A Digital Revolution in Pharmaceutical Industry: Mobile Health Applications

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Abstract:- Today Meteoric advancement has spread to the field of medicine also. Most importantly the smartphone technology which has played an accountable role in this direction and has made the medical provisioning via mobile a reality which one could never have thought of earlier. We have developed and evaluated mobile apps for smartphones working on different platforms (Android, iOS, Window's) to regulate and facilitate interactions between patients and doctors where patient capable to seek advice, diagnosis and treatment from the doctor from remote places around the globe.

Numerous innovations and development in mobile software applications also provide potential benefits to the public health since the mobile platforms are becoming more user-friendly, computationally powerful and affordable with each successive day. It is because of these innovative apps that have significantly contributed in clinical consultation complementing face to face interactions with doctors, healthrecord maintenance, patient management and monitoring, clinical decision-making, medical education and training and the list goes on. The GUI displays screens of the smartphones are incorporated with medical data that is required by the clinician to interpret and respond in most efficient manner possible.

In April 2018, the Health Ministry of Government of India came out with the draft proposal to amend the Drugs and Cosmetics Rules 1945 by inserting Part VIB to it after Rule 67H and before Part VII under the heading "Sale of drugs by e-pharmacy" which will legalise the e-pharmacies in the country. The new Rule defines e-pharmacy as a 'business of distribution or sell, stock, exhibit or offer for sale of drugs through web portal or any other electronic media' and prescription as 'instruction from a registered medical practitioner to a pharmacist, written by hand or in electronic mode duly signed to dispense a drug and the quantity to a patient. E-pharmacies are not permitted to dispense narcotic and psychotropic substances, tranquilizers and Schedule X drugs. E-pharmacies have to comply with the provisions of the Information Technology Act 2000 and the Rules there under. E-Pharmacies' are expected to open newer avenues for qualified pharmacists with insights for innovations in India. Pharmacists with Pharm, D. M. Pharm and other qualifications can take up e-pharmacies as a professional challenge in India.

I. INTRODUCTION AND BACKGROUND

Smart phones have become an essential part of everyday life around the globe. The availability of economical, faster and more capable devices has let to various innovations in every field where it can be applied. According to the given data the number of smartphone users worldwide today surpasses a whopping amount of three Billion users worldwide and is forecasted to further grow by several hundred million in the next few years with China, United States and India with highest number of smartphone users

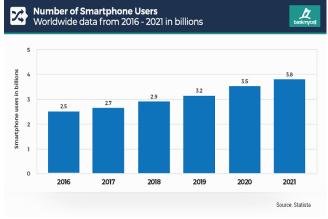


Fig 1

Mobile phone usage in particular is escalating across the developing world also, offering the opportunities to plunge other applications and services on both health and technological fronts. Modern breakthroughs in communication technologies have promoted the development and illustration projects in telemedicine, which is therefore considered an indispensable technology for reformed healthcare. The success of various digital healthcare applications is due to the following given factors

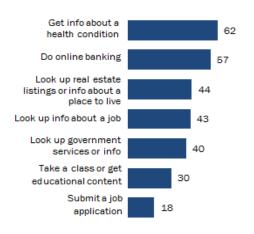
- Severe shortage of trained doctors and nurses in rural areas.
- Constant increase in traffic and transport difficulties in mega cities.
- Very low doctor to population ratios especially in developing countries.
- Poor socio-economic circumstances of rural people.
- Unequal geographic distribution of physicians.

All these above mentioned factors can be solved to a great extent by using smartphones with a dedicated health application. A mobile application which is known in short as mobile app is a software application designed to run on smartphones, tablets, computers, and other devices. They are easily available through different application distribution platforms such as Google Play (Android), Apple App Store, Black Berry App World and various others. Some of the mostly used mobile apps are calendar, E-mail, GPS and order tracking, games and the list is continuously increasing as the public demand is rising. The medical field is no exception here and is mutating the old traditional way of doctors and patient approach of healthcare. Numerous apps are designed for doctors themselves and others for patients. Apps designed for patients enable them to gather different diagnostic data through portable devices do-it-yourself procedures and is transmitted to doctors app on his phone for further recommendation of treatments.

