The Institution of Engineering and Technology Healthcare Technologies Network

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Printed and published by the IET, Michael Faraday House, Six Hills Way,
Stevenage, Herts SG1 2AY, UK

About the Speaker

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A PHARMACY STOCK CONTROL MANAGEMENT SYSTEM TO EFFECTIVELY MONITOR AND MANAGE PATIENTS ON ART

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Keywords: Open source pharmacy system, ART monitoring, resource constrained setting, South Africa

Abstract

This paper describes an open-source software system developed to dispense antiretroviral (ARV) drugs to HIV+ patients in South Africa. There are numerous constraints to the scaling up of antiretroviral treatment (ART) in resource-poor settings; one being the difficulty in monitoring and capturing of relevant patient data. South Africa has a severe lack of qualified medical staff, from doctors and pharmacists to nursing sisters, and it is imperative that the existing scarce resources are utilized effectively.

Based on an assessment of the local context, the system is comprised of two applications which reside at geographically separate locations. The first is housed at a central supply pharmacy where ARV drugs are packaged by a pharmacist for individual patients. The second application is housed at a service point or ARV site, where patients collect their medication from a nurse. Using HCI theory, it is designed to be user friendly and easy to learn for the nurses working at this health care facility. Features such as stock control and patient history (of timeous medication collection) make it easy for the pharmacist to assess each site receiving drugs from the central store.

In a resource constrained environment, it is important to assess software and maintenance costs to ensure long term sustainability of a project. By using open source software for development, additional costs of licensing are drastically reduced. The system described is developed in Java and connects to a PostgreSQL database management system. A client-server model is used to extend the outreach of trained pharmacists who can now dispense ARV drugs to a number of patients located in separate remote areas. The system focuses on patient monitoring and measurements of drug adherence through feedback between the applications. A prototype system was successfully implemented and has been in use for over a year. Currently over 2000 HIV+ patients on ART are being monitored on this system.

1 Introduction

South Africa has one of the largest populations of HIV+ people in the world. Antiretroviral therapy has been successful in drastically improving the lives of HIV+ people [13, 14, 15]. However, the logistics behind monthly dispensing and monitoring of people on ART is substantial. The system presented in this paper, the "Intelligent Dispensing of Antiretroviral Treatment" (iDart) is an open-source software system designed to assist pharmacists working in the field of ART in South Africa. This software was developed in a resource-constrained environment and in this paper a number of issues typical of this context are identified.

In a developing country such as South Africa, open source software development has major advantages. Benefits such as no licensing fees, ownership of software and prevention of vendor lock-in is vital to implementations in the public health sector in developing countries. In addition to using open source development tools, it is also highly advantageous to release public health tools in the open source community.

In the South African public health sector, antiretroviral drugs can only be distributed from a service point accredited by the government. A service point is defined as a group of linked health facilities operating through a hospital or clinic in a defined catchment area [12]. South Africa has a minimum of one service point in each of the 53 health districts [13], resulting in service points that are geographically remote.

A number of criteria have to be met to receive ARV accreditation; one of which is access to a pharmacist. Since legally, only a small group of health care professionals can dispense medication to individuals [4], we propose to extend the reach of the limited number of trained ART specialists by catering for the pre-dispensing of ARV drugs. This is done at a central dispensing pharmacy. The prescribed drugs are then distributed to different accredited service points. ART patients are then able to collect their monthly drugs from the nearest service point.

iDart has been designed to cater for the physical setup described above. It also addresses the problems arising from maintaining a secure and well-monitored drug supply to peripheral service points. The system aims to maximize the capacity of a pharmacist to rapidly increase patient numbers who visit remote ART service points. Through iDart, the pharmacist can monitor the drug supply chain from the time of stock entry into the system, through the dispensing process and up to drug delivery to any individual patient.

This application is robust, technologically simple, and requires minimal input from busy clinicians and other nursing staff. Due to the simplicity of the GUI, training time is also minimal – an important consideration for overworked staff.

