TRIO STUDIO: Wearable Devices Used for Detecting and Forecasting Health Events
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TRIO STUDIO: Wearable Devices Used for Detecting and Forecasting Health Events

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Attendees:
Siqi Zhang, Rush University Medical Center (RUMC); Emma Lynch, UChicago; Ellen Cohen, UChicago; Tom Best, UChicago; Kopal Mathur, UChicago; Micah Prochaska, MD, UChicago; Gerald Moose Stacy, ITM; Michael Msall, MD, UChicago; Pamela Gonzalez, UChicago; Rohit Allada, UChicago; Ashley Lopez, ITM; Amanda Kass, ITM; and Sherry Robison, ITM.

Summary:
Andrey Rzhetsky, Professor of Medicine, Department of Computational Biomedicine and Biomedical Data Science at the University of Chicago, introduced the Studio topic, Wearable Devices Used for Detecting and Forecasting Health Events. He has been invited to submit a grant to the American Heart Association and is looking for guidance from a TRIO Studio for enrolling human subjects in to his potential study.

Design Thinking Methodology was used to solve the problem faced by Andrey. Many suggestions based on experiences with different departments were made.

Top 3 Actions Proposed by the Studio Participants to Andrey Rzhetsky:

1. Collaborate Research With Other Established Labs - As wearable tech is becoming more available and popular, working alongside a group experienced in this department (e.g. Shirley Ryan, Activities Space Project- Kate Cagney) will provide useful insight as to smooth conduction of this research.

2. Better Answer for Participants asking "What's in it for me?" - Provide incentive for participation given the level of hands-on engagement required by subjects.

3. Flip Data from Quantitative to Quantitative & Qualitative - Use mixed methods to examine quality of life via interviews with participants.
TRIO Studio Problem Description:
Andrey Rzhetsky, Professor of Medicine, Department of Computational Biomedicine and Biomedical Data Science at the University of Chicago, explained the goal of his AHA grant submission which is to develop sensitive and precise diagnostic tool based on continuous stream of measurements from multiple wearable devices (cardiovascular and metabolic). He introduced his potential study, Wearable Devices Used for Detecting and Forecasting Health Events.

Andrey Rzhetsky gave background information on the continuous glucose monitors (CGM). They are manufactured by Abbott, Libre or DexCom G6. The standard is the ActiWatch or ResMed for sleep/wake measuring, but they are expensive at almost $1,000 a device. He explained he might use ActiWatch and then a Fitbit like device for step counting, heart rate, and sleep approximation.

Wearable electrocardiogram (ECG) devices include the Apple watch, the Kardia band or the Kardia mobile ECG. The single-lead ECG recordings provided by these devices allows to diagnose atrial fibrillation but not angina. Quanttus is a wearable device that measures blood pressure.

Andrey explained his goal of continuous recordings will be able to predict health findings both past or in the future.

He explained the potential problems of recruiting patients with various degrees of health, (from healthy to very sick in metabolic cardiovascular spaces), socioeconomic status from low-income to affluent, and distribution of participants sex, age, and ethnic background.

Wearable devices are defined as devices that provides a continuous stream of measurements and can be incorporated into wearable tech. This definition includes devices such as Apple Watches/ FitBits/ Kardia Bands (ECGs), Continuous glucose monitors (CGM), ResMed devices (sleep/wake measuring), and the Quanttus (blood pressure monitor). Dr. Rzhetsky hopes that through this research project, he and his team can develop more sensitive and precise wearable diagnostic devices.

A somewhat complicated design was discussed which included using a 2 x 2 x 2 design approach to addressing variables such as metabolic health, cardiovascular health, and socioeconomic status, Rzhetsky’s research team is looking to fulfill 8 categories or “bins” of participants: those scoring low on metabolic health (MH), low on cardiovascular health (CVH), and low in socioeconomic status (SES); low MH, low CVH, and high SES; high MH, low CH, and low SES; high MH, low CVH, and high SES; high MH, high CVH, and low SES; low MH, high CVH, and high SES; low MH, high CVH, and low SES; high MH, high CVH, and high SES (Figure 1).

He’d also like to perform some genetic testing which includes CVD and metabolic polygenic panel genotyping for research participants.
Given a limited number of available units, as well as a reliance on participants to send the equipment back after two weeks of wear for multiple occurrences, a major concern is how to ensure that participants cooperate with device return, which can be accomplished either via mail or in-person drop off. It may be impractical to ask participants to wear multiple devices at one time, even if it reduces the amount of times a participants must return a device.

