

PRACTICAL APPROACHES TO DESIGNING STANDARDS: THE CASE OF A DISTRICT HOSPITAL INFORMATION SYSTEM IN NORTHERN INDIA

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Abstract: This paper explores the issue of designing standards within the setting of a district hospital system in the context of a Northern State in India. The aim is to develop a practical approach to the design and implementation of standards during the course of the evolution of a hospital management information system (HospMIS) first in one hospital, and later to be scaled to a total of 20 such hospitals in the state. A three level framework of health information standards comprising of information needs, software and interoperability as been evolved through the HISP (Health Information Systems Programme) initiative is drawn upon to approach this issue of standards. While this framework has indeed been a very useful lens to understand standards, we have also contributed to its extension by additionally focusing on issues relating to the process of development, implementation and scaling of standards.

Key words: HospIS, Standards, OpenMRS, Scaling

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1. INTRODUCTION

While Hospital Information Systems (HospIS) based on Electronic Medical Records (EMRs) are indeed a popular phenomenon in the West (Coiera 2003, Øvretveit et al., 2007), and also to some extent in private hospitals in the developing world (Chae et al. 1994, Rotich 2003, Seedberg et al., 2009), they have found limited use in district hospitals within the public health system of the developing world. The reasons for this are both institutional and technological. Public health systems by and large have focused on primary health care, and correspondingly technology development efforts have been on the “HMIS” (Health Management Information Systems) for aggregate facility based statistics. District hospitals, which are predominantly curative in focus, have been largely ignored in computerization efforts to date. Arguably, patient based EMR (Electronic Medical Record) systems are more complex (at least technically) than HMIS, and since success in the HMIS domain has been also rather limited across the developing world, some may argue district hospitals are not ready for EMRs. Stories of experiences of implementation of EMR systems both from “infrastructure rich” contexts of the West (for example, McDonald 1997, Conn 2007) and from the developing world (Shaw 2003, Fraser et al. 2005, Sheraz 2010) have been far from encouraging, and have till date provided a strong deterrent to new developments, magnified greatly by their prohibitive costs.

There are strong arguments for strengthening HospIS of district hospitals in the developing world. Firstly, district hospitals typically consume significant proportion of district health budgets, and also provide a large chunk of primary health services related to antenatal, delivery and immunization. Ignoring district hospital data makes the district database significantly incomplete. Further, information about the working of the district hospital can provide useful insights into the effectiveness of referral linkages with the primary health facilities in the district. Data on communicable and non-communicable diseases required for national reporting to a majority extent are provided by district hospitals. Given this need for stronger and more integrated HospIS, a point of debate that is pertinent is not whether such systems are relevant but rather what kind of systems are appropriate? Should the focus be only on the aggregate statistics coming out from the hospital, or a “semi-EMR” which records patient based episodic details without attempting longitudinal tracking, or a relatively full blooded EMR but still not as may be seen in the West, say with electronic imaging?

Increasingly, as seen during the course of our work on health information systems implementation in India, there is an increasing demand from state health departments for EMR systems in their district hospitals. There is naturally a lack of clarity on what constitutes an EMR system; the hospital administrators don't fully comprehend the possibilities as vendors continue to sell them dreams of fully integrated paper less hospitals where patients in remote rural areas are scheduled for appointments on SMS and X rays and scans are part of the electronic archive!! Without going into a discussion on why these dreams are utopian, the important point in the context of this paper which focuses on the issue of *standards* is to understand what constitutes relevant standards in a HospIS, and what are practical approaches to their effective design and implementation. Standards are increasingly being identified as being fundamental to the effectiveness health information systems (Braa et al. 2007), in the context of both primary health (Hanseth et al. 2006) and also hospitals (Shaw

2009). However, given the relative novelty of HospIS in district hospital information systems in the developing world, not much has been written about the nature of standards, and even less so about how these are developed and implemented. Our experience of nearly 15 years of engagement with health information systems in the developing world under the HISP (Health Information Systems Programme) initiative (Braa et al. 2007), leads us to argue standards developed and implemented top down and which seek to be universal are doomed for failure. Instead, the HISP philosophy has been towards the realization of “flexible standards” (ibid) through engagement on the ground, representing “the third way” between universal standards on one side and complete relativity on the other (ibid).

While these ideas and concepts have been developed primarily through our engagement in the primary health care sector over the last decade, there are strong reasons to argue they will also find relevance in the district hospital system. The aim of the paper is thus to understand the nature of standards and approaches to their practical implementation in the context of a HospIS in district hospitals. Our empirical site primarily is a district hospital in Northern India, which we anonymously refer to as DDH. The broader empirical mission has involved the design and development of 10 modules (registration, billing, laboratory, radiology, pharmacy, inventory, out patient department (OPD), in patient department (IPD), blood bank and finance) which need to be deployed as an integrated HospIS first in DDH and then scaled to 19 other hospitals within the district system in the state.

The rest of the paper is organized as follows. In the next section, we provide a brief overview of the research context and methods used, followed by a theoretical section on standards – how can they be conceptualized within the domain of health information systems. Following which, we discuss the empirical case including the processes of requirements gathering and its interaction with design and development with a focus on standards. In the analysis section which follows, we use the framework discussed in section 2 to outline the nature of standards with corresponding examples emanating from the empirical work. In the discussion section, we discuss more broadly the issue of standards for district hospitals in developing countries and the challenge in making them scaleable.

