National Consultation on the Role of Mobile Technologies in Healthcare Delivery in India

Conference Proceedings Report

30th May 2015, Hall 1, IC&SR Auditorium (IIT-Madras)

Organized by the Centre for Technology and Policy (CTaP), IIT-Madras in collaboration with the International Union Against Tuberculosis and Lung Disease (The Union)

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We consider it a privilege to have had the benefit of the expertise of a range of speakers and participants and we sincerely wish to take your valuable inputs forward in suggesting suitable regulatory measures for the mHealth market in India in our report.

Thank you for your time and support.

Programme Schedule

09:30 - 09:45 - Opening Remarks: Dr. V.R Muraleedharan

Introductions by the Speakers

Session I: Role of Women as Frontline Mobile Health Workers

- How important are FHWs as carriers of new technology in medicine, particularly mHealth?
- What have been the past experiences with women FHWs in mHealth interventions- positives, challenges and learnings?

Chair: Dr. Kamakshi Kartik, RVRHC

09:45 - 10:00 - Dr. Regi George, Tribal Health Initiative [Sittlingi]

10:00 - 10:15 - Mr. Sandeep Ahuja, Operation ASHA [Delhi]

10:15 -10:30 - Dr. Nirmala Murthy, Project DRISTHI [Foundation for Research in Health Systems, Bangalore]

10:30 - 10:45 - Ms. Deapica Ravindran, Rural Technology and Business Incubator [Chennai]

10:45 - 11:15 - Discussion

11:15 – 11:30 - Tea Break

Session II: Doctors, Physicians and mHealth

- What is the connection between doctors/physicians and new medical technologies?
- How can we integrate this technology into the overall health system and what would that mean for health professionals?

Chair: Dr. Nirmala Murthy, FRHS

11:30 - 11:45 - Dr. Kartik Kalyanram, Rishi Valley Rural Health Centre [Madanapalle]

11:45 - 12:00 - Dr. Praveen Birur, Oral Cancer Screening Programme, [Bangalore]

12:00 - 12:15 - Dr. Praveen Devarsetty, SMART Health [The George Institute for Global Health, Hyderabad]

12:15 - 12:30 - Dr. Prasad, International Union Against Tuberculosis and Lung Diseases [Delhi]
12:30 - 13:00 - Discussion

13:00 - 14:00 - Lunch Break

Concluding Session

14:00 – 15:30 - Round Table on the Concerns of mHealth in India- Issues of Privacy, Medical Liability, Physician Compensation, Inter-Operability and the need for overall Regulation

Panelists may speak on one or more of the following issues: Each speaker may speak for about 10-15 minutes.

What should be the role of state in mHealth market? What kind of regulatory issues are we likely to witness in the Indian context? Will we have a body paralleling the FDA? Is it at all possible to have a fully regulated market? How can public-private partnerships enhance the potential of mHealth technologies?

Chair: Professor G. Venkatesh

14:00 - 14:15 - Ms. Lillian Olson, Dimagi [Delhi]
14:15 - 14:30 - Dr. Kamakshi Kartik, Rishi Valley Rural Health Centre [Madanapalle]
14:30 - 14:45 - Mr. Gowrishankar Nagarajan, AllChemist [Bangalore]
15:00 - 15:15 - Mr. Ram, E-Vaidya [Chennai]
15:15 - 15:30 - Mr. Sabarish, Kerala State Council for Science, Technology & Environment [Trivandrum]
15:30 – 15:45 - Discussion

15:45 - 16:00 - Concluding Remarks & Vote of Thanks

16:00 - Tea

Introduction

There is an intuitive appeal to the use of technology with regard to affordability and accessibility under the scheme of Universal Health Coverage. However, it is essential that we deliberate over questions such as: Who evaluates mobile applications? Is there an FDA equivalent? Do we have the capacity to develop such a regulatory framework? We have a multiple layered complex health system. There is a parallel organic connection with mobile technologies that is developing. How is infrastructure encouraging a connection between the two? These are questions we seek to address during the course of this Consultation.

Session I: Role of Women as Frontline Health Workers

- **Dr. Regi (Tribal Health Initiative, Sittlingi):**

  - The Tribal Health Initiative is situated in Sitlingi (Dharmapuri) and is a culmination of 22 years of work. Currently, this is a 30-bed hospital with secondary care, surgery and neonatal care. The initial objective was to examine how to empower a community to look after itself.
  - **Initial Challenges** primarily include misguided beliefs, large distances and poor infrastructure and lack of motivation among health workers to penetrate such forest interiors among several others.
  - Tribal girls, then, had education only till 8^{th} std. Now educational facilities permit education till the 12^{th}. A residential training program was provided at the hospital for 2 years. The tribal girls were trained to look after hospital work and community health. In case of segregation of such health workers, there was a high possibility that this could perpetuate the caste system. One of the major drawbacks here was that these workers could not make a reasonable impact on the field.
  - Further, it was decided to train villagers as health auxiliaries and this was prior to the introduction of ASHAs and the Muthulakshmi Scheme.
  - The first mobile health project in this area was taken up in the Kalrayan Hills. It was a research project that looked at how health workers follow protocols and which one works better for respiratory care: paper-based or mobile phone based systems.

