Review Paper

mHealth for Health Care in India – Defining the agenda of Bioethics – A meta-analysis

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ABSTRACT

Delivering health care through remote monitoring wearables' and personal devices such as mobile phones are collectively termed as "mHealth". mHealth has emerged as ubiquitous, omnipresent global phenomena. Adoption of ethical priority and challenges on implementation of them are often noted but not given adequate care. Meta-analysis of research data published from 2009 to 2018 were analyzed and the ethical concerns raised were grouped into 5 grids. 1. Privacy, security and the data ownership, 2. Process of obtaining informed consent, 3. Efficiency, prevention and maleficence 4. Empowerment, beneficence 5. Access to mHealth technology and its social justice were the major 5 concerns reported in the published literatures. Based on these reported concerns and on evaluation of these problems, for effective designing and implementation of ethical principles ten recommendations, concerns and concepts are designed. The proposed recommended steps for adopting implementations and to be used in developing mHealth apps are prioritized and tabulated along with Council for International Organizations of Medical Sciences ethical guidelines. Our study resolves that, the regulatory mechanism in India is in an evolution stage and speedy constitution of regulating frame works with ethical concerns is the need of the hour before the system goes beyond repair. Bioethicists play a vital role and are exceptionally placed to bring these more conceptual and empirical issues into the public debate and extend the current discourse beyond questions of effectiveness and safety of mHealth. The ethical issues are evolving and dynamic and hence constant evaluation and appropriate recommendations should be implemented periodically.

Keywords: mHealth, autonomy, security, privacy, ethics.

INTRODUCTION

mHealth is a novel healthcare delivery system using the mobile devices such as smartphones, patient monitoring devices, personal digital assistant tools and many wireless tools to improve and empower healthy life styles, behaviour, quality and wholistic wellbeing of an individual or groups [1]. In the modern era there are umpteen number of gadgets in the web portals showcasing the multiple wearable sleek and fancy gadgets and apps tuned to continuously monitor and capture

the body movements, physiological changes, calories burnt, vitals measured etc. and producing data based graphs to educate, notify, monitor and provide health advises and self-management tools to chronic and disabled patients. Apart from the patients, the healthy population, healthcare professionals, self-help groups and vulnerable people are also targeted with the mobile phones.
The doctor population ratio of India is only 0.7:1000 Doctors, and 1.3:1000 Nurses. Hospital beds per 1000 population are only 1.1, thereby creating a need for alternative channel like mHealth for delivery of healthcare. Apart, a large sect of population is deprived of even primary healthcare facilities too. Hence it is imperative to leverage and implement novel technology so as to achieve quality and affordable healthcare accessible to everyone. (Fig: 1)

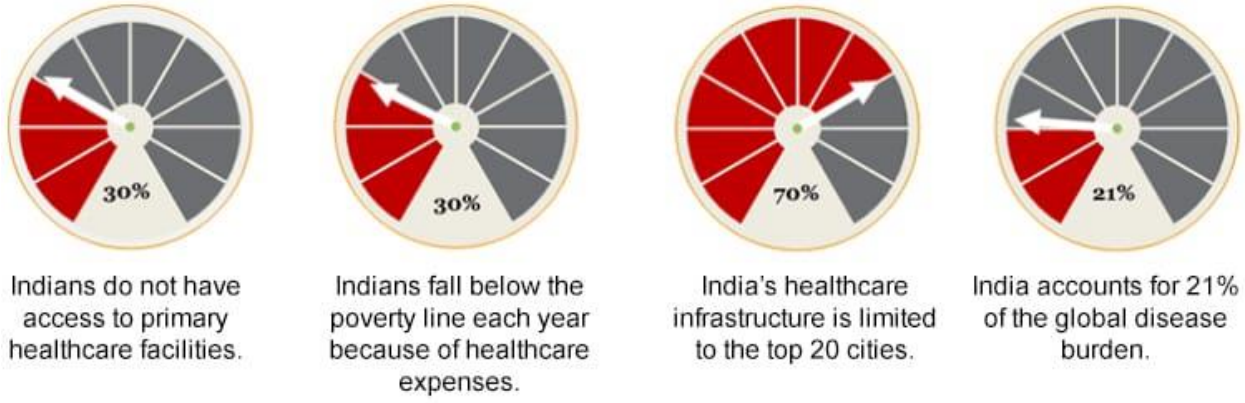

Fig: 1 Snapshots of Indian health care system (Source: PwC "The health care agenda 2015")

