### PD233: Design of Biomedical Devices and Systems (Lecture 2 - Bioethics)

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



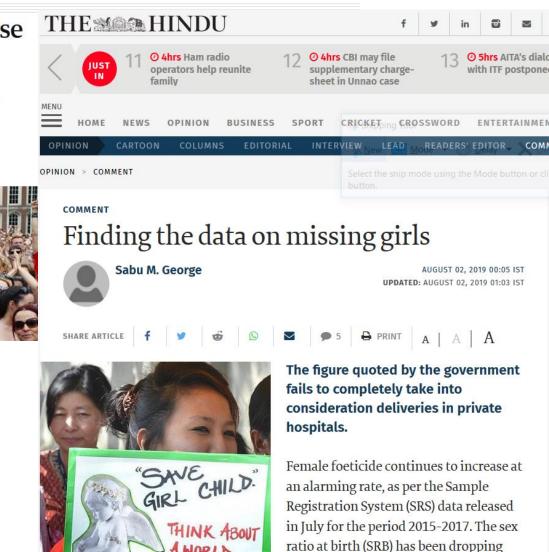
Media Society Law Scotland Wales Northern Ireland

#### 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





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#### 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



The draft bill says those commissioning violence or causing damage to the property of a healthcare facility can be imprisoned for six months to five years and fined between Rs 50,000 and Rs five lakh, officials said.

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The Mental Healthcare Act provides persons with mental illr treatment, right to information about their illness and treat their medical records. Photo: HT PTI

The Mental Healthcare Act, 2017, which w August 2016 and the Lok Sabha in March : reasons. For the first time in our country, t

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Updated:August 14, 2019, 11:34 AM IST

#### 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 trail 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 <u>http://icmr.nic.in/ethical\_guidelines.pdf</u>
- 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 **27<sup>th</sup> Aug 2019** 