He explained the goals of the potential study, if funded, is to learn to diagnose people automatically from single-device reading, attempt to diagnose non-CVD/metabolic conditions such as anxiety and depression, evaluate precision of diagnosis from more than one device, and use genotypes and Mendelian randomization, explore causality relationships between CVD and metabolic conditions.
Figure 2  Andrey Rzhetsky presenting
Main problem for the studio participants to solve:
How can we ensure a diverse participant pool (deep phenotypes) that includes subjects who fit into each of the 8 categories (MH, CVH, & SES), with deep medical phenotypic data, and to wear multiple wearable devices given a limited number of wearable devices?

Studio Methodology
Design Science approach was used as part of the TRIO studio to solve the problems.

Design Science Method
We used the Design Science approach with five steps:

1. Created a free form mind map of the problem and identification of issues – Mind Mapping technique
2. Actionable insights were identified
3. Generated ideas to address issues
4. Synthesized solutions from the smaller ideas – Creative integration of smaller ideas led by Design Thinking Expert facilitator was done using white boards.
5. Solutions were proposed and were rated by the team on implement-ability (0-4 scale)
Design Thinking Based Solutions:

Problem visualized with Insights
The group first discussed the problem and its context yielding the following context diagram:

Figure 3 Mind Map of Issues
Stakeholder Map

Figure 4 Stakeholder Map

Figure 5 Design Science Team
High level insights:
Following the context discussions, insights were generated as follows:

### Insights/ Initial Ideas

<table>
<thead>
<tr>
<th></th>
<th>Insights/ Ideas</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Focus on harder-to-recruit population first</td>
</tr>
<tr>
<td>02</td>
<td>Sequential matching of easier to recruit group</td>
</tr>
<tr>
<td>03</td>
<td>Multidimensional remuneration - Monetary, device, health insurance rebate, gym membership, etc</td>
</tr>
<tr>
<td>04</td>
<td>Collaborate with insurance companies</td>
</tr>
<tr>
<td>05</td>
<td>Collaborate with PIs already doing similar studies using activity monitors</td>
</tr>
<tr>
<td>06</td>
<td>Can we use existing devices like CPAP to retrieve data of interest</td>
</tr>
<tr>
<td>07</td>
<td>Partner with Lab like Shirley Ryan Ability Lab</td>
</tr>
<tr>
<td>08</td>
<td>Include device itself as compensation - no need to return device after data is collected</td>
</tr>
<tr>
<td>09</td>
<td>Can community organizations be used for data collection? Distributed data collection model</td>
</tr>
<tr>
<td>10</td>
<td>Can passive monitoring be an option?</td>
</tr>
<tr>
<td>11</td>
<td>Wearables for data collection like bionic socks</td>
</tr>
</tbody>
</table>

*Figure 6 Insights and Ideas Generated During Discussion*
Solutions Generated by Design Thinking Approach Team:
Five possible solutions were presented to help solve Rzhetsky’s presented problem. They are as follows:

1. **Collaborate Research With Other Established Labs** – Form partnerships with other research teams who have previously implemented wearable tech in their own studies to gain more insight into obstacles and solutions they experienced.

2. **Better Answer for Participants asking “What’s in it for me?”** - Clearly define patient incentives. Asking patients for more active participation [wearing devices, skin penetration (CGM), keeping devices charged and updated, delivering data, returning devices to the research team] requires a higher level of incentive compared to studies that do not require such a high degree of participant involvement.

3. **Flip Data from Quantative to Quantative & Qualitative** - Perhaps even utilize implantable devices to passively measure data from patients.

4. **Switch from Field Data Collection to In-Patient Data Collection** – If subjects are recruited from within the hospital, there will be no need for them to return the device thus saving money on lost/ stolen property.

5. **Partnerships with External Entities** - Establish partnership with other institutions (i.e. insurance companies, community organizations, wearable tech companies) to create incentive for participants and/ or reduce obstacles that would be encountered during data collection.
Barriers

01 Wearables are not being returned

02 Wearing Compliance - especially at night

03 Records older than 10 years are not being available (In-patient/Out-patient)

04 Remuneration needs to be there

05 Multiple participants sharing same devices ("grime" level, returning issues)

06 Not having a "clinic" can be an access problem

07 Multi-Device consistency needed for "data"

08 "What’s in it for me? Data Vs. Insights? (Sugar level, BP, HR, Device to sleep?)

09 Need to know if/ when subject is complying with wearing device

10 People will change behavior - How to account for that?

11 What motivates people?

Figure 7 Barriers Identified During Discussion
Solutions

01 Research collaboration with other established labs
- Shirley Ryan
- Clinics
- Activities Space Project - Kate Cagney

02 Better answer for participants’ question of “What’s in it for me?”
- Citizen Science (Health Coaching)
- Get a Device for participation
- Get Money or similar monetary incentives
- Patient Centered Outcomes - Qualitative information back to participants

03 Partnerships and collaborations will reduce barriers for the PI’s proposal
- Service Employees
- Community Organization
- Insurance Company
- Wearable Company
- Employer Health Plan

04 Flip data from “quantitative only” to “qualitative + quantitative”
- Quality of life
- Mixed Methods
- Exist Data + Interviews

05 Flip data collection from field to in-hospital participants
- 7 days of data from in-patients
- Clinic collaborations (Primary Care Group/Cardiology Study)
- Piggy back on existing studies
- Implantable Device

Figure 8 Solutions Prioritized for PI

<End of Document. Thank you.>
Appendix 1.
Slides used by Andrey Rzhetsky

Appendix 2.