Confederation of Indian Industries (CII) has stated along with PwC, mHealth is expected to be crucial and vital in making health care accessible in India. It also reported mHealth can save nearly 0.8 to 1 billion dollars in health delivery. As 70 percent of the country population are living in rural areas and inadequate distribution of medical facilities such as hospitals and clinics it is impossible to make healthcare accessible for all. The mobile penetration is almost 100% in India, the health App are also growing rapidly in India. Hence it has become norms of the day for health care ecosystem to explore various means in health Apps device integration and sensor technology seriously and start reap the benefit of this [2].
According to Nita Soans, CEO, Kaiterra India, m-health can go in a long way in helping people to be more in positive control and cognizant of their health, be more knowledgeable and aware about various symptoms and red signals of catastrophic diseases, their probable health score and risks, and also remedial needed steps for them to stay health. For e.g. Air quality data which is a raising concern in North India can be made known to people using mHealth [3].
Cagonkapur, Co-founder and CEO of Easy buy health, stated mHealth is a mobile health care in the ability of an individual to carry their own and their family's health data on their hand-held devices and keep their doctors literally at their touch of a button. Abhishek Mishra founder and CEO MeListo has said, mobile health care bring experts to small cities and give the excess to the general population for the care they deserve. The CISCO, VNI mobile forecast highlights in India mobile data traffic will grow from 2016 to 2021, a compound annual growth rate of 49%.
India rank 5th in health apps next to Australia, US, UK, Canada with 56%. However, the m Health apps are playing at present only 12%, compared to 100% in Egypt [4]. mHealth technology will improve accessibility, reduce health care cost, and increase health care work force productivity in India. However, the huge volume and fragmented market plays a spoil spot. At present, nearly 165000 Apps are available across the I-tunes and Android stores but more than 40% has less than 5000 users [5]. Many of them are dubious and have no proven record. At this ocean of available apps, population are at risk of knowing which good apps are. Many times, it will add more risk than benefits.
As per the Mobile health market report 485 million wearable devices can be expected to be sold in 2018. mHealth are expected to fostering efficiency and prevention in health care, increasing patient self-management and empowerment and promoting global accessibility to health [6].

Peter Reese and others [7] conducted two randomized controlled pilot trials over a year period in Canada, using text messaging to encourage cardiac medication compliance and exercise among patients undergoing rehabilitation after being discharged from the hospital following myocardial infarction and have reported there is significant long-term benefits in this mHealth process. Thus, mHealth has proven record of efficient and cost-effective solutions for disease prevention, monitoring and management - both short term and long term [8].
To live up to the promises made, mHealth system like other medical intervention, should not harm and should preferably benefit the users. However, there are uncertain grey areas on the safety, reliability and accuracy and other ethical concerns on mHealth [9]. Ethical principles and bioethics have important role in making of these mHealth apps and gadgets adhere to the principles of autonomy, beneficence, non-maleficence and justice [10].

Autonomy encompasses self-determination, right and ability to access to information needed for decision making, independence, freedom to choose, power to be in control and be responsible personally for his deeds.
Beneficence demand health care apps and gadgets to be and do only good in terms of own perceptions of the individual users.
Non maleficence is the basic principle in medicine that does no harm at all levels. This applies to health care delivery systems also.
Justice demand all people are treated fairly and equally irrespective cost, creed, and literacy, poor or social positions.
As the adaptivity of emerging mhealth systems are increasing, ethical evaluations and assessment are the major key components for the adoption and accreditation of the new technology. This study is intended to assess the ethical principles used in the prevailing mHealth Apps and systems and also to postulate ethical guidelines and future directions in the regularisation of the booming mHealth revolutions. This study will map the main ethical concerns and problems, identified and reported in the relevant literatures and will identify the key themes and principles to be adopted in the newer mHealth apps to be used in a mass scale.

