Jury: An Automation Framework for Protocolised Primary Healthcare Delivery

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ABSTRACT
It is often hard to get trained doctors as primary healthcare providers in rural India. In an emergent tiered model, clinicians trained in basic health practices are deployed at rural clinics, and instructed to follow structured clinical protocols. Medical records are maintained electronically and a regular medical audit is performed on the records by skilled doctors to ensure that the clinicians stationed in rural clinics provide high quality delivery of care. Manual audit of the medical records is however non-scalable and prone to error. We describe the development of Jury, a highly configurable and extensible framework for automation of clinical audit of electronic medical records (EMRs). Socio-economic complexities and paradigmatic differences between public health research and computer science throw up interesting challenges that were tackled on the way to arriving at a solution. A pilot implementation was done for the hypertension protocol. Our field partner ICTPH has evinced interest in integrating Jury into their regular workflow.

Categories and Subject Descriptors
J.3 [**Computer Applications**]: Life and Medical Sciences – *health, medical information systems*; I.2.1 [**Computing Methodologies**]: Applications and Expert Systems – *medicine and science*

General Terms
Standardisation, verification

Keywords
Protocol, healthcare

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1. INTRODUCTION
Clinical protocols are statistically driven and rule based "workflows to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [1]. They are developed by senior clinicians by reviewing research and clinical experience for treating a disease. Clinical protocols reduce inappropriate variations in the clinical practice and promote continued medical education and efficient use of resources. They are extremely useful in primary care practice as they standardize treatment and provide guidance on referral of the patient when the condition is not manageable by a primary care physician.

Protocols are also important because they provide criteria for auditing the quality of services provided to the patients. These medical audits are generally carried by a team of clinicians and medical records department to objectively measure the quality of care provided by the organization or a particular department. They are carried out to understand, learn and reflect upon various normal and abnormal variations in the care provided. Criteria mentioned in the protocol are used as a basis to assess the quality of treatment. Medical audits are carried out by organizations according to their policies and availability of the resources. The frequency of audits in various healthcare organizations is highly variable and depends on the governance mechanism of the organization. In India, many healthcare organizations do not conduct any audit at all.

We have partnered with ICTPH, a not-for-profit research organization focused on innovating inclusive primary healthcare delivery systems for rural Indian populations. With 70% of India's population residing in rural areas, the objective of ICTPH is to create a sustainable care delivery model targeting the local needs of rural populations. An appropriate combination of technology coupled with trained human resources allow for an evidence-based care delivery model to function and operate in a sustainable manner. ICTPH has chosen to operate in a paradigm where relatively lower skilled medical practitioners operate the clinics based on a given set of protocols and have their treatment steps audited by senior doctors, as opposed to a model where significantly more autonomy is given to the rural clinicians who are assisted by automated decision support systems.

ICTPH maintains all medical records in an in-house EMR system, Health Management Information System (HMIS), and follows an offline process of auditing the medical records undertaken by trained doctors. In addition to capturing patient-physician interaction HMIS also has functional units for supply chain management and human resource management. Modules such as monitoring and evaluation, clinical data analysis and community disease mapping aided by geo-visualization are under development.

The main contributions of our work with ICTPH are summarized below.

- We have identified the need for an automation framework for protocolised primary healthcare, and built and validated a prototype (called Jury) integrated with HMIS (Sections 2, 6).

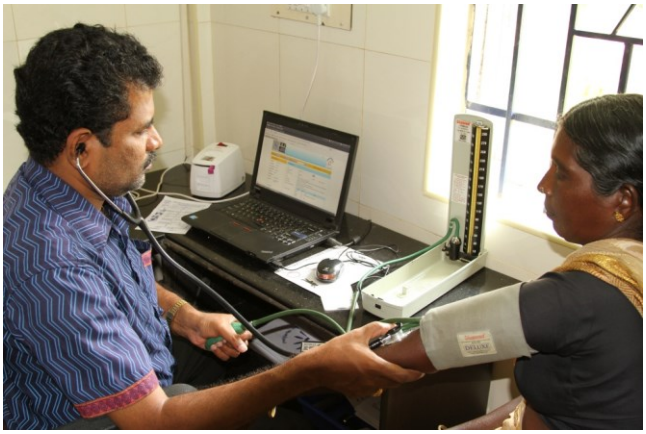

Figure 1. ICTPH clinician with a patient. A laptop running HMIS can be seen in the background.

- We have adopted the state machine model to represent the deep structure of a medical protocol (Section 4).
- We also articulate the challenges faced in translating paper protocols into software in the Indian rural context (Section 5).

2. AUTOMATING THE ICTPH AUDIT PROCESS

Medical audit helps a healthcare organization meet the objective of standardizing care across multiple clinics and improving the overall quality of healthcare delivery. Such organizations treat thousands of patients on a yearly basis, and there usually is a large amount of information associated with each patient. However, due to a shortage of both medical and paramedical staff to provide adequate services, having dedicated medical staff to conduct regular audits in an exhaustive manner is a very difficult proposition. For instance, ICTPH produces nearly 1,300 medical records each month, while it has only one auditor who is in charge of auditing these records. This highlights the importance of the role of technology in automating the audit process so as to assist the over-worked auditor(s) identify and address the few important violations out of a mostly compliant set of EMRs. Automated audit reports can also help track the performance of individual clinicians over time, and discover the specific instances where they require further training.