- **Advantages**: logs of work done available, symptoms and diagnosis was picturized, could be used by all workers regardless of level of education.
- **Disadvantages**: Larger concentration by HAs on the application than patients, having been developed in the USA pictures and messages unsuitable for a tribal population, no use of common sense in the presence of protocols
- The second project was an attempt to shift chronic care to the villages. Such chronic diseases are largely a genetic problem and not a lifestyle disorder. There is minimal/no treatment because of time and distance. The HAs were equipped with tablet devices that could upload real time data concerning BP and prompted them to follow protocols. This was aimed at ensuring better adherence to drug delivery and intake. Lack of Internet connectivity in the field requires HAs to sync the data after returning to the hospital.
- The third research project with FRHS encourages tribals to identify local herbs in their fields, which are validated by Ayurveda and bring it back into the system. The objective is to introduce a 4^{th} tier into an already established 3-tier health system. The concept of 'Pharmacy in the backyard' is to address reluctance amongst tribals to visit the hospital for drug purchase. In the dry season, of the 306 herbs identified, 186 have been medically validated. Mobile phones have been made available to upload data regarding the same. There were too many technicalities. Plus, the fact that volunteers (MA/BEd educated) were poor on spellings, drop down boxes were introduced to ease the process.
- **Observations in mHealth**: Health workers are more tech savvy, many such apps decentralize healthcare, need for reminder systems, real time uploads as useful for monitoring, divide in terms of health systems over connectivity and need to suit apps to local contexts. **Is it okay to compromise on the art of human healing by embracing technology?**

- **Mr. Sandeep Ahuja (OpASHA)**

- **Issues** include dealing with informal health workers-taking away their patients, problems of stigma (with TB, Hemophilia) and the need for long-term or lifelong care
- The objective here was to fill the gaps in govt. programs and correct market failures in the private sector through community empowerment and substantial use of technology. This ensured the use of local people only who bring in great socio-cultural assets with them and a pay for performance scheme only. In urban areas, work involved the local micro-entrepreneurs.

- Problem of huge distances was overcome by HWs going around to provide counseling, dispense medicines and picking up samples for treatment in urban areas.
- This initiative involves the use of 3 technologies, namely: **e-compliance** – entire data collected on tablets, backend development of summary reports, **e-detection** – used for mental health, hemophilia and TB, standard logarithm provided by medical association loaded on tablet, answers fed into tablets and algorithm decides counseling type, HWs can work out all symptomatics in a village, **LabAlert**: no automation in govt labs, tablets mimic govt manual lab registers, cuts out delay in transmission and loss to follow up
- **Advantages of such technology are aplenty, namely**: reduction of costs, high detection rates of 70% against national rate of 50%, use of minimal text and mostly pictures developed by American Film Company and approved after use in tribal areas (use of triangle and circle not oval, different colors), potential to be disruptive technologies even in high-income countries, technology alone isn't enough-need for it to be intuitive and tied into processes, need to account for over and under diagnosis, e-receipt system: SMS sent to beneficiary on receipt of medical device/equipment (like reading glasses), entire account keeping of incentives which triggers emails to finance dept. Receipt sent to beneficiary.

- **Dr. Nirmala Murthy, FRHS**

- The primary goal behind introducing a mobile technology was the simplification of paper-based records for ANMs, assist ANMs in reducing their burden and prepare monthly reports. Information systems with names of the target population were easier to sort and handle. This was inserted into DRISTHI. The use of PDAs decentralized the data collection processes
- The aims of **DRISTHI** were to reduce ANM's paperwork, automated report generation, improve use of data and continuum of care. The evaluation here doesn't concern how well the technology works, but how well the health outcomes have changed.
- Through this, 35 registers reduced to 5 digital registers and colors were used to indicate period of pregnancy
- However **functional issues** surfaced, such as: forms are too slow to open (2-205 seconds), tablets malfunction, poor network, forgetfulness in carrying chargers, issues of synchronization among several others.

- With 85% functionality, the question that was looked into was over why such complaints arise? This is because the data collected is eligible for supervision and can be screened for duplicity. ANMs have huge workloads. This is one out of the 10 programs they deal with. Data collection is not their priority. Also, there is the need for real-time uploading.
- Comparison of DRISTHI and MCTS data of the same district and period shows that the number of deliveries reported under government-initiated MCTS is around 40% and DRISTHI is >55%. Women who reported anemia came to 54% under MCTS and 100% in DRISTHI. TB-23% and 39%. Why this difference? There is no duplication of efforts.
- With further improvements, DRISTHI could better support MCTS. We could get a clearer picture of how many women received 100 IFA tablets with a dashboard.

