Welcome to Medical Device Design!
2.75 - 6.525 (G-H), 2.750 - 6.025J (UG CI-M)
Introductions

Prof. Alex Slocum
Prof. Charlie Sodini

Dr. Nevan Hanumara

Deborah Alibrandi

David Custer

Maggie Delano
Tyler Wortman
Dr. Jay Connor
Sandy Campbell
Christiana Chase
Subarna Basnet
Motivation - US Healthcare Expenditures

- $2.5 trillion, 17.6% GDP
  $8,086 per person

- Predicted 6.1% annual growth to 19.3% GDP in 2019

- 2.1% differential GDP vs. NHE growth rates
  
  • Technology accounts for 38% – 65% of cost growth
  • “Some technology may provide tremendous value while other forms are simply more expensive ways of producing similar outcomes.”

Social Security Advisory Board, “The Unsustainable Cost of Health Care,” 2009
A Contrast

da Vinci Surgical System
Replaces manual laparoscopy & open
Price: $1.34 million + service & consumables

www.intuitivesurgical.com

~ $10 disposable tools
Today’s Action Items

In Class
- Welcome
- Course overview
- Sample project cases
- Team dynamics & the communication component in 2.75
- Path to the $100K
- FUNdaMENTALS Topic 3
- 2.75 X: [https://lms.mitx.mit.edu/courses/MITx/2.75r/3T2014/about](https://lms.mitx.mit.edu/courses/MITx/2.75r/3T2014/about)
Course Overview
Nevan Hanumara
Classroom to Clinic

- Begun in 2004
- Funding: CIMIT & Corporate
- Clinicians submitted challenges
- Competitive project selection
- 3-5 person student teams
- 14 weeks to prototype solution
- $4000 budget for each team
- Course staff as project managers
- Hands on design experience
- Means for rapid identification, development & evaluation of potential technology
14 Weeks – Three Phase Design Process

- Clinician driven, NOT technology driven
- Coarse 14 weeks Fine
- Iterative Prototyping – weekly design reviews with mentors

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Design Engineering</th>
<th>Building &amp; Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Opening</td>
<td>6 Select <em>Strategy</em></td>
<td>10 Fabricate MCM</td>
</tr>
<tr>
<td>2 Clinician presentations</td>
<td>Identify FRs</td>
<td>Demo. MCM</td>
</tr>
<tr>
<td>Form teams</td>
<td></td>
<td>11 Fab. other modules</td>
</tr>
<tr>
<td>3 Define problem</td>
<td>7 <em>Brainstorm 3 Concepts</em></td>
<td><strong>Present final design</strong></td>
</tr>
<tr>
<td>Review prior art</td>
<td>Bench-level prototype</td>
<td></td>
</tr>
<tr>
<td>4 Brainstorm <em>Strategies</em></td>
<td>Select <em>Concept</em></td>
<td>12 Complete fabrication</td>
</tr>
<tr>
<td>Bench level experiment</td>
<td></td>
<td>Integrate modules</td>
</tr>
<tr>
<td>5 <strong>Present 3 Strategies</strong></td>
<td>Begin solid model</td>
<td>13 Complete prototype</td>
</tr>
<tr>
<td></td>
<td><em>Present 3 Concepts</em></td>
<td>Test! Debug. Test!</td>
</tr>
<tr>
<td></td>
<td>Identify <em>most critical module</em> (MCM) &amp;</td>
<td><strong>Present Prototype</strong></td>
</tr>
<tr>
<td></td>
<td>supporting modules</td>
<td>Document</td>
</tr>
</tbody>
</table>
Important Dates

- Next Week – Clinician Presentations
- 9/12 – Team Formation – no dropping
- 9/16 – Teams Announced
- 9/23 – Kinematic coupling (KC) proposal due
- 9/29 week – Strategy presentation
- 10/7 – KC writeup due
- 10/9 – EKG proposal due
- 10/16 – EKG writeup due
- 10/17 – Ximedica Tour (TBC)
- 10/30 week – concept presentations
- 11/3 week – Design review presentation
- 12/10 – Final Presentations
- 12/15 – All deliverables due

Link to Course Homepage & Syllabus
Fall: 2.75 - 6.525 (G-H), 2.750 - 6.02S (UG CI-M)

Design of Medical Devices

Since 2004 the course has partnered with CIMIT to bring together Boston area physicians and MIT engineering students in developing new medical devices. Physicians present their particular challenges then student teams work with them during the course of a semester to develop solutions.

