Design of a Phone-Based Clinical Decision Support System for Resource-Limited Settings

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ABSTRACT

While previous work has shown that clinical decision support systems (CDSS) improve patient care in resource-limited settings, there is little access to such systems at the point of care. Moreover, even when CDSS are available, compliance with care suggestions remain low. In this paper, we use a multi-method approach to document four failure modes that can affect CDSS implementations. Building from six iteratively derived design principles, we describe a phone-based system designed to address these failure modes. Through a formal usability evaluation, we discover six core findings that are important for implementers of mobile systems for health care providers in resource-limited settings.

Categories and Subject Descriptors

J3 [**Medical information systems**]; H5.2 [**Information Interfaces and Presentation**]; C2.4 [**Distributed Systems**]: Client-server

General Terms

Design, Human Factors

Keywords

clinical decision support, electronic medical health record, summaries, reminders, mobile phones, mHealth

1. INTRODUCTION

Of the 33 million people globally who have HIV [51], 22 million live in Sub-Saharan Africa where their clinical outcomes are worsened by strained health care systems [7]. Although Sub-Saharan Africa has 25% of the global burden of disease, it only has 3% of the world's health care workers – many of who are minimally-trained [34, 22, 23, 42, 10, 30]. Combined with the challenges of chronic disease management, it is no surprise that the region accounted for 72% of the world's AIDS-related deaths in 2008 [50].

There has been a push to use information communication technologies to help strengthen existing health care systems. Broad categories of interventions include informing populations about health issues [11], providing medical consultation remotely [25, 52], and enabling health data collection and retrieval [24, 5]. In this latter category of health data management, electronic medical records and clinical decision support systems (CDSS) offer promising approaches to improving care in these resource-limited settings.

1.1 Medical records and decision support

Electronic medical records have had a positive effect on clinical care in resource-limited regions [48]. Patient visits were found to be 22% shorter, with clinician time per patient reduced by 58%, and patients spending 38% less time waiting in the clinic [40]. Similar studies show improvements in legibility of clinical notes, prescriptions and lab tests [15], readily available patient charts [58], support for program monitoring [53], better management of chronic diseases [17, 8] and useful reminders and alerts about lab results and medications [21].

CDSS build on the data stored in electronic medical records and are particularly powerful when providing patient-specific care reminders (e.g., reminding a clinician during a diabetic patient's visit to order an overdue insulin test). In the developed world, CDSS has been shown to improve clinical practice and the quality of care [27, 6, 44, 41].

Studies have also shown that using care reminders is preferable to manual reviews of charts [14, 29] or to using clinician-directed continuing education [12]. Care reminders are ideal because they can be tailored for varying skill levels of clinicians and can efficiently support evolving care protocols. These properties of reminders are especially relevant for health care in resource-limited settings.

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1.2 Challenges with decision support

Extrapolating from the success of CDSS in the developed world, it is likely that such systems will change clinician behavior and improve quality of care offered to patients in resource-limited settings [32]. Early work in these settings used patient summaries that display relevant data and reminders on desktop computers to clinicians [1, 2]. Studies of such systems have shown that when made more broadly available to clinicians, computer-generated summaries and reminders can improve compliance with care guidelines [55, 56].

Despite these promising starts, there are still challenges in ensuring reliable availability of summaries and reminders at the point of care [33]. Moreover, clinician compliance with care reminders can be increased beyond [46] what earlier work has accomplished. Finally, as care systems incorporate comprehensive chronic disease management (e.g., hypertension, diabetes) programs [16], there will be a greater reliance on CDSS to help clinicians comply with the various (and complex) care protocols [49]. For these reasons, it has become increasingly important to improve availability of CDSS and clinician compliance. Mobile technology, which is being introduced in these settings, provides an opportunity to address these challenges.

Existing decision support research in the "mHealth" space focuses on tools for lightly trained health care workers. Examples include: Healthline, a 'call-in' system to hear health information [45]; e-IMCI, a PDA-based system for administering a clinical triage protocol [13]; CommCare, a phone-based patient management tool [28]; and persuasive messages about maternal health [39, 38].

In contrast with earlier work, we focus instead on tools that use patient-specific data stored within the patient's electronic health record to provide computer-generated guidance for clinicians at the point of care. Rather than relying on paper for the generated summaries and reminders, we use an entirely electronic system. Rather than generic advice about singular protocols, we deliver patient-specific reminders about any deviation in accepted standards of care.

1.3 Contributions

In this work, we document four failure modes that can affect CDSS implementations in resource-limited settings. These include: 1) physical movement of paper-based summaries is unreliable; 2) computer-generated reminders expose incorrect data that slows clinic workflow; 3) critical feedback on availability and response rates are not timely or reliable; and 4) surges of unscheduled patients can prevent paper-based summaries from being reliably printed.

To address these failure modes, we developed ODK Clinic, a phone-based CDSS. In this paper, we detail six design principles that emerge from our iterative design process and guide our implementation of ODK Clinic. These principles are: 1) support a variety of summary types; 2) assume unreliable or disconnected servers; 3) use large, minimal, and consistent widgets; 4) model the user interface on the existing paper-based system; 5) discard any functionality that duplicates work; and 6) optimize for speed and responsiveness.

Our evaluation discovers six findings that implementers of mobile systems for health care providers should consider. We find that clinicians: 1) want to enter patient data electronically and shift summary retrieval from nurses; 2) expect any implemented phone-based CDSS to have minimal impact on time they spend with patients; and 3) want to use the phone throughout their practice. ODK Clinic, when compared to current practice, is 4) considered fast and easy to use; but 5) lack of previous experience with smart phones as well as phone screen size negatively affect task completion speed. We also find that 6) clinicians are primarily concerned with how phones will be distributed and secured.