- **Ms. Deapica Ravindran, RTBI**

- The mobile health initiative is the Antenatal and Infant Monitoring Program in collaboration with CMC Vellore with a target population of 800 pregnant women.
- It is aimed at improving the status of maternal and child health with a comprehensive mobile reciprocal and support system. Advisories in Tamil are sent twice a week to pregnant mothers' mobile phones and are specific to term of pregnancy/age of infant (immunization schedules). Key health events are also sent across through advisories. Yes/No messages are the prescribed format for such messages and also, permission is sought to enroll them in postnatal care.
- Health workers have access to reports. This program rests on the assumption that target population is used to the system and can use it well.
- Health workers' cell phones are mostly used for self registration of beneficiaries largely due to zero balance on the latters phones or in the event that they forget their own mobile numbers. HWs help in identifying technical glitches and these were duly reported and looked into.
- Post delivery, registration is needed again.
- So, what is the **role of a female health worker** in this? They facilitate research activities, it is easier convincing beneficiaries about the ease of use of technology with HWs who are enthusiastic and prompt, they also facilitate easy recovery from server crashes. However, HWs are advised not to give medical advice.

- The **challenges** to this form of technology include the following: training requires time, handling computer equipment and tablets needed constant improvements, need for automation of entire system and need for a reduction in dependency on HWs.

- **Summary of presentations and take-away by the Chair**: Mobile applications are the way to go but with the following emphases. With technology on one side and beneficiaries on the other, it is important to interface them clearly. FHWs are important to this. Co-designing of apps with the end-user in mind is crucial to the success of such initiatives. Attention to inputs from the field is very important to keep in mind while designing the apps. We must keep in mind the limitations. ASHAs, ANMs or FHWs, who are the interested, responsible or trainable representatives from the local communities, need to be given attention with regard to the use of this technology, training with a lot of care and investment of time. For suitable health outcomes this is imperative. ASHAs are motivated health workers and there is a need to build a rapport with them. Given the burden of work on the HWs we need to think in terms of delinking too many jobs on their cards. Whether it is a private or public initiative, we need to keep in mind the load of work on them such that any additional work would still give suitable health outcomes.

Discussions:

- **With regard to loss to follow up in TB, among migrant workers, how will finger printing assist with this? Will face recognition be a better idea?**
    - Technology has the ability to transfer patient records across countries/states. There is often stigma associated with such diseases and this doesn't help with the concept of face recognition.
    - Every technology made at OpASHA is based on standards. It takes a week to develop the interface. However, the licensing of technology is available.

- **In the DRISTHI model, how comfortable are HWs with entering text considering how small the size of the form is? Has any incentive mechanism been tested?**
    - There is an option of separate entry on Excel. Writing and spelling is a problem and does exist.
    - An incentive mechanism has not been tested since if it is given then the government will have an issue.

- Such a system should be a win-win one with the workers. Tamil Nadu's PICME (Pregnancy and Infant Cohort Monitoring and Evaluation) system is currently operational. It involves the use of PICME number for tracking and payment under the Muthulakshmi scheme. Workers who are good find it to be a plus point. There is a need for governments to think together to eliminate paper based registers.
- How does one handle migration? The first child is always at the mother's house. The real problem lies in this database and in the lack of utility because the mother is always in for complications. Because of migration, 50% of the database has moved elsewhere and this is a good excuse to not use the database. What about Aadhaar linkages? NIC databases have security problems.
  - The Thayi card does the role of Aadhar.
  - In Kerala, there is UID integration under the E-Pramaan program.

- **As the database gets bigger bio printing takes time. There is a need for id proof in this case. How does scaling up work here considering migrants don't remember anything other than their bio prints?**
  - ASHA workers are not government employees. They are more like contractors or consultants. They are utilized as the starting point.
  - Technology should be expandable and scalable. The database of fingerprints remains on the local database. A system of intermediate resolution for fingerprints is crucial. Every fingerprint is given a card with an alphanumeric code, which travels across servers.
  - In Tamil Nadu, when fingerprinting is done, it is converted into an image file (metadata) and sent to server. Hence, fetching becomes easier. Any person anywhere in TN can fetch his/her data.

