Exchanging Health Information:

Setting an Interdisciplinary Research Agenda

Based on deliberations initiated at the seminar sponsored by the
Radcliffe Institute of Advanced Study at Harvard University
September 22-23, 2016

Cover Graphic: Network map of health data flow from paper records to consolidated databases, from the sub-center level upwards.

ACKNOWLEDGEMENTS

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EXCHANGING HEALTH INFORMATION:
SETTING AN INTERDISCIPLINARY RESEARCH AGENDA

In September 2016, the Harvard South Asia Institute, with support from the Radcliffe Institute of Advanced Studies, organized the two day seminar, Exchanging Health Information: Setting an Interdisciplinary Research Agenda. This report contains a summary of the seminar deliberations and a roadmap for prioritizing research and policy formulation for health information exchange in India.

The Seminar brought together experts in medicine, computer science, data science, public policy and law to identify a research and policy agenda that addresses implementation barriers to health information exchange. (See Appendix 1 for a complete list of participants). Building on international standards in health systems interoperability and learning from best practices from other industries, seminar exercises employed India as a use-case to anchor deliberations.

The Seminar follows a series of events on the Harvard campus focused on health information exchange and the role of mobile and cloud based technology in leapfrogging medicine and public health delivery in India.

In 2014, with support from the Radcliffe Exploratory Seminars fund, Harvard SAI hosted the Using Cellphones to Change Societies seminar, to discuss ways in which cell-phones would impact economic and social mobility in South Asia, with a focus on healthcare delivery and quality. A dominant and recurrent theme through the seminar was that the often

primitive construct of healthcare data collection, storage, and interpretation, limited meaningful data exchange or application -- hampering research, clinical care and operations.

The 2014 seminar laid the groundwork for a continuum of related inter-faculty research and educational initiatives at Harvard, including SAI's Annual Symposium panel, "Mobile Technology to Access Healthcare Services: Case Studies from the Global South" (April 2015); the book launch of "Kumbh Mela: Mapping the Ephemeral Megacity" in Cambridge (April 2015) and Delhi (August 2015), where several chapters were dedicated to research utilizing cellphone data and cloud-based healthcare analytics; the Using Mobile Technology to Change Societies Undergraduate Summer Program sponsored by the President's Innovation Fund for International Experiences, where Harvard college students studied the implementation, growth and future potential of mobile technology to enable social and economic mobility in India (http://goo.gl/nWG5Fm); and the 2015 Nashik Kumbh Mela Real-time Disease Surveillance Project in collaboration with SAI, Unicef and the government of Maharashtra culminating in a successful implementation of mobile surveillance systems for mass gathering medicine (www.HarvardSAIKumbMela.com).

The Exchanging Health Information Seminar was conducted against the backdrop of several related initiatives in India. In August 2013 and again in December 2016, India's Ministry of Health & Family Welfare (MoH&FW) released a set of highly developed recommendations for electronic health records that outlined key components of a standardized healthcare information ecosystem and a common language for organization of medical

terminology and data.[1] The document recommends the adoption of various relevant standards in interoperability for health information exchange, including, "Systematized Nomenclature of Medicine (SNOMED-CT)[a] and HL7[b]. In addition to the Ministry's report, we include here other key developments.

The MoH&FW has proposed the institution of a National eHealth Authority (NeHA) (or National Digital Health Authority (NDHA)), through an Act of Parliament. It will be the regulatory and standards setting body tasked with overseeing the digitization of health information. The NDHA will work with public and private stakeholders to promote the adoption of eHealth plans. The NDHA will continue to inform and make recommendations on the dynamic Electronic Health Records (EHR) Standards for India laid out by the MoH&FW, supporting standardized and consistent data collection and aggregation at local, state and central levels. NDHA will also create the architecture needed for implementation of e-Health stores, Health Information Exchanges and the National Health Information Network to facilitate the sharing and exchange of health data that is done with patient privacy, security and confidentiality in mind.

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[a] SNOMED is a systematic, computer-processable collection of medical terms, in human and veterinary medicine, to provide codes, terms, synonyms and definitions which cover anatomy, diseases, findings, procedures, microorganisms, substances, etc.

[b] Health Level Seven International (HL7), founded in 1987, is a not-for-profit, ANSI accredited standards developing organization "dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services." Its Indian counterpart, HL7 Healthcare Standard Institute (HL7 India), is an independent, non profit-distributing, membership based organization that exists to encourage the adoption of standards for healthcare information communication within India

In December 2016, the Centre for Health Informatics (CHI) released a Request for Proposals for the creation of an integrated health information platform (IHIP) that will have a health information exchange (HIE), built around a central storage repository.