2. BACKGROUND

The partnership between the United States Agency for International Development and the Academic Model Providing Access to Healthcare (USAID-AMPATH) is the one of the largest HIV treatment programs in sub-Saharan Africa and is Kenya's most comprehensive initiative to combat the virus. The program provides care to more than 100,000 active HIV-positive patients [47] through 26 parent and 26 satellite clinics (shown in Figure 1).

Figure 1: USAID-AMPATH provides care to over 100,000 active HIV-positive patients through 26 parent and 26 satellite clinics.

2.1 Existing clinical practice

USAID-AMPATH clinics use the AMPATH Medical Record System (AMRS) to store comprehensive electronic medical records for all patients [47]. AMRS is built from OpenMRS, an open-source electronic medical record system widely used in resource-limited settings [26, 43]. Instead of relying on free-text, patient data in AMRS (e.g., demographics, problems, diagnoses, medications, labs) are primarily stored as coded 'concepts' for easy search and analysis [54].

Clinicians at USAID-AMPATH do not enter data directly into AMRS but instead complete highly structured paper encounter forms. These forms contain questions and answers that map to previously defined concepts. After the patient encounter, data clerks with minimal computer skills and little medical knowledge enter all visit data from the encounter forms into AMRS. A data quality clerk also reviews the encounter data to ensure mistakes are not made. The paper encounter forms are then placed in the patient's chart, and made available to the clinician during the patient's return visit.

2.2 Clinical summaries and reminders

Using recommendations from the World Health Organization [57], the Kenyan Ministry of Health [31] and its own clinical experts, USAID-AMPATH has created a clinical summary module within AMRS. The module generates a printable, single-page summary (shown in Figure 2) that provides an overview of the most relevant data needed by clinicians. The module also appends patient-specific care reminders to the bottom of the summary.

Testarius Paul Kungu **014021634-2**

Male 39 Years,10 Months (01/01/1971) 4039MT-6

HIV STATUS: EXPOSURE TO HIV (06/12/2006)

First Encounter	Highest WHO Stage	6 Months HIV Rx Adherence
31/03/2010		Perfect

Problem List

Remove resolved problems through encounter form

1. MALARIA *(01/06/2010 ...3 more)*
2. BRUCELLA TEST *(31/03/2010)*

Immunizations

1. H.Flu B (1.0)
2. DPT (1.0)

Recent ARVs & OI Meds

1. TRIMETHOPRIM AND SULFAMETHOXAZOLE

ARV Side Effects

NONE

Maternal pMTCT: Med / Period / Doses Given / Rx Length

1. NEVIRAPINE / POSTPARTUM,ANTEPARTUM,INTRAPARTUM / [Unknown Dose] / 44.0 Weeks
2. LAMIVUDINE / POSTPARTUM,ANTEPARTUM,INTRAPARTUM / [Unknown Dose] / 44.0 Weeks
3. STAVUDINE / POSTPARTUM,ANTEPARTUM,INTRAPARTUM / [Unknown Dose] / 44.0 Weeks

Flowsheet (Initial + Last Four Value)

WT (KG)	HT (CM)	CD4	VIRAL-LD	HGB	SGPT	DNA PCR	ELISA	CREAT
6.0 06/12/2006	6.0 06/12/2006	(Test Ordered) 01/02/2010		(Test Ordered) 01/02/2010	(Test Ordered) 01/02/2010	(Test Ordered) 01/03/2010		(Test Ordered) 01/02/2010
60.0 01/02/2010	60.0 01/02/2010	200.0 (No Order) 01/09/2010				(Test Ordered) 16/03/2010		
60.0 01/03/2010	60.0 01/03/2010	65.0 (No Order) 19/09/2010						

Last 2 Chest X-Rays ***(check chart as needed for results prior to 14-Feb-2006)***

No chest x-ray results available.

Reminders : (Write number next to each reminder)

1-Ordered Today, 2-Not Applicable, 3-Previously Ordered, 4-Pt Allergic, 5-Pt Refused, 6-I Disagree with Reminder, 7-Other(Explain)

1. Please order HIV ELISA. Pt > 18 mo old with no valid ELISA result. (___)
2. Consider starting ARV Meds. Pt > 5 yrs with positive DNA PCR AND CD4 Count < 500 (___)

Last seen 31/03/2010 at MTRH Module 1 by The Super User
Encounter entered by The Super User on 01/03/2010
Next scheduled visit: 03/01/2007

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Figure 2: A sample clinical summary sheet with reminders.

Generated summaries are available in PDF format on AMRS via desktop computers, but since most of the clinicians do not have access to computers during patient visits, summaries are typically printed by nurses and attached to patients' paper charts just before the visit.

Summary data is created from different sources (e.g., HIV status is determined using encounter forms, electronic lab data and medication history) and so tends to be more accurate than data found in just the patient's encounter forms. To further increase data quality, when a patient presents for care, the clinician must review summary data and handwrite any corrections (in free-text, and primarily to the medication listing) on the printed summary.

Clinicians must also write responses to a set of care reminders on the summary. Responses to the reminders include: Ordered Today, Not Applicable, Previously Ordered, Patient Allergic, Patient Refused, I Disagree with Reminder and Other.