- **How to address technical glitches?**
  - Often such problems can be addressed. Data loss during syncing can be minimized. **It is necessary to address the concerns of health workers with regard to tablets but at the same time not encourage too many complaints.**

Session II: Doctors, Physicians and mHealth

- **Dr. Kartik Kalyanram, Rishi Valley Rural Health Centre**

- The Rishi Valley Rural Health Centre functions as a primary health centre(day care only) providing outpatient care for BPL populations. The centre is currently conducting research on hypertension and diabetes understanding the potential for long distance medical care.
- The largest issues with respect to digital health is what happens to initial diagnosis based on observation by a physician when technology takes over instead. Diagnosis is heuristic, the doctors argue. There are multiple causal factors to disease and conditions, especially for rural populations. No algorithm can help with this.
- There is always a fear of something, mostly technology, which grows when people grow older. most often, this fear revolves around the idea that doctors might get redundant. Any technology that comes into medicine, is based on western journal data collections. There is a wealth of data available in our country which is never measured or incorporated.
- Telemedicine is expensive as it needs heavy infrastructural investments including human resources, namely the doctors and paramedics. In a primary, village setting, we need a robust platform, idiot proof which can be used by anybody. Patients love to hear their names, the human element of relation is important which needs excellent case histories for the doctors. There is a probable usage of a kiosk with a nurse and a physician.
- To provide treatment at the point where the person is, needs a strong legal framework which is currently lacking.
- Peer support groups on the phone via technology platforms are an important area for mHealth, to help with those in NCDs and chronic disease. These initiatives could maybe have a physician partake, answering questions and giving out crucial reminders and advisory guidelines. These conditions need constant treatment.
- With particular reference to the handling of technology by frontline health workers and community health staff, there should be a focus not just on training but also on testing their usage of it and then providing re-training. This cycle has to be ongoing.

- **Dr. Praveen Birur, Oral Cancer Screening Program**

  - The early detection of oral cancer is one of the biggest problems in India. Reporting is often late because of late presentation of the disease. It is usually asymptomatic, making the patient far more vulnerable to being detected when the case has worsened.
  - As per the rules, a primary health provider does include a dentist, but this is hardly true of our system. Oral cancers are easily preventable with regular oral screening. Technology has a huge role with prevention in India, particularly cancer.
  - Local empowerment is absolutely essential even in the wake of technology and the easiest way to manage this is to use ASHA workers of CHWs. Challenge is not with identification, but with follow up and monitoring.

- **Dr. Praveen Devarsetty, SMART Health**

  - There are several uses and users of mhealth technology. However, there is a need for point-of-care diagnostics and the use of mobile as a medium or mechanism.
  - The primary objectives of introducing technology include the following: Creation of registries using mobile phones by health workers, data collection and reporting. Electronic Health Records (EHRs) facilitate transfer of records, distance support systems, provider-provider communication, provider work planning and scheduling, provider training and education (developing animations which can be deployed in remote areas), monitoring and evaluation, integration of supply chain management into mobile health care system, manage medications, financial transactions and incentives
  - **SMART Health**: (Systematic Medical Appraisal Referral and Treatment in Rural India) There has been an increase in chronic NCDs over last 10 years in rural areas. Doctors, health workers and health systems are present but everyone is working in silos and there is a lack of communication between these.
  - The two workable options here were to work with the PHC, which is good but non-functional, or with a private player. The former was preferred considering its capacity can be enhanced. Here, ASHAs carry tablets and conduct a house-to-house opportunistic screening of members above 30 years of age. They record basic parameters and the tablet predicts if the patient is at a high risk of CVD or not. This is not a diagnosis but only screening for possible strains of NCDs. Referral to a doctor happens in case of a risk. The

information on the tablet is available to the doctor via servers and is referred to when the patient visits with a referral card or ID. All the data is displayed on the doctor's tablet.

- **How can we expect a PHC to measure vital parameters in 2 minutes?** So here, the doctor can use his skills and the system will also provide some provisional diagnosis and management guidelines regarding patient and drugs. Once referral check is noted in the system, the health worker ensures follow up over time. Whenever variables are greater than risk, a referral happens.
- This initiative was a pilot involving 11 ASHAs, 3 PHC doctors and three components: **Decision Support System, Risk Communication and Workforce training program.**
- The results were not drastically surprising. Only 35% visit doctors post referral. Follow up with medicines after 3 months was only recorded among 30% of those who visited the doctors. Qualitative analysis helped in behavioral changes/improvements.
- The **major issues** were as follows: An ASHAs role was in conflict with that of ANMs. ASHAs had access to tablets while the ANMs did not. Poor access to doctors (unavailable when patients go for referral visits), restricted work due to absence of incentives/entitlements, poor access to medicines were other issues.
- **Key messages**: Technology works in rural areas but there are barriers to access. Access to medicines and doctors are major systematic barriers. Adherence to recommended treatments is also a major drawback.
- **Refinements based on pilot**: Further components were added to the existing framework. Government support is now seen as an important linkage for improving PHC medicine supplies. The use of multimedia (endorsed by local MPs) on tablets is crucial for improving behavior and adherence and the recall and reminder system which is an interactive mechanism based on target BP, prioritizes patients based on risk.
- SMS reminders have emerged as the only proven successful component of mHealth for behavioral change communication. Also, doctors observe enhanced doctor decision support during drug prescriptions, wherein notifications are enabled about the effects of the drug and the need to be careful. The information is also transmitted to the HW.
- **Virtual Training Program**: HWs gradually lose interest in the program, hence they are spoken to in a group frequently. Operator can enable or mute a HW during this to encourage a healthy discussion.
- In the event that SMS reminders fail to work in rural areas due to inability to read such messages even if in local dialect and illiteracy there is a need to use the **Interactive Voice**

Messaging System. This system talks with the database and groups them and accordingly sends 30 second voice messages. There are monitoring mechanisms to check the number of calls and screening processes and to check work schedules of the HWs.

