Patient-centered Medical Devices for Patients with Multimorbidity

Simeon T. Abiola, ALB
Translational Biomedical Science Ph.D. Candidate | AGRT Competition
University of Rochester School of Medicine and Dentistry
February 13, 2019
Implement innovation strategies to facilitate partnerships that create new device development.

2. Expedited pathways for development, assessment, and approval of important devices.

3. Encourages early conversations with developers to make sure their ideas are translated into technologies that both help patients and are proven safe and effective.
FDA receives a vast amount of information from a variety of sources, including product submissions, adverse event reports, de-identified patient data from health care providers, and results from surveys and basic scientific research. Successful integration and analysis of data from these disparate sources would provide knowledge and insight not possible from any one source alone.
Ensuring the FDA’s Readiness – Section 4

Number of 510Ks Cleared and Time Until Decision by Year
100 million Americans (and rising) have multiple chronic conditions.

Multiple chronic conditions (or multimorbidity) is:
- The presence of two or more chronic condition,
- Lasting 12 months or longer,
- Which place limitations on self-care,
- and require ongoing medical management.

“Although patients with multiple health issues use eHealth technology to support self-care for specific conditions, they also desire tools that transcend disease boundaries.”
Prior to our research...

Which medical devices are appropriate for monitoring which chronic conditions?
Filling the Gap: 510Ks & Clinical Practice Guidelines

Premarket Notifications (510Ks)
• Required for every medical device prior to sale in the United States
• Described within is the intended use, or uses, for the medical device

Clinical Practice Guidelines (CPGs)
• CPGs are ubiquitous to clinical practice
• CPGs provide evidence-based statements to assist practitioners in healthcare decision making
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

**Optical Character Recognition**

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

**MetaMapLite**

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm).

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
Filling the Gap: Applying Natural Language Processing

Medical Text Indexer (MTI)

<table>
<thead>
<tr>
<th>K182127</th>
<th>K180240</th>
<th>K170605</th>
<th>MTI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor</td>
<td>Monitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>Diastolic Blood Pressure</td>
<td>Blood Pressure</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>Heart Rate</td>
<td>Pulse Rate</td>
<td>Heart Rate</td>
</tr>
<tr>
<td>Appearance</td>
<td></td>
<td></td>
<td>Body Image</td>
</tr>
</tbody>
</table>

MetaMapLite *

*MetaMapLite was run a second time before organizing the output into a table.
Blood pressure (BP): Advise adults who would benefit from BP lowering to...

**Medical Text Indexer (MTI)**

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>ICD-10 Code</th>
<th>Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disease</td>
<td>I51.9</td>
<td>Blood Pressure</td>
</tr>
<tr>
<td>Disease (CVD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>E78.0</td>
<td>Blood Pressure</td>
</tr>
</tbody>
</table>

**Assigning ICD-10 Codes**

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>ICD-10 Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disease</td>
<td>I51.9</td>
</tr>
<tr>
<td>Disease (CVD)</td>
<td></td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>E78.0</td>
</tr>
</tbody>
</table>

---

**2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.**

**National Guideline Clearinghouse**

**Recommendations**

**Recommendations**

**Major Recommendations**

Note from the National Guideline Clearinghouse (NGC): National Heart, Lung and Blood Institute (NHLBI)

Evidence Statements are included for each recommendation. See detail in the original guideline document under each critical question review.

Each recommendation has been mapped from the NHLBI grading format to the American College of Cardiology/American Heart Association (Class of Recommendation/Level of Evidence/ACC/AHA CLASS/LOE).

Blood pressure (BP): Advise adults who would benefit from BP lowering to:


   *Data available from clinical trials or registries about the usefulness/effectiveness in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

   For comparative-effectiveness recommendations (Class I and IIa, Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

**Clinical Algorithm(s)**

None provided.

**Scope**

**Disease/Condition(s)**

- Cardiovascular disease (CVD)
- Hypercholesterolemia
- Hypertension

---

**MetaMapLite**
### Filling the Gap: Transitive Property on Inequality

Clinical Practice Guidelines | Premarket Notifications (510Ks) | A proprietary dataset*

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>I51.9</td>
<td>DXN</td>
</tr>
<tr>
<td>E78.0</td>
<td>DXN</td>
</tr>
<tr>
<td>I10*</td>
<td>DXN</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td>DXN</td>
</tr>
</tbody>
</table>

\[
\text{A} = \text{B} \quad \text{B} = \text{C} \quad \text{A} = \text{C}
\]

*Preliminary Results
Deriving Insights: Once the Gap was Filled

• **Medical Expenditure Panel Survey (MEPS)**
  - Collects nationally representative data on demographic characteristics, health conditions (**ICD-10 codes**), health status, use of medical care services, charges and payments, access to care
  - Linking our dataset with MEPS will help elucidate the diagnostic capabilities a device should include to monitor patterns of multimorbidity.

• **Nationwide Emergency Department Sample (NEDS)**
  - Is the largest all-payer emergency department (ED) database in the United States containing diagnosis and procedure codes reported using the **ICD-10-CM/PCS coding system**.
  - Linking our dataset with NEDS will provide insights into the diagnostic capabilities a device should include to augment existing telemedicine services.
Applying Insights: Once the Gap was Filled

• Determining Equivalence Using Machine Learning
  • Multi-label K-nearest neighbor
  • “In multi-label learning, the training set is composed of instances each associated with a set of labels, and the task is to predict the label sets of unseen instances through analyzing training instances with known label sets.”
In Summary

- **We developed a proprietary dataset**, using 50,000+ premarket submission, 1,409 clinical practice guidelines, natural language processing, and the Transitive Property of Inequality.
- **We showed how to integrated and analyze our dataset with two nationally representative datasets** to give medical device developers ideas for technologies with the potential to *ameliorate* patient’s burden of multimorbidity and reduce Emergency Department Utilization.
- We showed how this research may be used to *expedited the pathway for the development* and clearance of important devices.
- Wait there’s more...
Please join me on March 20th 12 PM in HWH!

School of Nursing Clinical & Research Grand Rounds

Simeon Abiola, ALB a Translational Biomedical Science PhD Candidate working with Dr. Kimberly Arcoleo, PhD, MPH, will present on "Patient-Centered Medical Devices for Patients with Multimorbidity."

A lunch of pizza and vegetable tray will be provided starting at 12 p.m., followed by the presentation from 12:10-12:40, leaving time for questions and discussion.

The School of Nursing Clinical & Research Grand Rounds seeks to engage faculty, staff, students, and other members of the healthcare community by presenting topics related to the research process as well as current research topics at the School of Nursing.

📅 Wednesday, March 20 at 12:00pm to 1:00pm

📍 Helen Wood Hall, SON Auditorium 1w304
255 Crittenden Boulevard, Rochester NY 14642
thank you!