



## DRIVING DIGITAL TRANSFORMATION USING MHEALTH IN CLINICAL RESEARCH: BRIDGING THE GAP TO TRUE PATIENT CENTRICITY

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### Abstract

MHealth technology is the practice of collecting and managing medical data using phones, tablets and other electronic devices which are being used by pharmaceutical companies, clinical research organizations and academics to improve the clinical trials. According to recent survey by SCORR marketing and applied clinical trials, 95% industries believe in using wearable devices in clinical trials. Data collection and management is done through two perspectives. Firstly involves industry prospective in which patients and protocol design is selected, e-consent is taken, real time patient feedback is checked, adherence is noted and then summary of the data is recorded. Secondly, it includes patient perspective in which patients are screened, patient compliance is checked and then includes continuous recording and tracking of patient data like monitoring of the vital signs for the cohort studies. The analyzed data is precise information which is very useful in the clinical trials and here comes the role of digital devices and how the digital transformation and clinical innovation is helping us in doing the clinical researches. Advantages and disadvantages go hand in hand, where MHealth aids in easy patient recruitment and saves time, it may pose certain hindrances in maintaining data quality. But barriers can be vanquished by using better connectivity options like Bluetooth 5, 5G internet connection, better sensors, more sensors and the charging issue resolved by using the super capacitors. So, this review aims to explore the role of MHealth services in clinical research.

**Keywords:** MHealth, SCORR, Marketing, Personal digital assistants

### Introduction

India is a diversified country with varied socio-economic backgrounds and features which is visible in its medical system. These include an inadequate availability of doctors practicing in rural and semi urban areas like small towns and cities. This also includes, updating the knowledge of the medical health care force not working or are new to rural healthcare system. Near about 80% of the population shows faith on non-allopathic medications and a study conducted by Indian pharma industry states that only 30% of the population goes for modern medicine (Das *et al.*, 2012; Gogtay *et al.*, 2002).

Many other residing factors like out-of-pocket expenses and travelling cost may lead to untreated and unmanaged diseases. This makes the recipients to rely on over the counter prescriptions or faith healers (Reddy *et al.*, 2011; Das *et al.*, 2007; Bhatia *et al.*, 2001; Banerjee *et al.*, 2004). The inadequate reporting system, improper case reports and cases series, unavailability of epidemiological studies further lead to limited approach to better healthcare systems (Jhaetal, 2006).

In the era of advancing medical strategies and outcomes, a major hindrance in achieving optimal outcome is the failure of the patient compliance (Riley *et al.*, 2011). The reports generated from World Health Organization states that, the patients suffering from chronic diseases adhere to only 50% of the drugs prescribed to them and the number is even lower in developing countries. The same report also reflects on two significant consequences of non-adherence: Suboptimal health outcomes for patients and increasing health care expenditure (Cramer *et al.*, 2008). MHealth comes under the broad category of Ehealth. The aim is to impart optimal health outcomes in terms of accessibility, quality, affordability, efficient monitoring and lowering the burden of disease. Smartphones have become integral part of our lifestyle; they are not just mere tool for communication.

They have spread their roots to health and medicine also. Mobiles and internet have bridged the gap between physicians and patients. Online pharmacies had enabled to deliver medications at our doorstep. Many smart apps have aided in keeping a track of the disease, medication adherence, weight loss, and cardio activity, even our sleeping and eating patterns (Riley *et al.*, 2011). So, this review aims to explore the role of MHealth services in clinical research.

### MHealth targetting heterogenous audience

The Global Observatory for eHealth (GOe) defines 'MHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.'

MHealth uses various tracking and messaging tools like SMS, PRS, 3G and 4G systems, GPS and Bluetooth technology to connect to the people (Guy *et al.*, 2012). Varied population including doctors, nurses, pharmacists, patients and even healthy individuals are using MHealth. Mobile applications for health can target heterogeneous audiences such as doctors, nurses, patients, or even healthy people. MHealth is the convenient way for personal care because mobile phones are personal to an individual and portable (Whittaker *et al.*, 2012; Fogg *et al.*, 2009). The emotional and physical attachment of the individual to the phone and the practice of carrying it everywhere are favorable to deliver health interventions (Ventola *et al.*, 2014; Klasnja *et al.*, 2012; Clayton *et al.*, 2015).