2. RESEARCH SETTING

The research is based in a state in Northern India which has developed a memorandum of understanding (MoU) with HISP India for the design, development, implementation and support of integrated HospIS, first in one hospital in the state capital to be subsequently scaled to the other 19 district hospitals in the state within a two year framework. There were various rounds of discussion between the state and HISP about what should constitute the core modules of the HospIS which were ultimately narrowed down to the 10 modules listed earlier representing a subset of 20 modules which the state had scoped earlier based on a vendor initiated requirement analysis. Further, a broad schedule was agreed upon for the implementation of the modules, featuring first the registration and billing modules (which were important for DDH because of the public interface) and then followed by other modules. It was agreed that OPD, being a complex module, would be taken up later.

The study is based on action research principles of collaborative action (of the HISP team with the state), where there is mutual engagement in defining problems, participation in identifying solutions, and processes of interventions. There have been continuous and iterative cycles of action, review and revisions based on mutual inputs. Outputs from this process have resulted in insights useful for practice and also to help generate new knowledge, in this case related to standards in the context of HospIS for district hospitals in developing countries. (Jacucci et al., 2006, Tierneya 2010, Øvretveit et al., 2007).

The HISP technical team was comprised of 10 people with a 11th serving as the project coordinator. Roughly half the team was responsible for implementation issues including gathering requirements, documentation and communication with the development team, participating in design discussions, and testing and training the hospital staff once the modules were in place. Developers comprised the other half of the team, with the responsibility of finalizing design, carrying out development and trouble shooting. As can be expected, there were challenges in defining these work boundaries and responsibilities which were constantly subject to negotiation and redefinition depending on personalities, availability, and the complexity of the task. In addition to the onsite team, there was support sought from global HISP team especially on issues relating to technicalities of OpenMRS (the chosen development platform), issues of server management, and more general questions on EPR (Electronic Patient Record) design such as related to security.

The process broadly involved of initially creating a two person team for each module (one each from development and implementation) with the implementer having the primary responsibility for requirements and the developer for development of that module. There were various challenges experienced in operationalizing this process, including knowledge gaps that existed between the team members, and often the developers privileging technical knowledge over the health or implementation systems. Trying to plug these gaps required a healthy atmosphere of mutual learning and trust, which was often not forthcoming leading to frequent crisis situations and fire fighting action. These created attritions in the team, but over time a reasonably steady state has been achieved with a core group of dedicated team members in place having a reasonable understanding of both the technology and the hospital systems.

As we write this paper, the first (and in some cases second versions) of 6 of the 10 modules have been deployed in the hospital, which were officially inaugurated by the Health Minister of the state. The plan is to have the completed integrated system in place for a March 31st inauguration by the State. While there are many stories to tell about the various processes, our focus in this paper is on the issue of standards.

3. THEORETICAL PERSPECTIVE: STANDARDS FOR HIS IN DEVELOPING COUNTRIES

This issue of standards requires a conceptual understanding, and in the current empirical case they manifest at different levels. At the first level, it is within a module of what should be the data collected, their formats and frequency. At the next level is between the modules, as there must be standards which enable different modules (for example billing and laboratory) to speak to each other. This involves the challenge of understanding requirements, a problem magnified by the fact that the hospital staff is unable to articulate them clearly (and for the implementation team to understand), making it complex to both develop appropriate design, and then finding the appropriate software solution. At the next level, the aim is for this application developed in the context of one hospital to be scaled up to all the other district hospitals in the state, and further have it generic enough that other states may also find it useful for their hospitals. At the next and more global level, since this development is being carried out in the framework of the global HISP network, there is also the need to consider how the application can have larger global implications. Standards provide the important glue to understand these different levels of scaling.

3.1 A Framework to understand standards

The topic of standards and interoperability is not new in IT, but in case of healthcare (especially in developing countries) it is still in a rather nascent stage and a subject of various debates. Beale (2004) differentiates health IT from ITs in other domains in the way they treat persons: *"It is often asked: what is the difference between health IT and IT in other domains? One well-known answer is "the patient". Systems in other domains such as banking and airline reservation have "customers" or "travelers" but these are grossly simplified abstract versions of a person. "Patients" in clinical systems are anything but: their biological and social complexity is manifested directly in clinical information, posing a far greater challenge than in other domains. ..."* (p. 301). For example airline reservation system may have a number of clearly defined procedures, like booking, purchasing or cancellation, each consisting of predefined formats and number of data elements. Indeed, in an EMR, the patient may undergo different routes of healthcare services depending on the illness and procedures for that particular treatment. Moreover data collected for one process may vary from the other; patient with positive X-ray results will have different prescriptions than with negative X-ray, negative result may even lead to other X-ray tests and so on. In one word there is a need to uniformly address these complex interactions in patient – care relations. Over time, various standards have emerged in the health domain to address representations, storage and transfer of patient records, namely HL7 v3 (2003), ISO18308 (2004), ASTM Committee E31.19 (2004), CEN 13606 (2004), HL7 Clinical Document Architecture (CDA) (2005), ICD1...10 (1900 to 2005) . Without going into the details of these (see www.openclinical.org for more details), it can be broadly stated that most of these standards have come into being largely in the context of Western hospitals, and making them relevant to the context of developing countries requires a lot of adaptation work, or the creation of new standards. In the last few months, the WHO has announced a standard called SDMX.HD (www.sdmx-hd.org) that is specific to the developing country context, providing guidelines on data transfer from patient systems to aggregated facility systems. But this touches upon only partially (related to interoperability) the issue of standards from our perspective.

