

HARNESSING REAL WORLD DATA FROM WEARABLES AND SELF-MONITORING DEVICES: FEASIBILITY, CONFOUNDERS AND ETHICAL CONSIDERATIONS

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Abstract — The increasing usage of smart phones has compelled mobile technology to become a universal part of everyday life. From wearable gadgets to sophisticated implantable medical devices, the advent of mobile technology has completely transformed the healthcare delivery scenario. Self-report measures enabled by mobile technology are increasingly becoming a more time and cost efficient method of assessing real world health outcomes. But, amidst all the optimism, there are concerns also on adopting this technology as regulations and ethical considerations on privacy legislations of end users are unclear. In general, the healthcare industry functions on some stringent regulations and compliances to ensure the safety and protection of patient information. A couple of the most common regulations are Health Insurance Portability Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH). To harness the true potential of mobile technology to empower stakeholders and provide them a common platform which seamlessly integrates healthcare delivery and research, it is imperative that challenges and drawbacks in the sphere are identified and addressed. In this age of information and technology, no stones should be left unturned to ensure that the human race has access to the best healthcare services without an intrusion into his/her confidentiality. This article is an overview of the role of tracking and self-monitoring devices in data collection for real world evidence/observational studies in context to feasibility, confounders and ethical considerations.

INTRODUCTION

mHealth is an abbreviation for mobile health (a component of eHealth), a term for the practice of medicine and public health supported by mobile devices [1]. It is the generation, aggregation and dissemination of health information via mobile and wireless devices [2].

The rapid proliferation of mobile platforms and incessantly increasing usage of smart phones has compelled mobile technology to become a ubiquitous part of everyday life. The practical utility, greater flexibility and opportunity for improving human health via mobile devices offers myriad opportunities for diverse industry verticals, especially the healthcare industry. Wireless medical sensors or mobile biosensors are rampantly being utilized by physicians and other medical personnel to accumulate real-time information holding invaluable clues to manage efficiently some of the most devastating human diseases

that are chronic in nature, more so non communicable diseases (NCD). From wearable gadgets to sophisticated implantable medical devices, the information extracted with mobile technology has the potential to revolutionize the manner in which clinical research is conducted and care is delivered [3]. Further, by providing patients with sensors, wearable gadgets and apps, data is captured in an unobtrusive way. This data is real time, objective and e-sourced. The information assimilated via mHealth allows physicians or investigators to work with more complete data sets and they can identify digital biomarkers that set the path for more intricate research. But, the greatest impact in instrumenting and accumulating patient data for clinical studies is the ability to rethink end points resulting in more effective outcomes, particularly for R&D. Hence, it is critical to make early mHealth projects a success to prove the value of data by applying data science techniques to derive actionable insights.

Designed studies often encounter obstacles in generating and collecting multiple data points. The likelihood arises from the desire of capturing direct evidence from patients [4]. Therefore, the utility of self-tracking devices comes into the picture here to generate meaningful insights on real-time basis. Though the research literature in this area is very limited, lessons can be learnt from other areas, which offer battling techniques for data breaches in mHealth [5]. But, there is the frequent drawback of mobile technology developers being unclear on the regulations and ethical considerations on privacy legislations of end users. For example, biosensors and wearable gadgets like fitness monitors, cry translators, diabetes manager, blood pressure monitors, and pain assessors with smart phones, to name a few, are intruding our lives and can raise many ethical issues in this digital era [6–8]. All these wireless access technologies are exposing our body to the outside world easily and like never before. There is no clear certification or clarity of precise functionality of these applications, especially concerning areas like protection of privacy and confidentiality, data security, lack of informed consent/assent of a minor etc. [9]. Many application managers take decisions based on patient feedback which may not be authoritative, reliable and can ignore mental limitations, leading to adverse consequences.