Over the past years, this class has become a highly effective mechanism for generating new research ideas and collaborations with patients and many of the projects receiving subsequent funding and accelerating from prototypes to products.

Projects identified to have a significant impact with a viable market can be continued into the spring term for the next level implementation.

2.750 is an alternative to the ME 2.009 requirement. Units: 4.0-8

Official Course Description (Registrar) | Course Pooter

Tuesday & Thursday 15:00 - 17:00 in 3-442

Student questions? - Please contact the course staff

*Special Energy Focus Project - contact Anthony Wong

Course Highlights

- Work with a local client on a real medical challenge
- Learn the design process & prototype a solution
- Applied mechanical & electrical engineering
- Weekly design reviews with the instructors
- Guest lectures from professionals
- Presentations through the course
- Journal quality final paper and possible patent application
- Explore Fast Projects
- MIT TechTV

2.75 in The News!

- Genie in a Classroom - ASME Article
- MIT students create new medical devices - MIT News
- Classroom to Clinic: Merging Education and Research to Efficiently Prototype Medical Devices (JTEHM)

MIT 2013-2014 - Call for Proposals is now Closed, thank you to all who submitted.
To be included in future calls please mail mdic@mit.edu
## 2014 Projects

### Tuesday 9 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation Title</th>
<th>Presenter</th>
<th>Institution</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:00</td>
<td>Mallet finger splint</td>
<td>Jay Connor</td>
<td>Mount Auburn Hospital</td>
<td>Orthopaedic Surgery</td>
</tr>
<tr>
<td>3:20</td>
<td>Compliant dental molar implant</td>
<td>Gili Naveh</td>
<td>Harvard School of Dental Medicine</td>
<td>Developmental Biology</td>
</tr>
<tr>
<td>3:40</td>
<td>Visually guidable suction catheter and applications in ICU</td>
<td>George Cheng</td>
<td>MGH/BIDMC/BWH</td>
<td>Pulmonary Critical Care</td>
</tr>
<tr>
<td>4:00</td>
<td>Allowing two handed endoscopic ear surgery</td>
<td>Michael Cohen</td>
<td>Massachusetts Eye and Ear Infirmary</td>
<td>Otolaryngology</td>
</tr>
<tr>
<td>4:20</td>
<td>Wearable defibrillator for survivors of acute myocardial infarction</td>
<td>Maulik Majmudar</td>
<td>MGH</td>
<td>Medicine</td>
</tr>
<tr>
<td>4:40</td>
<td>Development of customized ankle foot orthotics</td>
<td>Brandy Baker</td>
<td>MIT</td>
<td>UGrad Office</td>
</tr>
</tbody>
</table>
### 2014 Projects

#### Thursday 11 September

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Presenter</th>
<th>Institute</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:00</td>
<td>Anti-malarial bednet adherence monitoring in sub-Saharan Africa</td>
<td>Paul Krezanoski</td>
<td>MGH</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>3:20</td>
<td>Improved food component delivery</td>
<td>Micah Tsern</td>
<td>Director Engineering</td>
<td>Taco Bell</td>
</tr>
<tr>
<td>3:40</td>
<td>Aqua Runners</td>
<td>Halston Taylor</td>
<td>Track Coach</td>
<td>MIT</td>
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<tr>
<td>4:00</td>
<td>Semi-automated tube thoracostomy insertion system</td>
<td>Tomaz Mesar</td>
<td>MGH</td>
<td>Surgery</td>
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<tr>
<td>4:20</td>
<td>Course Staff – teaming</td>
<td></td>
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<tr>
<td>4:40</td>
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</table>
## Grading