DISCUSSION

Ethical issues reported in literature on mHealth for research and clinical setting are analysed in detail and are grouped into five groups and tabulated in Table 1.

Table 1: The ethical concerns depicted in searched journals

Privacy, security and data ownership	Informed Consent	Efficiency and prevention	Self management /empowerment	Social justice
Addonizio, G. The Privacy Risks Surrounding Consumer Health and Fitness Apps, Associated Wearable Devices, and HIPAA's Limitations ; 2017.	*Jefford M, Moore R.* Improvement of informed consent and the quality of consent documents. Lancet Oncology 2008;9(5):485–93.	*Robson Y., et al.* Caution in melanoma risk analysis with smartphone application technology. Br J Dermatology 2012;167(3):703-4.	WHO Media Centre, Diabetes, http://www.who.int/mediacentre/factsheets/fs312/en / Retrieved Oct 27, Greenberg, J Med Internet Res 2016;18:6.	*Andrejevic, M.* Big data, big questions and the big data divide. Int J Commun 2014;8:1673–89.
Akter S, Ray P. mHealth-an ultimate platform to serve the unserved. Med Inform 2010:94-100.	*Paterick TJ et al.,* Medical Informed Consent: General Considerations for Physicians. Mayo Clin Proc 2008;83(3):313–9.	*Huckvale K et al.* Apps for asthma self-management: a systematic assessment of content and tools. BMC Med 2010;10: 144.	*Whitehead L, Seaton P* J. Med. Internet Res 2016;18:5	*Bol N.* How to present online information to older cancer patients. Amsterdam: University of Amsterdam; 2015

Arora S. et al. Privacy and security in mobile health (mHealth) research. Alcohol Curr Rev 2005;36(1):143-8.	*Raich PC et al.* Literacy, comprehension, and informed consent in clinical research. Cancer Investig 2001;19(4):437–45.	*McKinstry B.* Currently available smartphone apps for asthma have worrying deficiencies. Evid Based Med 2013;101194	Zoffmann et al., Patient Educ Couns 2016;99:400-7	AppBrain. 2018. Android statistics. Retrieved Jan 22, 2018 http://www.appbrain.com/stats/android-market-app-categories
Avancha, S et al. Privacy in mobile technology for personal healthcare. ACM Computing Surveys (CSUR) 2012;45(1):3.	*Miller FG, Emanuel EJ.* Quality Improvement Research and Informed Consent. Waltham, Massachusetts Medical Society; 2008.	*O'Neill S, Brady RR.* Colorectal smartphone apps: opportunities and risks. Colorectal Dis 2012;14(9):e530-4.	*Istepanian RS et al.* IEEE Trans Inf, Technol. Biomed 2004;8:405-14.	*Bolle, S et al.* Older cancer patients' user experience of online health information tools: A think aloud study. J Med Internet Res 2016;18(7):e208.
Bhuyan SS et al. Privacy and security issues in mobile health: Current research and future directions. Health Pol Technol 2017;2:188-91	*Abernethy A et al.* Mobile health technology evaluation: the mHealth evidence workshop. Am J Prev Med 2013;45(2):228–36	*Ferrero NA et al.* Skin scan: a demonstration of the need for FDA regulation of medical apps on iPhone. J Am Acad Dermatol 2013;68(3):515-6.	WHO Global Observatory for eHealth. New horizons for health through mobile technologies. Geneva: World Health Organization; 2011:112.	*Arora S, et al.* A mobile health intervention for inner city patients with poorly controlled diabetes. Diab Technol Ther 2012;14(6):49296.
Cho et al., A multinational study on online privacy: Global concerns and local responses. New Media Soc 2009;11(3):395-416.	*Friedlander JA et al.* A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. J Med Ethics 2011;37(4):194	*Visvanathan A, Hamilton A, Brady RR.* Smartphone apps in microbiology--is better regulation required Clin Microbiol Infect 2012;18(7):e218-20	*Govette, J.* 30 Amazing Mobile Health Technology Statistics for Today's Physician, https://getreferralmd.com/2015/08/mobilehealthcare-technology-statistics/. Retrieved on Oct 27, 2016	*Carroll J. et al.,* Who uses mobile phone health apps and does use matter? A secondary data analytics approach. J Med Internet Res 2016;19(4):e125.
Dehling T et al., Exploring the far side of mobile health: information security and privacy of mobile health apps on i Android. JMIR 2017;3(1)	*Baer AR, Good M, Schapira L.* A New Look at Informed Consent for Cancer Clinical Trials. J Oncol Pract 2011;7(4):267–70.	*Weaver C.* Apps Aim to Detect Skin Cancer (The Wall Street Journal (WSJ), 16 Jan 2013) -		*Baker, et al.,* Building an understanding of the domain of consumer vulnerability. J Macromarketing 2015;25(2):128–39.
Dredge S. Yes, those free health apps are sharing your data with other companies. TheGuardian.com, Accessed 28 Sept 2017	*Selby JV, Beal AC, Frank L.* The Patient-Centred Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. JAMA 2012;307(15):1583.		*Heerden AV, Tomlinson M, Swartz L* Bull WHO 2012;90:393-4.	*Dallinga J. et al.* App use, physical activity and healthy lifestyle: A cross sectional study. BMC Public Health 2015;15(1):833.