We need to consider two main workflows to automate the audit process followed at ICTPH: the consultation workflow and the audit workflow. The consultation workflow describes the procedure followed when a patient visits a clinic, and includes systematic documentation of symptoms, medications and tests. This is where HMIS is used by the clinicians to enter all medical record data relevant for audit, supply-chain tracking, and maintaining the medical history of the patients. The audit workflow on the other hand is the offline process followed by the team of auditors in the head office to periodically go through the EMRs generated across different consultations and note down deviations from the protocol. This process is time-consuming as it requires the auditor to go through multiple past records of each patient before arriving at a conclusion about the correctness of the care delivered in the current visit. The system we have designed, Jury, is deployed in the audit part of the workflow to cut down the time and effort required for an exhaustive audit of the medical records, while making it more accurate by uncovering more issues than are currently discovered manually. Jury expects a protocol definition as an input, and applies a protocol conformity check on the medical records to find incidences of violation from the specified protocol.

3. NUANCES OF CLINICAL PROTOCOLS

We next describe certain design elements necessary to build medical protocol specifications.

Symptoms: This information is provided by the patient during the visit to the clinic. Symptoms, as observed or felt by the patient, can be subjective. Therefore in many cases, especially with chronic conditions like hypertension which are mostly asymptomatic, this information is supplemented with diagnostic measurements or laboratory tests. Symptoms, taken either individually or in combination with additional tests, form the entry conditions to determine whether Jury should evaluate an EMR against a certain protocol or not.

Treatment goals: Once a specific medical condition has been identified, the treatment goals for that condition are defined. These goals may vary based on certain patient-specific variables like age, co-morbidities, pregnancy (if female) etc. For example, the ideal blood pressure for the young and middle-aged patient is less than 130/85, while that for the elderly (i.e., over 60 years of age) is only less than 140/90. Medicines are required only till the treatment goal for *that* patient is achieved. Treatment goals are used by Jury as the exit conditions for a patient to leave the treatment plan of a protocol.

Treatment lines: Pharmacological therapy for a disease progresses in discrete incremental dosages and/or drugs, depending on the response of the patient to a certain drug and dosage. The details of treatment can vary based on patient-specific variables, just like treatment goals. The treatment lines too may be changed along the course of medication, based on the patient response. For instance, a young patient who is diagnosed with Stage 2 hypertension for the first time is prescribed Enalapril 5mg once daily (OD) for 15 days as the first-line treatment. If there is no improvement the dosage is increased, and if there is still no improvement then, the patient is prescribed another drug – Amlodipine 2.5mg OD – in addition to Enalapril. The protocol definition should therefore allow the specification of different treatment lines, and allow switching across the treatment lines based on pre-defined conditions.

Comorbidities: These are other diseases which the patient is suffering along with the main disease of concern. These affect the treatment goals and lines. For example, if diabetes mellitus is comorbid with hypertension, the patient is prescribed Enalapril only, and not Amlodipine.

Referral conditions: These are criteria which provide guidance to the primary care clinician on when to refer a patient to a higher (secondary or tertiary) center, in case of complication or any other specialized advice or treatment.

4. SOFTWARE REPRESENTATION OF A PROTOCOL

The simplest method of automating a protocol audit is to use a series of conditionals and associated actions as in ProtoVerifier

[2]. ICTPH protocols however have a higher level structure as explained in the previous section, and are amenable to a coarser description that can be easier to maintain and modify. We found that an abstract state machine model with specific types of states can serve this purpose, and describe it next.

4.1 The State Machine Model

The state machine model is a method of representation for the abstract protocol-dictated clinical states that a patient passes through during the course of consultation, pharmacological treatment and follow-up. For each protocol, a state machine can be arrived at through analysis and discussion with the protocol designers.

Each state is a container for zero or more of the following: medications, clinical tests and transitions. On evaluating the inputs from an EMR e, a machine makes a transition from an initial state St_i to a final state St_f, passing through zero or more intervening states. The audit process is an investigation of the differences between this expected final state St_f and the actual final state St_{actual} as recorded in the EMR. For the current implementation, any difference in the path through which the final state was reached is not considered.

$$St_i \xrightarrow{e} \underbrace{St_f \overset{\Delta}{\longleftrightarrow} St_{actual}}_{audit}$$

4.1.1 State types

While defining protocols, states can be classified into the following types depending on the action required from the patient or clinician.

Start state: All protocols start from an 'unknown' state. This corresponds to the observation that a patient who visits a clinic for the first time for the treatment of a particular condition has to be medically examined before his/her state can be *known*. This marks the entry point into protocol execution.

Intermediate state: If, before reaching a diagnosis, a test has to be done multiple times in a staggered manner, the patient is assigned to a state of this type. For instance, the hypertension protocol recommends that for a patient without a history of hypertension to be given pharmacological treatment, a reading of 140/90 or higher should be seen consistently in 2 or 3 visits separated by 2 days each. Intermediate states help in representing this interim period between the first visit and the ascertainment of a chronic ailment.

Diagnosed state: Once certain diagnostic tests have been carried out, the patient can be assigned to a diagnosed state (abbreviated as d-state). Depending on the diagnosis, the patient either moves to a treatment state immediately, or is maintained in the d-state.

Treatment state: If the patient is diagnosed as requiring pharmacological treatment, a transition is made to an appropriate treatment state (t-state). Depending on whether the patient gets better or worse, he/she either stays in the same t-state, or moves through a series of t-states or transitions to a treatment goal state.

