Soumitra Pathare

Enter email for newsletter

Sign Up



The Mental Healthcare Act provides persons with mental illness protection from cruel, inhuman and degrading treatment, right to information about their illness and treatment, right to confidentiality and right to access their medical records. Photo: HT

The Mental Healthcare Act, 2017, which was passed by the Rajya Sabha in August 2016 and the Lok Sabha in March 2017, is a landmark law for many reasons. For the first time in our country, the Act creates a justiciable right to

MORE FROM OPINION »

- Will the rural markets see revival in demand?
- Opinion: The imaginary fears around Comcasa
- Opinion | Karunanidhi: a giant who shaped Dravidian politics
- Opinion: India's wrong approach to paid maternity leave
- Opinion: When a witness is arrested in Bangladesh

What is Bioethics?

- Bioethics deals with ***intentional choices*** people make and ***moral principles*** they use for making these choices.
- These choices are important in:
 - Healthcare Practice
 - Biomedical Research (testing new drugs and devices)
 - Bio-Medical Device Design & Development

What questions does bioethics help answer?

Some examples from ***Healthcare Practice***:

- Do patients have a right to refuse medical treatment?
- What obligation does medical professional have about sharing information?
- What is the obligation of the state to provide healthcare?

What questions does bioethics help answer?

Some examples from ***Biomedical Research***:

- What is adequate level of information sharing about risk of new drug/device being tested?
- What treatment should be control arm of clinical trial be offered?
- How should the compensation paid to healthcare professionals and research subjects be decided?
Should this information be made public?

What questions does bioethics help answer?

Some examples from ***Medical Device Design & Development***:

- Should we build a device which allows changing genes of in a foetus?
- Should we build a develop technology which allows combining genetic material of three individuals?
- Should we develop technology which enables easy determination of sex of unborn child?
- What should developers reveal about how the device functions?
- Who has access to the internal data from medical device?

Law versus (Bio-)Ethics

- Law can be defined as a ***consistent*** set of ***universal*** rules that are widely ***published***, generally ***accepted***, and usually ***enforced***.
- Law may not be able to answer some of the bioethical question.
- Where law exist it must be followed- but it can be challenged and changed.

Need for bioethics:

- New ethical problems arise as
 - Technology advances
 - Societal expectations change
 - Science evolves

Need for bioethics:

- Multiple stakeholders have different interest-
 - Patients & research subjects
 - Healthcare professional
 - Hospital management
 - Public and the State (government)
 - Medical device companies
 - Medical device researchers and designers
 - ...
- Conflict of interest may arise.. And need to be resolved

How to answer bio-ethical questions?

- Ethical guidelines
 - ICMR guidelines for research involving human subjects
http://icmr.nic.in/ethical_guidelines.pdf
- Model code of conduct
 - IEEE model code of conduct
- Moral Principles ?

Moral principles in bioethics

For example:

- Truthfulness
 - Share information completely and correctly
- Fairness
 - Is the interest of all stakeholders protected fairly?
- Beneficence – ‘do good’
- Non-maleficence – ‘do no harm’
- Respect
 - For autonomy of the patients and research subjects
- Confidentiality
 - Understand what is privileged information and how to protect it

Implication of Bioethics:

Following have become law in various jurisdictions:

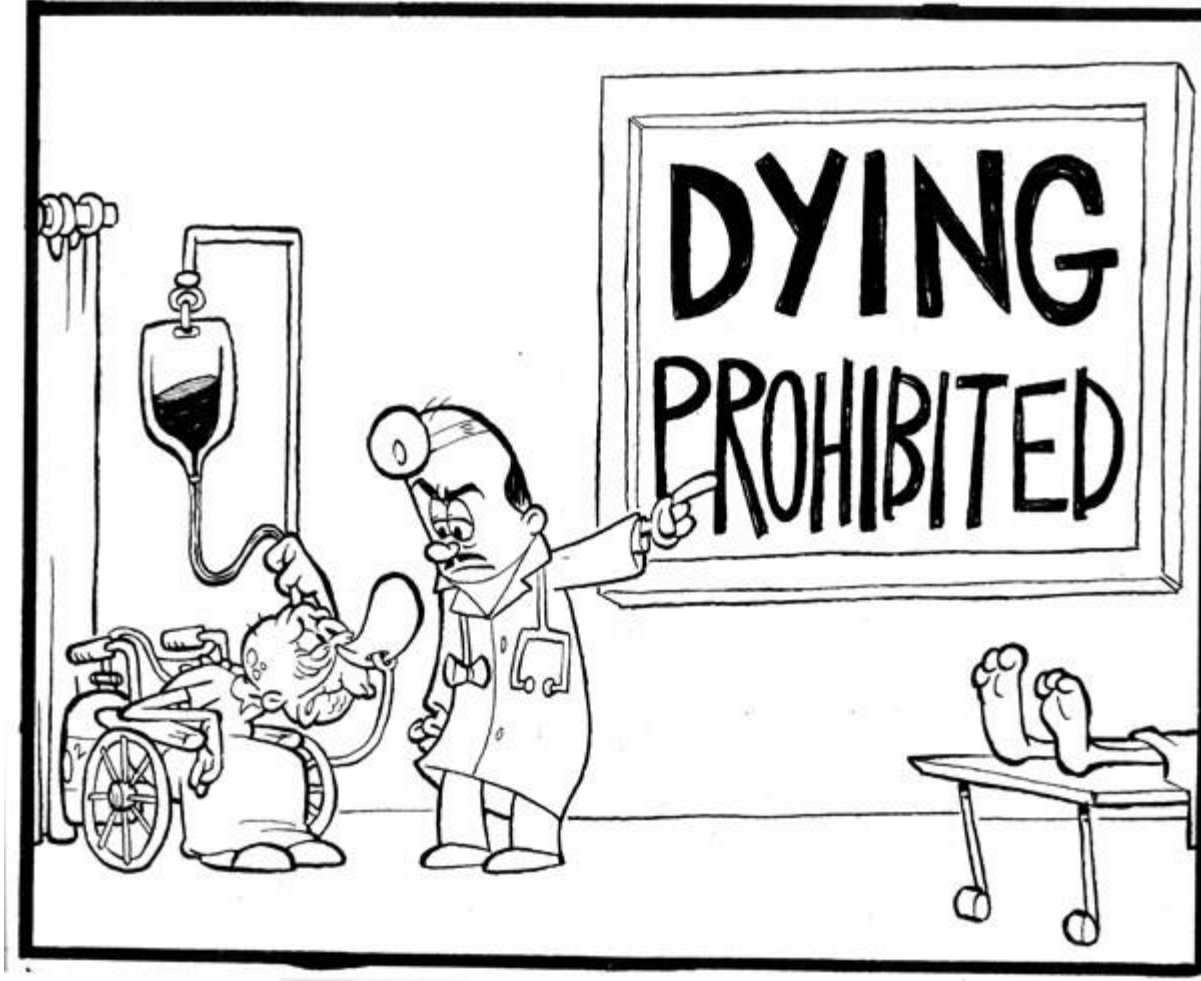
- Ban/tight control on ***research on human embryos***
- ***Informed Consent*** procedures for clinical practice and research
- ***Patient data protection*** regulations
 - See DISHA Act (Draft for public consultation)

Assignment 1:

Q1: Analyse any one of the bioethical question based on current law, ethical guidelines and moral principles.

Q2: Review ICMR 2006 Ethical guidelines and identify guiding principles used to frame these guidelines.

Please submit one page write up (500-1000 words, each) by next class (14th Aug 2018)



CHRIS ALLISON

TOONHOLE.COM