PROBLEM STATEMENT

Health information storage in India is extremely diverse. Most clinical encounters go undocumented or are poorly documented. The majority of recorded data are stored and transferred on paper, and their validity has been questioned. Electronic health information systems are largely restricted to databases of consolidated health indicators like Mother and Child Tracking System (MCTS) or District Health Information System (DHIS) in the public sector, or hospital based EHRs in a handful of large private sector enterprises where physician uptake has been limited. While this patchy ecosystem of largely absent health information data in India posits a formidable challenge to building out an effective exchange, the ubiquity of recent mobile networks and broadband provides a greenfield for bold, innovative solutions unencumbered by expensive legacy systems.

The Seminar explored two broad sets of questions:
1) What are the global best practices for efficiently and safely exchanging digital health information?

2) What are the technical and policy barriers in creating effective health information ecosystems in emerging economies? And in India, in particular? (What further research is required to answer this question or to address potential solutions? What role can an interdisciplinary team from Harvard play?) What would be the benefits and risks to patients, clinicians, researchers and payers?

THE STATE OF HEALTH DATA EXCHANGE

EHRs have traditionally been closed systems with little to no ability to share information across platforms. Health information is also generated and stored by hospital billing, legal and operations departments, pharmaceutical companies, device manufacturers and insurance providers. Yet patients, providers and researchers have long struggled with gaining timely access to data. A substantial portion of the individual and population data collected today remains inaccessible due to, in large part, legitimate privacy concerns, risk-averse administrators, and inertia.[2,3] The lack of standardization among data storage systems makes it virtually impossible to combine and collate data from multiple sources, resulting in duplication, redundancy, wastage and delays.

In recent years, additional individual and population health data have been generated by wellness gadgets (like Fitbit); web-enabled diagnostic devices (like AliveCor); patient-facing apps (like Stanford Healthcare); provider-facing apps (like Practo); or researcher-facing apps (like Apple's Research Kit). Each of these "apps" and "gadgets" create their own silos of health data. Exchange between these apps and between apps and databases and EHRs is, with very few exceptions, nonexistent. The problem is compounded manifold when records are not even digitized.

The call for universal compatibility and portability has come from many quarters. The need for clinicians to have secure access to patient data is obvious. The reluctance to make de-identified data available to researchers has stymied efficacious time-sensitive operational and clinical analysis.

Entrepreneurs and provider networks have responded to this need for data portability (and the potential for monetizing vast amounts of data) by creating their own ecosystems.

Additionally, there are now over 165,000 mHealth apps, of which 90% are free. Ten percent of mHealth apps can connect to a device or sensor that provides physical function data.[4] Global revenue projections for mHealth apps in 2017 are in excess of $26 billion.[5] Most of these mobile health apps promise compatibility between components within their system but not across systems, and may therefore result in larger but still isolated silos.

The US Experience

In the United States, the Affordable Care Act recognized these challenges and mandated that health information systems be digitized and allow for interoperability and exchange. This expensive and retroactive fix focusing on public-private partnerships is expected to take several years and health systems across the country, especially smaller sized practices, are struggling with implementation. Some states have been ahead of the curve and have proactively experimented with health information exchange, with limited success.[6]

Successful interoperability will rely on widely adopted standards of communication among health IT systems. SNOWMED ensures standardization in meaning and vocabulary, while HL7 enables health records and exchanges to be built with common architecture and structure. FHIR which builds off HL7 standards provides data formats and resources

for building application program interfaces (APIs) for facilitating exchange. Companies such as TrueVault and MuleSoft are leading an ecosystem of secure, HIPPA compliant ready-to-use APIs.

In late 2015, the FDA launched PrecisionFDA, an online cloud based portal to "allow scientists from industry, academia, government and other partners to come together to foster innovation and develop the science behind a method of "reading" DNA known as next-generation sequencing (or NGS)." Precision FDA follows the OpenFDA initiative that gives researchers access to FDA's large public datasets.

In March 2016, National Institutes of Health (NIH) in collaboration with the Office of the National Coordinator for Health IT announced the launch of the Precision Medicine Initiative (PMI) Sync 4 Science (S4S) program. This pilot program seeks to allow individuals to access their health data and send it to researchers. The program will build off existing community standards and specification efforts, including FHIR, SMART Health IT, Argonaut, and CMS EHR Incentive Program, to give patients an easy way to share their health data with researchers. The greatest challenge that this initiative will face is likely to be individual and collective concern over data security and privacy.

THE CAUTION WITH EXCHANGE:
PRIVACY CONCERNS AND LEGAL PROTECTION

The benefits of interoperability and the potential for solving health issues at scale using machine learning, big data and standardized systems are clear. The challenge is to engineer health information exchanges that provide medical benefits without compromising data security, user privacy and other basic rights like inclusion, agency and autonomy.