Thus, mobiles serve the patients in everyday lives to keep record of the medications, medication adherence, hospitalization visits or in emergency situations (Sherry *et al.*, 2012). Current evidence suggests that the use of mobile technology can improve diagnosis and compliance with treatment guidelines, as well as patient information, and can increase administrative efficiency (Das *et al.*, 2007).

MHealth have been shown to be effective in various serious and chronic medical illnesses like diabetes mellitus, hypertension, and effective in smoking cessation, rheumatoid arthritis, dealing with obesity issues and STDs (Evans *et al.*, 2012).

### MHealth in Clinical trials

The MHealth is revolutionizing the conduct of clinical trials, by using mobile apps and services to shorten the gap between the investigators, sponsors, clinical research organizations and desired participants. This has been demonstrated by the data of 185 clinical trials updated on clinicaltrials.gov between 2013 and 2015 depicting the use of 'MHealth'. The figures have almost doubled up to 371 for the studies updated from 2016. The MHealth helps in safe and effective recruitment of patients to safeguard their rights and wellbeing. It helps in reducing the patient's overall expenses by minimizing the travelling costs and negligence to visit the doctor (Mosaet *et al.*, 2012). Unnecessary visits to the trial site can be minimized by forwarding the detailed medical reports directly to the patient. The patient can have access to the studies relevant to the specific disease and health needs, can easily answer various questions through questionnaires, can participate in online surveys and helps in improving patient education (Synder *et al.*, 2011). Patients are kept informed through SMS, voice mails, emails and are kept engaged to the study through various gamification techniques (Mosa *et al.*, 2012). The MHealth apps aid in managing patient cohorts, thus generating a link between individuals which can help each other in providing emotional and social guidance. Moreover, the online MHealth apps help in designing clinical databases on diversified diseases, medications, adverse events encountered or any new indication of any drug or combination of drugs (Wallace *et al.*, 2012). Employing online system assists in reducing unnecessary paper work by designing eprotocols, econsent, patient feedback forms and summary of data. The system can keep record of the remote patients via video calls and voice messages. This helps in remote sample size collection and recording extended follow ups. Various medical assessments (BMI, SF-36) can be easily done by patients using MHealth apps. Studies have depicted that 70% of the medical practitioners and students use one medical app on regular basis and 50% of them use one medical app daily (Wallace *et al.*, 2012, Murfin *et al.*, 2013).

### Initiatives taken by Government of India

Government of India has taken the initiative to use mobile phones in improving quality of life of patients. Benefits to be considered in utilizing MHealth services:

- To improve the efficacy of the collected medical data by eliminating the duplicity in medical tests and reports.
- Improving the health and quality of life of patients by monitoring the healthcare assessment timely, prescribing and auditing the medication regimen to individualize the patient reports.
- Imparting and implementing evidence based medications to practice and gaining knowledge through CME.
- Providing the patients and consumers power to choose among various medication choices and treatments.
- To encourage the patients to adhere to the medication regimen and to the treatments by communicating with them through voice mails or video calls.

- To educate the physicians on advance healthcare systems and new drugs through online CME.
- Exchange of information and knowledge across the countries is become easy and accessible.
- The knowledge and treatment facilities should be extended to various geographical boundaries.
- The right, safety and well-being of the patients should be secured.
- The healthcare assessment and facilities should be available to all sections of the society as internet and mobile facilities are still a concern in remote underdeveloped areas.

Around 73 MHealth apps including websites have been launched by Indian government to make the mobile based healthcare system accessible to everyone (National Health Portal of India). Some of the apps and websites are summarized in (Table 1).

### Hyped market values of mobile devices

Since 2014, smartphones have witnessed hype and have outnumbered the world population. The number is multiplying at five times than the world population. Going by the census, the number of mobile devices will increase up to 1.5 per capita, leading to a total of 11.6 billion and the global rise in mobile connection will speed globally by >20 megabits/sec (Boulos *et al.*, 2011). Pew Research Center reports show elevation in internet use and smartphone ownership in developing and growing countries. In the year 2013 to 2015, the number of individuals owning a smartphone has doubled in developing countries and the world's mobile health app market has estimated its value at 28.32 billion USD in 2018 which is expected to rise to the value of 100 billion in the upcoming 5 years. The advancement in the technology of mobile devices (Fig. 1) has shown a major breakthrough in the public health care system (Kay *et al.*, 2011).