In most jurisdictions worldwide, except the USA, there is no privacy legislation to define the collection, use and disclosure of data, including healthcare data collected through consumer facing apps [10]. The United States of Food and Drug Administration (US FDA) released its long-awaited final guidance on mobile medical apps in September 2013 and reissued it in February 2015. It positions the agency's present ideas on the fast-evolving mobile technology space. The US FDA has made it clear that this guidance applies only to a subset of mobile apps that can transform a mobile platform into a regulatory medical device [11]. On this ground, the US FDA has cleared around 23 notable digital health apps devices in 2014 [12].

The US Department of Veterans Affairs has embarked on a new clinical trial of post-traumatic stress disorder by using PTSD apps. The study is designed to “assess the feasibility of recruiting participants and get a preliminary read on the efficacy of the technology with or without clinicians” [13].

In general, the healthcare industry functions on a few regulations and compliances to ensure the safety and protection of patient information. Regulations for patient privacy and safety with mHealth apps are:

- The Health Insurance Portability Accountability Act (HIPPA);
- Health Information Technology for Economic and Clinical Health (HITECH)

The first act was made a law in 1996, whereas the second one came into being in 2009. Importantly,

HITECH regulations do not replace HIPAA regulations. Rather, “it adds greater fines and penalties for noncompliance” [14].

The mobile healthcare space is a high growth area. It is estimated that around 500 million smartphone users worldwide are expected to use a healthcare app by 2015 [15] and half of more than 3.4 billion smartphone and tablet users likely will have downloaded mobile health applications by 2018 [16]. According to Healthcare Information and Management Systems Society (HIMSS), around 100,000 health, fitness and medical related apps are available in more than 60 app stores as per the latest estimates. It is expected that developed countries are likely to spend nearly 15 percent of their GDPs on healthcare within the next two decades [17]. The signs are indicative of groundbreaking changes in the medical sciences arena.

HIMSS defines four sectors in healthcare that deal with mHealth [17]. But, regulatory guidance is yet to be shaped on the following:

- Consumer-oriented medical apps
- Apps for medical professionals
- Apps for patient engagement
- Clinical care apps

DISCUSSION

Tracking and self-monitoring devices usage is on the rise and it is unquestionably transforming the healthcare industry

The preceding years have demonstrated a gradual shift from orthodox modes and traditional instruments to self-monitoring devices or mobile apps to identify and gather patient data. But, the understanding is still limited on the diverse array of healthcare apps available to consumers, their roles, and the barriers to enhance their recommendation and support from providers, as well as the essential requirements for mobile apps for a passage into the mainstream of healthcare.

New patient technologies help caregivers work more efficiently with real-time information on patients and updates on labs, orders, and other notifications that are crucial to their workflow. Tracking technologies optimize the “flow” of patients in the emergency department (ED), the inpatient setting and increase the number of acute care transfers entering a facility [18].

Self-report measures may be a more time and cost efficient method of assessing psychosis than clinical interviews, as they do not require the presence of a trained assessor. Thus, self-report measures may be the more attractive option for clinical assessment [19].

Self-monitoring devices include those that assist patients to manage diabetes and prevent cardiovascular complications (CVCs). Although recent surveys

indicate that patients are willing to manage their own care, the clarity is missing on the knowledge level of these patients on self-monitoring techniques, their accessibility, and feasibility of their implementation into daily life.

Remote patient monitoring with cell phones, smart phones, and other wireless technologies (internet-based applications) are becoming accessible, especially to self-manage diabetes and adhere to exercise and diet regimens. These data collection tools can be used in a home setting or while traveling, at a minimal cost to the patient and the provider. Also, simple reminder schedules for self-monitoring can be established using such tools, and healthcare providers can oversee the progress via patient monitoring databases.

The impact of usability on self-monitoring device adherence is especially important in certain populations, such as younger patients with T1DM or T2DM, who may need additional encouragement and support to use their devices and regulate their metabolic functions [20].

