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

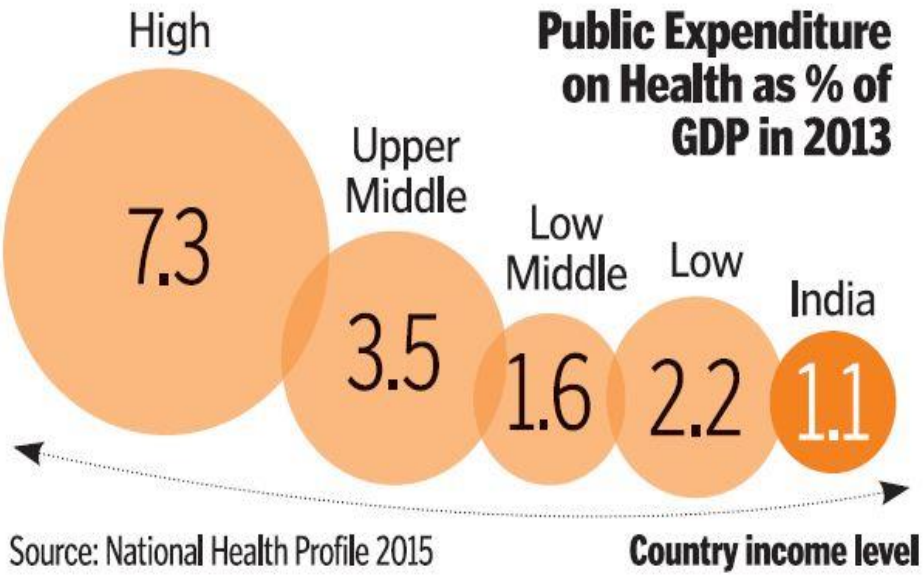
Healthcare in India

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.

	India	World
Government Funding (% of GDP)	1.1	7.4
Out of pocket (%of total expense)	64.6	18.5

Infographics via: http://www.thehindu.com/sci-tech/health/policy-and-issues/malady-nation-remedying-indias-healthcare-colossus/article8956304.ece retrieved 08-08-2016

WorldBank data.worldbank.org

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


ARAVIND EYE HOSPITAL
ARAVIND
EYE HOSPITAL
Airtel
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NAS
CATERING INSTITUTE

Aurolab introduced IOLs at $10 while others were selling them at $60-$100. Aurolab now manufactures more than two million lenses annually and exports to 160 countries.

Changing Regulatory System

New Medical Device Rules (MDR 2017) came into effect in 2018. These rules are meant to regulate design, manufacture, import, sale and distribution of medical devices.

Six bodies registered with CDSCO to audit medical device manufacturing sites as per new MD Rules

0 Editors Pick, Implants / Devices, News, Policy August 4, 2019 A- A+

New Delhi: Through a recent public n drug regulatory body, Central Drugs St Organisation(CDSCO) has notified six out an audit of manufacturing site under of the Medical Devices Rules, 2017.

In this connection, six bodies have been registered with CDSCO. These audit services providers include New Delhi-based Intertek India Pvt. Ltd which was established in the year 1997; TUV Rheinland India Pvt. Ltd located in West Wing, Electronic City in Bengaluru; TUV Sud South Asia Pvt. Ltd situated in Mumbai; Dnv GI Business Assurance India Private Limited, Mumbai; BSI Group India Pvt. Ltd, New Delhi and BSCIC Certifications Pvt Ltd situated in Faridabad.

livemint

Manufacturers will also have to seek licences from the Drug Controller General of India before their product enters the Indian market

Soon, import, manufacture and sale of all medical devices may need CDSCO certification

3 min read . Updated: 09 Aug 2019, 11:56 PM IST

Course Syllabus (2:1)

Lectures Tuesday & Thursday 10-11 am
Project discussion session: Monday 9-12pm
Two day workshop 5-6th Sept (TBC)

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/deliverables:
    1. Problem Identification (Week 4)
    2. Domain Knowledge Capture (Week 8)
    3. Device Requirements (Week 12)
    4. Prototype (Class 1) or Mock Proto + Master Device Design file for regulatory approval Class 2 and above (week 16)

Project Topics

Problems defined for ReImagineHealth Hackathon

<Geriatric Health Focus>

https://indianinstituteofscience-my.sharepoint.com/:f:/g/personal/siddharthnair_iisc_ac_in/EqFMD-uFRwFClJg6AGY4e4YBz_vCF2837HlmHEAhx1_ilw?e=1IA9LB

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

  (Last date for proposals 19th Aug 2019)

Reference Book:

- **B Ravi, The Essence of Medical Device Innovation, 2018**
- 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
- 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)