Treatment goal state: If on using the prescribed medications, the patient reaches an appropriate treatment goal, the state machine corresponding to this patient moves to a treatment goal state (tg-state). Goals may differ depending on various factors like age group, co-morbidity etc. Thus tg-states enable the representation of all the various goals that a protocol may have.

Refer state: A patient who cannot be managed solely by primary care is referred to an appropriate secondary or tertiary facility. This state represents the case where a referral action is taken.

4.1.2 Hypertension protocol

To demonstrate the state machine model, we next describe the protocol specification for hypertension. Figure 2 shows the state diagram for the ICTPH hypertension protocol [3]. Only a high-level view of the t-states and tg-states is shown. The red ovals represent d-states. As shown in the figure, a patient with a blood pressure (BP) value less than 140/90 will be diagnosed as optimal, normal or pre-hypertensive; these d-states are shown on the left side of the figure. Otherwise, to ensure that drugs are absolutely necessary, BP measurements are taken on two different days (separated by 2 days each) to filter out any anomalous reading. During this period the patient transitions through the 2 intermediate states shown. Once it is confirmed that it is a case of hypertension, the patient is relegated to one the following d-states: Stage 1, 2 or 3 hypertension. The first two lead to t-states, while the last leads to a direct referral.

An expanded view of the t-states in the hypertension protocol is shown in Figure 3. Each blue oval represents a t-state as it has one or more associated medication. Each t-state can have 3 kinds of transitions associated with it. These are described below.