Aside from recreational uses, global positioning system (GPS) devices are extremely beneficial to a number of social groups. A couple of articles recognized the benefits of GPS in tracking wandering dementia patients - "Technology Applied to Address Difficulties of Alzheimer Patients and Their Partners" [21] and "Location System for Dementia Wandering" [22].

The first article discussed convergence as the devices used in the prototype were made from a combination of GPS and GSM (global system for mobile communications) technologies. The second article "Location System for Dementia Wandering" discussed the combination of GPS and a mobile phone to discover the practical applications of tracking dementia patients. This program is known as "Guide Me" [23]. The devices also maintained the privacy of dementia patients as they did not want to be contacted openly by their caregivers and divulge information that was uncomfortable for them to share openly.

Intel Corporation launched a personal health system known as the "The Intel-GE Health Care Management Suite" post an approval from the Food and Drug Administration [24]. It combines a device used by patients at home with an online interface that permits healthcare professionals to remotely monitor and manage the medical conditions of patients. It generates continuous information about patients' vital signs and offers educational information, patient reminders, surveys, and video-conferencing capability [25].

Self-monitoring devices are an important component of wellness and engagement. They generate volumes of data that venture beyond the commercial realms of improving profits and reducing overheads, and are used at advanced levels to predict epidemics, cure diseases, improve quality of life and tackle avoidable deaths [26]. The challenge lies in accumulating sensible data out of the snowballing data sets that are

rampantly on the rise and utilizing them accurately. Too much data can be sometimes overwhelming.

The technology sphere is also witnessing remarkable refinements in wearable devices. "While personal devices today are largely if not completely external, the next generation may be ones that are implanted under the skin. Such devices could include artificial retinas, glucose monitors, organ monitors, cancer detectors, and general health monitors" [27]. In this case, technology needs to play a crucial role in enabling and educating the patients to understand, use and accept medical devices. Technology also enable self-monitoring and self-maintenance, allowing patients to lead a quality life without external dependence all the time. There are areas in which patients may be ignorant and educating them in these areas helps counter symptoms earlier than anticipated. There are instances where technology is going beyond traditional paths in patient education. It proved to be an effective tool for them to understand the symptoms, aura and take action earlier.

Drawbacks in data tracking and self-monitoring devices

Self-monitoring devices like SMBG (self-monitoring blood glucose) have consistently been effective to assess glycemic control in resource-rich settings for patients with high risk to develop diabetes-related complications. But, questions are still raised on their performance within resource-constrained settings.

Research necessitates evaluation of Interventions and outcome measures with respect to feasibility, adherence, and satisfaction of diabetes self-management devices and many trials use qualitative surveys or depend solely on the frequency of device uploads to the server to evaluate these. Calculating percentages in self-monitoring devices, evaluating patient or provider compliance with statistically rigorous methods can be difficult. In many cases, patients and providers are mostly contented with self-monitoring technologies, and self-management interventions, possibly due to better inspiration after learning how to use the technologies, and regular feedback [28].

Researchers argue that blood results from glucose meters are not as accurate as those from laboratory methods, although they are far more accurate than the earlier approach of visual color matching. However, there are confounding variables [29].

Operator-related errors are a more significant source of error than instrument-related errors [30]. For example, patient failure to calibrate the glucose meter regularly is a common cause of error. Improper storage of test strips, which exposes them to humidity or excessive temperature, can falsely elevate results. Glucose meters are also less reliable in the lower ranges of glycaemia and may overestimate true glucose values in the high glycemic range [31].

Similarly, a number of problems and limitations were recognized in studies related to patient's data tracking. A feasibility study inferred that the positioning of GPS and tall buildings had an effect on the experiments. Not only that, this experiment was also affected by the problems that arose due to environmental conditions like large snowflakes. There are limitations when using GPS to track dementia wanderers, although some solutions are suggested to overcome these [23].