The mobile phone app for healthcare available to consumers today are produced by variety of developers ranging from small to large commercial organizations with a specific commercial goal and include a wide range of scale, investment, and returns in business models and therefore the app user needs to pay the developers either directly or indirectly. For example one particular globally reputed mobile phone application developer charges the consumer in range of \$1.99 to \$5. There may be situations when a consumer needs to purchase an upgraded subscription that

More Than Half of Smartphone Owners Have Used Their Phone to Get Health Information or Do Online Banking

% of smartphone owners who have used their phone to do the following in the last year



Pew Research Center American Trends Panel survey, October 3-27 2014.

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Fig 2

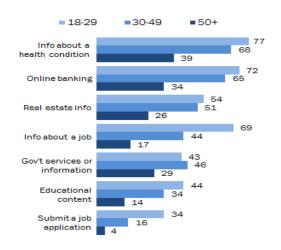
may range accordingly to different features provided and interest of developers.

On the other hand, the app designed for the doctors are included with databases about drugs and diseases to sophisticated monitors that read a person's blood pressure, glucose levels, heart rhythms or other exclusive disease symptoms which are received from patients. This paper describes the development of simple medical applications which is user friendly and can be easily accessed via internet. These applications may be used by doctors and patients to save the time of travel and expenditure to visit the clinics for a follow-up diagnosis. It will allow doctors to attend more patients of urban as well as rural residents in his saved time from one to one consultation with the patients.

Below are some statistical data that represents the dominating role of health applications among variety of smartphone users where Figure. I clearly shows that majority of people have used their phone to get health information, Figure.II indicates that seeking health information is becoming a new custom overthrowing the earlier tradition of doctor-patient physical meetings and Figure.III shows that lower-income smartphone owners are making most of their smartphones to information about a health condition which not only decreases the economic burden on poor people of traditional method of meeting the doctors but also plays keen role in overall health status of the entire nation.

Young Adults Rely Heavily on Their Smartphones for Job Seeking, Educational Content, and Health Information

% of smartphone owners in each age group who have used their phone in the last year to do the following



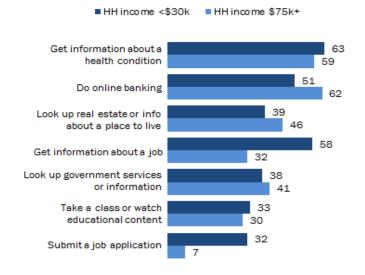
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Fig 3

Lower-income Smartphone Owners Much More Likely to Use Their Phone for Job Seeking

% of smartphone owners in each income category who have used their phone in the last year to...



Pew Research Center American Trends Panel survey, October 3-27 2014.

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Fig 4

There are about eighty e-pharmacies in India doing good business. Some of the major existing-pharmacies in India include 1MG, Netmeds, Bookmeds, mChemist, Medidart, Medlife, Medstar, Zigy, Savemymeds, and Save On Medicals. Traditional pharmacies like Apollo, Medplus, Guardian lifecare etc. also started on-line business in India.

> E-COMMERCE

E-commerce stands for electronic commerce and can be defined as the business activity of buying and selling of products on line with the services of internet and computer connectivity. These days' smart phones are widely used to make the e-commerce more comfortable and popular. E-commerce typically uses the 'world wide web' (WWW) in large through E-mails, WhatsApp, Facebook, sms etc. are often used. Application of technologies like electronic fund transfer, mobile commerce, online transaction method, electronic data interchange etc. helped a lot to popularize e-commerce activities.

➤ E-PHARMACY

E-pharmacy refers to the buying and selling of medicines and other pharmaceutical items with the support of e-commerce activities. In many countries, legitimate online pharmacies are given specific operating licenses. During 2010-15 periods, there were some controversies with regards to e-pharmacies in India. The issues like whether e-pharmacies are legal in India or not, selling of prescription medicines without a doctor's prescription and the presence of 'cyber physicians' on some sites were seriously debated and discussed and were looked upon on for different situations and there solutions that may arise due to E-Pharmacy.

> E-PRESCRIBING

E-prescribing or electronic prescribing is a technology framework that allows physicians and other medical practitioners to write and send prescriptions to a participating pharmacy electronically instead of using handwritten or faxed messages. At the beginning there were some doubts about the legal status of e-pharmacies in India among experts and regulator.