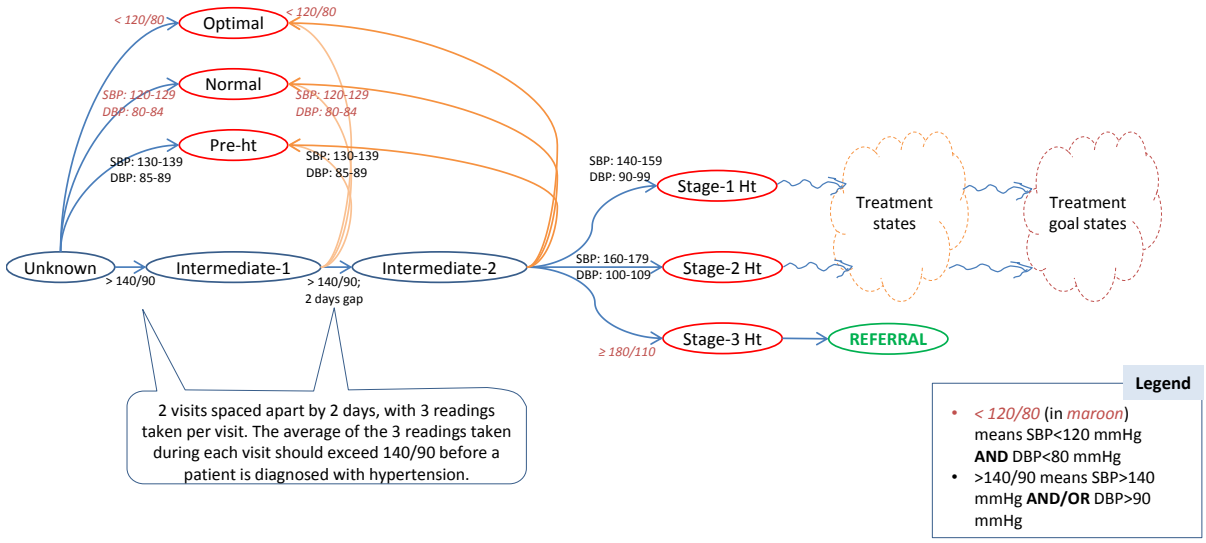

Figure 2. States and transitions for the ICTPH hypertension protocol

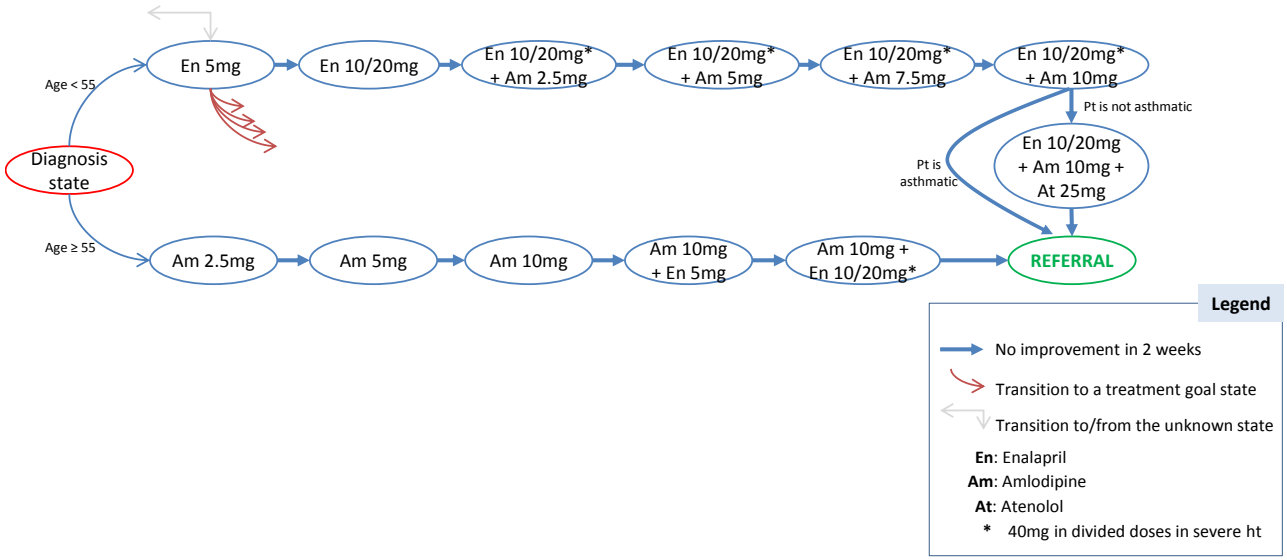

Figure 3. Treatment states in the hypertension protocol. The case where the patient has a co-morbid condition (diabetes mellitus or hyperlipidemia) is not shown to avoid overly complicating the above diagram.

- A transition can be made from a t-state to a treatment goal state if the patient's condition improves sufficiently on taking the prescribed medication(s). Similarly, a transition is made to the referral state if there is a drastic deterioration of the patient's health. These transitions are represented by the maroon arrows.
- Patients can also transition to the unknown state if they do not turn up at the clinic for a very long period of time. A patient who is a known case of hypertension and is on anti-hypertensives prescribed from some other external healthcare provider (e.g., government primary health center (PHC) or another private clinic) can directly transition from the unknown state to the corresponding t-state. These transitions are represented by the grey arrow.
- If there is no improvement even after taking the prescribed medication(s) for 2 weeks, the patient transitions to the next higher dose (or next treatment step). This is represented by the thick blue arrow.

For ease of representation, the first two kinds of transitions are shown only on one t-state in the diagram; these transitions are possible from and from/to every t-state respectively. In the ICTPH protocol, both Stage 1 and Stage 2 hypertensive patients are recommended the same treatment lines. This is why the figure does not have separate sets of treatment lines for different d-states.

To illustrate, an elderly patient can move from a d-state to Amlodipine 2.5mg and to Amlodipine 5mg in a couple of weeks if there is no improvement. At this point, the patient may exit the treatment line and attain the treatment goal appropriate for him/her. Alternately, the patient may not visit the clinic for a very long time and thus move back to the 'unknown' state.

A patient can transition from any treatment state to an appropriate treatment goal state (tg-state) if the necessary conditions (shown in Figure 4) are met.

4.2 Protocol description language

While designing Jury, it was decided that the configuration of the state machine should be kept separate from the logic (code). This

```
<state id="stage1_htension" type="d">
  <transitionref id="to_amlodipine2_5" />
  <transitionref id="to_enalapril5" />
</state>
<state id="enalapril5" type="t">
  <medref>
    <name>Enalapril</name>
    <dosage unit="mg">5</dosage>
    <frequency>OD</frequency>
    <duration type="days">15</duration>
  </medref>
</state>
<transition id="to_enalapril5">
  <deststate id="enalapril5" />
  <cond>
    <lt>
      <profile attribute="age" />
      <ivalue>55</ivalue>
    </lt>
  </cond>
</transition>
<medication id="Enalapril">
  <bname>Dilvas</bname>
  <bname>Enpril</bname>
  <maxDosage>40</maxDosage>
  <test>
    <name>Creatinine</name>
    <cond>
      <irange>
        <testattr name="serum_creatinine"/>
        <lb><fvalue>0.7</fvalue></lb>
        <ub><fvalue>1.3</fvalue></ub>
      </irange>
    </cond>
  </test>
</medication>
```

Listing 1. A snippet from the hypertension protocol

enables changes to the machine with little or no changes to the code. While the ideal protocol configuration builder should provide a graphical interface, for the purposes of this pilot implementation we decided to go ahead with a suitable form of textual representation. XML was selected as the medium of representation as it is relatively easy for medical professionals to manipulate according to their needs. The availability of good parsers enables straightforward interfacing with the code base.

The protocol artifacts that need to be represented in the protocol description language (PDL) are states, transitions and actions. An important guiding principle during design was that the length of the protocol description file should be kept at a minimum; at the same time it should not be cryptically short either. The XML description file for hypertension contains approximately 850 lines, for instance.

To illustrate this XML representation, a snippet is shown in Listing 1. Here, a transition is made from the d-state stage1_htension to the t-state enalapril5 if the patient is younger than 55 years. In this state, the patient should be prescribed Enalapril 5mg OD for 15 days. To be prescribed this drug, the patient should have normal serum creatinine values (0.7-1.3). There may be multiple brands available in the market for the same generic medicine; these mappings are represented using the *bname* tag. The *medref* subnode always refers to the generic name and not the brand name.

4.3 Evaluation engine

The evaluation engine, implemented in Java, reads in the protocol description XML and verifies an EMR against it. Making the implementation generic enough to allow other protocols to be represented was an important consideration while building the application.

5. FROM THEORY TO PRACTICE

Several unanticipated challenges were encountered in translating paper protocols into an appropriate software representation. We describe our experiences and how these were solved. We believe that the insights we gained are sufficiently generalizable to inform similar research and interventions in developing regions.