- Issues largely revolve around that of ***Pilotisis***. The Gartner Hype Cycle demonstrates the expectations from a new form of technology and its trajectory from its trigger to a peak of inflated expectations and later a trough of disillusionment.

- **Dr. Prasad, The Union**

- The first point of care/contact in several rural areas is quacks or what we often refer to as Less Than Fully Qualified. Moreover, there is a severe lack of understanding and the influence of medical representatives in the purchase of drugs and higher generation antibiotics. There is the need to bring them out of such a system. Often, Lab technicians have great level of dependency weighing down on them and hence the need to regulate them.
- The objective here was to bridge the first point of care with the health system through an application called CommCare that performs all diagnosis and ensures adherence. With private practitioners as end-users, doctors for rural patients, and a public health system for treatment, this initiative aimed at bringing these two together.
- Of the many hands-on rural health care providers or RSVPs visited, only a few were interested. Even after having filtered 60-70 there were dropouts post intensive training. This system was integrated with the lab. It was recognized that repeated messages for referral is necessary.
- Problems with motivation and attitude were dealt with constant one-on-one personal interactions to increase referrals and suggestion to not prescribe higher generation tests and antibiotics for TB. A major issue was the use of phones by practitioners/RSVPs for personal purposes such as downloading of other apps like YouTube. Lots of advocacy was resorted to to respect the contributions of RSVPs and their referrals. Simplification of tablets and menu options and the supervision of workers were also undertaken.
- A DOTS module was also adopted within the app. Every time the results flash on the mobile, there is a need to start providing DOTS. This records every time a dose is taken and automated SMSes and IVRS go to various people if a dose is missed. If another dose is missed volunteer will extract patient out of community and ensure compliance.

Essentially, a Closed Loop was created. There is constant monitoring via CommCare server and problems of Internet connectivity have almost been overcome.

- Multimedia content like videos and quizzes were prescribed for RSVPs and early diagnosis and treatment adherence were identified as the focus of the app. Any mismatch generates an alert. It is necessary to realize that the incentive for RSVP is not the mobile phone and recharges which are postpaid. Incentives are soapboxes, toothbrushes and such items. Biggest challenge is that of acceptability. An oft-quoted reason for postponement is that 'We will refer tomorrow not today'. High-end diagnostics is seen as market driven.

- **Discussions**

- **Do you see a difference as to how health consultants look at mHealth and how physicians view it?**

  - Government regulations do not allow for such forms of technology
  - Issue as a specialist is that one does not know patient perspectives. However, one cannot deny that in the end, one can concentrate and reach a larger population with just one worker as a point of contact. This gives a lot of sensitivity to patient problems and a lot of variability in opinions.

- **Is there something like brush cytology that can be done and reports be uploaded such that patients approach hospitals with a definitive and specific diagnosis and not nonspecific diagnosis and again undergoing a biopsy and treatment?**

  - After cytology and upload a pathologist confirms if cell is atypical or typical. This creates a referral pathway. A physician is often okay with a photograph and does not need an additional procedure.
  - There is an ongoing debate on brush cytology. For oral cytology brush must be deep and this is difficult. The objective here is to make the patient move out of his/her comfort zone. Once they come to clinical care or a nodal centre it is easy. We don't need a high-end technician to do such things. There is a need for low skilled people. Photographs are more convenient.

- All this technology is disruptive and challenges do arise from the govt, MCI and WHO.

- **Who were the FHWs in Biocon?**

  - Fresh recruits are out of the system. Basic criteria as education or age?
  - There is a call out for volunteers from rural areas. Most of them are 10th pass to degree holders. They are in direct control and paid directly, hence are working well. Earlier, there was an attempt at the integration of 7 dentals schools and it was realized that the govt is poor on data collection even with incentive based mechanisms in place.
  - In the program currently operational, the recruits are subject to a training program with a specialist on site.

- **Do you expect a sustainable model where clients pay?**

  - There is a need for good point of care diagnosis. Priorities vary across NCDs. Cancer being a lifestyle disorder is given low priority.
  - Over diagnosis is necessary to get them out of comfort zone.