Emerging research highlights the risks of data-driven or algorithmic decision-making.[7,8] Technology is not neutral, and most systems encode values and biases, however unconscious.[9,10] Biometrics, which systems rely on for identity verification, have been shown to have higher error rates (false positives and false negatives) for darker skin tones and eyes. Data mining, even of anonymized information, can reveal very sensitive data. Insurance premiums (in a less regulated healthcare system), for example, can be modified based on zip codes, browser history or seemingly unrelated shopping habits.[11,12]

Emerging economies often lack dedicated privacy laws, relying instead on a patchwork of consumer protection laws, telecommunications statutes, human rights provisions and other measures to tackle data breaches, privacy violations and constitutionally protected rights to equal treatment. However, as government welfare and benefits are increasingly delivered through online platforms on the backs of newly digitized databases, there is a need to ramp up the legal infrastructure in parallel.[13] This need is

critically felt when examining the ability of (digitally) illiterate users to provide informed consent, and to exercise control over valuable data.

Yet, physicians, providers and researchers continue to desire (and demand) easier data access and portability. The "internet of health things" has been imagined by many, but begs to be constructed. And when conceived, it must keep privacy and data security concerns in the forefront.

The Seminar examined ways to mitigate these risks, as well as think creatively about business and policy incentives that have privacy and security as part of the design of an HIE. Collecting and storing data is as much a burden as a benefit, and the more the issues around responsible data ethics are mainstreamed, the better for all stakeholders. By engineering interoperable systems that are designed to protect and empower users by offering them control and discretion over data sharing arrangements, one can optimize the benefits of exchange without compromising privacy or security.

CAN LESS-DEVELOPED HEALTH INFORMATION ECOSYSTEMS BREAK THE GRIDLOCK?

mHealth technology has served as a leapfrog vehicle to expand healthcare services in emerging economies where personal computers and fixed-line phone connections may not have enjoyed universal market penetration, but where mobile devices are ubiquitous. This fertile ground in the contemporary developing world posits a unique opportunity to create a backbone for national HIEs. Still, major questions remain: Can one develop an ecosystem where patients always have access to their health data, irrespective of their source of origin? Can providers access data across systems? Can providers and patients pool data from multiple media and sources? Can researchers access de-identified data easily? Can databases be queried across different systems? Can such big data be available more readily? Will such big data advance public health and the medical sciences? And harder questions: What risks do we pose for individuals and populations by allowing such seamless data travel? Who owns the data? Can such data be sold? If yes, does the patient have a claim? A stake? What protection measures need to be put in place? What legislative change does one need? What legal risks do patients, providers, scientists and governments expose themselves or each other to? What will this entail technologically? Can such secure, encrypted, failsafe ecosystems be made? Is the technology available, or are we not there yet? What are the current best practices in health information exchange? What can we learn from other industries? What can countries and organizations starting learn from more advanced systems such as the US and Europe? Why did previous attempts fail? What were the barriers to implementation?

STATE OF HEALTH INFORMATION IN INDIA

Health is a state subject in India. Consequently, any discussion about changes in healthcare delivery must acknowledge the scope and limits of central and state policy making. There is wide variation in quality of care within and among states, both in the private and public sector. In India, on average, 70% of healthcare is delivered through the private sector, which encompasses state of the art tertiary facilities, nursing homes, polyclinics, general practitioners and a significant workforce on healthcare providers with no medical qualifications.[14] Thirty three percent of the world's poor reside in India, and their access to care is determined by their ability, or lack thereof, to pay for the often-limited quality services available to them. The conversation about HIEs must acknowledge these on-the-ground realities, as well as the near absence of digital health information in most clinical transactions.

Data that does exist, even in the public sector, have been collected through different, overlapping, local, state or national mandates, or dictated by the needs of sponsoring philanthropic foundations. The quality and validity of these data remains questionable. To date, despite the recommendations by the MoHFW, there are no interoperability standards implemented for data among the government's or private sector's various health related databases, resulting in vast amounts of redundant data.

This lack of implemented standards has led to challenges in accessing health data for policy making or public health interventions. The Indian Council of Medical Research (ICMR), India's foremost body for biomedical

research, for example, has limited access to vital health data captured by the private sector. The government's Revised National TB Control Program also has no ability to follow patients (or monitor their care) once they seek treatment in the private sector. Even if private sector entities were willing to share data, there currently are no mechanisms to do so. Procedural hurdles, lack of necessary human resource and skill, fear of transparency, and absence of political will ensure that whatever data are available, are seldom used for effective policy making.