Healthcare professionals, medical students and general population now-a-days are using medical apps (table 2) for: maintaining and accessing health records, gaining information about new drug therapies and medical devices, patient monitoring and counseling, managing time, answering medical queries, checking references, communicating and making clinical decisions (Murfin *et al.*, 2013). The percentage usage (Fig. 2) is increasing tremendously due to time constraints and wide data coverage.

### Economic Status

An economic and cost effectiveness study was conducted consisting of 39 studies covering 19 countries including upper and upper middle class income countries (34, 87.2%). Among these 70.6% depicted positive cost outcomes. Among the studies conducted majority of the studies took MHealth as a primary intervention (35, 89.7%) and other as component of intervention ((4, 10.3%). From both the groups three quarters of them reported positive costing outcomes. 27 studies out of 39 were based on medication adherence (27, 69.2%) which also reported high costing outcomes. SMS services used in intervention (22, 56.4%) showed (77.3%) positive costing outcomes. The MHealth tend to be cost effective and time managing. (Iribarren *et al.*, 2017). The MHealth apps are showing promising results (Fig. 3) and great global market potential for the future gains.

Studies conducted using MHealth have given mixed results which states that MHealth can be a useful tool in clinical trials but various precautions and safety issues are important to consider (Anguera *et al.*, 2016). In a previous study status of depression was evaluated by implementing fully mobile based clinical trial. In this study all the healthcare assessments and administration of medications were done using mobile devices. However, the study helped them to recruit large number of patient in a short period time and minimal cost but the engagement was challenging (Williamson *et al.*, 2018). Another study was conducted to evaluate the efficacy of MHealth resources in asthmatic pregnant women. A project website was designed containing links to the MHealth resources and questionnaires and links were also posted on twitter and Facebook. This approach does not fetch them patients despite social media is extensively used (Varnfield *et al.*, 2014). A randomized control trial assessed cardiac rehabilitation in post myocardial infarction patients using smartphone based homecare model that resulted in positive outcomes as the model helped in improving the physiological and psychological parameters. Similarly, many controlled clinical trials have been conducted to assess the effects of nutritional labels on food items, salt intake in cardiovascular patients, regulating blood glucose levels in Diabetes mellitus, managing Rheumatoid Arthritis and various STDs by using the MHealth services. Moreover, many clinical trials are in a row for checking the efficacy of MHealth in various chronic diseases like hypertension.

In a survey conducted globally, the highest benefits and the therapeutic domains where MHealth is widely cherished were depicted, including the setbacks faced. The biggest assets of MHealth are improvement in the quality of data, patient engagement, recruitment, patient adherence to the study, early safety signal detection and improved communication between CROs, investigators, sponsors and

the participants. MHealth was widely used to study sleeping and eating patterns, cardiac safety, oncology, respiratory problems, neurological illness, depression and mental health. With every asset, there come drawbacks (Marcolino *et al.*, 2018). The huge challenge faced by MHealth was improper knowledge for operating MHealth in clinical trials. Due to which data security and validation concerns were posed. Another setback was the funding issue, as improper knowledge of MHealth raised speculations among CROs and sponsors to invest money on clinical trials using MHealth (Abaza *et al.*, 2017). Moreover, with improper knowledge to run the MHealth based clinical trials, it became a tedious task to educate patient and get their consent. Patient adherence and compliance became a major issue. With all these drawbacks piling up, FDA acceptance of the trial also became troublesome. Recent survey conducted in North America, Europe and Asia demonstrated that two-thirds of the clinical trials utilized MHealth services via mobile apps and other half used monitoring devices like glucometer (Abaza *et al.*, 2017). However, drug delivery devices and activity trackers were seldom used. Many big companies are looking forward to expand the utilization of MHealth resources, in future.