  - Photograph will be more than sufficient. With local skills at use, it is difficult to conduct brush cytology and this requires minimum infrastructure for screening purposes. **Eventually, how do interactions with community and family further ensure compliance to treatment and improve diagnosis?**

PANEL SESSION

- **Ms. Lilian Olson, Dimagi**

- Dimagi does not produce telemedicine or diagnostics, but produces job aids for service delivery, largely for healthcare.
- The company is based out of Boston and was started by MIT graduates The technology is open source, motivated by the company's principle that learning is shared; the use of the tech is free up until 50 users, following which it is prices at 1 dollar per user.
- Products available are of three kinds- *CommCare*, which doesn't need any coding experience, can be used by anyone, similar to survey monkey, tracking patients over time, *CommConnect*- IVR and SMS and *CommTrack*- supply change management. The applications are used by ASHA workers for counselling of best practices and data collection/analysis. The CommCare platform uses image, audio and video display, cloud storing, data collection, supervision. Its ready to go and depends on the the party's idea on what questions are trying to be answered. The App can be made in a matter of weeks after this decision of what it is being used for is certified.
- The design format used by the company is called 'under the mango tree', indicating a completely user designed element where the reactions from users is a core part of the offering. Dimagi wants the platforms to be easily accessible, making people to use the software.
- Dimagi currently operates in over 40 countries with over 100s of different partners, which has helped in understanding much from these initiatives for the future of mHealth policy. Public Private Partnerships are important for lesson sharing, teaching ideas and observations revolving around what needs to be thought of in terms of resources, human and otherwise.

Main concerns regarding regulation- Although there is an explicit mention about the National E-Health Authority or NEHA in the chapter on ICT and development drawn up by the Government, there is little clarity on the role of this body. The particular points to be addressed include the following:

- Unified national health card- how will we integrate databases and systems?

- Holistic approach to public health- departments/ databases on energy, sanitation, education, environment, nutrition all need to be linked. Are they?
- Upgrade of health centres with ICTs- places that could benefit from ICTs are those with poor infrastructure. Handheld tools in place of paper entry, now it's a supplement and not the norm. They need training, not just the instrument. We need capability.
- State as a provider of guidelines- standards for data, technology, coding as well as the need for supervision of basic human resources. There is the need for supervisory staff on the payroll to help with the CHWs.

- **Mr. Gowrishankar Nagarajan, AllChemist**

- The main aim of AllChemist in the long-run is to enable every Indian to access health products, health data on their mobile phones, including having access to medical history, diagnostic records on the phone. The idea ultimately to go paperless is the long term vision for healthcare in India.
- The initiative began by piloting with pharmacies, drawing up a platform to connect existing pharmacies onto the mobile market, using the marketplace model. The name of the App, as it suggests, connects all chemists, from where it is possible to order medicines and avail home delivery in a two hour window. The App also allows for doctors to send reminders on when the medicine is to be taken. It intimates the user on when the supply will run out and must be renewed, validating prescriptions done by a team of pharmacists.
- The current regulation on pharmacies and drug dispensing is based on a law in 1940, which doesn't allow for online retailing of medicines. Schedule H and X drugs cannot be sold without prescription, for H1 it needs a register to be maintained at the pharmacy and for the X drugs, there needs to be two copies of the prescription-one with pharmacy and one with patient. License to sell drugs is given to someone with a BPharm degree from a 10*12 shop, as per current regulation. Also, the license restricts the place of sale to the shop, now allowing for home delivery of medicines is not legally allowed as per legislation.
- Doctors are supposed to prescribe generics, but sometimes give branded medicines. In this case, pharmacists aren't allowed to suggest alternatives. Now, with increased awareness, consumers look for alternatives, even for savings. The curious case of drug delivery in India, is that people are not finding medicines at pharmacies and hoped to source them on the platform.

Main concerns regarding regulation-

- How do we validate prescription, especially in the case of chronic patients? It lasts only for 6 months and the prescription needs to be renewed after a check up. Right now, it is an expiring link to the pharmacy that is sent, valid for two hours. However, as the App scales up, how is this to be tackled?
- App wants to take information from pharmacies for EHRs as they already maintain an electronic billing system. This way, the record of which medicines are being bought most and used is easily accessible. Many questions arise about how EHRs can be constructed and maintained, especially with regard to privacy, sharing and storage.
- Can a digital image of a prescription be considered a legal document based on which medicines are then dispensed? This is the biggest question for any online pharmacy platforms.
- One of the biggest loopholes is that India does not have unique tracking of prescriptions, like barcodes in the US. These allow for the for the double dispatching of drugs, to the patient/customer as each pharmacy will not know if the drugs have been purchased elsewhere.
- The App hopes to work on a Market-Place Model, where it offers the drug prescription to five local pharmacies in the area, who then compare stocks and suggest the most competitive prices. However, can this document be given to 5 different pharmacies? Can they store it? These questions have not been addressed and impinge on the areas of legality in terms of privacy and medical record/history?

