

Wireless labor monitoring for developing settings:

*From idea to prototype to testing
and beyond*

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Learning objectives

How to bring doctors and engineers (and others) together to transform an idea into something truly useful

- Prototype development
- Optimal use cases

I have no conflicts of interest to declare.

Outline

- The problem
- The idea
- The team
- Building on existing technology
- The development process
- Identifying optimal use cases
- Pilot testing
- Summary of lessons learned

The problem

- Every year, 343,000 maternal deaths, 3 million stillbirths, and 3.7 million newborn deaths occur globally, many of which could be prevented (e.g. post-partum hemorrhage, sepsis).
- While several incentive and community outreach programs are increasing linkage to care, millions of women still give birth with little to no skilled assistance.

The idea

- Develop a wireless biosensor to detect active labor and complications of labor
 - Planned for use in the community where women can not or are not accessing facilities for delivery
 - Use the biosensor data to identify problems (e.g. high temperature indicating sepsis)
 - Use GPS coordinates to link the women with the nearest support services
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- Initially...

The team

- Physicians (Center for Global Health at MGH)
 - Myself
 - David Bangsberg
- Engineers (MIT Media Lab, Ashametrics)
 - Rich Fletcher
 - Rich Redemske
 - Olufemi Omojola
- Process for meeting
 - a New Year's Eve party

Existing technology

- iCalm (*Fletcher, IEEE, 2010*)
 - Wireless detection of vital signs
 - electrodermal activity (galvanic skin response) to assess sympathetic nervous system activity
 - temperature (National Semiconductor LM60 sensor IC)
 - motion sensing (Signalquest SQ-SEN-200; analog motion with an integrator circuit)
 - Transmits via Bluetooth to a smart phone, then to a server via cellular networks
 - Used in studies of autistic children, recovering drug users

Existing technology

- LifeBand
 - Similar device and data transmission with the addition of heart rate (electrocardiogram; ECG) and 3-axis accelerometer
 - Piloting ongoing in rural Uganda

Adaptations needed for the developing world

- Battery life
 - Most potential users do not have electricity
 - Potential solutions through solar chargers, possibly power harvesting (heat and movement)
- Cost
 - Minimize technology needed
 - Smart phone versus feature phone (e.g. Java-enabled)
- Durability
 - Robust to sweat and dirt
 - Designed to minimize diversion
- Cultural acceptability

LaborBand prototype

- Uterine contraction monitoring
 - Piezoelectric sensor
 - Electromyography
- Maternal monitoring
 - Blood pressure (pulse transit time)
- Fetal monitoring
 - Fetal ECG

Now what?

- We had an idea, a team, and a prototype concept
- We didn't know how to develop a device that would avoid the pilot pitfall

Goal of commercialization

- Principle: If you can't commercialize it, you can't scale it.
- Learned that device development must include a business plan and product development early on
- MGH resources
 - Innovation Support Center
 - Research Ventures & Licensing
 - Center for Integration of Medicine and Innovative Technology (CIMIT)
- MIT resource: Sloan Business School

Goal of commercialization

- Dilemmas
 - Intellectual property
 - A challenge for academics with traditions of multi-institutional collaborations
 - Potential funders also want some control
 - Personal stakes not allowed by academic institutions
 - Device regulation
 - Complex, expensive process
 - Especially complex in the international setting

Identifying optimal use cases

- Talk with experts in the field
 - Added an MGH obstetrician (Blair Wylie) to the team
 - Learned that non-invasive detection of active labor may be impossible
 - Learned that the best use case may be with in facility monitoring

Identifying optimal use cases

- Talk with potential end users
 - Met with obstetricians in Mbarara, Uganda (Joseph Ngonzi, Godfrey Mugyenyi)
 - Conducted a focus group of pregnant women and their partners

Identifying optimal use cases

- Learned that in facility monitoring is indeed high yield
 - Nurse to patient ratios of 1:60 at night
 - Average of 30 deliveries per day
 - During two days on rounds, I learned of 14 fetal deaths and 1 maternal death
 - Primary causes
 - Delayed presentation with obstructed labor post-partum hemorrhage, sepsis
 - Previously unrecognized high risk pregnancies (e.g. placenta accretia from multiple prior C-sections)

Optimal use cases

- The problems (refined)
 - Inadequate human resources for monitoring
 - Data needed for proper triaging
- The stakes
 - Lives of the women and babies
 - The success of programs to promote in facility deliveries
- The solutions
 - Improved monitoring and triaging in facilities for more efficient care delivery
 - Improved monitoring and triaging in the field for more efficient referrals

Pilot testing of the technology

- Use of Sense4Baby (West Wireless Institute) + LifeBand, given costs of development and time required for new devices
- Sense4Baby measures uterine contractions and fetal heart rate by cardiotocography
- Similar data transmission through cellular networks
- Ultimately combine the most useful technologies in one band (the LaborBand)

Pilot testing of the technology

- MGH pilot for feasibility and acceptability
 - 5-10 pregnant women to verify no interference with standard of care monitoring
 - Up to 120 pregnant women to correlate readings
 - Up to 250 pregnant women to assess for prediction of outcomes
 - Acceptability questionnaires/interviews with pregnant women and clinical staff for device modification (e.g. design)

Pilot testing in target settings

- Although the goal is use in developing settings, local pilot testing will allow for technical and design “tweaking”
- Next steps
 - Field testing in Mbarara, Uganda, including hospital and community settings
 - Field testing in Nagpur, India (Pat Hibberd and Archana Patel’s group)
 - Work with product developer
 - Finalize a business plan

Lessons learned

- It takes a village to go from idea to prototype testing and ultimately to commercialization
- Making money is a good thing when it comes to helping people in developing settings
- Product development is a complex process and not intuitive to physicians (and likely others)

Platforms for innovation

- Platforms should speed efficient and effective development
 - Skunk Works
 - CIMIT
 - MGH Center for Global Health Maternal Newborn Child Technology Initiative
- Established processes should be an improvement on chance meetings at cocktail parties and experts working outside their expertise

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