Biodesign Program: Training approach and outcomes

NAE 2018 Annual Meeting
Paul Yock
The concept -- 2001

EDUCATION
- Design Thinking
- Entrepreneurship

TRANSLATION
- Seed Funding
- Mentoring, Facilitation

Other Verticals

MEDTECH
Innovation training philosophy...
Design thinking

empathize  define  ideate  prototype  test

user-centered
What if your “user” is the 8-headed monster called \textit{healthcare}?
To deal with this complexity...

“The Biodesign Process”
A well-characterized need is the DNA of a great invention!
Process & Training Architects...

Josh Makower
Todd Brinton
Lyn Denend
Uday Kumar
Jay Watkins
Stefanos Zenios
Biodesign fellow teams

Identify >200 needs
Need screening

Screen to the best few needs
Need statement

A way to solve a specific problem…

in a well-characterized population…

in order to achieve a measurable outcome
“A better way to detect potential rhythm disturbances in non-hospitalized patients with suspected arrhythmias to improve the patient experience and reduce the cost of diagnosis”
NOW it’s time to invent!

“Given enough time, sugar and caffeine, you will invent something!”
Brainstorming the Zio patch…

- Orientation may vary based on best skin contact.
- All enclosed in soft gel, no sharp edges felt underneath.
- "Inners"
Concept screening

Then filter down to the most promising ideas
Final phase: Implementation planning
Stanford Biodesign trainees

- **161** Innovation Fellows since 2001
- **1,700** Stanford students since 2001
- **111** Global Fellows and Faculty since 2005
- **38** Stanford Faculty Fellows since 2012
Learning resources...
Stanford-India Biodesign
Japan
Translational Outcomes

Kate Garrett (‘12)
Founder, CEO, Ciel Medical
VP Airway Technologies, Vyaire Medical
Ventilator Associated Pneumonia (VAP)

One of the most common ICU infections\textsuperscript{1}, leading to:

\begin{itemize}
  \item 10\% increased mortality\textsuperscript{2,4}
  \item 6 extra days in the ICU
  \item Broad spectrum antibiotics
  \item Hospitals held accountable for the $40k treatment cost
\end{itemize}

3.5M patients at risk for VAP annually in USA

\textsuperscript{1}NEJM 2014; 370:1198-208
\textsuperscript{2}Crit Care Med 2011; Vol. 39, No. 12
\textsuperscript{3}Rello et al., CHEST 2002; 122:2115–2121
\textsuperscript{4}Infect Control Hosp Epidemiol 2014;35(8):915-936
# Known Pathophysiology

The #1 cause of VAP is aspiration of secretions that are pooled above the endotracheal tube cuff.

Minimizing pooled secretions above the cuff has been shown in 13 randomized controlled studies to reduce the risk of VAP by 55% and the average ICU stay by 1.5 days.  

Catheter coils in mouth

Aspiration risk persists.
Need statement

An improved endotracheal tube to reduce the risk of aspiration in ventilated patients
Existing technologies are focused on one solution: specialized endotracheal tubes (ETT).

BUT, only a small percentage of patients require long-term ventilation.

Broad upfront utilization of specialized ETTs is expensive.
Need statement

An improved endotracheal tube to reduce the risk of aspiration in ventilated patients.

A way to reduce the risk of aspiration in long-term intubated patients that can be applied post-intubation.
Sherpa Suction System™
R&D / Manufacturing
- Animal studies
- 30+ cadavers
- Injection mold tooling

FDA
- V&V
- Biocompatibility
- Sterility
- Documentation

Clinical Studies / Early Customer Adoption
- Product evaluations
- Poster presentations
- Value analysis assessments
- Multi-center trials

Commercial Launch
- Acquisition by Vyaire Medical
- April 2017
SHERPA SUCTION SYSTEM
EA 10 515674
CM28010
The best measure of translational impact:

Patients Reached!

premiermhc.com; ahrq.gov; consultqd.clevelandclinic.org
MORE THAN 1.5 MILLION PATIENTS HELPED
SO FAR BY TECHNOLOGIES INVENTED DURING STANFORD BIODESIGN TRAINING
Our “product”
Alums who have started & led new Biodesign-like programs

Cornell
Akhilesh Sista

Cleveland Clinic
Shubhayu Basu

Duke
Nandan Lad

Oregon
Jonathan Steinberger

Minnesota
Marie Johnson

Northwestern
S Gnanashanmugam

UC San Diego
Garrett Smith
Alumni pool includes 30 current start-up CEO’s...
Challenges ahead…
A perfect storm for medtech innovation…

- new technology is driving healthcare expense!
- diminished venture funding
- weak pipeline of technologies for patient care
Value-Based Innovation

Can we develop a discipline of inventing biomedical technologies with a focus on maximizing value (health benefit:cost?)
Adjusting the process…

Value Proposition
Adjusting the process...

Value exploration!
<table>
<thead>
<tr>
<th>Icon</th>
<th>Practice-Based value signposts</th>
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<tbody>
<tr>
<td>🏥</td>
<td>Shorten length of hospital stay</td>
</tr>
<tr>
<td>🏥</td>
<td>Change to less expensive venue</td>
</tr>
<tr>
<td>👤</td>
<td>Lower number of staff</td>
</tr>
<tr>
<td>🕒</td>
<td>Reduce procedure time or resource use</td>
</tr>
<tr>
<td>🚜</td>
<td>Shift intervention to lower cost provider</td>
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The economic need

patient with palpitations

cardiologist

internist

electrophysiologist

Holter
Saving $620 per AF patient per year
Challenges, continued

Team dynamics…
including diversity issues
Team dynamics

The Biodesign “Shrink”

Doug Rait, PhD
Director, Team Learning & Design
Mix of engineers and physicians

- Different perceptions of risk (medical, technical)
- Different approaches to decision making
- Stress is compounded by flat team structure
Mix of academic and industry culture

• Learning a process… or inventing a product?
• Exploring openly… or delivering on milestones?
• Sharing discoveries… or protecting I.P.?
Gender-based issues

Anonymous survey of alumni fellows, 2017:

22% of fellows experienced (and 41% observed) problematic workplace issues – largely gender based—during the year.

Biodesign Diversity Task Force
Kate Garrett, Chair
Women in Executive or Senior Management Roles

- 17% (MEDTECH*)
- 27% (S&P 500**)

*MDDI survey, April 2018  **Catalysts census, 2016
Women Grad Students In Biodesign-Related Fields

- BME Masters*: 43%
- BME PhD*: 39%
- M.D.**: 51%

*ASEE American Society for Engineering Ed, 2017 ** AAMC News, 2017
The opportunity for Biodesign...

"The beauty of Stanford Biodesign is that it puts incredible career options at your fingertips."

"Seize this opportunity! It enables you to explore every aspect of health technology innovation."

"I’ve met so many incredible women in medtech whose careers would get a super-boost from the Innovation Fellowship. Represent! Apply!"

—Shreya Mehta, MS
2013-14 Stanford Biodesign Innovation Fellow
Co-Founder & CTO, Zenflow

identify

CATALYZE YOUR CAREER IN HEALTH TECHNOLOGY INNOVATION

BIODESIGN INNOVATION FELLOWSHIP

invent
2018-19 Innovation fellows
Questions… comments?