PD233: Design of Biomedical Devices and Systems

(Introduction Lecture)

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

Motivation

- Health along with education basic human necessity if not basic human right
- Well designed medical devices and systems ***can save lives*** but also ***prevent financial hardship*** for the patient and family
- Medical devices (and systems) are in most cases ***systemically-complex, technologically-intensive, and socially-impactful solutions***
- Designer need to aware of ***unique attributes*** of medical device design
- Unique challenges of healthcare in India

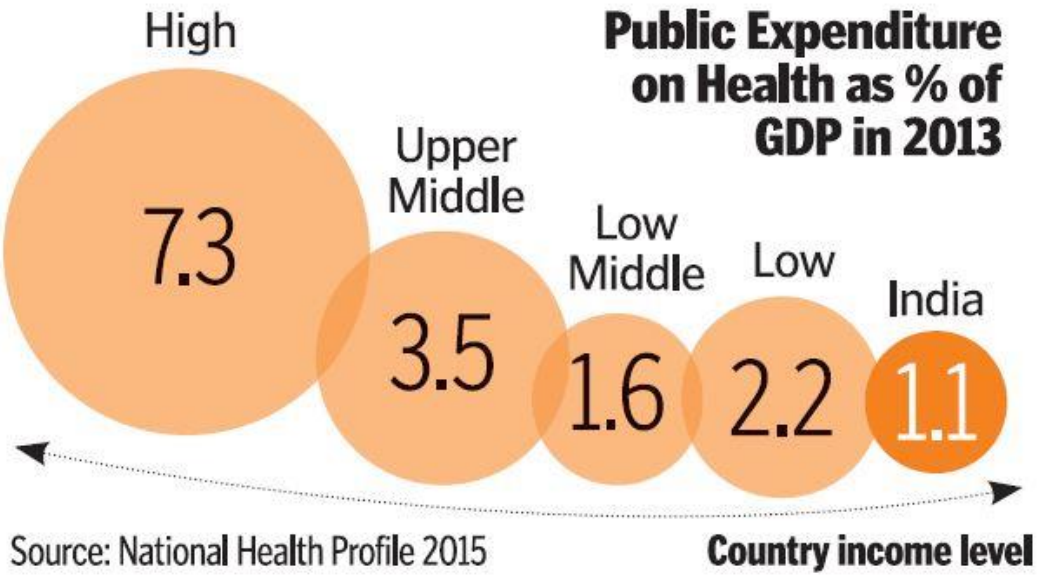
Healthcare in India

1 doctor per 1700 people, far below 1:1000 minimum mandated by WHO

- Disproportionally located in bigger cities
- Up to 1/3rd PHC positions vacant in some states
- Many doctors posted in rural sector remain absent

Almost one-third (31 per cent) of those who claimed to be allopathic doctors in 2001 were educated only up to the secondary school level and 57 per cent did not have any medical qualification

Public Healthcare Spending in India Remains Low



'Out of pocket' expenses are very high

39 million Indians are pushed to poverty because of ill health every year.

Infographics via: http://www.thehindu.com/sci-tech/health/policy-and-issues/malady-nation-remedying-indias-healthcare-colossus/article8956304.ece

08-08-2016

List of equipment at secondary level: Community Healthcare Center (CHC)

(Serving about 1.2 Lakh people each, with 6-7 Doctors)

Surgical Sets – Forceps, Knifes, Needles etc.
IUD Kit
Normal Delivery Kit
Sterilizer
Wheel Chair
Vacuum extractor
Weighing machine
Diagnostic X-Ray Unit ← ~ Rs. 1 Lakh
X-ray view box
Cold Storage for vaccine and blood

Not Included:
Ultrasound Scanner

~Rs. 5-10 Lakh

Source: Indian Public Health Standards (IPHS) guidelines for Community Health Centres Revised 2012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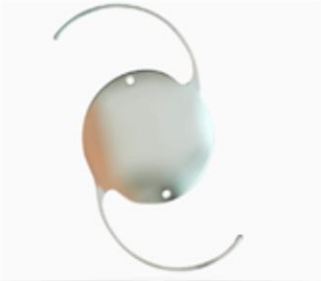

Course Syllabus (2:1)

Lectures Tuesday 10-11am, Thursday 2pm-3pm.
Project discussion session: Monday 2-5pm

Softcore

- Empathy, Bioethics, Privacy
- Medical Device Classification
- Design Control & Regulatory Requirement

- Biocompatibility and Sterilization Techniques
- Design of Clinical Trials

Hardcore

- Biopotential measurement (EMG, EOG, ECG, EEG)
- Medical Diagnostics (In-vitro diagnostics)
- Medical Diagnostics (Imaging)
- Minimally Invasive Devices
- Surgical Tools and Implants
- Medical Records and Telemedicine

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Project Requirements (40%)

- Go deeper into one clinical need
- Done in groups
- Four assessments:
  - Problem Identification (Week 4)
  - Domain Knowledge Capture (Week 8)
  - Device Requirements (Week 12)
  - Prototype (Class 1) or Mock Proto + Master Device Design file for regulatory approval Class 2 and above (week 16)

Project Topics

- TBC..

- You can also propose projects provided you have contact with healthcare professional willing to guide you

(Last date for proposals 14th Aug 2018)

Reference Book:

- Peter J. Ogrodnik, Medical Device Design: Innovation from Concept to Market, Academic Press Inc; 1 edition (2012), ISBN-10: 0123919428
- Zenios *et al.*, Biodesign: The Process of Innovating Medical Technologies, Cambridge University Press; 1 edition (2009), ISBN-10: 0521517427
- **Paul H. King, Richard C. Fries, Arthur T. Johnson, Design of Biomedical Devices and Systems, Third Edition, ISBN 9781466569133**
- **John G. Webster (ed), Medical Instrumentation: Application and Design, 2007**
- Khandpur, Handbook of Biomedical Instrumentation, 2004
- **B Ravi, The Essence of Medical Device Innovation, 2018**
- Online resources:

  http://cpdm.iisc.ac.in/utsaah/courses/ (Course website)

  http://www.cdsco.nic.in/forms/default.aspx (GoI notifications)

  http://www.ncbi.nlm.nih.gov/pubmed (Biomedical Research)

  http://biodesign.stanford.edu/ (Biodesign process)