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

• 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 acreta 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 cardiotococgraphy
• 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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