The proposed system maintains ARV stock control at all stages of the supply chain, generation of reports and programme evaluation information. Real-time programme evaluations would include dates and numbers of patient initiating ARV therapy, date and times of drug switches, retention of patients on treatment, adherence (missed prescriptions) and regimen switches.

2 Background

2.1 Challenges facing ARV delivery in resource-poor settings

There are numerous challenges facing the delivery of life-saving ARVs in resource-constrained settings. Those that affect software development, deployment, maintenance and support need to be identified.

Firstly, there is the severe lack of personnel: this is applicable through-out the chain of medical staff and caregivers, from doctors to nurses [8, 14]. Additionally, trends suggest that this problem could be exacerbated in the future due to high HIV infection rates among staff in this field [14]. Also, there is a high staff turnover at public health facilities in South Africa, resulting in loss of organisational memory and inexperienced staff. Software training should therefore be kept to a minimum. It is also imperative that existing human resources are utilized effectively and efficiently with minimum interruptions to their current working schedules. In South Africa in 2005, only 14.9% of the 10824 registered pharmacists were working in the public sector [5]. With this severe shortage of pharmacists, it is impractical to have a pharmacist working full-time at all ART service points.

For successful ARV treatment, patients require a high level of adherence to their medications [3, 16]. Particularly in remote areas, ART patients often have to travel long distances to service points to collect their monthly ARV medication. Public transport costs are extremely high in South Africa (especially for unemployed individuals) and this is a hindrance to successful ART. Often, patients cannot afford the transport costs to the nearest service point.

In line with financial considerations is the monetary value of the drugs themselves. The South Africa government yearly expenditure on ARV drugs is substantial, and it is thus imperative to be able to electronically track the location of any drug monitored on the system.

Patients need to take their medication daily. There is thus a need to ensure a constant, reliable supply of drugs to service points. However, due to storage capacities, expiry dates of medications and drug theft, it is not possible to maintain large stock levels at peripheral ART service points.

Wherever medication is stored, an accurate reporting mechanism is required – one that is accessible to the staff responsible for the stock. Using a paper-based system is labour intensive and time-consuming, especially as patient loads increase. Additionally, paper-based records take a considerable amount of time to be generated and to become accessible to higher levels of administration. Electronic reports however, are available in real-time.

2.2 Open Source vs Propriety Software

Developing dispensing software in the public health sector in South Africa, particularly in the field of ART is relatively new and unexplored. Because of this, initial software and development costs should be kept to a minimum. Using open source development tools, over proprietary ones, gives an initial low cost of acquisition [7].

The basic principle behind open-source software is that the source code is freely available to the general public. The primary benefit behind this is to allow programmers from any organization to work on the project and among other things, create additional features as requested by different end-users. There is a great deal of flexibility and customisability in the development of open source products.

Most propriety or closed software systems usually require a licensing fee for each system on which the software is installed. As more health care facilities in South Africa increase their technological infrastructure, multiple license fees deserve particular mention.

Using proprietary software creates a dependence on particular vendors. With this dependence comes the potential for externally imposed upgrades, which often results in additional licensing, training and hardware costs [10]. Also, there is a concern that, should the company cease to exist in the future, support for particular products would not be available. However, with open-source, the source code is available to the general public and frees clients from vendor lock-in [10]. This affects the sustainability of the project as a whole.

2.3 Software Development in Developing Countries

Due to various factors, computer literacy in the general South African population is relatively low. Additionally, it is not important for nurses, or even doctors, to be computer literate to perform their jobs. For this reason, designing software for this group of end-users is particularly challenging. Basic guidelines have however been identified [6, 9]. Some of these include the use of buttons, intuitive icons and consistency through-out the application.

South Africa has 11 official languages and customising software to suit local languages can be effective in encouraging users to adopt the system. This is particular important since many end-users of iDart may have English as only their 2nd or 3rd language. Using technology that easily allows for the setting of languages is thus desirable. Java provides for this through internationalization and the setting of locales.

2.3 ARV Dispensing Software

There is an abundance of pharmacy dispensing software available. However, most of these systems are propriety and thus require license fees. During an analysis of existing software, it was also found that most were too generic for ARV-specific dispensing. An important measure, used to determine the success of ART, is a patient's adherence levels. And ART dispensing software should include functionality for this measure. This feature is highly beneficial to medical staff in identifying non-adherent and vulnerable patients who may require immediate attention.