**Conclusion**

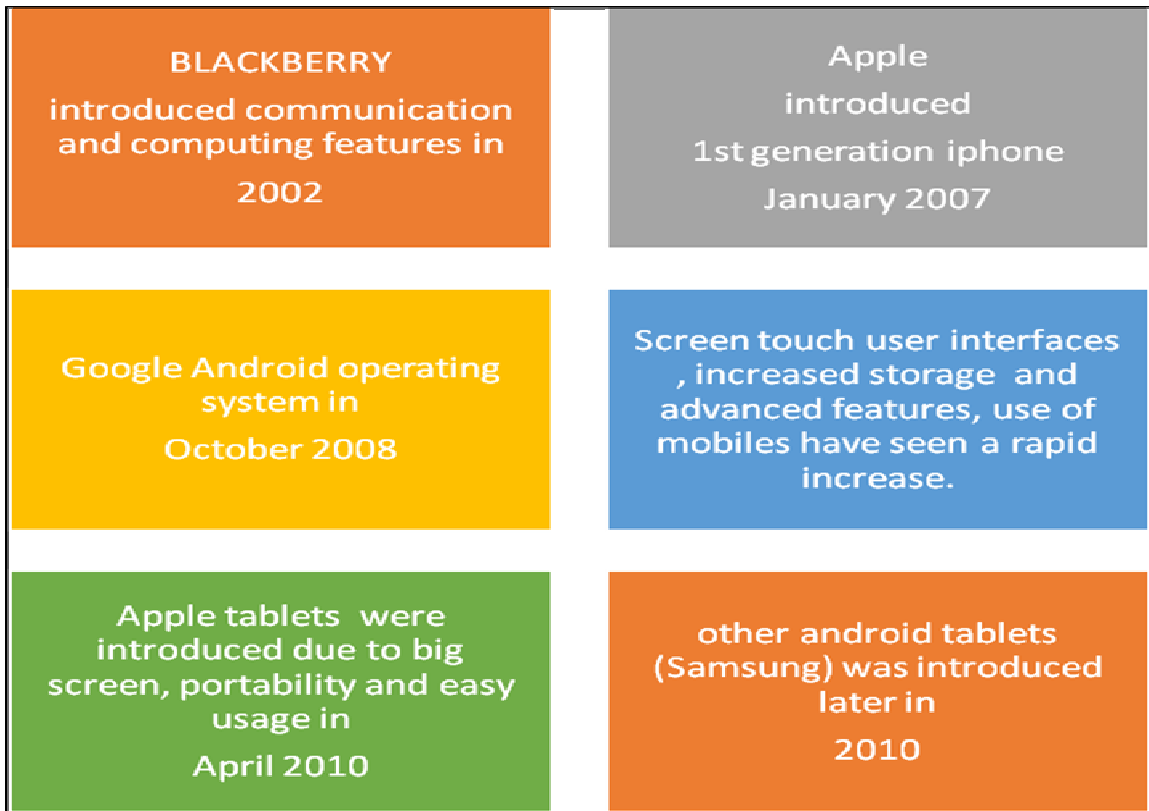
In conclusion, the use of MHealth services in near future is expected to optimize clinical trials including smartphones as well as wearables is expected to surge in the near future. While chronic medical conditions being the focused area of interest for MHealth research, a shift in trends is expected as the application of MHealth interventions spreads to other under-studied areas. MHealth promises to have a transformational impact on health-care and clinical research by improving patient compliance, recruitment and satisfaction, trial timelines, and increasing the speed, and convenience of data capture in general and particularly in pharmaceutical R&D.

**Table 1 :** Various MHealth apps and websites designed by Government of India.

<b>AIIMS-WHO CC ENBC</b>	<b>Mobile- Family planning tool</b>
My Fitness Pal, Nutritional database & Calorie counter	Malaria Early Epidemic Detection System (MEEDS)
Safe pregnancy and birth	Frontline SMS
Mswasthya – CDAC	Mobile for health improvement
National portal health India	Health Unbound (HUB)
1mg	H-Connect

**Table 2:** Medical apps usage by medical professionals, clinicians and students.

Gathering of information and references	Epocrates, Micromedex, Medscape Johns Hopkins Antibiotic Guide
Patient monitoring	Medcalc, Archimedes , Pocket lab values
Managing information	Evernote, Google drive, Notability
Consulting	Doximity
Continuing medical education	Medpage today, QuantiaMD