These responses take into account the fact that most recommendations are for ordering tests or referrals, or involve medications for the patient. In addition, the clinician has to hand-write a requisition form for any orders (e.g., labs, chest X-rays or medications). Summaries, once reviewed, are marked with a large diagonal slash by the clinician. Like the encounter forms, the marked summary is collected and any changes that can be entered are added to the patient's record in AMRS.

If the summary is not available, clinicians must rely exclusively on a time-consuming manual review of previously completed encounter forms and lab result sheets to find the relevant patient data.

3. PROBLEM ANALYSIS

Summary availability and accuracy is critical because clinical summaries, especially those with computer-generated reminders have been shown to improve clinician compliance with care guidelines and thus improve patient care.

In a prospective comparative study at USAID-AMPATH [56], printed summaries with reminders for overdue CD4 tests (an important indicator in HIV care) were made available to an intervention clinic but not to the control clinic. In the study, the CDSS identified 21% of patient encounters with overdue CD4 tests. In the intervention clinic where summaries with reminders could be printed, CD4 order rates were significantly higher when compared to the control clinic (53% vs. 38%) – this analysis considered all return visits in the intervention, whether the summary with reminders were printed or not. When the comparison was restricted to encounters where summaries with reminders were printed, order rates in the intervention clinic were even higher (63%). Furthermore, a before and after comparison shows a 50% increase in compliance rates with CD4 ordering guidelines at the intervention clinic.

Summaries and reminders are only effective if the underlying data is accurate. In a preliminary analysis of data from an ongoing study at one USAID-AMPATH clinic, we found that some potentially significant data quality errors or omissions – like incorrect medications in the electronic records, or laboratory results that had not been entered in AMRS. From this observation, we recognized that tools that help clinicians quickly correct mistakes in the patient record would be critical for improving care.

The expansion of the CDSS to all USAID-AMPATH clinical sites has also introduced another challenge. Given that there is no direct connectivity between sites, some of which are very remote, it has become increasingly difficult for the CDSS team to ensure that updated clinical summaries and reminders are printed and readily available at the point of care and that clinicians correct mistakes in the patient record and respond to all care reminders.

Furthermore, because corrections done on paper must be later verified by data clerks before entry into AMRS, this expansion has meant an increase of data cleaning work for the team.

3.1 Methods

To better understand gaps in existing practice that affected the CDSS, we observed clinical workflow at a number of clinics. We then conducted self-administered anonymous surveys and semi-structured interviews with six clinicians from a clinic with an average availability rate. We also surveyed and interviewed six members of the CDSS team responsible for daily implementation of the system. The focus of these observations, surveys and interviews was to understand the challenges of implementing and using the existing CDSS.

Additionally, from September 2010 to January 2011, we collected data on availability rates for summaries for patient return visits across 18 clinics. As shown in Table 1, 11 of the

Table 1: **Infrastructure of Study Clinics**

	Rural Site?	Reliable Power?	Reliable Network?	On Site Print?
Clinic P	Yes	No	Yes	No
Clinic R	Yes	Yes	Yes	No
Clinic Q	Yes	Yes	Yes	No
Clinic C	Yes	No	Yes	No
Clinic V	No	Yes	Yes	Yes
Clinic I	Yes	No	Yes	No
Clinic K	Yes	Yes	Yes	No
Clinic O	Yes	Yes	Yes	No
Clinic S	Yes	Yes	Yes	Yes
Clinic J	Yes	Yes	Yes	Yes
Clinic H	No	Yes	Yes	Yes
Clinic M	No	Yes	Yes	No
Clinic T	No	Yes	Yes	Yes
Clinic D	Yes	Yes	Yes	Yes
Clinic N	Yes	Yes	Yes	Yes
Clinic B	No	Yes	Yes	Yes
Clinic G	No	Yes	Yes	Yes
Clinic A	No	Yes	Yes	Yes

clinics are rural, 15 have reliable power, 10 have computers and printers on site, and all 18 have reliable cellular network (and thus some Internet access). This data was collected as part of routine care by CDSS staff.

Clinicians surveyed have three to four years of undergraduate education and one internship year of practical medical training. Most are between 30 - 40 years of age. They earn approximately \$6,000 annually (about \$1,300 more than a government clinician and \$3,500 less than a private clinician) and are thus in the lower end of Kenya's middle class income range (\$2,500 and \$40,000 [19]). CDSS team members earn approximately \$4,400 annually and have two to four years of undergraduate education. They are on average 30 years of age.

3.2 Results

We define a summary as available if for a return visit patient, the summary could be found somewhere in the clinic (though not necessarily in the patient's chart). We define a summary as marked if a clinician marked it viewed with a large diagonal slash through the summary. For each clinic, n represents the number of established patients with recorded return visits by each clinic. This number is roughly correlated with average patient load – a small n generally reflects a more rural clinic with fewer patients and fewer clinicians.

For the study period, there were 51,186 return visits, 41,176 (80.44%) of these had summaries available. As many as 10,010 patient encounters did not have printed summaries and thus may have received sub-optimal care. As shown in Figure 3, availability rates did not depend on clinic patient load.

In clinics we analyzed more closely (five clinics, 15,135 return visits), we found that clinicians did not mark a third (4,999, 33.02%) of the summaries as viewed. This makes it difficult to confirm whether clinicians even viewed the summary, but it reflects potential suboptimal care and potential errors in the patients' records.