International lessons have taught us that nations often look to the insurance sector for a starting point for digitizing health information. However, the private insurance sector in India is largely restricted to inpatient hospital care, while the large public insurance schemes operate in clinical environments that are least digitized. Large private hospital systems do own Hospital Information Systems (HIS), but these are largely delegated to monitor the in-house supply chain, and not really meant to follow the patient from "cradle to grave."

User adoption remains a concern and is best addressed through careful attention to workflow and customization. Proposed solutions must add value to the involved stakeholders, the initial cohort of whom may not necessarily include physicians. While a range of ready-to-deploy software products is available, there is a near absence of solution delivery entities. Some of the larger private entities, HIS, PACS and LIS, have found a footing, yet customized systems catering to needs of primary care physicians, operation theaters and specialty clinics are largely absent.

In spite of these daunting realities, public and private sector players have made some significant strides in working toward interoperability and standardization. The Government of India has adopted SNOMED and is making it available for free to health systems across the country. Organizations like Healthcare Information and Management Systems Society (HIMSS) and the India Health Information Network are other key stakeholders. Most importantly, the newly proposed NDHA is slated to be the key regulatory authority for health information (and exchange) in India. While the government intends to establish interoperability standards, the greater challenge of change management remains unaddressed. Who will bear the cost of these new systems? What will be the institutional and individual incentives? How will the system be seeded, populated and sustained?

Were digitized data to be finally available, there will still need to be technical and legal mechanisms in place to ensure the safe, secure, legal and ethical exchange of data. Health data are generated jointly by the patient and the provider, and are used for myriad of purposes including clinical care, research, innovation, quality control and public health.

PROPOSED SOLUTIONS

The greenfield nature of Health IT in India allows for the development of a model that avoids the pitfalls of entrenched legacy EHRs, while taking advantage of the latest advances in information technology. Based on available technology and current laws, listed below are desirable characteristics of a Health IT ecosystem in any new environment.

Distributed Architecture

The current practice of modern medicine necessitates that the patients interacts with multiple components of the healthcare delivery system, for almost every single encounter. A simple visit to a general practitioner may result in the creation of a medical record, a bill, a visit to a laboratory, a radiologist and the pharmacist. Each of these interactions essentially result in the creation of additional "health data" specific to the patient and provider. While we understand that hospitalizations result in the creation of an electronic medical record at the hospital, in practice, the majority of the patient's health record is being constantly generated elsewhere – albeit at multiple locations and over time: vaccinations, simple ailments, medical screening, prescription medications, laboratory testing and so on.

We propose here a distributed architecture for India's health IT system, where captured data remains at its source of origin, but can be queried and accessed when needed. For example, a patient could populate her own electronic health record by querying all providers who are on the health IT network: physicians, laboratories, and hospitals, for example. An authorized physician could directly access labs from the laboratory; or a

hospital could get access to patient's drug allergy history from the patient's records at all other locations.

A distributed network so constructed would obviate the need for constructing large national or regional databases of the patient's "entire" medical record. Centralized databases can be not only duplicative and prohibitively expensive, but be the single point of failure where security breaches could result in massive data compromise.

Only relevant information would move directly from one node in the system to another provided requisite permissions are in place. Every stakeholder in the system would only be able to access data they are authorized to. Appropriate, authorized data flow would be regulated by a combination of technical and legal tools.

Technical Basis and Local Precedence
The use of Application Programming Interfaces (or APIs) would underpin the proposed distributed architecture. An API is a set of routines, protocols, and tools built into a software application that enables it to communicate easily with other applications. APIs specify how software should communicate, and provides a roadmap to building interoperable software and data exchange services. Industries like banking, finance and social media, have successfully tapped into the explosive growth of software applications by adopting API-based solutions.

India's own experience with wide-scale API adoption has been regarded as hugely successful: the Universal Payment Interface, rolled out in 2016, has

demonstrated both the feasibility and the advantages of adopting an API-based ecosystem.

Globally, the healthcare industry has been more cautions, even reluctant. But there are exceptions: Platforms like OpenMRS, Emissary™ and the SMART Health IT platform at Boston Children's Hospital have long pursued API-based data ecosystems. For wide-scale adoption, whether in India or elsewhere, data transfer between entities would require not only open APIs, but also standard APIs adopted at a national scale, and requiring buy-in from multiple stakeholders - something that may be facilitated by a governing body such as NDHA, through incentivization, legal mandate or market demand.