Emmnauel U, Mohammed T. Cyber security, threat intelligence: Defending the digital platform. J Int Technol Inform Manage 2016;26(1):138-60.	*Tate EB et al.,* mHealth approaches to child obesity prevention: successes, unique challenges, and next directions. Trans Behav Med 2013;3(4):406–15.			*Berg, I.* Consumer vulnerability: Are older people more vulnerable as consumers than others. Int J Consumer Behav 2015;39(4):284–93.

Privacy, security and data ownership:
The technology of Geo location (GPS, WLAN) will reveal range of personal information. Privacy is the power and ability to control the recording and sharing of the personal information with others. Anonymizing the mobile phone data are paramount difficult to achieve. Also, the data shared in the public repositories can be either legally intercepted by government agencies (eg. Subpoena), third party by via hacking of information sent over the internet or via Bluetooth (sniffing), telecommunication companies, cloud storage providers, big field players like Google, Amazon may claim ownership of data recorded by or transmitted through their network.
Encryption is vital for the power storage transmission of the data using mobile technology. However, the study by Dongjing et al., [11] on the security concerns in Android mhealth apps, it is reported many mHealth apps do not use and incorporate encryption while transferring data. There are multiple incidents reported where there are potential privacy violations by the use of computer malware as virus programmes or using malevolent app developers who steal data for commercial or criminal intents. Mobile health developers must ensure that the data collection by mHealth app are not available to other apps or programme contained in the phone [12].

Obtaining informed consent:
In the process of implementing mHealth care delivery, it is mandatory to get informed consent from the participants. Accordingly, the user must be adequately informed about the risk and benefits of using the particular mHealth technology, and they must be in a position to understand that and make uncoerced decision to take part or use the technology. The areas of concerns raised are

a) How much input should participants have over what they wish to have recorded and shared?
b) How will the data be used?
c) Where will be it stored, in what form as to whom and how will it be shared?
d) How long the data will be made available?
e) What will happen to the data once their participation is complete?
f) How much scope and security for privacy of data?
g) At what circumstances it will be shared without their consent?