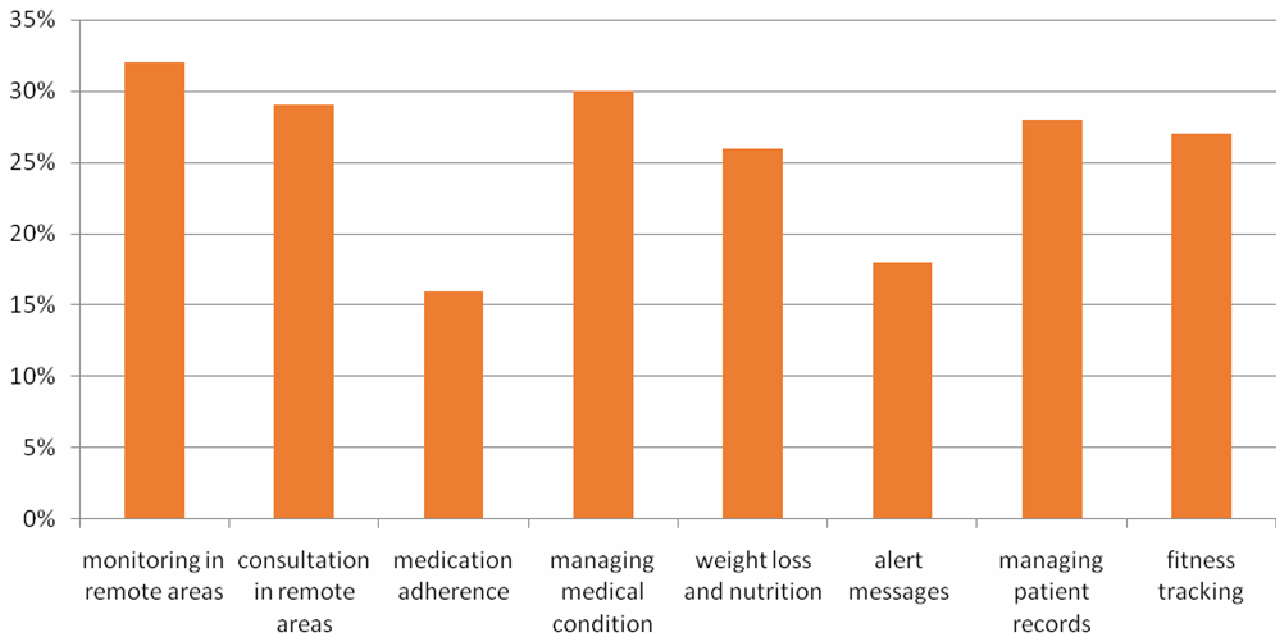


**Fig. 1:** Upgradation in mobile technology in chronological order.

June 2012 Manhattan Research Physician Channel Adoption Study .		
<p style="text-align: center;"><b>In General Smartphone and tablet User : 87%</b></p> <p style="text-align: center;"><b>Computer User: 99%</b> 85% - 90% of population</p> <p style="text-align: center;">ranging from classroom to hospital use mobile devices. (Wallace S et al.,2012)</p>	<p style="text-align: center;"><b>Doctors owning tablets and computers: 66%</b></p> <p style="text-align: center;"><b>Doctors using tablets and computers in practice: 54%</b></p> <p style="text-align: center;">No age barriers, physicians above 55 using smartphone: 80%</p>	<p style="text-align: center;"><b>Medical professionals and students spending</b>  <b>Desktops/laptops: 67%</b>  <b>tablets: 29%</b></p> <p style="text-align: center;"><b>smartphones: 13%</b></p> <p style="text-align: center;"><b>CME viewers: 55%</b></p> <p style="text-align: center;">(Chase J et al.,2013; Moodley A et al.,2013)</p>

**Fig 2:** Percentage usage of mobile devices, laptops and computers among clinicians.

### **The categories of mobile health app that will provide highest market potential globally in coming year (2016-2020)**



**Fig. 3:** Graphical representation of MHealth services in market.

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