The lack of reliable 24/7 electricity and robust internet connectivity in India pose a specific challenge. A distributed architecture is predicated on an "always-on" model where internet connectivity is guaranteed and where data flow occurs in real time from one node to the other. Given the connectivity challenges in India, particularly in the rural hinterland, this is currently nearly impossible to achieve. Limited, critical data may therefore need to be copied and stored offline (and cached frequently), whether in a central repository or a personal device, or at a designated institution of choice, to account for connectivity delays and failures. In instances of poor connectivity, data prioritization will allow the flow of critical data at the expense of less time-sensitive data exchange. One example is the designation of a "favored" patient health record, where an institution-based medical record routinely and periodically accesses and collects critical patient data from all sources, in return for a subsidy, a user fee or negotiated data access rights.

A Universal, Unique Patient Identifier

Prima facie, querying the distributed architecture would require a universal ID – no matter where the patient interfaced with the medical system, their data would be tagged with that unique identifier. While normally a daunting system to create, the near universal penetration of India's unique identification program, Aadhaar, offers a solution to this challenge. Aadhaar has been built around the principles of *privacy by design* and *data minimization* that are particularly relevant in security-sensitive applications like healthcare. The system is actively used today for the central government's direct benefit transfers and subsidies programs and has also been used by several banks and telecom operators, particularly for facilitating e-KYC[c] at the time of account opening. By the end of 2016, more than 95% of the population was enrolled in Aadhaar, making it the most widely deployed single ID system anywhere in the world.

Identifying medical records by the Aadhaar number, would not – by deliberate design - give anyone access to information linked to the Aadhaar number. While Aadhaar only "verifies" identity, if necessary, patients could be provided an additional universal medical number, should they choose to not have their records linked to their Aadhaar number. Access would be restricted to authorized entity, be specific to the nature of their query, and for a stipulated period of time only. For example, a patient admission to a hospital could trigger (voluntarily, or automatically, if previously consented

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[c] Know your customer (KYC) is the process of a business identifying and verifying the identity of its clients. The term is also used to refer to the bank regulation which governs these activities

or implied) authorization to the admitting hospital to access the patient's previous medical records from multiple sources. The access to the patient's entire record may expire at a fixed time after the patient is discharged.

This architecture where consent is a prerequisite for flow, but where the architecture for consent and flow are separated has also already been successfully implemented by the Universal Payment Interface system.

Legal Framework
Currently a Bill is being drafted by the MoHFW, in collaboration with NLSUI, Bengaluru for Healthcare Data Privacy and Security. While the Bill's expectd declaration of the patient as the data's owner is prudent, we must re-define the concept of "ownership" to successfully apply it to an API-based, distributed health record model. "Ownership" is classically viewed to mean that the entity that "owns" the data has a right to determine the acquisition, use and distribution of said data. This definition leaves the owner with complete and total control of data - including the editing and deletion of this data.

Such cannot be the case for medical data as editorialization of a health record can lead to loss or deletion of clinically relevant information. Instead, we must broaden the definition of "ownership" to include the concept of "data processor" and "data controller." In this system, the patient takes the role of "data controller" giving them complete control over what data is made available and to whom for each individual interaction. A data processor co-creates and adds data to the patient's

health record, and accesses it when implicitly or explicitly authorized to do so.

In this context, it might be useful to think about control in the context of a tiered hierarchy of permissions. At the highest level is the patient who controls the data. Immediately subordinate to the patient are a category of stakeholders who have access to the data by virtue of having been involved in its creation and to whom the patient has given implicit or explicit consent. Below them will be various other stakeholders who can only gain access to the data if the patient allows them to.

Fundamental to this legal framework is the principle that the patient is the ultimate "date controller," and allows various stakeholders to access that data from time to time. No matter where the data is created or where it resides in the distributed database, the patient must always have unhindered access to it and the power –within reason -- to allow others to access it.

For data processors, who were instrumental in creating these data by conducting tests or performing medical interventions on the patient (diagnostic laboratories, physicians, hospitals, etc.) it might be necessary to stipulate an implicit right to use data that derives from their role in its creation provided that any such right is recognized to be subordinate to the fundamental control that the patient exercises over the data.

In this manner it will be possible to map out various permissible pathways through which the data can travel automatically while there may be others

through which it cannot pass without the patient's agreement. For instance, diagnostic laboratories should be permitted to send their reports to the patient's physician who requested the test but will need authorization from the patient to send it to any other doctor (such as one to whom the patient goes for a second opinion). When permitted by law, the labs should also allow public health agencies to access de-identified test results for epidemiological surveillance, for example. Hospital administrators may be allowed access to anonymized clinical and workflow data to improve quality, performance and outcomes.

Thinking of personal health data in the context of simple ownership also results in the creation of an implicit property right in personal data, which from a legal perspective, could result in unfortunate outcomes. For instance, ownership implies value so does this mean that whenever personal data is transferred it must take place for monetary consideration? Would it possible, for a person to sell his personal medical data, and if he does so is he deprived of the ability to use it himself?