A general framework to understand the different levels of standards which has emerged out of the HISP engagement with health systems over the last 15 years is depicted in Table 1 below.

Three Levels of the Health Information Architecture	
Level 1: Information needs, users and usage	The users' information needs and actual usage of information; the business processes and functionalities to be supported by the HIS. Documented through users specifications and requirements within the context of the relevant business processes and organizational. The defining layer of the architecture!
<i>Level 1 uses services from the level below (level 2)</i>	
Level 2: Software applications and information systems	Applications and systems responding to the users' needs and providing the needed information and services to the users. Documented through SW application documentation, manuals and actual implementations!
<i>Level 2 uses services from the level below (level 3)</i>	
Level 3: Data exchange, interoperability and standards	The technical level of data exchange and interoperability; the glue of it all, data and technical standards for interoperability of data between systems and applications, enabling data flow. Types of standards described differently, from formal standards for data exchange to data dictionaries of data standards and semantics.

Table 1: Three levels of the Health Information Architecture

This table can also be conceptualized as in Figure 1 below, with a focus on interoperability issues.

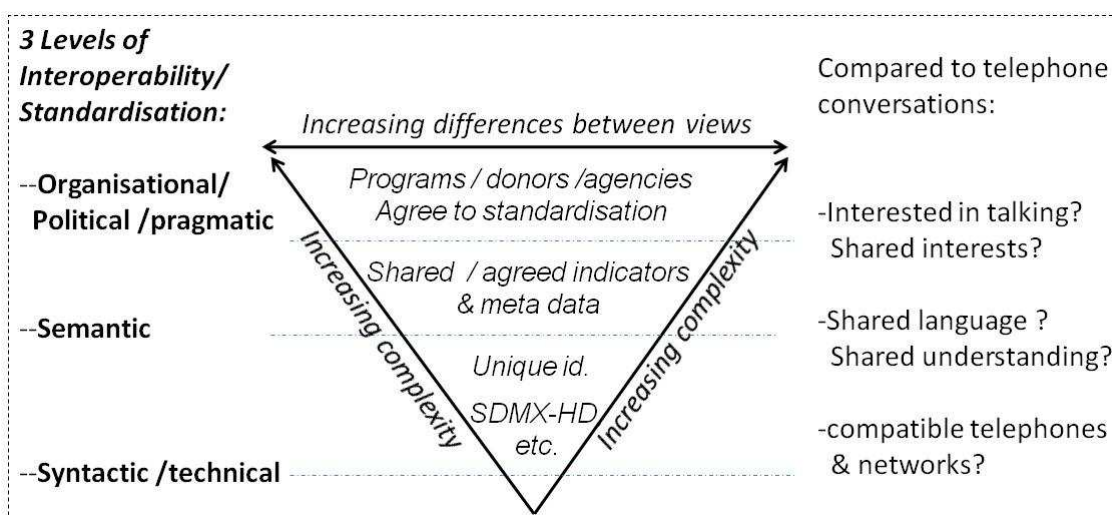


Figure 1: Three levels of standardization of increasing differences and complexities

- **Syntactic / technical level:** Data transfer and interoperability. For example, the SDMX-HD standard is a syntactic description of how to write the data for export in a file so that it can be

understood by the system importing the file – thus compatible with both the sender and receiver. In a manual system, paper based registers and data reporting formats will be similar. Also here the data to be registered or reported are syntactically described so that it can be understood both by the sender and receiver. The practical difficulties in changing paper based reporting forms make up an important driving factor in the fragmentation of HIS and problems facing data standardization. While SDMX-HD is software based, and therefore changeable, paper formats are hardware based, not changeable!

- **Semantic level:** Meaning and shared understanding. This is the level of standards for data and indicators, data and indicator dictionaries and meta-data on e.g. procedures for calculating indicators, health facility lists with related data and categories, ICD10, the international classification of diseases.
- **Pragmatic – organizational, political level:** This is the level with decision making power when it comes to deciding on standards at, mainly, the semantic level, the data and indicator standards. The standards for interoperability at the syntactic and semantic levels will also be reflected by “softer” standards at the inter-organizational level, in terms of procedures, mandates, responsibilities and job-descriptions needed in order to effectuate the other standards.

3.2 Approaches to building standards and their acceptance in use

It has been studied (Shaw 2003) that implementing HospMIS in developing country is a challenging task mostly due to socio technical complexity in healthcare domain including relating to how standards are created and adopted. “Standards emerge and gain acceptance through work on the ground”, not by imposition from the top (Timmermans and Berg, 2000). Drawing from the case of adopting of new medical protocols they illustrate how standards emerge and gain “*universality*” through local practices. “*Work practices are made more "efficient," professional practices are supposed to become more "scientific," and technical practices should obey "universal" standards. The disorder of current practices, according to such discourses, should be replaced by scientifically established, rational, and universal modes of working and understanding*” (p 31, *ibid*). Shaw (2005) demonstrates how an “*essential data set*” strategy in a remote district leads to formation and evolution of standard, and influences other organization hierarchies to benefit from it. Braa et al., (2007) proposes a “*flexible standards strategy*”, where standards evolve in the course of practice and adapt to the environment. A similar approach is used in OpenMRS Concept Cooperative (OCC), an online repository created for the OpenMRS concepts’ dictionary. OCC tends to provide a global vocabulary of well formed concepts from different implementations of OpenMRS worldwide (Martin 2006, Mamlin 2007).