Course grade based on: A = 90-100; B = 80-90; C = 70-80

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight</th>
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<tbody>
<tr>
<td><strong>Term Project – Team Grade</strong></td>
<td>50%</td>
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<tr>
<td>Execution of the design process</td>
<td></td>
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<tr>
<td>Meeting scheduled milestones</td>
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<td>Use of time and $</td>
<td></td>
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<tr>
<td>Quality of design &amp; execution (details &amp; execution)</td>
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<tr>
<td><strong>Formal Communications</strong></td>
<td>15%</td>
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<tr>
<td>Team Presentations</td>
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<td>Final Paper</td>
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<tr>
<td><strong>Individual Performance</strong></td>
<td>15%</td>
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<tr>
<td>Contributions to project (Monitored via weekly check offs)</td>
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<tr>
<td>Use of lab notebook</td>
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<td>Peer evaluation results</td>
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<td><strong>Preparation: In-Class Short Quizzes</strong></td>
<td>10%</td>
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<tr>
<td><strong>Individual EKG lab &amp; KC Labs</strong></td>
<td>10%</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td>100%</td>
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</table>
Sample Project Cases
Nevan Hanumara
Exemplary Projects

Thoracoscopic Screwdriver

Kidney Cooler

CardioPort

Sleep Sensing Shirt
Dr. Suresh Agarwal, BU Medical School
- Rib fractures cause painful, paradoxical chest motion, compromise reparation
- Only two modern treatment options:
  - Intubation & Sedation
  - Mechanical fixation (via thoracotomy)
- But fixation requires large frontal incision

“Develop a tool to thoracoscopically place screws and secure osteosynthetic plates via posterior access.”
  - VATS common procedure
  - Implants readily available
  - No existing screw placement device
Thoracoscopic Screwdriver – Solution

Functional Requirements

- inside of rib
- articulating tip
- 12 mm trocar
- anterior
- posterior
- 60°
- 120°

Licensed

2 Generations of Prototype

Most Critical Module

- adapted to fit surgical drill
- projecting flex shaft
- nitinol spring
- screw secured
- screw released
Kidney Cooler (2010) – Clinical Need

Open Partial Nephrectomy
- Renal cooling possible
- Kidney bathed in ice slush
- ~2.5 hr surgical working time once blood clamped

Laparoscopic Partial Nephrectomy (LPN)
- Gold standard treatment for renal cell carcinoma which affects 60,000/yr (US)
- LPN technical more challenging
- But only 30 minutes operating time before onset of ischemia

Dr. Nadeem Dhanani, Mt. Auburn
“Develop a minimally invasive cooling solution for LPNs.”
Kidney Cooler – Solution

- Bag deployed through trocar
- Positioned around kidney
- Ice slurry injected via tube
- Phase change removes heat

- Tested @ Intuitive Surgical May 2011
- Core cooling to 20°C achieved in 13 min

*Patent filed, Available for license*
CardioPort (2005) – Clinical Need

- Drs. Pedro J. del Nido & Nikolay V. Vasilyev, Boston Children’s Hospital
- Transcardiac access into the beating heart shows promise, but...
- Technically challenging to introduce multiple complex devices
- Blood loss is a risk, especially with wildly varying intra-cavity pressure
- Air entrainment must be avoided
- A small device is needed that:
  - Allows instrument introduction
  - Prevents embolisms and bleeding
  - Is compatible with ultrasound for image-guided procedures

"We need a universal cardioport.”
CardioPort (2005) – Solution

- Port sutured to heart
- 11 mm diameter body
- Interchangeable instrument sleeves
- Valve system to stem blood loss
- Fluid purging to remove air
- Ex vivo testing validated function
- 5 porcine trials in left & right atria & ventricles, septal defect closure
- Exchange of tools during the procedure
- Maintained seal in hi and low pressure
- No bleeding or structural damage
- Positive feedback on ergonomics