5.1 Protocols: on-paper vs. on the ground

There are several instances where significant differences exist between the protocol recommendations and actual practice. The hypertension protocol, for example, mandates three consistent blood pressure readings that have systolic BP (SBP) > 140mmHg and/or diastolic BP (DBP) > 90mmHg taken during visits spaced apart by 2 days. Following this recommendation, the protocol was built using two intermediate states that followed the 'unknown' state. However, on analyzing the database, it was found that this recommendation was not followed for any patient. Due to this anomaly, no protocol evaluation run proceeded beyond the intermediate states to appropriate treatment states when Jury was first executed on archived EMRs. Consequently it was decided to remove these two states and allow a transition from the 'unknown' state to a t-state during the same visit. This implies that the patient can be prescribed medicines on the very first visit without a compliance issue being flagged.

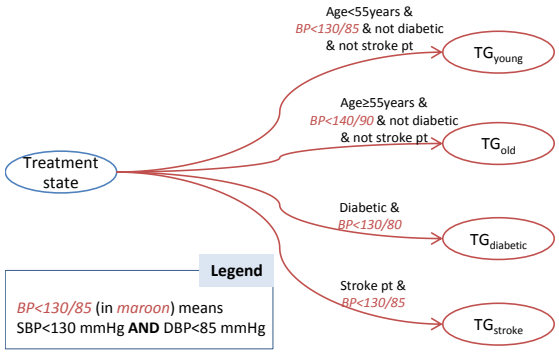

Figure 4. Treatment goal states in the hypertension protocol

Upon conversations with ICTPH, such violations were found to be happening due to several reasons. The patient might be a known case of hypertension and already on anti-hypertensive medication, but this may not have been recorded in HMIS. Or, the BP reading was alarmingly high during that visit that non-prescription of a drug was inevitable, but this medication step was not formally documented in the protocol description.

A second instance concerned the medications recommended by the hypertension protocol. For patients younger than 55 years of age, Enalapril was specified as the first line of treatment. The same drug constituted the second line of treatment for elderly patients (those over 55 years). The third line of pharmacological treatment in both cases was Atenolol. However these specific medications were never prescribed because the drugs were not available in the master list of the ICTPH clinics. Instead, the clinicians recommended various doses of Amlodipine and Losartan which were not mentioned in the protocol description. Consequently a modified description was provided by ICTPH and incorporated in Jury.

5.2 Gaps in protocol specification

Throughout the course of this pilot project, the protocol documents served as the software specification using which the application had to be built. Several disparities were however noticed in these documents in the process of developing Jury, and had to be reconciled with help from ICTPH doctors. Significant time and effort had to be spent on this, since the original protocol description had been prepared by other doctors who had left ICTPH by then. Some specific disparities in the hypertension protocol description are outlined below.

5.2.1 Overlapping classes

According to the protocol description, a patient who had a BP of 160/90 (a common reading for many hypertension cases) fell into two classes – Stage 2 hypertension, because the SBP lay in the range 160-179; and Stage 1 hypertension, because the DBP lay in the range 90-99. In this case, the fallout is not very serious as the action to be taken is nearly the same (initiate pharmacological therapy). However, if the two overlapping classes have different associated actions to be followed, the implications are more worrying. For instance, 133/93 can be classified as either Pre-hypertension because of the SBP, or as Stage 1 hypertension because of the DBP. Conversely, the reading 146/86 falls into the same classes because of SBP being in Stage 1 hypertension range and DBP being in Pre-hypertension range. Similarly, the readings 136/100 and 160/89 fall into the categories of Pre-hypertension and Stage 2 hypertension. In these cases, one class recommends that the patient start taking medicines while the other one does not.

The reason for this ambiguity is two-fold: the presence of 'and/or' clauses in the classification criteria, and lack of a precedence order between the various classes. One possible solution is to

establish a precedence order among the classes. For instance, Stage 3 > Stage 2 > Stage 1 > Pre-hypertension. This implies that if either of SBP or DBP falls into a class with higher precedence, the patient is considered as belonging to that class, regardless of the other value. This was a solution arrived at after a discussion with the researchers and medical doctors at ICTPH.

5.2.2 Unhandled combinations

Certain combinations of SBP and DBP had no associated action plan, and the patient fell through the cracks leading to a violation. In some cases, it was also found that the BP values recorded in HMIS were not legitimate, such as values of 110/180 and 120/240 where the SBP is less than the DBP. This is likely to have happened because HMIS validates SBP and DBP individually, but not in tandem. Such checks had to be incorporated directly in Jury.

5.3 Extracting implicit information

In several cases, information implicit in the protocols was extracted through trial and error. For example, it was seen that patients already in a 'good' d-state (like optimal or normal) or in a tg-state may take a turn for the worse at some point in time. To handle this, outward transitions had to be provided from d-states and tg-states. In another example, a patient undergoing treatment may not turn up at the clinic for an extended period of time (longer than the protocol-mandated monitoring interval of two weeks). The commonest reason was that the medicine helped lower the blood pressure, due to which the patient did not feel necessary to visit the clinic until the next incidence of high BP. In such a case of long periods with no visits, we added transitions in Jury to move the patient back to the unknown state.

5.4 Missing data from HMIS

Many critical pieces of patient or visit data were found to be missing in several cases.

5.4.1 Record of person

In several cases no record was found corresponding to the person ID mentioned in the visit documents. Consequently, Jury terminated the processing of the corresponding visit records prematurely.

