Smartphone Applications
Valuable New Source of Data and Innovation in Healthcare

Society for Technology in Anesthesia Annual Conference
January 17, 2020

Introduction
Smartphone penetration rate as share of the population in the United States from 2010 to 2021

Global Mobile Consumer Trends, 2nd Ed. Deloitte
Introduction

- Hardware
  - Camera, Screen, Microphone, Speaker, Accelerometer, GPS, Internet connectivity
  - External attachments
  - Progressive miniaturization allows each iteration to retain function at smaller size, or increase functions at same or larger size.

- Software
  - Adds new capabilities through novel utilization of available hardware

Possibilities

- Innovation
- Rapid iteration
- New sources of data
  - Distributed vs Centralized
  - “Real world” vs Controlled Environment

Innovation...
Also innovation...

Innovation

We need to allow for new ideas and rapid iteration...

BUT

...we can't compromise efficacy and safety!

Data Sources

- Centralized
  - New data is gathered during clinical encounters
  - Decision loop can only close during clinical encounters
- Distributed
  - Smartphone apps can allow data gathering outside of traditional encounters
  - Decision loop can close between clinical encounters
  - Miniaturization will allow more and varied sensors to be embedded into patients' lives
  - Internet of Things (IoT)
Possibilities

- Patient Generated Health Data (PGHD)
  - Health-related data that is created, recorded, or gathered by patients, their families, or other caregivers to address a health concern
  - Examples:
    - Blood glucose, Blood pressure, Diet, Activity
  - Benefits:
    - Improve patient engagement
    - Improve care coordination
    - Reduce cost of care

Pitfalls

- Oversight
- Accuracy
- Volume
- Security

Pitfalls - Oversight

- Food & Drug Administration (circa 2015)
  - What is a medical device?
    - “…objects into which it is intended to diagnose, cure, mitigate, treat or prevent disease…”
  - Mobile Medic
    - “…software application…be used as an accessory…”
  - What if the software functioning as a mobile device is
Pitfalls - Oversight

- Food & Drug Administration (today)
  - Regulation is catching up with innovation
- Software as a Medical Device (SaMD)
  - "...software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device"
- Intention plus Function define a Medical Device
  - Hardware vs Software is no longer part of the equation

Pitfalls - Accuracy

Without oversight, there is no gatekeeper to ensure accuracy of generated data.

Comparison of smartphone application-based vital sign monitors without external hardware versus those used in clinical practice: a prospective trial

John C. Alexander1,2, Abu Mirza3, Jask joshi1,2

Pitfalls - Volume

- More data ≠ Better information
Pitfalls - Security

These apps may have told Facebook about the last time you had sex.

Facebook users' data has been exposed. Hackers didn't steal just email addresses. They stole information from tens of millions of users.

PHI of thousands of mobile health app users at risk in mobile app security breach.

Next Steps

- Accuracy
  - Collaborate with developers for clinical research
  - Participate in FDA oversight process
- Security
  - Prioritize data security, especially when PHI is involved
- Integration
  - How do we present actionable information without overwhelming with data?
  - EMR dashboards, Clinical Decision Support tools, etc.

Where’s the value?

- Value = Quality/Cost
- Integrating these sources of data will cost time and money. Why should we do it?
How can data provide value?

- Data provides value when it either improves outcomes (quality) or reduces costs.
- How do we do this (in a value-based world)?
  - Predict poor outcomes prior to clinical presentation
  - Foster communication and interventions between clinical encounters
  - Prevent high-cost episodes of care
    - Keep patients out of the hospital as much as possible
Real World Value

Wearables prove reliable in determining mortality risk in adults, study shows

Data from the accelerometers allowed researchers to correctly rank the mortality risk using 30-40 percent more accuracy than when using data about smoking status or a patient’s stroke or cancer history.

The Predictive Performance of Objective Measures of Physical Activity Derived From Accelerometry Data for 5-Year All-Cause Mortality in Older Adults: National Health and Nutritional Examination Survey 2003–2006

Very “valuable” data

Most recent venture capital investment

Total venture capital investment

Conclusion

- Sources of PGHD will be funded based on their perceived ability to improve quality at a lower overall cost.
- Quality improvements should be demonstrated in peer-reviewed clinical research.
- Safety and efficacy must be confirmed by FDA oversight.
- PGHD sources meeting these criteria must then be securely integrated into a user-friendly clinical decision support system (CDSS) as part of a larger Electronic Health Record (EHR) or Anesthesia Information Management (AIMS) ecosystem.
References