In a study to determine the feasibility of obtaining written informed consent for participation in the Registry of the Canadian Stroke Network, patients neither gave nor refused to give consent because they were cognitively impaired, and a surrogate decision maker was not available. It was argued that in a publicly funded healthcare system, patients have a social obligation to permit their de-identified healthcare data to be used without their consent so that the healthcare system can be monitored and improved for overall benefit. But, it was also suggested that the decision to grant waivers of informed consent for clinical registries must be made carefully and should be based on the judgment of an independent research ethics board [32]. Ethical guidelines dealing with good moral duties over bad obligations were originally designed to protect individual human research subjects [33]. Developing country context has pushed the extrapolation of these principles to the community level, not only for research but at all levels of life. These include any actions for modifying disease progression, its prevention, curbing the morbidity and psychosocial wellbeing of an individual in a society.

Privacy is always a concern when using and tracking data via self-monitoring devices. Researchers are also attempting to distinguish the concepts of "privacy" and "security". "Privacy" is the right of an individual to make preferred choices in the collection, use and disclosure of their personal data. "Security" is the safeguard to protect the confidentiality, integrity and availability of data. Attempts are on to develop an appropriate legal scheme to share information amongst healthcare professionals across healthcare organizations globally. Advancement of internet technology in the health sector is showing a declining trend of face-to-face doctor-patient interaction on health related issues. Discussions on social media, online free advices and suggestions on any ailment with the aid of latest gadgets have virtually created a lot of confusion in patient management. As the patient diagnosis, treatment modalities and the entire patient related information are exchanged online, with no clear assurance of safeguarding the privacy and confidentiality, discussion on these ethical issues has become an important issue these days [34–36]. There is a belief that such privacy legislations are found mainly in developed countries [37]. Developed countries are using different steps to address these issues; like mandatory use of privacy settings which can safeguard patient

information online [38]. But such checks have their own disadvantages as there is no assurance that there would not be any breach of privacy or confidentiality with these checks. Digital monitoring and tracking of patient activities using advanced gadgets can breach the trust of professional relationship which outrages the autonomy [39]. In a recent study, researchers at the London School of Economics argued that developing countries are not adequately equipped to prevent patient privacy [40]. Hence, a review was invited on the national law on privacy of health related information. In the survey report of 2006 [41], it is concluded that in most countries there is some form of privacy protection law which governs and guides the collection and dissemination of personal information, but it also states that only a few countries have specific legislation addressing medical privacy.

From the discussions, a few questions arise:

- Are we doing more harm than good?
- Is non-maleficence overriding beneficence?
- Are the individual's privacy and choice protected?
- Is the risk-benefit assessment adequate and appropriate?
- Is the quality of life compromised?
- Is everyone equally benefitted?
- Or a basic question – Is technology required for the concerned situation?

It is important to address these questions before interventions and technology affect our lives in a way that they compromise our healthy tomorrow.

CONCLUSION

Overall the scope for mHealth to revolutionize the way healthcare is delivered is right now at a tipping point. The platform for delivery being almost ubiquitous, data penetration to the remotest corners of the globe, high acceptance of trackers and wearables leading to generation of data and the ability to not just manage, but prevent and manage diseases outside of a hospital setting holds high promise in an industry that is already expensive. However, challenges do exist in terms of reliability of service providers, patient privacy, data security and the accuracy of collected data to be able to make informed inferences and act on them. On the bright side, there are clear regulations shaping up, intra-operability standards are emerging and tools that help mine and understand the large amounts of data are being used more. There is a promise that in the near future there will be a time when personalized healthcare and prevention become a possibility on a mHealth platform combined with other technology innovations like drones. The motto goes "Healthcare is expensive; health is affordable" – it as to be seen how mHealth will help prevent diseases as well as reduce cost of disease management with remote tracking and management in the evolving future.

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CONFLICT OF INTEREST

The authors declare that there are no conflicts of interests regarding the publication of this paper.

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