While there is indeed a need to monitor patients on ARV, the amount of data collected should be kept to a minimum. If the capturing process is too time-consuming, it has been shown to actually impede effective service delivery [17].

3 System Description

The complete iDart system consists of two distinct applications which are installed at a minimum of two geographically separate locations. The first of these is called the pharmacy application and is housed at the central dispensing pharmacy. This is where the pharmacist works on a daily basis, organizing and packaging ARV drugs for a number of ART patients. The second, the so-called clinic application, is a subset of the pharmacy application, and is installed on a computer residing at a (minimum of one) remote clinic or service point, situated some distance from the central pharmacy.

3.1 System Overview

Figure 1 shows the general supply chain of ARV drugs from warehouse to ART patients. A pharmacist working at the central pharmacy orders batches of drugs from the depot. Upon arrival, the pharmacist enters the batch information and other stock information into the iDart system.

Typically, ART consists of triple therapy. This involves taking 3 different types of drugs for a 28 day cycle. At the dispensing pharmacy, the pharmacist creates a physical package consisting of these 3 ARV drugs for each patient enrolled on the system. Upon completion, the packages are sent to the remote ARV site or service point with a courier service. It is at this facility that ART patients visit regularly, to see doctors and to fetch their medication. When a patient receives the packaged drugs, the nurse or pharmacist assistant signs out the package and through iDart, creates a feedback mechanism, prompting the pharmacist at the central pharmacy to create the next month's drug package.

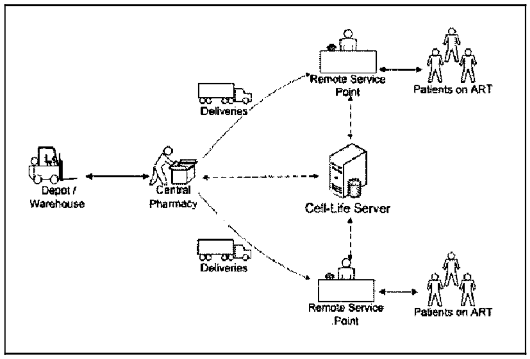

Figure 1: System Overview of iDart

3.2 Pharmacy Application

The pharmacy application comprises of a number of key features that allow the pharmacist to dispense medication regularly to numerous HIV+ patients on ART.

New Patient:
The pharmacist uses iDart to register patients onto the system. The amount of data to capture here is left to the pharmacists' discretion. There are 4 fields that are compulsory (unique ID, first name, surname and date of birth).

New Prescription & Update Previous Prescription:
At the time of registration onto iDart, patients have a new prescription from a doctor. Specific details from this prescription are then captured. In South Africa, ARV-specific prescriptions are usually valid for 6 months (1 issue and 5 repeats). For patients that have completed their 6 month prescription, a new prescription is required from a doctor for a further 6 months. If the prescription needs to change during the 6 months (e.g. patient changes regimen due to side effects), a new prescription is required. When any of these events occur, a field is required from the user specifying the reason for the new prescription. This can be one of "Renewal", "Toxicity", "Failure", "Intolerability" or "Other".

Create ARV Package:
iDart creates a list of patients that are currently in need of a monthly package of ARV drugs. This list includes both patients with new prescriptions, and existing patients already enrolled in the system with a valid prescription. The pharmacist then systematically works through each patient's drug requirements, creating a month's supply of ARV medication. Batch processing of prescriptions is encouraged since iDart indicates how many patients are currently

requiring ARV drugs. A dispensing label is created for each drug, specifying the pharmacy details, responsible dispensing pharmacist, dosing instructions, patient ID and date of dispensing. The months supply is then packaged together into an inexpensive plastic bag which is marked with a package label. This label contains information regarding the current repeat of the prescription, the patient ID, the date of dispensing, the remote ARV service point for which this package is destined, and a unique barcode identifying the entire package. This unique barcode is used to track the drugs through-out the supply chain. Once the package has been physically composed, it is ready to be sent to the remote ARV site, and eventually, to the patient.