- **Mr. Ram Kadambi, E-Vaidya**

- The company commercially supports the private sector and government with telemedical consultations with physicians. The telemedicine/mHealth market is incipient and the laws are archaic. This is perhaps the biggest conundrum in this sector.
- It started as an online doctor portal, exclusively for IT companies. It was meant to be a corporate wellness initiative, until Saidai Doraisamy, a minister in Tamil Nadu, saw it and suggested that it be used for rural people due to the skewed ratio of physicians to patients. Specialists from Australia were accessible thanks to this initiative in the slum settlement of Kannagi Nagar in Chennai. It almost functioned like a multi-specialty clinic, although virtually. The company has developed a small box as a tool kit, which keeps all the

needed apparatus such as an ECG and other equipment in it. This box can then be connected with a LAN, dongle or any other method of connectivity and be fixed to a TV, giving connectivity to the doctor at the other end.

- Other than touch, the doctor can hear, see the fundus of the eye and enjoy high levels of inspection. Recently, ultrasounds have also been put in.
- The system constantly keeps pooling in the data, which can then be analyzed. The doctors wanted to use basic data to make an EHR, including pictures progressively. Questions about drug efficacy are something they hope to answer. Making population comparisons across spaces and time is what the data allows.
- The data has helped with predictions on malaria, dengue to an extent as well as IVF estimates based on captured data.
- The system was designed as a mobile App, but the pilot site in Vijayawada taught them that nobody had a smartphone, which could be the case in many other remote parts of the country. The access methods should thus be brought down to the lowest level of phones, including the Nokia basic phones. Whatever prescriptions are generated is now translated into a text message and sent to the recipient. The people loved it and it worked well. A reminder system was also included whereby the phone gave you a beeper if there was a reminder to take the tablet. This was a timer system. The SMS was the biggest success. Medicines also given with images- sun/moon to indicate what time and pictures of food to explain before or after.
- Doctors feel better to write prescriptions rather than typing out, as has been observed. This resistance should be adequately considered before the system of going paperless is developed. This is also true for patients who feel psychologically better when they receive a sheet post being checked. Thus, E-Vaidya prints prescriptions, with a photo of the doctor, digital signature as well as the MCI number and the vitals. Big hurdle in telemedicine is that the doctor has to prescribe in front of the patient. The legislation allows for telemedicine even though it does not explicitly say so, as long as there is some visual media. Thus, use of the television for the same.
- All medicine inventories is loaded onto the system and the doctor picks from these options what to prescribe, based on the availability in the location. This inventory is regularly updated. Thus, procurement can also be tracked, avoiding expiry.
- Doctors have access to data through some medium; however, there is an no confidence in what the regulation is for the same? Currently, the nurse does patient history. Doctor

reinforces this dialogue with the patient. The paramedics do this at E-Vaidya and the data is captured on the system and the doctor can see it. There is no clarity what the law is for the same.

- A recent project involved health advocacy virtually with a physiotherapist from Hyderabad, working with Amma canteen workers in Kannagi Nagar suggesting methods for controlling hypertension, diabetes and other NCDs through fitness, diet and exercise. This also encouraged regular monitoring of their own vitals.

Main issues of regulation-

- Standards are essential, but this part is still vague in mHealth data, as we have no prescribed standards either nationally or internationally. Kerala hopes to begin this journey by using the HL7 in their latest initiative.
- Telemedicine Authority in India and the Indian Medical Association share an ambiguous because it doesn't certify whether telemedicine can be done or cannot.

- **Mr. Sabarish.K, Kerala State Council for Science, Technology & Environment**

- The Government should be a facilitator rather than a regulator in mHealth. The mHealth space has three layers- services, platforms, products. The government's role is to facilitate platforms, which then help with products and services.
- The technological ecosystems harnessing these new fields of technology require huge infrastructural investments. It also needs collective interlinks between the various providers.
- Unlike the Internet, which is free and open, mobiles become a private space. Hence, it is highly regulated. For instance, in terms of bulk SMSs, TRAI stepped in. The various telecom operators are also looking to be competitive and make profits, which is also one of the features of cellphones being a private economic space.
- Integrated platforms with geographical, mobile and Internet technologies combining, for instance, discussing an epidemic break would be an ideal area to strive for. Crowdsourcing options like USHAHIDI, an open source system could be extremely helpful.
- Data Sharing- NDSAP, data sharing policy, departments started putting open data online. In Kerala, this has started being utilized under the overall banner of e-Governance, where

different departments share their data. However the rules need to be specified for the different stakeholders.

- One single EHR accessible on a national basis, this would be the ultimate aim of NEHA or National E-Health Authority. Kerala has begun working towards this scheme and intends to roll it out soon.