II. GENERAL WORKING

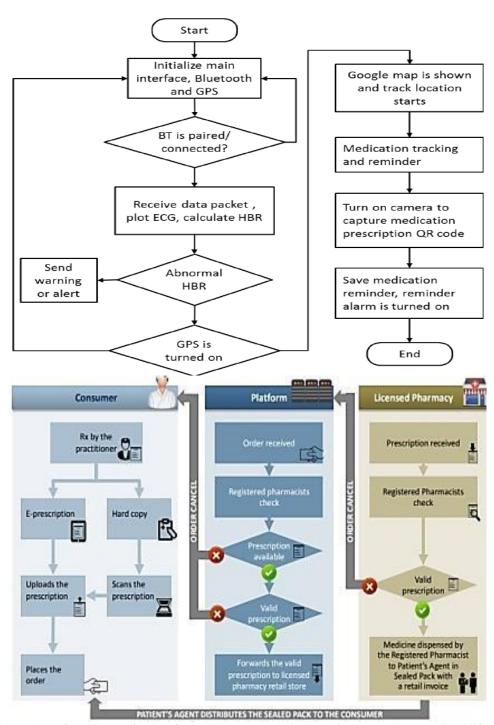


Fig 5:- (Flowchart of mobile application for health status real-time monitoring and personalized life assistant)

> REGULATORY BODIES AND E-PHARMACIES

There were discussions and deliberations during 2010-15, on topics like whether e-pharmacies are legal in India, whether selling a medicines without a doctor's prescription is right and on the presence of internet/cyber physicians on some sites? However some e-pharmacies were selling quality medicines at reduced prices to patients while some others were doing certain questionable dealings and practices before providing the drug to consumers. Though, doctors could prescribe medicines to their parents through an electronic prescription, the question was whether the

prescriptions can be dispensed from both physical (bricks and mortar or B&M pharmacies) and online pharmacies or from a physical pharmacy only? The Drugs and Cosmetics Act 1940 and its Rules 1945, did not differentiate online and offline pharmacies. Indian laws were totally silent on functioning of e-pharmacies till 2018. The drug laws framed during the pre-independence period were not up dated to incorporate the achievements of electronic and information technology and developments and changes occurred in the area of pharmacy practice and dispensing.

The food and drugs administrations (FDAs) of some states like Maharashtra, Gujarat, Telangana and Karnataka filed legal complaints against online pharmacies. The Maharashtra FDA in May 2015 filed an FIR (First Information Report) against the online seller 'Snapdeal' for selling prescription drugs on the internet along with overthe-counter (OTC) drugs. It was based on a raid conducted by them at the Mumbai office premises of Snapdeal in April 2015. Similar raids and FIRs were filed against Delhi based Mchemist, Mumbai based Pharmeasy and Mera Medicare in Gujarat2,3. There was no issue regarding online sale of nonprescription drugs. Complaints and issues were with respect to the sale of prescription drugs only. The Maharashtra FDA took the stand that online pharmacies can sell only OTC and not prescription drugs until the policy on e-pharmacies are framed. The basic argument about the legality and viability of the online pharmacies has been regarding the sale of prescription drugs. Many e-pharmacies have adopted a method where the consumers are required to upload a copy of their prescriptions or an e-prescription, which is then verified by the online pharmacy and accordingly the medicines are provided to the customers. As the law regarding e-pharmacies wasambiguous, it was interpreted in positive and negative ways, 4, 5. In November 2016, the major online pharmacies formally united and formed an association Indian Internet Pharmacy Association (IIPA) and published 'self-regulation code of conduct for epharmacy sector. Mr. Prasahant Tandon, founder of 1mg became the president of IIPA6.

III. INITIATIVES TAKEN BY INDIAN GOVERNMENT TOWARDS E-PHAMACIES

In 2016 itself the Government of India initiated the home work to use information technology in medicine use and distribution in India and for that purpose started steps to launch a centralized online e-plat form for medicines. An eplatform will act as a tracking system for medicine from manufacturer to end use by patients, which was totally lacking in the country. The Health Ministry started utilizing the 'Sugam' software for the purpose. According to the plan, the pharmaceutical manufacturing firms will be required to register themselves with the portal and enter data related to sale and distribution of drugs to different distributors (stockiest/wholesalers or otherwise) along with batch number, quantity supplied and expiry date of the batch, All distributors will, also be required to register themselves on the portal and enter details of stocks received and supplied by them to other distributors or retailers. The data can be entered online and by using mobile phones. Pharmacies located in rural and remote areas also can do it through mobile phones. No retailer, chemist or e-pharmacist outlet shall be permitted to sell any medicine or drug unless such pharmacy is registered on the e-portal. The GST system introduced on 1st July, 2017 acted as a catalyst for the scheme as all the pharmacies in the country managed to be computerized and started issue of computer bills. The eplatform can also be used for the quality assurance of medicines in different ways like uploading the test reports, billing and moving details etc. The All India Organisation of Chemists and Druggists Association (AIOCD) conducted a

nationwide agitation on 30thMay 2017 against the decision of making e-platform for medicine registry in the country.