The issue of standards have also been discussed in detail within the domain of design science. For example, Owen (1997) describes the design research process as “*Knowledge is generated and accumulated through action. Doing something and judging the results is the general model . . . the process is shown as a cycle in which knowledge is used to create works, and works are evaluated to build knowledge*”. Similarly, our approach to standards see them as products of iterative actions of refining artefacts to match the ground level needs. Standards represent “*knowledge*” encapsulated in ongoing design and implementation cycles, which over time are stabilized and accepted by concerned parties, for example in our case of interoperable modules of OpenMRS. So, knowledge gained in one module, could be used by other module, or there would be common patterns of knowledge gained, which could form standards that could be circulated from one setting to another. The figure 2 below represents such a practical approach to the development and implementation of standards.

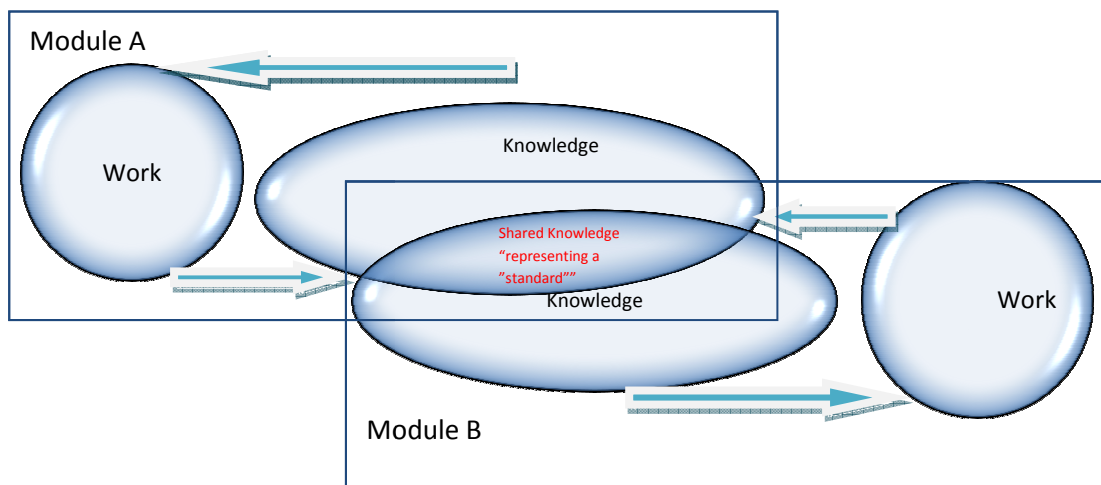


Figure 2. Illustration of shared knowledge representing a “standard” (adopted from Vaishnavi and Kuechler 2004/5)

In summary, our approach to develop and implement standards involves:

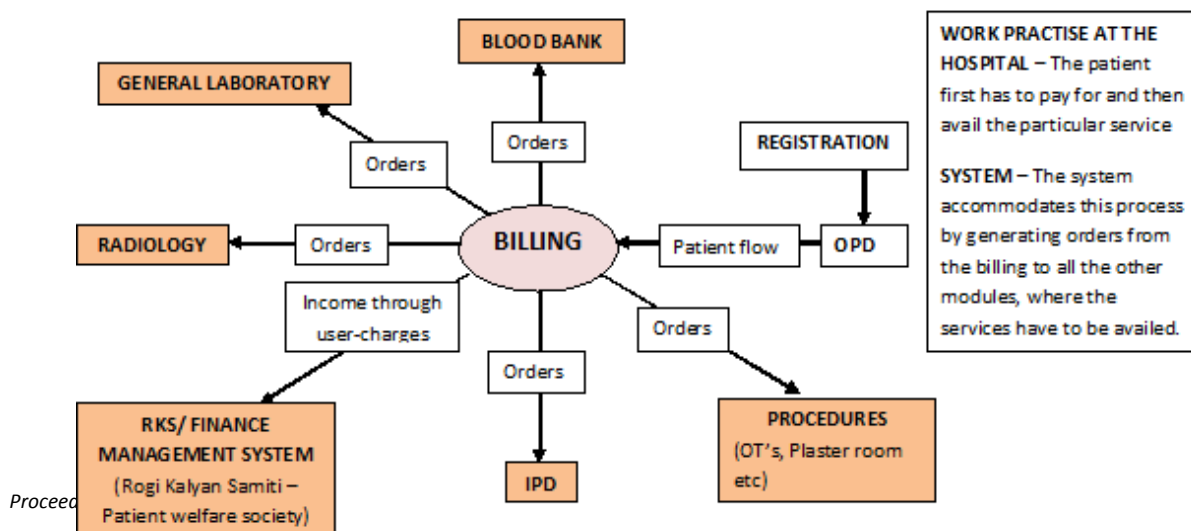
- a. Enabling standards to evolve bottom up, based on practice, while adhering to global and national definitions and guidelines.
- b. Standards follow a hierarchy where the lowest level requires the most detailed standards and subsequent levels above more abstracted.
- c. The aim is to develop standards that are flexible and allows inputs from practices to be incorporated over time and use.

4. CASE STUDY

We use the three level architecture framework to provide some examples from the case that can help to understand the nature of standards.