Deliveries:
After all the listed patients' monthly ARV supply has been packaged, the pharmacist quickly scans the packages out and places them into a large sealed cardboard box. A report is automatically generated detailing the packages contained in this particular shipment. A courier service is then summoned and it is their responsibility to deliver the large sealed cardboard box to the specified remote clinic. Since the pharmacist pre-packages a patient's medication as soon as their previous month's supply has been collected, the packages are ready for collection well in advance of the expected pickup date. Also, since only the current month's supply is packaged, only a minimum supply of drugs is stored at the remote ARV site. This combats the space limitation issues addressed earlier, and assists with control since stock is more manageable and is already assigned to a particular patient.

3.3 Clinic Application

The second application of iDart is housed at the remote ARV service point. This particular application has been designed for users with minimum prior computing experience. Care was taken to ensure that only relevant data and features were available initially. Patient loads are extremely high in government clinics in South Africa, resulting in staff time being highly valuable. Training time was thus kept to a minimum. From a GUI design perspective, simple widgets (i.e. buttons), layout consistency and intuitive icons were used.

Two specific events occur at an ARV site that iDart needs to monitor. These are:

- A driver arrives with a box of packaged drugs dispensed to patients who are regular attendees at this facility.
- A patient arrives to collect their month's supply of ARV drugs from a nurse.

Upon arrival at the remote clinic, the box from the pharmacy is opened by a nurse and the packages are quickly scanned into the system. These packages are then kept in a secure location, ready for collection by the patient. When the patient arrives at the clinic and picks up their monthly ARV medication, the database is updated to reflect the collection. The patient ID is scanned in at this point to ensure that the correct patient received the specific ARV package. The pharmacist is then informed of this event through iDart and is prompted to create the patient's next month's supply of ARV drugs.

From a legal perspective, a nurse is not allowed to dispense drugs to patients. With iDart however, the pharmacist dispenses the medication at the central pharmacy and places a label on each of the drug containers with the relevant information (including the patient ID). At the point in the supply chain where the patient is receiving their ARV medication, the nurse is not dispensing, but rather distributing the drug to the patient.

The clinic application also included functionality to print information labels for each patient. These labels include basic information such as name, surname, gender, date of birth, and a barcode version of the patient ID. This label is placed on the front cover of the patient's clinical folder. This serves to both clarify the identity of the patient between staff, as well as to provide an easily accessible barcode of the patient ID for use in iDart or any other barcoded application.

3.4 Monitoring:

An important advantage of an electronic system for ARV dispensing, is that of monitoring. It is important to monitor both drug supply and patient adherence to their medications.

Drug Tracking:
The location of ARV drugs is identified at 4 points in the supply chain. Figure 2 highlights the flow of drugs through-out the system from initial dispensing to patient collection.

The points of data capture are:

1. The date the drugs are dispensed by the pharmacist (i.e. the date the package is created)
2. The date the packaged drugs leave the pharmacy.
3. The date the packaged drugs arrive at the remote ARV service point.
4. The date the patient collects the packaged drugs from the service point.

All these dates are captured using a barcode scanner. The database is automatically updated, based on the date and time at which the event occurred. By keeping records of these four dates, the pharmacist is able to identify drugs that have not been collected, or drugs that might have gone missing during the delivery. Recording these dates is also important for the pharmacist in terms of personal responsibility – from the point it leaves the dispensing pharmacy, to the time the patient receives it.

Patient Monitoring:
By recording patients' current and previous ARV prescriptions, and recording medication collections by these patients, general adherence to ARV treatment can be

calculated. Different reports can be created using this captured information, showing history on ART and levels of adherence obtained. This allows the pharmacist to assess each service point receiving drugs from the central pharmacy, and assess individual patients.