Main issues of regulation-

- Even the FDA in the United States, with perhaps one of the most progressive digital markets, is finding mHealth App regulation extremely difficult. The cases of prank Apps and others unsafe require a body to prescribe and administer standards. This could possibly be NEHA for India. Our country also has no ruling similar to the HIPAA, addressing privacy concerns. It might be an idea to have one. The IT Act of 2000, amended in 2008, talks a small bit on data privacy. Medical records need explicit data protection legislation and privacy codes.

- **Discussion**

- Tests done by ISI labs should be valid to quash incentives that doctors and laboratories earn when they insist on tests from various labs. We need a regulation for this as it impinges on data sharing. In theory, NATL certified lab results are valid for 6 months theoretically, according to legislation. This needs to be implemented. It is important in terms of OOP expenditures as well as data sharing and one EHR.
- How can we make kiosks and anytime Medicine work in terms of drug delivery?
- What does the Law dictate in terms of various tiers like ASHA workers, CHWs delivering medicines?
- What happens with WhatsApp, SMS and email consults and drug prescriptions, what is the definition of a legal drug prescription in the wake of technology?
- Technology in place of a doctor, considered a wholesome replacement, ignores the spirit of the human, reducing him to become but a physical statistic of his disease. Only human contact can help with this and hence doctors can never be done away with, despite our advancements with technology. This should never be forgotten.
- App developers should not be solely driven by data. They have to keep in mind what patients feel about it, what doctors feel about it and the paramedics involved.

SPEAKERS & PARTICIPANTS IN THE CONSULTATION

Speaker	Organization	Email-ID	Contact No.
Dr. Nirmala Murthy	Foundation for Research in Health Systems	murthy.nirmala@gmail.com	9448116094
Dr. Kartik Kalyanram	Rishi Valley Rural Health Centre	rvsrhc@gmail.com	9701733913
Dr. Kamakshi Kartik	Rishi Valley Rural Health Centre	rvsrhc@gmail.com	9440236821
Dr. Regi George	Tribal Health Initiative, Sitlingi	thisittilingi@gmail.com	9488344325
Dr. Praveen Birur	Oral Cancer Screening Program, Bangalore	praveen.birur@gmail.com	9845136960
Dr. Lilian Olson	Dimagi, New Delhi	lolson@dimagi.com	9599753427
Dr. Praveen Devarsetty	SMART Health, West Godavari	dpraveen@georgeinstitute.co.in	9959777623
Dr. Prasad	The Union, New Delhi	bmprasad@theunion.org	9999296958
Mr. Sabarish K.	Kerala State Council for Science, Technology and Environment, Trivandrum	sabarishtvm@gmail.com	9447811556
Mr. Sandeep Ahuja	Operation ASHA, New Delhi	sandeep.ahuja@opasha.org	9310298004
Prof. G. Venkatesh	IIT-Madras	gv@ee.iitm.ac.in	9962580831
Mr. Ram Kadambi	E-Vaidya, Chennai	ram@evaidya.com	9500041219
Ms. Deapica Ravindran	Rural Technology and Business Incubator, IIT-Madras	deapica@rtbi.in	
Mr. Gowrishankar	AllChemist, Bengaluru	gowrishankar.nagarajan@gmail.co	8861086219

Nagarajan m

Participant	Organization	Email-ID	Contact
Dr. Soumya Swaminathan	National Institute for Research in Tuberculosis, Chennai	doctorsoumya@yahoo.com	
Dr. Sriram Selvaraju	National Institute for Research in Tuberculosis, Chennai		9600479021
Dr. Dina Nair	National Institute for Research in Tuberculosis, Chennai	dinanair73@yahoo.co.in	
Dr. Padmapriyadarsini	National Institute for Research in Tuberculosis, Chennai	pcorchids@gmail.com	
Dr. M Muniyandi	National Institute for Research in Tuberculosis, Chennai	mmuniyandi@yahoo.com	
Dr. Muthu Ramalingam	IIT-Madras	muthudr123@gmail.com	
Dr. Mohan Kumar	Department of Public Health, Tamil Nadu		9790878976
Mr. N. Mani	Department of Public Health, Tamil Nadu		9003046878
Dr. Manivannan	Department of Public Health, Tamil Nadu		9444174891
Dr. Lakshmi Murugan	State TB Officer, Revised National TB Control Program		
Dr. N. Rajeev Roy	Tamil Nadu Health Systems Project, Chennai		
Dr. Amenda Tampoe Samuel	Tamil Nadu Health Systems Project, Chennai		9445030715

Dr. Tarun Bhatnagar	National Institute of Epidemiology, Chennai		9962180594
Participant	**Organization**	**Email-ID**	**Contact**
Dr. P. Manickam	National Institute of Epidemiology, Chennai		9444030527
Dr. Viduthalai Virumbi	National Institute of Epidemiology, Chennai		9894726160
Ms. Nupur S Gunthe	Rural Technology and Business Incubator, IIT-Madras		8939734979
Ms. Karthika Narayanan	Rural Technology and Business Incubator, IIT-Madras		8939114746