5.4.2 Date of birth

HMIS uses the date of birth (DoB) of a patient to work out the age. Various aspects of the protocol hinge on this vital piece of information. The hypertension protocol, for example, recommends two separate lines of pharmacological treatment based on the age of the patient. This raises the question about what can be done if the DoB is missing from the database. One of the safest courses of action is to abort the processing of a visit record through a preliminary check if the patient's DoB is found to be absent.

5.4.3 Differential diagnosis

There were several records that described visits of hypertensive patients on active pharmacological therapy which however, did not list hypertension in the 'differential diagnosis' (DD) input field. Such omissions where the DD field is not filled correctly can pose a problem for some protocols, since the entry point into the protocol cannot be accurately determined based on a combination of symptoms alone.

On a related note, several HMIS records did not contain the chief symptomatic complaint of the patient either. This is a case of clear non-compliance with the process aspect of any protocol.

5.5 Socioeconomic and pharmacological realities

The realities of Indian society are starkly different from those of the developed world. This gives rise to certain unique complications. There are several cases in which patients were unable to buy medicines from a ICTPH clinic, or were given only a part of the prescription, due to poverty. In certain cases patients got medicines for free from the nearby government PHC but came to the clinic just for clinical advice. On the other hand, patients who were relatively well-off got opinions from other private clinics in addition to advice and/or medicines from the ICTPH facility. Since there were no pre-defined inputs on HMIS for recording such anomalies, these visits were flagged for various protocol violations.

Over-prescription of medicines is another common issue in India [4]. As a result of this malaise, patients do not respond well to protocol-mandated dosages which are relatively lower. Lack of expected improvement in health has been an important reason for patient drop-outs in ICTPH clinics. While we have considered such drop-outs as instances of protocol violation, some patients will be lost to follow-up in the event that they move to a different clinic in the private or public sector. This problem can be practically solved if the EMRs of different clinics are linked together, but this is not the reality currently.

5.6 Data usability issues

The ideal mode of patient data entry during consultation is through pre-defined inputs such as drop-down menus, radio buttons, check boxes etc. However certain crucial data points like patient/medication history are hard to represent via pre-defined indicators and so HMIS carried a free-text field named history of presenting illness (HPI). More often than not though, the contents of this field are not amenable to automated parsing due to spelling, grammar and sentence construction errors. In such a scenario, an automated audit is forced to proceed without this basic knowledge.

This fundamental issue was brought up during conversations with ICTPH. However, certain concerns prevented the implementation of these changes: additional inputs are expected to cause the clinician to spend extra time on the EMR system for each patient; moreover, appropriate training will have to be imparted to the field staff for each revision of the software's user interface.

5.7 Difficulties of hitting moving targets

The EMR system and the protocols have been moving targets, making the implementation of Jury quite challenging during the pilot project.

Frequent addition of new features and modification of existing ones in HMIS meant that the backend underwent structural changes quite often. Even the protocol definitions were changed frequently. Some of the modifications were trivial to implement and involved only alterations to constants like drug dosages, treatment goal values etc. Others were more far-reaching and required significant changes. These revisions forced us to repeatedly think about designing Jury in a way that is configurable enough to adapt to and accommodate such changes without hassle. Examples include the introduction of pre-requisite diagnostic tests for some drugs, enforcement of multiple BP readings before confirmation of the diagnosis and addition of new treatment goals and co-morbidity conditions. In the case of the first example, a whole new construct had to be introduced into the

PDL to represent drug-linked tests; this had to be hooked up with the medication artifact.

6. RESULTS AND VALIDATION

We had discussions with the audit team at ICTPH to validate the notes generated by Jury. This section summarizes the various aspects of the feedback, grouped thematically. The results in this section were gathered from a portion of the HMIS database that runs from October 2011 to March 2013. The selected data set includes over 19,500 visit records of roughly 9500 individuals collected from 7 rural clinics located in various parts of Thanjavur district in Tamil Nadu. During this period, there was an average of 45 visits per day to all the clinics. The footfall at the clinics currently is low but from a long term scalability perspective, automation of auditing will help. The number of clinicians will have to grow linearly with the number of clinics, but the number of auditors required will grow more slowly with a larger scale of operations.

Since the clinics offer only primary out-patient care, most of the important compliance issues are related to medications. Others related to non-compliance to the non-medical components of the process have also been identified and recorded.

6.1 Accuracy, prioritization and efficiency

During the manual audit process followed by ICTPH, 64.76% of all the EMRs in the period studied were audited and protocol violations were identified in 12.98% of all the visits. These issues pertain to all protocols in the ICTPH system, and not just the hypertension protocol; this is because currently there is no way to categorize the manual audit messages by protocol or by priority.

Jury on the other hand analyzed 100% of the records, including all past records of a patient, and classified violations as errors, warnings, and informational messages. Errors relate to showstoppers like issues with medication or crucial information like patient age being missing from the patient profile. Warnings and informational messages have more to do with process adherence than patient well-being, the latter relating to issues of lower priority. While auditing the hypertension protocol, 8.33%, 33.09% and 32.72% of the visits were identified as having caused errors, warnings or notes to be generated. ICTPH confirmed that Jury had led to a significant improvement in the number of protocol violations identified, and that being able to analyze all records including historical medical records of a patient is a great value addition that Jury brings to the table.

Categorization of violations also enables the auditor to review just the important issues each day, leading to an improved efficiency of the overall process. A regular sanity check can be carried out by going through a random sample of messages, if needed. Jury enables quick closure of the feedback loop of auditor-clinician-patient in case something is seriously amiss in the prescription or recommendation given.