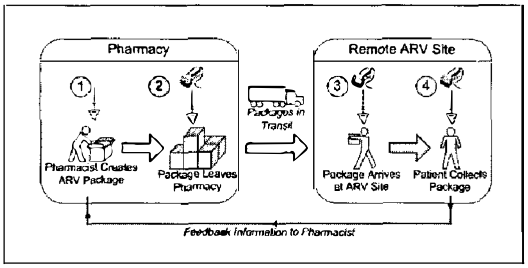

Figure 2: Tracking of ARV drugs along the supply chain from the pharmacy to the patient. The 4 points of data capture are shown.

3.5 Equipment Used:

Besides basic keyboard and mouse, input to the system is primarily done through a barcode scanner. This piece of equipment is inexpensive to buy and replace (± £50), and due to familiarity with the device, people find it easy to use. It also aides with bulk data capturing and minimizes erroneous data entries caused through human error.

Since there is communication with a central database, Internet connectivity is required at all facilities where iDart is installed.

A required feature of dispensing software is the ability to print labels containing patient information, dispensing instructions and other relevant information. For this reason, a label printer is required as well as a constant reliable source of labels. Experiences highlighted the need to use a thermal transfer printer, since ink on other labels was removed through heat and handling of the drugs.

3.6 Software Engineering Processes

Through participatory design involving a number of pharmacists working in the ART field, a set of features were initially identified [11]. These pharmacists would become end-users of the system. A prototype was rapidly created, using Visual Basic. The process from initial meetings gathering basic user requirements to installation of the prototype, took 4 months to complete. As is typical of evolutionary prototyping [2], this version was constantly updated with bug fixes and feature requests. The main purpose of this prototype however, was the development of a clear set of user requirements. This software engineering approach was chosen since the area of ARV dispensing software in resource-constrained settings is new and required a multi-disciplinary approach. Also, the software was urgently needed since patient numbers were rapidly increasing and a paper-based system could not suffice.

3.6 Technologies Used

Since the two applications are implemented entirely in Java and open-source technologies, the two applications can be run license-free on both Windows and Linux operating systems.

Hibernate (v3) is a powerful, high performance object / relational persistence layer for Java. It is used extensively in iDart, providing a level of abstraction between the Java code and database. It creates a persistent layer and provides for database agnosticism.

The database that was used for implementations is PostgreSQL, originally developed at University of California, Berkley. PGAdmin (v1.4.0) is a GUI-based application comprising of PostgresSQL Tools needed for database management. The choice of database however is flexible since Hibernate provides a level of database transparency. That is, it is simple to change the database.

Eclipse (v3.2) was chosen for development due to its large open-source community and large supply of available plugins. Visual Editor (VE) (v1.0) was also used extensively. VE is a plugin for Eclipse that aides with the visual design of GUI-based applications.

One of the key outputs of iDart is report generation. JasperReports (v 1.1.1) is a powerful, open source report tool for Java. iReport (v1.1.0), which uses JasperReports, is a report template design tool. Using iReport ensures that new reports can be easily generated, and can be modified to accommodate requirements from sponsors.

4 Implementations & Findings

A prototype system was successfully implemented and has been in use for over a year. Currently over 2000 HIV+ patients on ART are being monitored on this system.

4.1 DTHF Pharmacy and Masiphumelele

The Desmond Tutu HIV Foundation (DTHF) has been involved in dispensing ARV drugs to patients living in Masiphumelele since June 2004. Masiphumelele is an informal settlement situated in Ocean View, 40km south of Cape Town. A clinical study is under way to establish the HIV prevalence in this township [1], but current estimates have been high. One pharmacist works at the central pharmacy at DTHF, housed at the Medical School of the University of Cape Town, 30km from Masiphumelele. The pharmacist uses iDart to dispense monthly ARV drug supplies to patients visiting this remote ARV service point. Two doctors, two nurses and two study coordinators work at this health care facility. In March 2005, the prototype system was installed and was in use for 10 months.