- Focus on harder population first
  - Sequential maturing of the easier to recruit group.
  - Multi-dimensional renumeration
  - Collaboration with insurance companies
  - Collaboration with P.I.’s already conducting similar studies using activity monitor tech.
  - Using other existing devices to retrieve data (e.g., CPAP)
  - Partnership with Shirkey Ryan Lab
  - Include monitor device in compensation - no need for return
  - Use partnership to reduce barriers (e.g., CRC ability lab)
  - Distributive model for data collection
Stakeholders

- AHA
  - American Heart Association
- 4 institutes
- Participants 2100
  - Ethnic
  - Age
  - Sex
  - Smoking
- EHR
- CAPriCORN
- UChicago
- Study protocol
- Advisory board
- Hospital

Potential stakeholders:
- Insurers
- Companies that already run wearable device studies

Selection of participants:
- 1 unit
- 4 yrs grad
- If data is used in article, it should be
- Get device wear 2 wk
- Get resilience return old device
USER JOURNEY

Goal: Creating the data faster than giving the fuzzy features

GOT (watch) Blood pressure devices

1st

Follow

2nd

Come back

1/1

Get a new device

Removed patient from the remaining trial

Return the watch

No one claiming them?

Notes

Sticky note
TRIO STUDIO: Wearable Devices Used for Detecting and Forecasting Health Events

Diagram with mind map:
- Wearable devices
- Diagnose heart health
- Database needed
- Various devices (Wearables, KDio Band)
- Stream of measurements
- Precision, Sensitivity
- Recruitment
- N = ?
- Various degrees of heart health
- Cardiovascular, Metabolic

Notes:
- Mind Map
- MIND
- Map
- With deep phenotypic data
- With patience to wear wearable
- Multi-Institutional Cell ITM Members?
BARRIERS

- Wearables not being returned
- Wearing compliance
- 10 yr records not being available
- Remuneration needs to be there
- Reuse of devices worn by others
- Not having "a clinic" can be an access problem
- Multi-device consistency needed for "data"
- "What's in it for me?" Sugar and BP
- Data vs. Insight? Data to keep?
- Need to know "when device is not worn?"
- People will change behavior - How to account for that?
- What motivates people?
SOLUTIONS

1. Partnerships will help the proposal to reduce barriers
   - Service Employers
   - Community Orgs
   - Insurance Companies
   - Wearable Companies
   - Employer Health Plans
   - Schools
   - Research Collaboration with other established labs

2. Better answer for Participants’ “What’s in it for me?”
   - Citizen Science
   - Get a device
   - Get money
   - Health Coaching
   - QoL
   - Patient Control Outcomes
   - Field study to in-hospital sample
   - 7 days of data from in-patients
   - Clinic collaborations
   - Primary Care
   - Cardiology study
   - Paying back on existing studies
   - Implantable Devices

3. FLIP DATA
   - Collection from field to in-hospital
   - FLIP participants

4. FLIP data from Quantitative only to Qualitative
   - Quality of Life
   - Mixed Methods
   - Existing data + Interviews
Solutions

1. Research collaboration with other established labs

2. Better answer for participants: "What's in it for me?"

3. Partnerships with other organizations to reduce barriers

4. Flip data for Quantitative only to mixed Quality + Quantitative

5. Inpatient recruitment Clinical
Addendum 1 – Follow Up

Misc.: AHA grant proposal was not funded.

About the Institute for Translational Medicine (ITM)

The ITM is a partnership between the University of Chicago and Rush in collaboration with Advocate Health Care, the Illinois Institute of Technology (Illinois Tech), Loyola University Chicago, and NorthShore University HealthSystem that’s fueled by about $35 million in grants from the National Center for Advancing Translational Sciences at the National Institutes of Health through its Clinical and Translational Science Awards (CTSA) Program.

We’re part of a network of more than 55 CTSA Program-supported hubs across the country working to slash the time it takes to develop and share new treatments and health approaches. We work with you and for you to make participating in health research easy, so that together we improve health care for all.

Join the movement and learn more about how we help researchers, physicians, community members, industry, government organizations, and others. Visit us at chicagoitm.org and connect with us on Facebook, Twitter, Instagram, YouTube, and LinkedIn @ChicagoITM.

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