4.1 Level 1: User and information needs

Each of the 10 modules identified in the scope of work were subject to a requirement analysis with the view to understand the information needs from the user perspective. The idea then is the module



functionalities could be identified and communicated for development. The functionalities would need to cover at least two levels of information needs. The first is at the level of operational transactions, for example what information should be captured while carrying out a registration transaction for a patient. The second level is of the analysis reports that need to be generated for the management. This would include both the transaction reports (for example, category wise break up of patients registered in a day) and the indicator reports (say comparing registered patients with hospital capacity in relation to beds, human resources, and financial outlays). Standards at this level then require defining what data needs to be collected, periodicities, formats, and the formulation of various reports and indicators. We illustrate this with an example from the requirement study carried out for the billing module.

The billing module is one of the key and central modules as it represents the operational core at DDH. We began the requirement analysis by first studying the existing system of billing, including the underlying process and how it is inter-related to other processes such as registration and investigations. We observed and analyzed the flow of patients to and from the billing counter and identified all the possible permutation-combination of processes in the hospital, where the billing process/counter played a role. This was followed by days of observation of the process of billing to gauge the load of patients, per-patient time for billing and the average waiting time per patient in the billing queue. A list of all the services, along with the unit prices was collected from the hospital. Informal interactions were held with the billing staff and other hospital officials, regarding how they work, the problems that they face with the existing system and what are the changes that they would want to see in the system and the overall processes (see figure 3 above).

The empirical analysis conducted then allowed us to make a first draft of the “requirements document” describing the basic functionalities expected from the module. This draft was then discussed internally with the team, revisions made, and then subsequently with the panel of officials at the hospitals – they were explained the existing working process and the proposed system, what were the value additions and benefits they would get from the new system; and were asked for their feedback on the mock ups presented. The draft was also presented to and discussed with the billing staff, the actual users of the system for their feedback. Based on the feedback received from both level of users – administrative and operational - the requirement document was then revised and finally written in the form of use-cases which explained in detail the required functionalities and features from the module and provided the basis for the system development. In the box below we provide example of two use cases.

Use Case 1: Generation of a bill of services for each patient**Description**

Billing Clerk should be able to generate a bill/ cash memo with the final amount to be paid by the patient/person which has details of service against which payment is made, name of person/id number and date

Work Flow

- 1 The patient should come to the billing counter with the name of the services to be availed on the OPD/ IPD/ discharge slip/ tender document/ambulance slip
- 2 The system should display 12 main categories (with sub-categories under each) under which billing can be done
- 3 The system should display the correct match for the patient record, in case of patient
- 4 The Billing clerk should the select the respective match
- 5 The Billing clerk should have the option of adding a new bill or only viewing the previous bills
- 6 The Billing clerk should not be able to cancel or void any bill
- 7 To add a new bill, the Billing clerk should select the "add new" option
- 8 The Billing clerk should tag all the services to be billed
- 9 The system should display the names of all the services, amount of money to be paid for each service as well as the total amount to be paid by the patient and date

Use Case 2: Generating a work order for investigations**Description**

Billing Clerk should be able to generate work order for all the investigations conducted in the hospital (under general lab, radiology, radiography, blood bank lab, ICTC lab, DOTs lab, IDSP lab). As soon as a service has been billed for, the respective laboratories, conducting the tests receive an alert that a test has been ordered for, for a given id number.

Work Flow

- 10 The billing clerk should select the services that have to be billed
- 11 After all the services that have to be billed have been selected and the appropriate quantity of each service filled in, the system should generate the bill
- 12 As the system generates the bill, it should also send a request to the respective laboratory regarding the test to be conducted, for patient with id. No., the quantity of the test to be conducted and date of order of the service. (This should be displayed as an order, on the screen of the respective laboratory, to be accepted by the lab technician)
- 13 In case any investigation is non-functional in one of the labs (due to any reason), the lab technician should disable the particular test. The billing clerk should be able to view the enabled or disabled status of each test and bill/generate work order only if the test status is functional

Box 1 – Example of use-cases prepared for the billing module

As we started to work on the other modules, an important part of analysis and discussion was on the role of this billing module in the overall system. As the box 1 above describes, operationally, the billing serves at the central core. There was hence the dilemma of whether the module should serve only the purpose of collecting the user charges, but also be a point of generation of orders, to be sent out to other modules. Being a module serving only one major functionality (of collecting user-charges, as opposed to the OPD/IPD modules that serve multiple functions), it was thus decided that the billing module would also act as a point of generation of orders for various services to be conducted, such as laboratory investigation. It thus became essential, that all the services provided by the hospital, be populated as a part of the billing module. Hence, we needed to create a ‘hierarchy of

services’ for billing, where all the services provided by the hospital, charged or free, were incorporated in the design of the module. The various services were grouped under different categories, based on the functionality of the service and the physical location of provision of the service. 12 broad categories were identified, as described in the box below.