> REGISTRATION AND LICENSE

E-pharmacies are required to apply for the grant of registration to the Central Licensing Authority (CDSCO) in Form 18AA through online portal along with the required fee. (it is originally fixed as Rs 50,000). The registration issued to the e-pharmacy in Form 21AA shall remain valid for three years and the premises of the e-pharmacy centre will be inspected by a team of officers authorised by the Central Licensing Authority every two years. The e-pharmacies can sell medicines only with the support of cash bill or credit memo generated through e-pharmacy portal. These bills or memos shall be maintained by the e-pharmacy registration holder as record and shall contain

- 1. Name, address and sale license number of the licensee as uploaded in the e-pharmacy portal.
- 2. Number and date of the bill or memo.
- 3. Name of the drug, quantity, batch number (not mentioned in the draft Rule), expiry and manufacturer of medicines dispensed.
- 4. Name and address of the e-pharmacy registration holder.

➤ MAKING E-PHARMACIES PROFESSIONAL

If the Aadhaar number of the patient, doctor and the pharmacist are linked with the e-pharmacy plat form, the functioning of e-pharmacies can be made more perfect. In some Indian States the community pharmacy drug licenses are being linked with the Aadhaar of the pharmacist and the licensee based On Court directions. In some other states the professional registration of doctors, pharmacists and the nurses are also being connected with their Aadhaar. If all professional Councils like Pharmacy Council initiate process of linking Aadhaar with the registration, certain unethical practices can be stopped to a certain extent. According Rule 67K and 67 M, the e-pharmacies need to maintain the records of patients and the services provided. The data base regarding the patients/ customers have to be kept confidential by the e-pharmacies. It should not be disclosed to any other person other than the CDSCO or the Government of India and should not be transmitted or stored outside India by any means. It may be noted that this type of data will help for research studies, framing of policies and future plans and projects

> POTENTIAL FOR E-PHARMACIES IN INDIA

At the global level e-Pharmacy was having a market of 29.3 billion US dollars in 2014. Both North America and Europe shared the market. It is estimated that by 2023, the global market of e-pharmacy will be 128 billion US dollars. According to one Boston Group report in 2016, China was having an e-pharmacy market share of 1.1 billion US dollars. The potential area for the global e-pharmacy market lies in the Asia Pacific market. Though e-pharmacy is a newly born baby in India, it has the potential to become a very large industry segment in the very near future. Rapidly changing consumer behavior, increasing penetration of internet to the rural areas and the availability of smart phones are some of the major driving forces for the popularisation of e-commerce and e-pharmacies in India.

> RESTRICTIONS FOR E-PHARMACIES

E-pharmacy shall not distribute or dispense medicines covered under the categories of narcotic and psychotropic as referred in the Narcotic and Psychotropic Substances (NDPS) Act 1985,tranquilizers and Schedule X drugs. All epharmacies have to comply with the provisions of the Information Technology Act2000 and the Rules made there under. E-pharmacy registration holder is responsible for all the violations of the Rules and provisions of the law.

IV. ADVANTAGES OF E-PHARMACY

A. Medicine Authenticity and Quality-

The IT based tracking systems of e-pharmacies will help in back tracing the manufacturer/ channel / supplier of the sub-standard or low quality medicines and counterfeit medicines. This will help to make the medicine market transparent and authentic. The display of the quality control test report of the manufacturer and the bar-coding in the labels of medicines will help to ensure the quality of medicines supplied. Since e-pharmacies are supposed to get most of their items from the manufacturers directly and are supposed to dispense medicines of selected few manufacturers, e-pharmacies can play an important role in ensuring quality medicines to the society.