Finally, it is important to ensure that all persons who have access to the data at any point in time, regardless of the fact that they have been expressly given such access by the patient, have a fiduciary responsibility toward the patient, and are held accountable for the manner in which the data is used. At all times in their use of the data they should be held responsible for the consequences of their actions - in particular if such use results in any harm being caused to the patient. It should not be a defense, in such circumstances, for the person with access to the data to say that the patient's consent to access absolves that person of all responsibility

with regard to the consequences of use. This is particularly relevant where the patient is incapable of understanding the consequences of the use of data given the technical nature of the utilization. The consequences for a breach of the accountability principle should be severe, including a loss of the privilege to access such data in the future, fines, etc.

The distributed API-based architecture should allow, by design, the functionality described above. Information exchange would be governed by consent for the transfer or specific data points between authorized stakeholders for stipulated periods of time.

Data for Research

The Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University and the Wellcome Trust, recently concluded an interdisciplinary meeting on the future of clinical trial data sharing, recognizing the need for sharing data from clinical trials, while protecting those conducting the primary research (often in low-income countries) from feeling exploited by wealthier counterparts that may have better resources to conduct analysis. A related New England Journal of Medicine (NEJM) article citing this work observes, "More complete and complex patient data from genomic sequencing, electronic health records, personal sensors, and mobile devices, combined with vastly increased power to analyze data, will undoubtedly shed new light on ways of diagnosing and treating diseases and help to further elucidate their natural history".[15] Easy access to data for research while incredibly important is also fraught with risks.[16] Research (that by nature, may not directly benefit the patient in real time), and clinical application of data are two entirely

different enterprises and their confluence must be considered very carefully. The projected growth of Precision Medicine where big data is to be harnessed for customizing an individual's treatment plan is likely to hasten the need for this conversation.

Health data will often be used for purposes other than what they may originally be intended for. Lab results, for example, when initially generated to treat the patient, may eventually play an important role in some research. Even if some public good were to come out of that research, it is important to acknowledge that the data are being used beyond their originally intended purpose. It would therefore be important to provide both technical and legal levers to prevent misuse.

The technical solutions could center around data-tagging and alerts. In Hong Kong's centralized health information system, for example, patients are notified every time their data are accessed. All access is time- and user-stamped. In the future, metatags on data could make them "intelligent" enough, for access to be turned on and off based on a variety of factors including time since generation, user identity and purpose of data-use. Data exchange on a distributed system would therefore require transactional transparency and a permanent record of these transactions, similar to the Blockchain technology supporting the Bitcoin ecosystem.

It is equally important to recognize that patients are not always qualified to understand the implications of approving requests for access that they receive. An innocuous request may have pernicious consequences given that in this age of machine learning the ultimate use to which the data can be put is not always self evident. In this context one option that could be

considered is the inclusion in the legal framework of the concept of a *Learned Intermediary* that negotiates data flow between the data generator and data user, and is able to do so in a responsible, reliable, timely and transparent manner. It is important that this intermediary be demonstrably unbiased in order to ensure that the interests of the patient are paramount.

The proposed Learned Intermediary could have both a technical and legal layer. The technical layer is a "consent manager" that responds to requests for access (not unlike that of the UPI). The legal layer, perhaps NDHA or an autonomous entity that includes representation from the public and private sectors and from civil society, would require to set criteria and agree on the social contracts that will define control and access in India's health IT ecosystem.

WHAT NEXT?

In January 2017, the Ministry of Health and Family Welfare released an RFP for vendors to submit proposals for a health information exchange. The RFP envisions large centralized repositories of data. The authors of this document advocate that the exchange consider instead the distributed architecture we have proposed.

In order to continue to contribute to the technical innovations and legal solutions required to support a seamless and secure health information exchange, the Harvard South Asia Institute and the Harvard FXB Center for Health and Human Rights announces the launch of the **Exchanging Health Information Initiative**. We welcome public and private sector stakeholders that would like to work with our consortium to prototype and trial the concepts outlined above.

Use-cases: Providing Contextual Intelligence
Mobile health technology and cloud-based analytics are expected to drive the health information growth boom in emerging economies (such as in India). Adopting these international (and national standards), and facilitating the widespread use of an API-based ecosystem could potentially meet the clinical and research needs of the region. Adequate policy levers need to be in place to ensure that APIs allow the secure and permitted exchange of health data, while protecting individual rights.