There were large variations in the rates with which clinicians in different clinics marked summaries as viewed. This

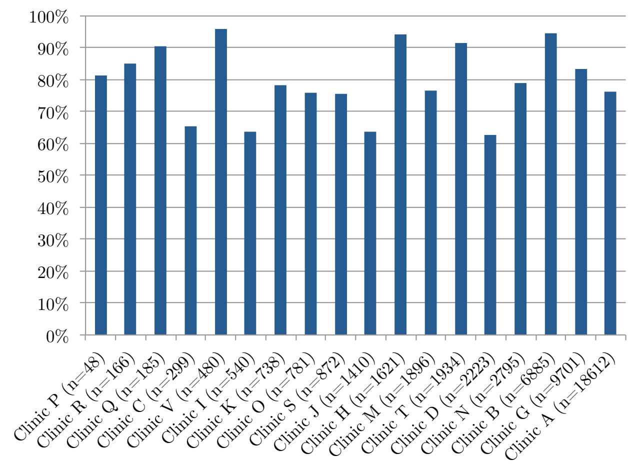

Figure 3: Proportion of patients with clinical summaries available during visits from study clinics. Clinics are sorted by number of return visits (n) starting from the smallest number on the left.

is reflected in Figure 4, where Clinics C, I, and D show much lower rates of summaries being marked when compared to Clinics G and A. It is notable that the clinics with lower rates tend to be smaller and more rural, which we suspect reflects an inadequacy of supervision at these sites.

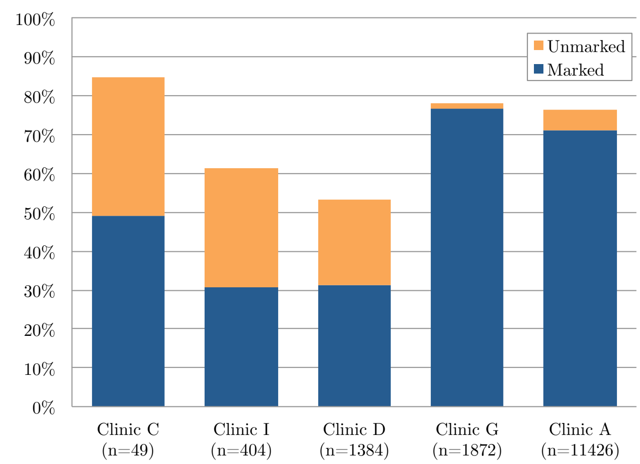

Figure 4: Proportion of patients with clinical summaries available and marked during visits from evaluated clinics. The gap between the top of the bars and 100% reflect missing summaries. Clinics are sorted by number of return visits (n) starting from the smallest number on the left.

When clinicians were asked why they used the CDSS, responses were unanimous.

> *"Saves time on clinical decisions [and provides] ready data for comparison."*

Clinicians noted that while data accuracy in the summary was sometimes problematic, they found summaries were always available and always marked. Their responses regarding availability and marking rates did not match the quantitative data gathered from clinics.

To address this discrepancy, we surveyed six staffers (again, self-administered and anonymous) responsible for implementing the CDSS to understand this discrepancy. When asked why summaries were not available or marked, staffers noted that failures were often driven by nurse workload.

> *"Nurses are sometimes overwhelmed by their work, so printing of unscheduled early patients summaries [is] not possible."*

> *"[Nurses] assume or neglect [printing] because they feel that it is an additional duty and not their work."*

Although patients are scheduled to appear on a certain day, most do not. In some cases, they forget the exact date or simply cannot afford the trip at that time. Many of these patients, when they eventually present, tend to do so early in the week (and early during the day) and this causes surges in patient numbers that can be hard to manage.

Staff also cited problems with broken computers or printers, network outages and physical transportation of the summary data between clinics.

> *"Summary sheets for remote sites have not been reaching on time since there is no readily available transport."*

Due to connectivity challenges, remote clinics must have summary data of every patient copied to an encrypted USB key and driven from a central site every few days. Once the vehicle arrives, previously printed and marked summaries are collected and driven back for data entry. Even with dedicated vehicles for summaries, shortages of transport in other parts of the hospital result in CDSS vehicles being used for other purposes.

The survey to staffers also asked why clinicians might not be marking summaries as seen or correcting mistakes. Staffers noted that clinicians were busy and forgetful and sometimes saw correcting summaries as a burden that could be ignored.

> *"[Clinicians] have been neglecting and not knowing the importance and seeing the pink sheet [the summary sheet] as an additional job."*

This neglect is likely the result of the long delay between when corrections are made on paper by the clinician and when they corrected in the electronic records (and thus reflected in subsequent printed summaries). As all changes have to be entered and verified by a data clerk, delays in these corrections mean that clinicians must correct the same mistake multiple times. As a consequence, the clinician may tire and simply stop marking the summary. Staffers noted that clinicians preferred to use the system when their changes were immediately reflected and when the summary had clearly actionable reminders.

When asked how to increase compliance, staffers wanted to reduce workload by hiring more clinicians, nurses, or data clerks. They also suggested more training and more supervision of clinicians and nurses.

> *"[There should be] regular visits by the person in charge of summary sheets to ensure that summaries are printed and marked by clinicians."*

Trained health care providers (clinicians and nurses) are a scarce resource in developing regions. Furthermore, while more non-medical staff might increase the printing rate, these staffers would not solve the problems documented in the next section.

3.3 Failure Modes

Earlier work at USAID-AMPATH described several factors that led to the complete failure of an early version of the CDSS [33]. These factors included, "not considering delayed data entry and pending test results; relying on wrong data inadvertently entered into the system; inadequate training of clinicians who would sometimes disagree with the reminders; and resource issues making generation of reminders unreliable."