Key features were identified during use of the prototype at this facility. These were:

- Reports of packages awaiting collection by the patient (aide with stock control)
- Reports of patients who failed to collect their monthly package (to be used for patient follow-up)

One particular technical bug that deserves mention was the choice of barcode font used for the initial prototype. Initially we used Code 39, which does not use any compression nor make use of any cyclic redundancy checking (CRC). As a result, certain barcoded package IDs could not be scanned into the system since they were too long for the barcode reader. Improvements were made in this regard by using Code 128

In January 2006, the first installation of the clinic application of iDart was successfully launched at Masiphumelele. To this day, 350 patients are actively being monitored on the system. All clinical staff are involved in the scanning in of pre-packaged drug supplies, and scanning out of these packages to patients. Accurate reports are now accessible to the staff working at Masiphumelele, and to the pharmacist working at DTHF.

4.2 DTHF Pharmacy and Hannan Crusaid Centre

The Hannan Crusaid ARV Treatment Centre is situated in Gugulethu, 20 km outside of Cape Town, and was the first dedicated ART Centre in the Western Province. Today it actively serves more than 1800 HIV+ patients on ARV therapy. Initially, the pharmacist working at the central pharmacy at DTHF created monthly ARV packages for all patients at the Hannan Crusaid Centre, in the same manner of operations as that described for Masiphumelele. However, patient loads increased dramatically over the past 12 months, resulting in dispensing moving to the pharmacy at the Hannan Crusaid Centre.

This move has helped to identify key challenges in the practicalities of implementing a software solution in resource-constrained settings, especially at a health care facility with extremely high patient loads.

The first of these challenges is that of physical space capacities of remote service points. This is typical of other government clinics in South Africa. Although a pre-packaged set of drugs for a patient is desirable, it takes up more physical space than neatly stacked drug containers.

Another challenge is that of constraints around time and human resources. Patient loads at the Hannan Crusaid Centre are extremely high and staff work under high stress conditions. Presently, there is one pharmacist and 2 pharmacy assistants employed at this facility. It takes a considerable amount of time to pre-package a set of drugs for a large patient load. For this reason, iDart has been modified to include the ability to dispense directly to the patient visiting the clinic.

Until recently, the Hannan Crusaid Centre did not have Internet connectivity. The solution to this at the beginning of the prototype installation was to use the empty, barcoded packet as confirmation of the patient receiving their month's supply of ARVs. These packets were collected by the pharmacy assistant, and given to the driver who delivered them to the central pharmacy. Subsequent packages were then created for each patient at the central dispensing pharmacy, and delivered to the patient at the remote ARV site.

5 Conclusions

In this paper the preliminary work with iDart, an open-source software project designed for ART pharmacists working in a resource-constrained environment (i.e. South Africa) was presented. A prototype was rapidly developed and has been deployed at two service points in the Cape Town area. Currently over 2000 HIV+ patients on ART are being monitored.

Besides the two service points currently using iDart, Cell-Life has investigated other health care facilities in South Africa. From these investigations, it has been realized that each clinic is unique in its operations and expectations. The age-old saying of "one size fits all" does not apply in these settings. This is also due to a number of different NGOs that have worked in a number of clinic sites in the past. Each clinic has their own business process and due to the large workload of the staff working at these facilities, it is not viable to retrain an entire clinic with regard to their procedures. The software needs to adapt to the clinic and its associated business process.

An important challenge that has been identified is the lack of interest in using a new system. Health care workers at government clinics and service points cannot see the immediate benefit to using a computerised system. It is perceived as additional work. However, through participatory design, typical end-users are involved at all stages of development.

There are a number of successful pilot studies that have been conducted in South Africa in the field of ART delivery. The challenge at this point, is to scale up pilot implementations to larger, national implementations. Unfortunately, there is no recorded pharmacy system working in the public health sector that can effectively assist with the provision of ART in a resource constrained environment. But, by understanding the local context within which a ARV dispensing system needs to be implemented, and by having a flexible approach, Cell-Life is in the unique situation to be able to offer a solution to the management of ART in South Africa.

Acknowledgements

Firstly, the authors would like to thank Nicola Killa, the pharmacist who has provided us with countless hours of

assistance, from user requirements to system testing. Also, to everyone at Cell-Life who have been involved over the years of the system evolution. We would like to the team at the Desmond Tutu HIV Foundation for their contributions and the Doris Duke Charitable Foundation for financial assistance.

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