While it is a given that healthcare delivery is highly contextual and subject to a myriad of influences including GDP, national health systems, payer

mix, provider training and availability to name a few, *the reception and use of services is even more so*. Understanding whether populations (patients or providers or regulators) want to exchange health information, and to what avail, would be key to exploring how information can or should be exchanged. A use-case would provide the contextual intelligence required to make actionable recommendations, and contribute to mapping a tangible follow up plan.[17]

PROTOTYPE 1

As a starting point, we propose the creation of a patient medical record (or "Medi-locker", inspired by the current Digi-Locker in India, a cloud based repository for issuance, storage and verification of relevant documents and certificates issued by government agencies) that can access patient data from laboratories and chemists. Creation of the Medi-locker would entail:

1) Adoption of standard APIs by chemists and laboratories in the target population, and
2) Data storage in a structured format, allowing its use for interpretation and clinical application.

This API-based network would allow the creation of the following **use cases**:

A) Applications for PATIENTS:
Medication alerts
Laboratory trends (blood sugar, for example)
Allergy alerts
Drug combination adverse reaction alerts

B) Applications for PUBLIC HEALTH AGENCIES AND POLICY MAKERS

   Laboratory data-based epidemiological surveillance

   Pharmacy (chemist) drug dispensation based epidemiological

   surveillance looking for spikes or atypical clustering

Proposed collaboration with iSPIRT

The Indian Software Product Industry RoundTable (iSPIRT), which founded
Aadhaar, is a volunteer-driven think-tank that aims to galvanize software
product innovation in the country. iSPIRT is the lead organization in the
creation and implementation of IndiaStack,[d] a suite of software technology
standards to facilitate product innovation in the financial and health
technology industries. India Stack encapsulates critical building blocks for
user identification, authentication, payments, data storage and data
exchange which are provided as an open and standard set of APIs for
anyone to use. India Stack components have been successfully applied in
the financial technology industry with the launch of standards like Unified
Payment Interface (UPI), e-KYC (Know Your Customer), and e-Sign
(electronic signatures based on Aadhaar. These standards are already
being used to deliver financial services (like digital payments and digital
lending) to several millions of Indian citizens.

iSPIRIT is now well poised to make critical contributions to India's
distributed health IT ecosystem; we envision that the technical component

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[d] IndiaStack is a set of APIs that allows governments, businesses, startups and developers
to utilize a unique digital infrastructure to solve India's hard problems towards presence-
less, paperless, and cashless service delivery. www.Indiastack.org

of Case 1 would be led by iSPIRIT.

PROTOTYPE 2

We propose the development of standard APIs for existing electronic health records of large hospital systems in the public or private sector; or for large public health research databases secured at government agencies. APIs in either setting would allow the creation of crowd-sourced solutions for patients, providers, researchers and administrators.

Kaiser Permanante, one of the largest health care consortium in the US, launched its first open API, INTERCHANGE,[SM] in 2013. By providing developers with an easy and secure connection to Kaiser Permanente's public data, INTERCHANGE shortens development time, and expands the variety of health-management apps available to consumers, allowing them to use what aligns with their lifestyles. Aetna's open health API, CarePass, began as a data sharing initiative, but evolved to be more of a consumer health dashboard that brings different apps together.

Steps:
1) Prototype 2 would be pursed by first identifying a range of needs (of patients, providers, administrators, policy makers) and developing APIs to allow secure access to select data.
2) APIs would be shared with developers through select invitations or open hackathons as appropriate to invite innovative solutions to identified needs (and to needs not pre-identified by the consortium)
3) The Consortium would lends its research expertise to help local

partners to monitor and evaluate the efficacy of the proposed solutions as they go through development and trials.

4) The Consortium will test existing and proposed legal frameworks in these real-world case-studies to examine their adequacy and scope, with the goal of advancing the existing legal framework to be in sync with new and coming health information technologies.

We look forward to continuing our deliberations at follow up events in India, and begin testing the concepts outlined in this documents.

APPENDIX 1: SCHEDULE

DAY 1
8.15am   **Introductions**   Tarun Khanna, others

9.00am   **The State of Health Information in India**

Rahul Mullick · BMGF
        · data in the public sector: quantity, quality, access

        · the National Resource Repository
        · implementation conundrums

Arvind Sivaramakrishnan · Apollo Hospitals
(with Ashokkan VR · Columbia Asia via videolink)
        · data in the private sector: quantity, quality, access
        · ownership
        · current application (clinical, billing, research)
        · projected use

Sanjay Mehendale · ICMR
        · accessing data for policy
        · what works, what doesn't
        · burden of the problem
        · barriers, solutions, plausible incentives

Moderator: Barbara Bierer

10.30am   **Coffee**

10.45am   **Incentivizing Exchange: Global Practices**
Joaquin Blaya   Thought Works
        · Open HIE
        · Successful health exchange implementation models
        · Indiana Health Exchange
(TBC: Paul Biondich / Shaun Grannis · Indiana HIE, OpenMRS via videolink)