As the CDSS has grown and evolved, so too have the problems associated with it. In addition to milder relapses of earlier failures, our analysis reveals four additional failure modes: 1) physical movement of paper-based summaries is unreliable; 2) reminders expose incorrect data that slows clinic workflow; 3) critical feedback on availability and response rates are not timely or reliable; and 4) surges of unscheduled patients can prevent summaries from being printed. These new failure modes are described below.

3.3.1 Physical movement of paper-based summaries is unreliable

Every few days, AMRS generates summaries for all active patients. Due to unreliable power and network connectivity at remote clinics, the CDSS team puts all the summaries in an encrypted format on USB keys to be transported via car to each remote clinical site. Once at the hospital, the data is synced to local machines where they can be printed. If transport is not available, or the USB key sync malfunctions, updated summaries cannot be used until the next generation cycle.

Interviews with supervisors suggest the remote site process fails approximately half the time. When failure occurs, clinical personnel sometimes fail to report the problem (see Figure 5) instead choosing to use outdated summaries. Without a more transparent monitoring system, it is difficult to correct these failures.

3.3.2 Reminders expose incorrect data that slows clinic workflow

Reminders use data in the electronic record that often differs from the data in the paper record. Discrepancies in this data become evident within the first few weeks of reminder creation. Each mistake then has to be corrected by a clinician and the change has to be verified and entered by a data clerk (sometimes by returning to a remote clinic to review the encounter form).

This correction process slows patient interaction for clinicians and introduces a backlog of work for the data clerks. As the clerks process the backlog, frustrated clinicians continue to see and are forced to continually correct the same mistakes. This process repeats each time new reminders are added to the CDSS.

While these errors tend to occur in the first few weeks of the creation of a reminder, the growing frequency of reminder creation introduces the potential for worsening the backlog of corrections.

Figure 5: In this clinic, the nurse sits in the right chair, and the patient sits on the left. The patient's feet (or her young children) might accidentally disconnect the cables and disable summary printing. Because of a lack of technical ability and power dynamics at the clinic, weeks often pass before such problems are properly diagnosed and reported to supervisors.

3.3.3 *Critical feedback on availability and response rates are not timely or reliable*

Limiting the overall number of reminders, improving integration of reminders into workflow, adding the ability to document problems and receive feedback drives adoption of CDSS [36, 35, 18]. The manual system with which USAID-AMPATH clinicians currently interact makes reliable and timely feedback difficult to achieve.

For monitoring and evaluation, USAID-AMPATH must understand the availability of summaries at the point of care and response rates to individual reminders. Without this data, it is hard to properly staff clinics, incentivize clinicians, provide extra training, correct unclean data, change unnecessary reminders, etc. Moreover, if this data is not available in a timely manner, supervisors cannot ensure only accurate and relevant reminders are shown to clinicians. As a result, clinicians grow frustrated and start to rely less on summaries and reminders.

3.3.4 *Surges of unscheduled patients can prevent summaries from being printed*

Nurses print summaries for scheduled patients ahead of time, but patients often do not arrive on the day they are scheduled. If a surge of unscheduled patients arrives, the nurses cannot both manage patient care and print all the necessary summaries.

Our data shows 15.64% of return visits across all sites were unscheduled patients. Clinics with more patient load showed higher rates, and the maximum rate of 33.47% across the study period was found at Clinic A (an urban clinic with the highest patient load).

Resolving the above failure modes is key to ensuring that the CDSS is reliably available during patient care at the USAID-AMPATH clinics. From our analysis of the failure modes detailed in this section, we believe that by equipping clinicians with mobile phones connected to AMRS, we can ensure summaries are more available at the point of care.

Once clinicians have summaries on a mobile device, they can correct serious mistakes and have their changes immediately reflected in the patient's electronic record. With clinicians responsible for retrieving summaries, nurses can focus on other responsibilities when unscheduled patients arrive. Additionally, supervisors will be able to quickly monitor and evaluate the effectiveness of the CDSS.

4. SYSTEM OVERVIEW

Open Data Kit (ODK), is an extensible, open-source suite of tools designed to build information services for developing regions [20]. In a population surveillance study with community health workers at USAID-AMPATH, ODK was shown to be easy to use, less error-prone, and more cost-effective than paper alternatives [37].

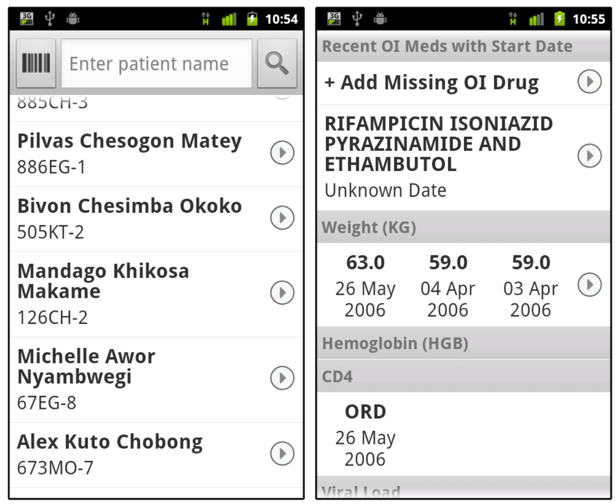

Figure 6: Users can filter, search and download summaries. Choosing a patient enables viewing and editing of that patient's summary. All data shown is for test patients.

Building on the ODK framework and our understanding of the failure modes, we created ODK Clinic, an Android application that connects to AMRS (over secure Wi-Fi or cellular networks) to download pre-generated XML summaries for offline use. Once summaries are downloaded, users can search for a particular patient (local to the device or remotely on AMRS), review data (e.g., see the latest lab results), correct summary data (e.g., mistakes in the list of medications), and respond to reminders or alerts (e.g., order a lab test). The user interface of ODK Clinic is shown in Figure 6 and Figure 7.