The developers and introducers of mHealth apps must be prepared to share these ethical challenging data before they obtain informed consent. One of the issues reported was, recording conversation of participants of mHealth app for people with Parkinson diseases. Even if the participants have given consent, the conversation involves third bystander it is necessary to have their consent too are a challenge [13].
It is suggested it can be done only with their consent and an alert can be created in their mobile, to get their consent to record their conversation as a part of therapeutic measure for Parkinson patients [14].

Efficiency and Prevention
In diabetic related retinopathy, the key to prevent its complication of vision loss is embarked by early detection through regular screening. It is not possible by the consultant ophthalmologist to

be available in every part of our country. However, if primary care physicians are equipped with the screening tool, it can be done at their first contact level using the mHealth App, function as retinal camera. It is convenient and cost effective than the traditional retinal scans [15]. Similar apps are developed for early detection of skin cancers, detect EPS in Parkinson, epileptics etc. However, there are still concerns on its efficiency and full proof for prevention potential. The smartphone retinal scan may not accurate and may fail to detect an early stage Proliferative retinopathy and a skin scan on melanoma [16].

The benefits and risk are most often not uniformly dispersed among stake holders. However, it must be taken care risk of harm shall not be predominantly on the patient side. Though there is ecstasy on the efficacy of the m-health apps on early detection and prevention it is not uniform, user dependent, signal based and lot of noises are there in transmission and interpretation of data. Synchronising personal care without human interphase is still a mandatory requirement on m-health care. Developers of App shall constantly pay attention to study on the feasibility, cost effective, accuracy and efficiency. Non maleficence shall be the prime objective.

Self-Management, Empowerment and Social Justice.

mHealth apps are intended to give empowerment to its users to self-manage their problems and render social justice to get the solution when he is incapacitated by various means to reach health care. Many patients having Non-Communicable Diseases like Diabetics, Obesity, COPD are using wearable sensors, belt etc to monitor their calorie intake, exercise, partial oxygen saturation etc [17].

Though at a first look it appears, these Apps and digital tools empower patients and enhance their autonomy, when critically analysed it is not so. It appears these provisions and technologies often discipline the users towards certain predetermined medical workouts or tasks, rather in real sense empower them [18]. The monitoring health parameters and ensuring health as a fundamental right is the responsibility of the state. By shifting this role by the wearable Apps and technology, responsibility of fundamental right is shifted from state to individual. This responsibility is a challenge to social justice. The health care ensures personal rapport and humanistic relationship between patient and Doctor. By the presumption of empowerment of Individuals, with loading the data with them without interpretation of it with due ethical and empathetic tone, will build up tension and take away the social interphase resulting in depression and agony.

The possibility data leakages may distort the impression of an individual on the society and may lead on to decrease in self-esteem and respect which are counterproductive to the concept of empowerment [19]. Illiteracy, slow net connectivity, low dexterity, visual or auditory impaired, poverty imparting their access to smart phone, all leads to social injustice in the delivery of health care system.

Access to m health technology and social justice

Though there is rapid penetration of mobile phone technology, the access is impaired by the poor internet penetration, illiteracy, language, affordability for a smart phone. This is an ethical imperative not to exclude these patients from benefitting from health monitory.

The physical disability and lack in hearing, vision, touch sensation and perception disorder will also affect the implementation of mHealth strategies [20]. The researcher must have alternate plans to make these mHealth technology made available to the vulnerable disabled groups.

Setting the agenda for the ethics of mHealth

Based on the meta-analysis of the reported articles, the following Ten Guidelines and recommendations on ethics to be adopted in the future design and adoption of mHealth Apps are made out for use of mobile phones apps in the health care delivery. These recommendations are linked with the International Ethical Guidelines for Health-related Research Involving Humans prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) [21]. (Table 2).