1. General Laboratories	2. Physiotherapy Department
3. Cardiology	4. Dental Department
5. X-Ray	6. National Programs i.DOTS center ii.ICTC iii.IDSP Laboratory
7. Radiology i.Ultrasound ii.Doppler iii.Special investigations	8. Blood Bank
9. Hospital Charges i. Refraction room ii. Minor operation iii. Major operation iv. Delivery charges v. Special ward vi. Minor procedure in plaster room	10. Ambulance
11. Medical Examination i. Medical examination (G) ii. Medical examination (NG) iii. Medical examination for fitness iv. Medical examination for driving license v. Re-medical exam for gazetted vi. Other medical examinations vii. Re-medical exam State Govt iii/iv empl	12. Tenders

Box 2 – 12 Categories of billing

Taking the example of the general laboratory in the hierarchy, the general laboratory was divided into 5 sub-categories: Hematology, Biochemistry, Serology, Cytology and Urine examination. Under each of these categories is listed, the individual tests. This categorization was done based on the work-flow of the laboratory. Each of the categories of the tests are conducted together, at one physical location within the laboratory and by one lab technician. Hence these tests were grouped together in the hierarchy and the same categorization carried forward in the laboratory module (the work-lists for the lab technicians and test results for each of these categories are entered together). The categorization of the general laboratory is illustrated below:

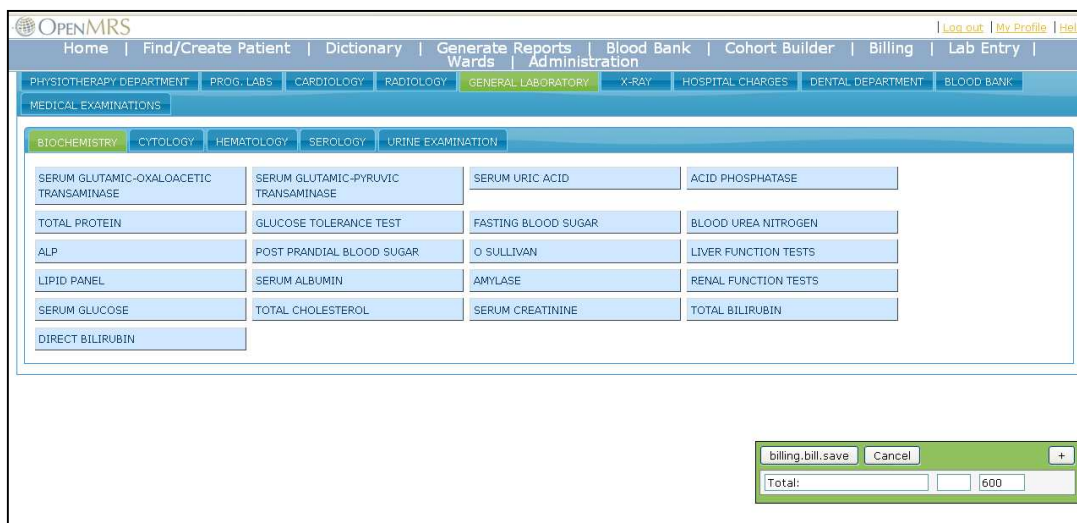


Figure 3 – Hierarchy for general laboratory

Similarly, categorisation of hierarchy of X-Rays is illustrated below :

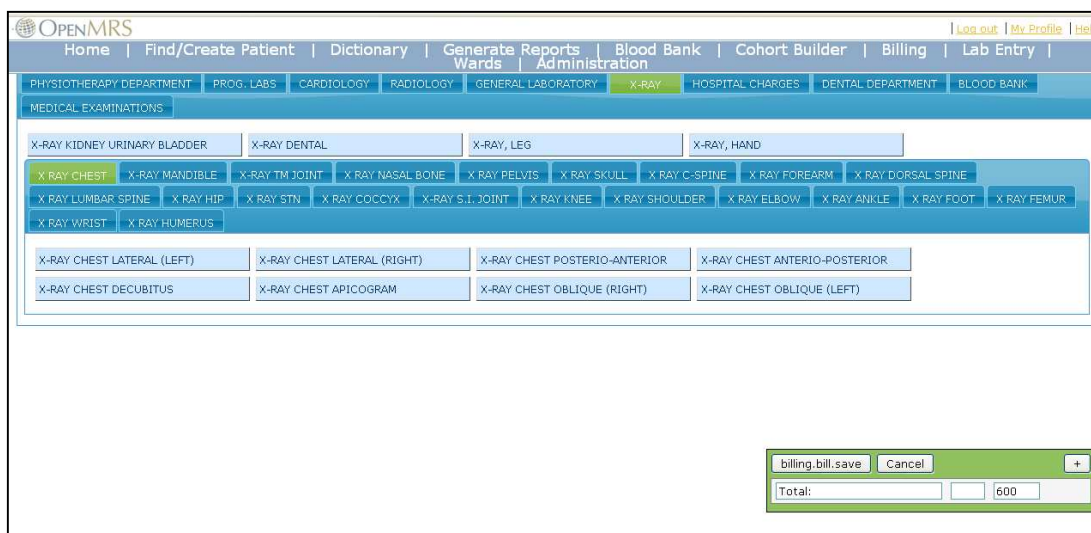


Figure 4 – Figure for X-ray hierarchy

Billing module was also required to fill into the reporting needs of the hospital, especially accounting. We categorized the reports into three categories – transaction reports, management reports and indicator reports. Transaction reports included the core one – daily cash report (giving details of cash collected under each of the 12 categories). Management reports from billing, included – for example, Investigation wise report – giving details of money collections under each investigation type. Indicator reports from billing included – BPL (Below Poverty Line) services support – this give details of amount spent by the hospital on treatment of poor/BPL patients.