ODK Clinic also supports barcode scanning for faster input of patient identifiers, requires a user-specified PIN to unlock the application when it first starts (or times out) for security, and can refresh summaries automatically if a user forgets to do so. All data is stored on the device's internal memory which is not user-accessible without 'rooting', an unlikely attack vector in the environments where ODK Clinic will be used. Future versions of the application will also encrypt patient data.

Any corrections to the patient's record and usage data (e.g., what parts of the summary were viewed) are sent to AMRS each time summaries are downloaded. This data is made available for analysis by supervisors.

To provide data input beyond corrections to the clinical summary (e.g., to complete an encounter form), ODK Clinic can launch ODK Collect, a data collection client that connects to AMRS.

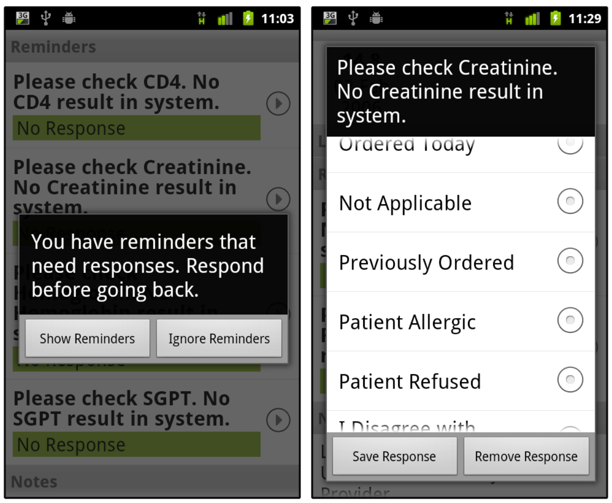

Figure 7: If a user exits a summary without responding to reminders, they are alerted. Responses to each reminder mirrors existing system.

4.1 Design Principles

ODK Clinic was created using an iterative design process with USAID-AMPATH clinical and decision support staff. In that process, six design principles emerged: 1) support a variety of summary types; 2) assume unreliable or disconnected servers; 3) use large, minimal, and consistent widgets; 4) model the user interface on the existing paper-based system; 5) discard any functionality that duplicates work; and 6) optimize for speed and responsiveness.

4.1.1 Support a variety of summary types

Although originally designed to support clinicians seeing adult HIV patients, ODK Clinic also supports a variety of summaries and users. For example, it is possible to design a summary that only displays information relevant to a pharmacist using a tablet at a dispensary (e.g., a patient summary with all prescribed medications and reminders about drug interactions). Only the summary generated in AMRS must change to support this new scenario.

4.1.2 Assume unreliable or disconnected servers

When a user downloads summaries, ODK Clinic fetches the most appropriate (as determined by AMRS) cohort of patients. In the case of clinicians at a particular clinic, they receive summaries of patients expected a week before and a week after the current date. This ranging method ensures that patient records for the next few days are available locally without downloading every patient summary in AMRS. Corrections to the patient's record and usage data are sent back each time summaries are downloaded.

As the connection to AMRS can be unreliable from remote sites, ODK Clinic can also connect to a more local server, if necessary. This will be an unlikely deployment scenario because synchronizing patient data across multiple remote servers has been a challenge for USAID-AMPATH to implement reliably.

4.1.3 Use minimal, large, and consistent widgets

Our previous experience with providers using mobile devices in this setting showed that responsiveness of touch-screens might be impaired if individuals had calloused fingers. Further, a good number of our users tend to have uncorrected vision. Users also tend to glance quickly at the interface when seeing patients.

To counter these challenges, we use minimal, large, high contrast widgets. Important functions are always visible on the screen. All touchable items have an icon that suggests that they are actionable. Finally, user input is channeled through two easily explainable interactions – i.e. scroll and touch. We use no pinch, swipe, or long press and minimize keyboard input.

4.1.4 Model user interface on existing system

To ease training, we mirror much of existing paper layout and content, but with optimizations for device size. For example, because clinicians are trained on reading lab values in columns, we do not graph lab values. We also only display data that is critical to point of care decision-making. If there are many reminders for a patient, we only show the five with the highest priority. And while we could display every value in AMRS, we display the same amount of data as on the paper summary. As users grow familiar with the phone-based system, we expect this to change.

4.1.5 Discard any functionality that duplicates work

As part of care, clinicians must always use a paper encounter form to document patient visits. USAID-AMPATH would like to maintain this particular workflow so we do not implement any functionality in ODK Clinic (e.g., recording a patient's current blood pressure) that also exists on the encounter form. Moreover, USAID-AMPATH expects to use ODK Clinic exclusively for summaries and to continue using paper forms for documenting encounters. This is despite the availability of form filling in ODK Collect.

Much of this decision is shaped by the realities of care delivery at USAID-AMPATH. Encounter forms are at the heart of every patient encounter and changing this in-grained and well-understood mechanism, even for a pilot, is logistically impractical. Rather than consider this a limitation, USAID-AMPATH views replacing paper summaries with ODK Clinic as the first step in understanding how to replace the paper encounter forms with tools like ODK Collect.

4.1.6 Optimize for speed and responsiveness

ODK Clinic uses a multi-threaded HTTP connection manager that spawns multiple connections to the medical record system. This approach enables fast downloads of hundreds of patients. Additionally, because AMRS can selectively send the most relevant set of patients, we save bandwidth by not downloading all available summaries.