B. Generic Dispensing by professional Pharmacists-

India has already introduced the system of generic prescriptions and dispensing. Doctors, who were not taught

about brand names or trade names during the education period, are prescribing costly brands to poor people in the name of quality. Quality is not related to brand or generic names, but to the manufacturers and their process. If consumer movements become strong nobody will dare to prescribe costly medicines, if low cost alternative generics are available. However it is essential that pharmacies and pharmacists maintain professional ethics in pricing and dispensing activities. E-pharmacies allow the consumer to choose from a wide range of generic equivalents for a particular branded drug.

C. Promotion of e-prescriptions. –

E-pharmacies would also enable the doctors to adopt e-prescriptions in a big way, which in turn can address issues of errors due to misreading of doctors' bad handwriting and also help to recording of data for public health planning programs.

D. Drug Information and Patient Counseling-

Through e-pharmacies society will get value-added services like drug information, patient counseling and education and pharmaceutical care. Pharmacists can provide advice regarding drug interactions, side effects, quality of medicines, medicine regimens, and information on storage and proper use of medicines. This power of knowledge will enable the consumer to promote prudent and rational use of medicines.

Pre-COVID-19	During COVID-19 Lockdown	Post-COVID-19 Forecasts
3.5 Mn ePharmacy Households in FY 20	9 Mn Households using ePharmacy in May'20	70 Mn Households to use ePharmacy by FY 25
50+ ePharmacy companies in India	50% new households onboarded from non-metro cities	70%+ users willing to use ePharmacy post-COVID-19 due to positive COVID-19 experience – stronger adoption among low income households (Source(s): RedSeer surveys)
\$700 Mn+ ePharmacy investments in FY 20	19 out of 29 state government identified ePharmacy as essential service post MHA guideline	Co-existence of ePharmacy & offline pharma to drive consumer impact
30k+ people employed by ePharmacies	70%+ consumers positively impacted by ePharmacy player initiatives during lockdown (Source(s): RedSeer surveys)	Social health initiatives to receive positive thrust as government adopts ePharmacy technology
60 Mn addressable households that shop online & are willing to use ePharmacy	+ve sentiment among investors towards the ePharmacy market	Chronic care streamlining opportunity with tech-led pharmacy system

Fig 7:- (During COVID-19,the E-Pharmacies played a paramount role in educating and saving the lives of millions of people such apps include AAROGYA SETU, QUARANTINE MONITOR, TEST YOURSELF, MAHA KAVACH, QUARANTINE WATCH and many more.)

V. WILL E-PHARMACIES DO HARM PHYSICAL PHARMACIES?

As in the case of introduction of computerisation in the 1980s, currently there is a lot of misunderstanding about epharmacies in India. Some believe that it will have an adverse impact on the traditional brick and mortar pharmacies. Some others estimate that it will take away the employment potentials of pharmacists. Yet others expect that it will promote unethical practices in pharmacy practice. All are just hypothetical phobias. In reality, e-Pharmacy models will help the existing traditional pharmacies to grow and expand. E-Pharmacy will help community pharmacies to cater to a broader set of customers and ensure that the inventory is consolidated by reducing the budget requirements, removing wastage from system and increasing margins, thereby making the community pharmacies more sustainable-pharmacies will help to bring employment potential for qualified pharmacists who can introduce innovations in pharmacy practice. In many countries the permission to start e-pharmacies are given only to registered pharmacists.

Existing physical pharmacies too can start online operations and serve a broader set of customers. Similarly a network of pharmacies also can integrate one platform and access a broader customer base. Since e-pharmacy has a stringent documentation process, the taxes paid on all transactions will largely benefit the Government.

VI. CONCLUSION

Breaking the barrier of information lying with the experts, such services are brought to the common man anywhere at any time6,7. A unique feature of information technology is its ability to break barriers E-governance, e-health, e-pharmacy are all its beneficiaries In an era of globalisation, e-pharmacy is a need of the land. It is essential to develop concrete infrastructure for the e-pharmacies in the coming years.

E-Pharmacies enhance the services of pharmacists to the society. It can provide easy and affordable access of medicines to the consumer at their doorstep and is expected to create huge demand in the days to come. Easy access and convenience factors associated with e-pharmacies are very much helpful for not only old and sick, but also for rural population who have to travel for buying medicines. Indian pharmacists have a responsibility to make the e-pharmacies professional and ethical in its activities.

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