4.2 Level 2: Software application

After careful analysis of existing open source software hospital applications in developing country settings, and also exploring the possibility of building an in-house application from scratch, we came to the conclusion to build HospIS on basis of existing electronic medical record (EMR) system -

OpenMRS. This decision was based on characteristics of OpenMRS – a free and open source software (FOSS) for EMR, which is collaborative effort between teams at Regenstrief Institute in Indianapolis and Partners in Health (PIH), an NGO in Boston, USA. The ongoing collaboration has contributed to the development of patient record based applications for HIV/AIDS and TB projects in developing country contexts such as Western Kenya, Peru and Haiti (Mamlyn et al., 2006). The vision of OpenMRS as stated in 2004 was: “...to provide the foundation and “building blocks” from which fledgling implementations can begin constructing health information systems to meet specific needs. Admittedly, as a fledgling effort, we’re just another stovepipe; but we hope that by using freely available tools, employing modular design techniques, and sharing our work, we can seed something bigger.” (ibid). (pp. 529)

This collaboration itself provided the basis for the development of a new standard, and scaling it bottom up to “something bigger,” quite similar to the approach of the HISP network. This idea was put into the foundation of OpenMRS design and development: *flexibility and generatively*– the notion of a “concept” and their data model; *extendibility* – modular design and development; *scalability* – ability to increase in size and number of users, installation locations; *gateways* – service APIs; and deployment and interfacing with *existing standards* – HL7, ICD10, LING, SNOMED and nowadays SDMX-HD support as a module. Its scalability was evident in the fact that though OpenMRS had been built originally for HIV/AIDS and TB (Seebergt et al., 2009), it had been applied to different domains in more than 25 developing countries (Tierneya et al., 2010). This large user base was supported by teams of collaborating IT and medical doctors, the use of active knowledge repositories through mailing lists, web sites, workshops, and publications. In short, there existed a vibrant and well supported user community around the application. Taking into account these technical and institutional characteristics of OpenMRS and their focus on developing country contexts, this was the platform chosen. In choosing this, we acknowledge that this platform was a clinic based system suitable for a district hospital where patients visit a clinic, but not so for the primary health care system which is based on outreach services.

Very briefly, OpenMRS is mainly organized as entities for recording encounters of patients with the hospital, which leads to observations, each of which is linked to a concept, represented as an answer or in the form of another question, which was answered at a later stage. A foundational feature here is the concept entity with its *hierarchical, referential and multi format* data structure. There are two other important entities to note: order and drug order, detailed also as concepts.

Using this core, we started the process of developing/customizing the 10 modules which were to provide the building blocks for the HospIS. While some of these modules (such as billing and finance) were external to the OpenMRS core, they still could use the core functionalities (such as using concepts to store services, lab tests and drug orders to notify other modules, etc.) and feed other modules with relevant information to help construct bottom up the overall hospital information infrastructure. Given the challenge and aims of scaling, we tried to use the existing standards and developed new ones to match our emerging needs.

As was noted earlier, the first two modules developed were registration and billing. Registration was an addition to an existing patient registration functionality provided by OpenMRS, while the billing module developed was completely new to OpenMRS. Also, the hospital had previous systems for both these modules and staff was quite familiar with its use. The initial version of the billing module had its own tables for services and pricing and corresponding concepts were linked to billing services. In version two, the need for creating a hierarchy of services was demanded by hospital. This

eventually led to using concepts as services. First, the concepts already had a hierarchical structure which allowed us to generate hierarchy of various forms. Secondly, now we could uniformly use concepts all over the system via the OpenMRS core APIs, eliminating redundancies. We then linked prices to concepts and corresponding service concepts were created based on the services available in the existing hospitals system, but now in a tree like hierarchy. Creating this hierarchy represented the creating of a standard.

During iterative cycles of development and testing, the billing module started to undergo major changes, conceptually, and with it the data structure and functionality. Now billing had to initiate and trigger service delivery requests such as notifying the laboratory, radiology and blood bank modules once the patient was charged accordingly. Billing thus became central to the HospMIS, and we are currently debating how it should become a part of the hospital core. We also expect further changes to the module as the OPD and IPD modules become functional. This represents the emergence of standards through practice.

4.3 Level 3: Interoperability

The interoperability issue manifests at different levels, the first being sharing of data across modules. An example of the interaction between the billing and radiology modules is described. While creating for the billing module the concepts, which were either made new or selected from the pool of existing ones (populated in the standard OpenMRS database), was done through series of discussions with hospital doctors. There were mismatches in initial presentation of the module and existing hospital practices, for example in setting hospital services for the radiology department. According to the current DDH operations, radiology services patients were charged based on size and quantity of films used. Mainly there were 3 types of film sizes to charge patients for irrespective of the type of radiology and its complexity. But according to the design of the billing module, which had to follow concept standards, this was not acceptable. First the billing module had to trigger an order notifying radiology department for a x-ray to be taken and hence the service couldn't be named "X-ray film 18x12", and required more details to enable the radiologist to know which x-ray type to perform. Secondly, the billing clerk had no knowledge on what film size and quantity to assign to the case. This is known only by the radiologist who selects film size based on x-ray type and age and body size of patient. After bringing the issue to the attention of the hospital management, a meeting was organized, where this issue was discussed. Next day the hospital came up with new list of x-ray grouped into types, and views as subtypes. In total there were 74 x-ray types presented. Our baseline concept database didn't have concepts matching this list, and required new concepts to be prepared. Creating this flexibility for the radiologist raised side effects for the billing module. It was hard and time consuming for the billing clerk to find and select the appropriate x-ray from the 74 types. This led to another round of meeting and discussions between the HISP team and hospital staff where it was agreed to organize concepts in sets and redesign the graphical user interface to follow the same hierarchy to make selection of x-rays easy for billing clerk. This example represents how the creation of a standard involved various negotiations and agreements between the different interest groups.