While parallel connections may lead to lower aggregate throughput [9] on the high latency, low bandwidth links found in developing regions [3], we did not observe this limitation at USAID-AMPATH sites while using Wi-Fi, 3G or EDGE.

5. USABILITY TESTING

5.1 Methods

Supervisors from two clinics (five participants from one clinic, one from the other) where we expected to pilot the system selected a convenience sample of six clinicians. The sample had two women and four men. Clinicians in the sample were 30 - 40 years of age. Two owned Android phones while the rest had feature phones. Only de-identified patient data was used, but each test was designed to mirror a real patient interaction. Each clinician was evaluated separately.

We used touchscreen smart phones with no physical keyboards. All phones ran Android OS 2.2 and were sourced in the United States. Two of the usability tests were performed on a Huawei U1850 IDEOS (528 MHz ARM 11 processor, 2.8" TFT screen, $140) while the others were on an HTC Nexus One (1 GHz Scorpion processor, 3.7" AMOLED screen, $275).

Each test started with a training session on the device, a demonstration of the application, a guided walk-through of the functionality with the clinician using the phone, a task for the clinician to complete, and a semi-structured interview. In order to ease disruptions to the clinic, trials were not controlled – clinicians could and did respond to interruptions. We did no direct comparisons with a paper summary.

Tests were approximately 30 minutes long. Clinicians were asked to verbalize their actions during the entire test. All but one clinician consented to have an audio record of the interaction. We also took notes when usability issues occurred and prompted clinicians if they had difficulty proceeding through the task sequence.

We asked clinicians to unlock the secured device, download new summaries, find a patient in the middle of the list, view the summary, remove incorrect medications, add missing medications, view lab results, respond to reminders, search for a patient on the phone, search for a patient on the server, scan a barcode, and send results back to the server. Rather than require clinicians to remember the entire sequence, we reminded them of each next step.

At the end of all the usability tests, we also invited all clinicians (not just those who completed the usability testing) from two clinics to a group meeting to discuss the proposed system. Clinicians were encouraged to voice their concerns with the system. This session was also recorded.

5.2 Results

All clinicians in our usability testing were able to complete the task with minor prompting. We observed that previous experience with smart phones and phone screen size affected how quickly the task was completed. Clinicians self-reported that they preferred using the ODK Clinic phone-based system to the current paper-based system. They also felt that the mobile system was faster and easier to use than the current practice.

We found that clinicians wanted to be responsible for summary retrieval and patient data entry. They expected ODK Clinic to have only negligible effects on patient interaction time, and they also wanted to use the phone throughout their practice. The primary concerns of the clinicians were related to how the phones would be distributed. Clinicians were also concerned with the liability and security issues of patient data on expensive phones.

> *"Whoever thought of this idea was thinking about us. This is a brilliant idea, which is going to go a long way in helping us deliver the best service to our clients."*

5.3 Core Findings

5.3.1 *Desire to shift summary retrieval and patient data entry to clinicians*

Clinicians were particularly interested in the ability to retrieve summaries without involving the nurses. They considered use of nurses to print summaries a misuse of resources. Additionally, despite backup computers and extra training, they confirmed regular instances where the system failed and they could not get summaries. They preferred ODK Clinic because it enabled summaries at the point of care.

> *"You can easily access data when in the room versus printing summaries. We have many people for that process; here I can do it on my own."*

This was a surprising result. Our previous experience with paper summaries suggested that clinicians would not want to add more tasks to their workload, but there was a strong desire to try any technology that would potentially reduce paper work and increase reliability. Clinicians also saw ODK Clinic as a step towards replacing paper forms altogether.

> *"Get rid of paper. This is what is actually eating us up. We are filling too many papers."*

Clinicians expressed a desire to ensure that data they entered (medication corrections and reminder responses) reached AMRS quickly and accurately. The certainty of knowing their data would go directly to the patient record without a potential data clerk error was appealing.

5.3.2 *Impact of phone on time with patients expected to be minimal*

When asked if shifting summary retrieval to clinicians would slow patient care, there was consensus that although the first few times would be slow, they would come to adopt the system. Those who had recently learned how to use a smart phone or computer recalled their experiences struggling for a few days and then mastering the technology. When asked, clinicians familiar with smart phones considered it faster than current practice. Clinicians that struggled in the tests agreed their usage would become faster over time.

> *"The technique, the buttons, the hands. It's a little tricky to start with, but it's an issue of practice."*

ODK Clinic's ability to store unscheduled patient records and search across USAID-AMPATH's entire list of patients was reported as a reason to adopt the system. We had assumed that reducing download time and per patient interaction time would be very important, but we observed that these more holistic improvements to the workflow were equally important. For example, one clinician liked ODK Clinic because they could look up patients without having to walk all over the clinic looking for paper records. When asked to compare with a desktop computer, another clinician said that not withstanding cost, the portability of ODK Clinic was an important feature.

5.3.3 *Desire to use phone throughout clinical practice*

Clinicians did not expect patients to be concerned about the use of a phone as part of their care. In fact, there were requests to add more functionality than was currently available. One clinician asked if the phone could send images of X-rays to his supervisor for review. Another wanted to install an obstetric application to aid in care. A third wanted a calendaring application to schedule patients.

Despite these desires, there were likely limitations to what clinicians would use a phone for. In the group session, clinicians were given the opportunity to complete an encounter form with ODK Collect's single prompt per screen mode on a phone. The density of elements in the form resulted in a lengthy form-filling process that clinicians did not enjoy. Based on these observations, we believe that for long encounter forms, ODK Collect's multiple prompt per screen functionality on a tablet-sized device would be preferable.