Barbara Bierer   HMS, MRCT, Vivli
        · MRCT, Vivli

        · prerequisites for collaborative research
        · recruiting, incentivizing, funding
        · big data, genetics, precision medicine: pushing the
frontiers

     Ram Sahasranam   Praxify
        · working with existing systems
        · interoperability across systems
        · case-studies from the US and Asia

     Moderator: Satchit Balsari

12.15am   **Lunch**

1.30pm   **Caution with Exchange - Law, Ethics, Security & Trust**

     Rahul Matthan   TriLegal
        · the Indian legal health IT ecosystem
        · what's worked out, what isn't
        · who will drive this change?
        · local, state, national, international

     Malavika Jayaram   Digital Asia Hub
        · global practices
        · lessons from other sectors

     Ifeoma Ajunwa JD PhD   Berkman Klein Center
        · ethical frameworks for big data

     Moderator: Paul Salins

2.30pm   **Is APIzation the solution?**

     Adrian Gropper   HealthURL
        · Blockchain technology
        · Use-cases, how to, financial incentives
     Aarti Borkar   IBM

· APIzation experience in India
Saurabh Panjwani   iSPIRIT
          · India Stack
                    · What is, goals, big picture
                    · UPI, Digilocker: identifying the stakeholders
                    · Nuts and bolts. How does it work?
                    · Is there a magic pill?

Moderator: Rahul Mallick

3.45pm   **Coffee**
4.15pm   **GROUP WORK (<u>Presentations due on Day 2</u>)**

GROUP 1: Guarding the data ecosystem
Led by Barbara Bierer and Rahul Matthan
Answer the following questions:
          Who do the key stakeholders need to be?
          What should the overseeing entity look like?
          Who owns the data? (Is ownership the right model? Are
          variations on licensing, rights of access or stewardship a
          better frame?)
          Which gaps in law a) can be addressed most easily b)
          should be the highest priority? Stakeholders? Process?
          Roles of any of the entities here?

Blaya, Gropper, Fortenko, Jayaram, Mehendale, Salins, SND

GROUP 2: Building the next game-changer
Led by Arvind Sivaramakrishnan and Rahul Mullick
          · What should be built next? What problem will it solve?
          · Who will the stakeholders and partners be? From the
          participants here? Others?
          · What exchange barrier will it address? Who will benefit?
          · Who will fund it now, and later? Sustainability? Growth?
          · Will it help define the contours of the ecosystem?

Annamalai, Borkar, Khanna, Lal, Panjwani, Sahasranam,
Shankar

6:00pm   **Dinner**

DAY 2
8.30am   **Presentations**
20 minute each (any format)
30 min Q/A and discussion each

9.45am   **e-Health Systems: Buy or Build ?**
NT Cheung   CIO, Hospital Authority, HK

(VideoLink)

              - why HK went the build route
Arvind Sivaramakrishnan Apollo Hospitals
        - build vs buy. Realities in India
        - costs, talent, infrastructure, expectations
Joaquin Blaya   OpenMRS, Open HIE
        - the cost of open source software
        - do freebies work ?
Ken Mandl   SMART Health IT
        - negotiating with the hosptials system (buy-in)
        - scale and funding

11.00am   **Coffee**

11.15am   **The National eHealth Authority**
Supten Sabadhikari   National Health Portal (via

videolink)   - scope of NEHA
        - projected timeline
        - needs (change management, implementation partners)
Facilitator: Sanjay Mehendale

11.45am   **Managing Change**
Arvind Sivaramakrishnan Apollo Hospitals
Sayon Dutta   Partners
Melliyal Annamalai   Oracle
Shashank ND   Practo

Moderator: Adrian Gropper

1.00pm   **Lunch Keynote:**
Ken Mandl: Sync*ing* for Science.
- background: PMI
- partnerships / negotiations / consensus building
- incentivizing legacy EMRs
- what if Sync for Science works?

2.15pm   **All Group Exercise 1**
eHealth Readiness Framework and Checklist
(Refer to Global Digital Health Index and OECD tool under "Resources")
Led by Julia Adler-Milstein and Joaquin Blaya
- What exists? What needs to be developed?
- Stakeholders?
- Content
  - legal scope
  - technical scope
- Partners for design and implementation
- Who will fund it?
- Commitments, roadmap, timeline

3.15pm   **All Group Exercise 2**
Barbara Bierer and Tarun Khanna

Defining the health exchange ecosystem
- Identifying immediate, short and long term deliverables
- Partners and funding
- Timeline and commitments

4.15pm   **Digital Hub Asia - follow-up events in Asia**
Malavika Jayaram

4.45pm   **Closing Remarks**

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