

Smartphone Applications

Valuable New Source of Data and Innovation in Healthcare

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Introduction

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

Year	Smartphone penetration rate (%)
2010	29.2%
2011	39.8%
2012	38.8%
2013	45.7%
2014	53.6%
2015	59.4%
2016	63.9%
2017	67.3%
2018**	69.6%
2019**	71.4%
2020**	72.2%
2021**	72.2%

Details: United States: eMarketer; 2010 to 2018: Individuals of any age who own at least one smartphone and use the smartphone(s) at least once per month.

© Statista 2019

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Introduction

Category	Any mobile phone	Developed	Developing
Any mobile phone	91%	91%	90%
Smartphone	80%	87%	82%

Country	Any mobile phone (%)	Smartphone (%)
Canada	83%	83%
USA	89%	89%
Belgium	92%	92%
Finland	96%	96%
France	92%	92%
Germany	92%	92%
Ireland	94%	94%
Italy	93%	93%
Luxembourg	95%	95%
Norway	95%	95%
Poland	94%	94%
Sweden	94%	93%
United Kingdom	94%	93%
Australia	93%	72%
Japan	92%	92%
South Korea	92%	92%
Argentina	87%	87%
Brazil	87%	87%
Mexico	93%	93%
Russia	93%	93%
China	87%	86%
India	86%	86%

Global Mobile Consumer Trends, 2nd Ed. Deloitte

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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

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Possibilities

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

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Innovation...



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Also innovation...



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Innovation

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

BUT

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

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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)

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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

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Pitfalls

- Oversight
- Accuracy
- Volume
- Security

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Pitfalls - Oversight

- Food & Drug Administration (circa 2015)
- What is a medical device?
 - "...objects intended to prevent disease, treat or mitigate symptoms..."
- Mobile Medical App
 - "...software application intended to be used as a medical device..."
- What if the software application is functioning as a medical device?



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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

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Pitfalls - Accuracy

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

J Clin Monit Comput (2017) 31:825–831
DOI 10.1007/s10877-016-9889-6



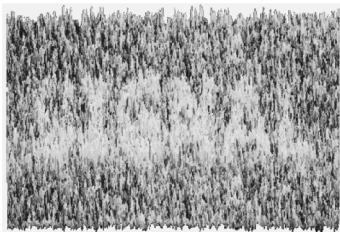
Comparison of smartphone application-based vital sign monitors without external hardware versus those used in clinical practice: a prospective trial

John C. Alexander¹ · Abu Minhajuddin² · Girish P. Joshi³

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Pitfalls - Volume

- More data ≠ Better information



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Pitfalls - Security

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

A new report found that period tracking apps Maya and MIA Fem shared intimate information with Facebook.

Hooked on Facebook Users' Data Has Been Exposed

Hackers claim to have harvested user data, including whereabouts of millions of users.

PHI of Thousands of Mobile Health App Users at Risk in Mobile App Security Breach

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Next Steps

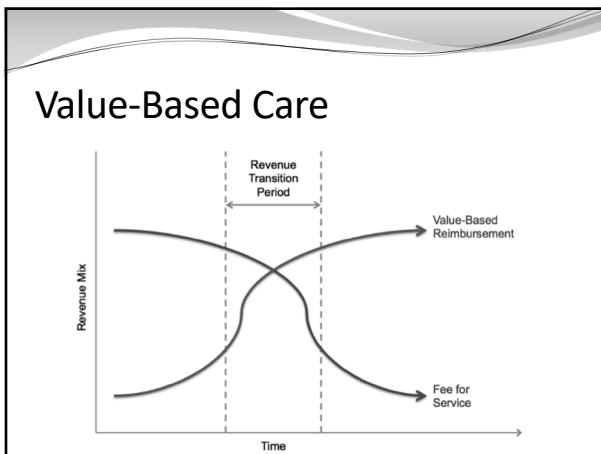
- Accuracy
 - Collaborate with developers for clinical research
 - Participate in FDA oversight process
- Security
 - Prioritize data security, especially when PHI is involved
- Integration
 - How do we present actionable information without overwhelming with data?
 - EMR dashboards, Clinical Decision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

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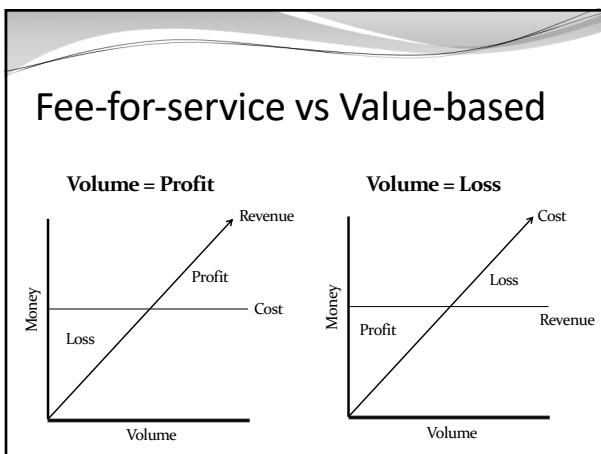
Where's the value?

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

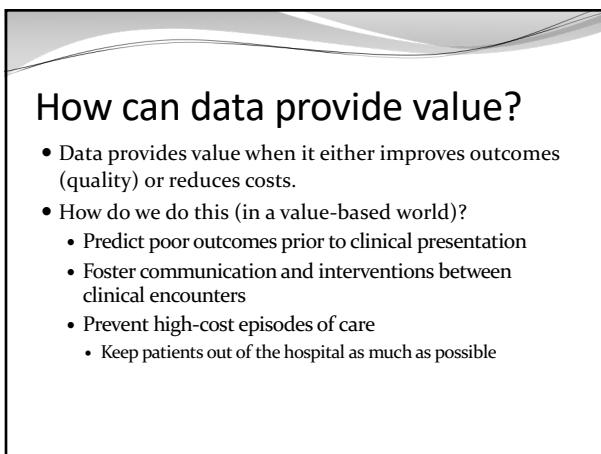
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Real World Value

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

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Very “valuable” data

Babylon: Aug'19 // \$550M, Feb'20 // \$635M (Total venture capital investment). Described as a digital health app that enables users to talk to a doctor or GP and get medical advice via video consultations, phone calls, or text messages.

Healthy.io: Sep'19 // \$60M, Jul'20 // \$78M (Most recent venture capital investment). Aligned with Amgen, Aransas Holdings Singapore, Alpha, Amgen Ventures, Google Startup Growth Fund, JOY Capital, NBS Innovation Accelerator, Samsung NEXT. Described as a mobile health company aiming to turn smartphone cameras into medical devices.

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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.

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References

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