5.3.4 *User interface considered easy to use with minimal training*

All clinicians reported that patient searching feature, as well as the barcode scanning function, was easy to use. Viewing and correcting the summary was also considered straightforward. All clinicians struggled with the undo functionality we had implemented, as well as with the user interface for changing medications with unknown start dates. As both features were not necessary, we resolved to remove them from the final system.

Clinicians are often interrupted (usually by other providers asking questions) while seeing patients, so we use no transient status or error messages. The application always requires some user input before it will proceed.

Finally, we had assumed that training clinicians to use the application would be challenging, so we included a 'wizard' mode that would provide transient help screens to prevent errors before they occurred. For example, AMRS requires three or more letters before searching for patients, so in ODK Clinic, we displayed this information as the clinician typed the first two letters. During the usability tests, it was clear that these help screens were ignored. This unnecessary functionality will also be removed from the final version to further minimize the user interface.

5.3.5 *Experience with smart phones and phone screen size affect interaction speed*

The local mobile carrier in Kenya recently started selling the IDEOS U8150 Android phone. The phone is considered affordable (about $90). In fact, two of the six clinicians tested own Android phones.

We observed that those familiar with Android were able to use ODK Clinic with very little training or prompting. Users not familiar with Android struggled with the responsiveness of the IDEOS screen (especially the soft keys). Scrolling was difficult and the visual clarity and size of user interface elements on the small screen was also a self-reported problem. Clinicians who owned the IDEOS reported that while it was adequate, the larger form factor and higher quality touchscreen of the Nexus One made it much easier to browse summaries. The processing speed of device did not seem to play a role.

Informal tests with an HTC HD2 (1 GHz Scorpion processor, 4.3" TFT screen, $300) suggests that while some clinicians would use the much larger phone, most preferred the Nexus One because the form factor worked better as a personal phone. With the wide availability of the IDEOS, there was also an expressed interest to use a more exclusive phone.

Given the impact on usability (and thus training and adoption), USAID-AMPATH has decided to pilot devices that can comfortably fit in a clinician's lab coat (3.7" to 4.3"). Future pilots will likely target tablet-sized devices.

5.3.6 *Clinicians concerned about phone distribution and security*

In the group session, many questions centered on the logistics of how phones would be deployed. Because phones would likely be assigned to a clinic and not to an individual, clinicians were curious how phones might be securely stored.

Clinicians expressed interest in using the phones as personal devices in order to simplify deployment, get familiar with Android, review patient records when at home, and to avoid carrying two phones. Clinicians were also concerned with the financial and legal implications of loosing an expensive phone with patient data.

"I like everything but the security of the phone."

Phones alone cannot solve every problem with CDSS. As the clinicians suggest, effective logistics play an equally important role. To secure against data loss, clinicians will synchronize their phones with AMRS at the end of every workday (approximately 30 patients). ODK Clinic can also automatically refresh summaries if they grow stale or after a number of summaries have been modified. If a phone with ODK Clinic is misplaced, broken or stolen, spare phones will be available on site. In the rare instance when a spare phone is not available, patient charts are still adequate for care. Security of the data stored in the devices is also important. As such, we use user authentication, secure data transmission protocols and automatic time-outs of devices.

Further, in a logistically challenging project at USAID-AMPATH involving health workers and Android phones, device loss has been minimal – we expect a similar result here. Where differences exist, we expect solutions will emerge as the system is piloted.

6. CONCLUSION

In this paper, we have documented four failure modes that can affect CDSS in resource-limited settings. These are: 1) physical movement of paper-based summaries is unreliable; 2) computer-generated reminders expose incorrect data that slows clinic workflow; 3) critical feedback on availability and response rates are not timely or reliable; and 4) surges of unscheduled patients can prevent paper-based summaries from being reliably printed.

Building from six iteratively derived design principles, we presented the design of ODK Clinic, a phone-based CDSS that addresses many of the failure modes we documented. These principles are: 1) support a variety of summary types; 2) assume unreliable or disconnected servers; 3) use large, minimal, and consistent widgets; 4) model the user interface on existing system; 5) discard any functionality that duplicates work; and 6) optimize for speed and responsiveness.

In our evaluation, we describe six core findings that implementers of mobile systems for health care providers should consider going forward. We find that clinicians: 1) want to enter patient data and shift summary retrieval from nurses; 2) expect impact on time with patients to be minimal; and 3) want to use the phone throughout their practice. ODK Clinic, when compared to current practice, is: 4) considered fast and easy to use; but 5) lack of previous experience with smart phones as well as phone screen size negatively affect task completion speed. Finally, we find that 6) clinicians are primarily concerned with how phones will be distributed and secured.

The uncontrolled setting, small sample size, short evaluation period, and lack of usage in actual clinical practice limit our results. Additionally, the use of self-report and surveys can be unreliable due to a tendency for participants to wish to please the researchers [4].

To address these limitations, we are conducting larger scale controlled trials in which we directly compare the usage of ODK Clinic with current practice across more clinics and with less trained users (e.g., nurses and community health workers). In these evaluations, we are also exploring the use of automation (e.g., a response to a reminder about an overdue lab test will order the test) and comparing total cost of support and maintenance with the existing system. We hope to document the limitations and unresolved challenges of the phone-based CDSS when deployed for a long period of time. We also hope to show the effect of ODK Clinic on availability, compliance and patient outcomes.

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