6.2 Compliance analysis

Several interesting analyses are facilitated by the audit notes generated by Jury. Some results have been included in this paper to show the graphs as to highlight the kind of detailed analysis that can be made possible through such a framework.

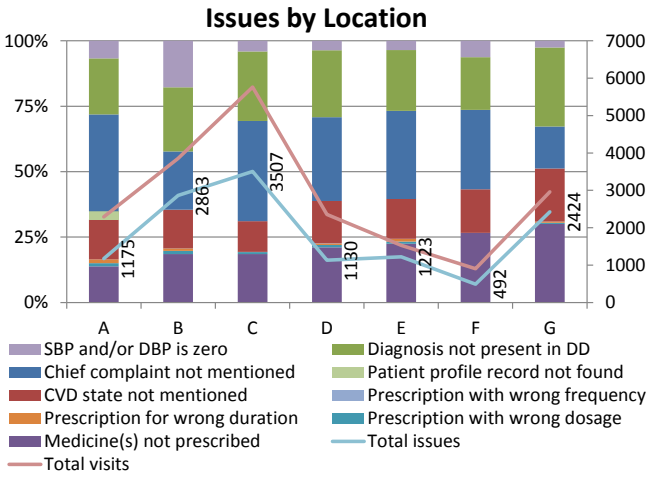

Figure 5. Compliance issues categorized by clinic location.

Among all the issues, the important ones pertain to the prescription of drugs. In some cases the drugs mandated in a state were not prescribed at all or only partially. In other cases, various parameters of the medicines – dosage, frequency or duration – were incorrect. Certain other notes refer to the concerns regarding missing data touched upon in section 5.4.

Figure 5 shows these issues identified by Jury, grouped by the location of the clinic. This graph has been anonymized; each clinic location is represented by a different alphabet. The blue line graph (and associated labels) represents the volume of messages generated for that particular location, i.e., the absolute value represented by a bar; while the pink one shows the total number of visits at that clinic. Medication-related issues are grouped together at the bottom and process-related issues above these in each bar. The bars have been arranged in the increasing order of the percentage of "medicine-not-prescribed" violations (violet color segment at the bottom of each stacked bar) from left to right. According to this metric, the clinic at C has higher compliance than the one at G although the total number of patient visits and violations are lesser at the latter. The largest chunk of issues (38.24%) reported at A are "chief complaint not mentioned" warnings; at G, this issue contributes to only 16.05%. On the other hand, the number of medication-related errors is the highest (30.90%) at the latter and quite low (19.30%) at the former. C is the oldest ICTPH clinic, with the maximum number of footfalls per day. An interesting observation that can be made from this graph is that clinic A is the only one with "patient profile not found" errors. On discussing with ICTPH, we understood that this was due to a bug in the system when a special enrolment drive was carried out at this clinic.

Several of these violations are also due to reasons that the system is currently unable to capture data in a structured manner. For instance, a patient may be prescribed tablets for only 5 days instead of the protocol-mandated 15 as he/she has insufficient money to pay for them. The reason is usually to be found in the free-text field mentioned earlier, but is not parsable by Jury generally.

Figure 6 analyzes the issues along another axis: the individual clinician. IDs have been used instead of names on the X-axis to preserve anonymity. The line graph shows the total number of audit messages associated with a clinician, and the bar graphs show the break-up of these messages. This figure uses the same color scheme and ordering as the previous one. Some clinicians have just about as many issues as visits; this does not necessarily imply that all visits handled by this clinician are non-compliant. We found that in all such cases, there were multiple issues per visit, and several visits without any issue. Visits handled by clinician #105 have the highest number of issues; this is because this clinician has the maximum number of visits. It can be observed that no errors of prescription for a wrong duration can be made by this clinician, in contrast to most others. In fact, this clinician was responsible for managing clinic C; this bears out with the fact that there are almost no issues of the aforementioned kind at this clinic.

The ICTPH protocol directs all clinicians to measure BP for all patients who are not minors. There are a few striking aberrations where over 25% of all visits handled by a clinician have no BP recorded – clinician #101 (41.87%) and #106 (31.65%). An interesting observation is that there exists a very strong correlation between the number of violations related to dosage and duration of a prescription. This means that a clinician who has a history of prescribing a drug with a wrong dosage has a higher likelihood of recommending the drug for a wrong duration.

Such analyses can enable performance-based incentivization for field staff and identification of 'star clinics' based on compliance measures. This preliminary analysis demonstrates that much more meaningful information can be gathered by examining the audit data in conjunction with other parameters.

6.3 False positives

Some of the messages emitted were found to be non-issues or invalid violations. In some clinics, the doctor was found to have prescribed a drug dosage that is a notch higher than the protocol-mandated one. Nevertheless, this enhanced dosage helps the patient achieve the appropriate treatment goal, and so he/she is prescribed the same dose in subsequent visits. Here Jury flags errors that the medication was of an incorrect dose, as it sticks to the previously saved (correct) dosage. The root problem in this case is that paper protocols do not have the level of precision required for a software implementation. Consequently, the implementer makes several assumptions, some of which are found to be incorrect through discussions with the auditors.

In several cases, BP was not measured or no drugs were prescribed to known hypertensive patients. This was found to be because these patients had come for some other purpose (like buying outpatient products or for a diagnostic test) and not for BP treatment.