Table 2: Recommendations and ethical principles for mHealth apps

No.	Ethical Issues	CIOMS Guidelines	Recommendation
1	Privacy and Confidentiality	3,4,11,12,20,22	• Digital Identity, Data Resilience and Data Redundancy shall be customized. • Patient shall retain their control over the sharing and ownership of data. • Patient must have a right to not know if desired. • It shall not impair the autonomy of the physician and ability to treat each patient as individual than as cohort mass • Design with the user, understanding the existing ecosystem and ensuring data privacy and security is the top priority right from the conceptualization to post implementation.
2	Informed Consent	9,10,16	• Participants must be adequately informed about the pros and cons, risks and benefits and hiccoughs in data storage and transmission. Adequate comprehension via multi-media, enhanced privacy, traceability (including ability for withdrawal) and confidentiality shall be ensured
3	Collection, Storage and Use of Data	11,12	• Improved Data Quality, Fidelity, Provenance and Data Reliability shall be maintained. • Adequate encryption to prevent risk of privacy violation and secure vaults for data in the instruments shall be provided.
4.	Data Transparency, third party usage and Sharing	8,12,22	• Increased Data and Study Transparency right through all stages. • Individuals must be informed the possibility of third party access of the data by subpoena (or) hacking or retaining the ownership by the telecommunication and steps taken to prevent it.
5	Anonymity and de identification	10	• If De identification is not an option developers must communicate this to users while obtaining consent.
6.	Beneficence	4,6	• Commercialization of health promotions shall be curtailed. • Risk of the depersonalization/ de humanization of the interphase shall be reduced. • Need to generate valid, reliable data using rigorous standards. • App must be geared towards patient welfare, and research must be patient centered and focused rather than outcome based and academically focused.
7.	Non maleficence	4	• Faulty design of app, or instruments shall not cause injury and harm. • Data collection shall be limited to only what is necessary and pertinent • Risks shall not outweigh benefits based on valid information. • Those interpreting data must be appropriately qualified. • M-health shall not pave way for Internet addiction, information overload and stress, big brother concern, digital divide, isolation and devolution.
8.	Communication of clinical relevant results and active engagement of participants	7,8	• Feedback of clinically relevant or critical information shall be communicated only by a qualified health care professional and only when there is strong empirical evidence to support it. • Humanity concerns and empathy shall be maintained.

9.	Justice	3	• Adaptive choice needed for disabled/blind/illiterate with contents and presentation adjusted to ensure usability by all. • Must be available, accessible and affordable by all regardless of socio economic status, creed, locality and technical illiteracy and net penetrability.
10	Regulations of m health products	23	• As on date existing Indian laws does not adequately address concerns related to m health information. Need for legislation to support standardization and demonstrate indisposed safety. • Ethical committee to ensure implementation of ethical concerns shall be constituted and put in to action;

CONCLUSION

mHealth is a boon in health care delivery system. In the country of vast poor population with fewer toilets and more cell phones, imparting the needed data and support to the people with the ethical principles of Autonomy, Maleficence, Social Justice and Confidentiality are real concerns for the promoter. Though mHealth emerge out with the shiny promises of revolutionizing medical care, but do not explicitly exhibit their use versus harms, which is absolutes and mandatory parameter for ethical considerations and assessment of these Apps. Literature review on the meta-analysis explain various ethical concerns analysed and reported by umpteen researchers. Based on their report, we design 10 principles of ethical concerns the developer must adopt before rolling out their apps to open market.

The enforcement and designing the control and ethical principles on the mHealth are only in the evolutions stage in our country [22]. Primum non nocerea (first to do no harm) being the hall mark in any health care delivery, mHealth Apps must also adopt this strictly and there must be adequate control to evaluate and enforce it. Developers must learn from past inadequacies and adapt to future needs based on the pillars of ethical principles autonomy, beneficence, maleficence, and justice. mHealth affects and distorts the noble relationship between healthcare experts and patients, as well as their understandings of self-care and management amidst the data jungle. The meanings of mHealth services for individuals and collectives should be explored both empirically and conceptually. Bioethicists play a vital role and are exceptionally placed to bring these more conceptual and empirical issues into the public debate and extend the current discourse beyond questions of effectiveness and safety of mHealth [23].

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