At another level, interoperability involves the sharing of patient level data with the (aggregated) facility level database. For example, valuable data collected through the everyday operation of hospital such as related to patient details (age, gender), OPDs visited, diagnosis, tests conducted, date and time of events need to be aggregated and summarized for being useful for managerial decision making. For example, the Health Secretary wanted a report on how many patients were registered from 8 pm to 8 am to examine whether the hospital provided efficient services during night time.

Further, aggregated data also could need to be ported to other systems requiring both portability and interoperability. In OpenMRS, each concept could be mapped to ICD10 standard codes, which while providing semantic uniformity to enable data exchange, it still requires data to be made portable in relation to metadata standards and well defined structure and syntax. SDMX-HD is a standard released by WHO that seeks to enable this. SDMX-HD defines the structure of aggregated data as well as validation rules for ensuring the completeness of the data.

5. DISCUSSION

We take the example of billing provided in this paper to describe the making of a standard in the context of HospIS:

5.1 The name of the standard - Billable services in a district hospital

In context of DDH over 155 services were being billed. The challenge was to create a 'standard' that defines all these services in categories based on a hierarchy, which should be in sync with hospital processes. E.g. for: the process of centralized billing agreed with hospital and now all billable services are channelized through billing.

5.2 Process of development

155 billable services in DDH were categorized into 12 categories, forming the 'hierarchy of services'. Based on 'billing type', these 12 categories were further classified into four types – patient services, ambulance services, billing for tenders and a miscellaneous category of services. Taking the example of X-ray hierarchy - hospital does 72 types of X-rays; these were divided into 26 types based on body parts and further divided into views. (Figure 4 depicts this– X-ray hierarchy)

The billing system is also catering to other kinds of billing services such as billing of tenders (floated by hospital for purchase of various items), which is capturing data such as the name and address of the company applying for tender, something the hospital did not have earlier. Similarly other billing is for rent (being collected for leasing out space), student internship fees (being collected from nursing or pharmacy interns); these items are now being billed and details being maintained under the miscellaneous category of billing.

Creation of the 'hierarchy of services' thus helped to create a standard frame-work, for all the billable services of the hospital. This when scaled to the other 19 hospitals in the state, would potentially serve as a standard (or base), which could be customized to the specific requirements of the particular hospital.

5.3 Process of implementation

This billing framework was implemented through the hospital's horizontal, vertical and locational processes, using tools in the OpenMRS framework such as 'concepts', 'encounters' and 'orders'. Each of the billable services in the hierarchy has been defined as a concept, using the OpenMRS dictionary. Concepts as defined in the OpenMRS framework are individual points of data collected from each patient. Thus, through these concepts, data about the tests being conducted by each of the patients is being gathered. Each of these services/concepts is in-turn associated to an 'order'. As each service is billed, an 'order', is generated/triggered, to be sent to the respective department (module). Different 'order types', have been defined based on the location and functionality of the service. For example – for billing of all tests being conducted in the general laboratory of the hospital, the order type is 'General Lab order', similarly there are 'blood bank orders'. These processes, being conducted

at different locations and serving different purposes, are also linked through 'encounters'. An encounter represents a single interaction of the patient with hospital. Different 'encounter types' based on different locations have been defined such as a 'billing encounter' or a 'lab encounter.' Based on the nature of the encounters, different security roles were developed and applied to the use of information through an authorization process.

Implementation of the 'hierarchy of services' also led us to understand the various processes and practices that would need to be standardized at DDH. For example, X-rays, that were previously being charged based on the size of X-ray films being used, was now changed to a standard price per film, for all X-rays. Services such as tenders, rent, student fees, have now been standardized, with a specific process in place and details of each of these transactions being captured.

CONCLUSIONS

The example of billable services presented above has been developed through the case study where elements of its design, development, and implementation have been identified in the process of the making of the standard. As we see standards to be developed and reified in practice, through use, it may be still premature to conclude of how successful or effective this standard will be – on this, time will tell. Overall, the process described has helped to identify the framework within which the various standards across all the modules can be identified. The three level architecture consisting of levels of information, software, and interoperability will be drawn upon to sketch out the various standards.

While making this standard work in one setting through use in DDH is of course the primary challenge, at the next level we need to see how this standard (and others) can be scaled to the other 19 hospitals in the state. Our approach would be to take the identified standards as the reference list as we go to the other hospitals and then study the existing systems there within this background, and see what is it that is additional or not. Through this process of analysis, the aim would be to develop a set of "core standards" that the state could define as a state benchmark. This would imply that all the hospitals in the state would need to adhere to this core standard, while having the flexibility to add something to cater to local requirements. They would however, not have the freedom to remove anything from the core list. This is essence divides the process of the making and the scaling of standards as envisaged by us for DDH in particular, and to the state more generally.

In summary, our understandings of standards from the domain of primary health care systems have provided us with a firm foundation to approach the complex issue of standards in the district hospital setting. As these standards are not being imposed from the top, but have evolved through practice based on a strongly participative approach, we expect there is a higher potential of it being accepted as something useful and useable. The future challenge would be to take these standards into the other hospitals, where undoubtedly local practices and traditions will challenge these standards, which may be then seen as "imposed from the top." Continuing this participatory approach while allowing for local flexibility within a defined framework will be our proposed approach.

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