We have not done a detailed enough analysis of the false positives yet. A future study can include a more thorough look into the following: (i) the proportion of compliance issues identified that are merely false positives, and (ii) the percentage of issues identified through the manual audit process that was missed by Jury.

6.4 Cross-disciplinary challenges

A few false positives encountered were due to a misinterpretation of the paper protocol by the implementer. Such issues are more or less inevitable given the inter-disciplinary nature of this work. For example, Jury considered treatment goal states as ones where no more medication is required, and flagged an error when a patient who is in a tg-state of a protocol was prescribed drugs for that protocol. In actual practice, the patient is advised to continue the last dosage or to gradually taper the medication over a period of time. To cite another such instance, all EMRs which did not record blood pressure readings were flagged with errors. Under normal circumstances, BP will not be usually measured if the patient is a minor. So such visits should not have been flagged with BP-not-measured errors.

7. RELATED WORK

There have been several studies on how the use of technology helps in improving healthcare outcomes, especially in resource-constrained primary care settings [5, 6, 7]. Most of these, however, concentrate on how to aid the care provider during or just before the patient visit. In contrast, our study focusses mainly on making the post-consultation audit process smoother.

The general direction of this project is the same as that of a

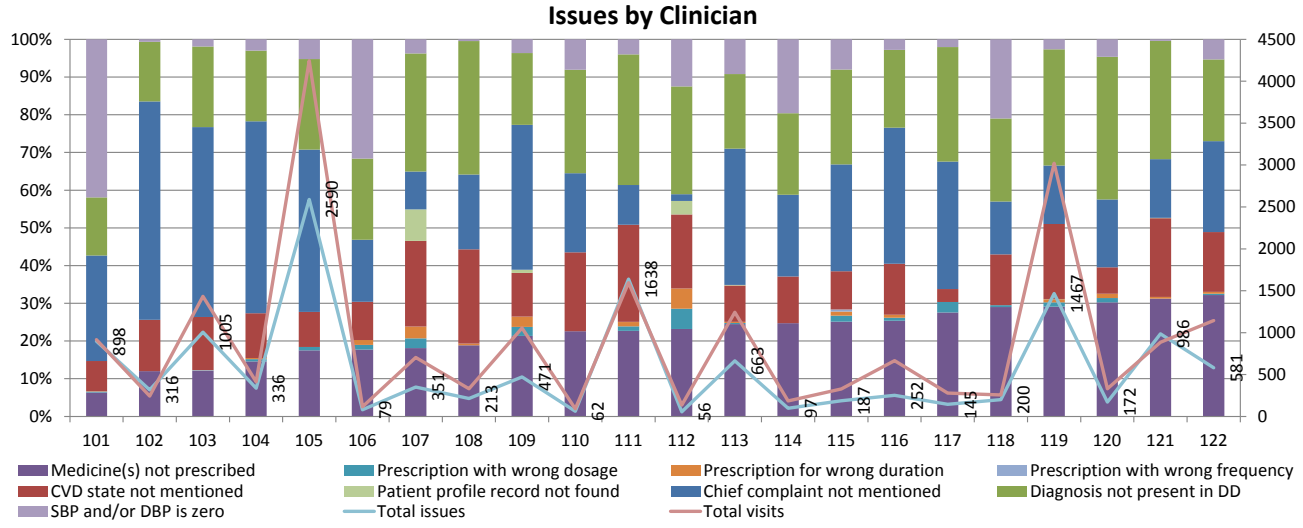

Figure 6. Compliance issues categorized by clinician.

clinical decision support system (CDSS) [8, 9], yet differs from it in certain significant ways. A CDSS assists the clinician in reaching a diagnosis, and is thus usually an online system – i.e., it is an interactive system that gives live suggestions to the doctor. Jury, on the other hand, is meant for assisting the audit process, and works in an offline mode. Decision support systems are often probabilistic in nature, to mirror the mathematically fuzzy character of medical diagnosis. In contrast, Jury operates in a completely deterministic manner since the problem of testing protocol obedience requires only a test of how closely the suggested treatment method is followed – and does not require the program to arrive at probable diagnoses. In a seminal paper, Ledley and Lusted [10] describe the logical groundwork that underpins any CDSS. NxOpinion [11] is a CDSS developed for use by health extension workers and community health professionals in rural areas of developing countries. OpenCDS [12] is an open source CDSS that is undergoing active development. While these CDS systems take a probabilistic approach, our requirements are to deterministically detect errors in protocol adherence.

Our work relies heavily on the functioning of EMR systems, being the upstream application for Jury. In the course of our research, we evaluated several such systems. Our work was primarily based on HMIS [13], the system that ICTPH uses. OpenMRS [14] is a popular open source health information system that several other implementations have built on.

8. CONCLUSION

We identified the need for an automation framework for protocolised primary healthcare. We described how the state machine model can be used to represent the detailed structure of a medical protocol. Further, we articulated several challenges faced while translating paper protocols into software. Insights from this work will be helpful for implementers who work at the interface of healthcare and software technology in rural contexts. Analyses provided by Jury allows for systematic performance assessment of clinical staff, as well as clinical outcomes at the enterprise level allowing provision for metric-based incentives. An automated compliance management system such as Jury allows for large scale implementation of process-driven protocols, which benefit from low human resource intervention and lead to efficient systems for social enterprises working on scalable models for primary healthcare delivery in India.

Our current observations are based on the implementation of a single protocol, but we invite other members of the research community to experiment with more protocols on similar lines.

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