*Patent Filed, Gen 2 Device Designed, Ongoing animal studies, Seeking partner*
Sleep Sensing Shirt (2010) – Clinical Need

- Dr. Matt Bianchi, MGH Neurology
- 1 in 3 Americans report insomnia
- 10 million use prescription sleep aids
- Diagnosis based solely on patients’ perception & reporting
- Sleep labs are disruptive
- Over 20 connected sensors
- Unnatural setting
- Studies cost thousands of dollars

“Develop a clinically applicable, at home sleep monitoring system.”
Sleep Sensing Shirt – Solution

- Breakthrough: Most doctors use a single “sleep score” …
  … so what if we only sense respiration?
- Comfortable, form fitting, shirt
- Thin, vinyl & conductive ink capacitive sensor pads
- 5 day on-board data storage
- Unrestricted movement
- Data uploaded to website
- 30 s processing algorithm
- Provides “sleep score” equivalent

Patent filed, Startup funded – restdevices.com
IRB approved testing, Research sales
Consumer Product - mimobaby.com
Medical Device Companies Hiring Alums

- **STORZ**
  - Tyrel Waagen, BS ‘13

- **Smith & Nephew**
  - Alan K Xu, BS ’13
  - Katie Inman, BA ’13
  - Mireille Akilian, PhD ’08

- **HOLOGIC**
  - Farreha Safir, ’13
  - Michelle Lustrino, MS ’11

- **MIMO**
  - Pablo Bello, Thomas Lipoma, Carson Darling, BS ’11 (Founders)

- **DNA Medicine Institute**
  - Julia Zimmerman, MS ’11

- **ETHICON ENDOSURGERY, INC.**
  - a Johnson & Johnson company
  - Emily Houston, BS ’10
  - Richard Timm, MS ’06

- **GE Healthcare**
  - Sarah Cooper-Davis, ’09

- **Claros Diagnostics**
  - Matthew Dirckx, PhD ’10

- **3M Health Care**
  - Stephan Hawthorne, BS ’11

- **Medtronic**
  - John Gray, MS ’04

- **HeartWare**
  - Christina Simpson, MS/MBA ‘11

- **Intuitive Surgical**
  - Yash Narang, MS ’13

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Communications & Team Dynamics
Dave Custer
Notes on first customer meeting

- When you contact your customer, provide your agenda for the meeting and solicit the customer’s agenda items.
- Designate three roles for the meeting: facilitator, time keeper, & documenter/minutes taker
- Consider scripting the meeting along the lines of:
  - introductions
  - make a pitch for what you need. Let your customer know what your design process is and what you need to know to get started.
  - Listen
  - identify customer "harping points" & FRs
  - make a “show” of acknowledging these focus points
  - say "Yes, and..." Avoid saying "No, but...“
  - end the meeting by summarizing the FRs that the customer has identified, the range of success criteria from the minimum threshold of success to pie in the sky success
  - thank your customer for his/her/their time & attention
  - follow up with an e-mail that summarizes your understanding of the FRs and asks the customer to verify that indeed you have it correct. doing so:
    1. provides a base line to reduce mission creep
    2. helps both parties to the same page
    3. gives both parties a night to sleep on it
As a medium, presentations “look” the same; as genres, presentations differ dramatically.
Path to the $100K
Christina Chase

100K: http://mit100k.org/#x-content-band-2
Thor's website: http://www.thortourniquet.com/
Today’s Action Items

In Class
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- Path to the $100K
- FUNdaMENTALS Topic 3
- 2.75 X: https://lms.mitx.mit.edu/courses/MITx/2.75r/3T2014/about

After Class
- Fill team member pre-survey on Wiki: https://wikis.mit.edu/confluence/display/275/Home
- Get a design notebook today or on Tuesday (black $12, blue $14)
- Install Solid Works: https://web.mit.edu/mecheng/computing/Software/SW2014-15/instructions.html (Note new link as of 8 September)
  Or Inventor: http://www.autodesk.com/education/free-software/inventor-professional
- Begin reading course material and investigating the course: http://web.mit.edu/2.75/
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