INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS XXX (2014) XXX–XXX

journal homepage: www.ijmijournal.com

Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system

Beth Chaplin[a], *Seema Meloni*[a], *Geoffrey Eisen*[a], *Toyin Jolayemi*[b], *Bolanle Banigbe*[b], *Juliette Adeola*[b], *Craig Wen*[a], *Harry Reyes Nieva*[a], *Charlotte Chang*[a], *Prosper Okonkwo*[b], *Phyllis Kanki*[a,*]

[a] *Immunology and Infectious Diseases, Harvard School of Public Health, Boston, MA, USA*
[b] *AIDS Prevention Initiative in Nigeria, Abuja, Nigeria*

ARTICLE INFO

Article history:
Received in revised form
18 September 2014
Accepted 19 September 2014

Keywords:
HIV therapy
Electronic medical records
Continuity of patient care
User–computer interface
Nigeria
Africa

ABSTRACT

Objectives: The implementation of PEPFAR programs in resource-limited settings was accompanied by the need to document patient care on a scale unprecedented in environments where paper-based records were the norm. We describe the development of an electronic medical records system (EMRS) put in place at the beginning of a large HIV/AIDS care and treatment program in Nigeria.

Methods: Databases were created to record laboratory results, medications prescribed and dispensed, and clinical assessments, using a relational database program. A collection of stand-alone files recorded different elements of patient care, linked together by utilities that aggregated data on national standard indicators and assessed patient care for quality improvement, tracked patients requiring follow-up, generated counts of ART regimens dispensed, and provided 'snapshots' of a patient's response to treatment. A secure server was used to store patient files for backup and transfer.

Results: By February 2012, when the program transitioned to local in-country management by APIN, the EMRS was used in 33 hospitals across the country, with 4,947,433 adult, pediatric and PMTCT records that had been created and continued to be available for use in patient care. Ongoing trainings for data managers, along with an iterative process of implementing changes to the databases and forms based on user feedback, were needed. As the program scaled up and the volume of laboratory tests increased, results were produced in a digital format, wherever possible, that could be automatically transferred to the EMRS. Many larger clinics began to link some or all of the databases to local area networks, making them available to a larger group of staff members, or providing the ability to enter information simultaneously where needed.

Conclusions: The EMRS improved patient care, enabled efficient reporting to the Government of Nigeria and to U.S. funding agencies, and allowed program managers and staff to conduct quality control audits.

* *Corresponding author at*: 651 Huntington Avenue, FXB 405, Boston, MA 02115, USA. Tel.: +1 617 432 1267; fax: +1 617 432 3575.
E-mail addresses: pkanki@hsph.harvard.edu, bchaplin@hsph.harvard.edu (P. Kanki).
http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006
1386-5056/

1. Introduction

This report describes the development of an electronic medical records system (EMRS) for an HIV/AIDS care and treatment programs in Nigeria. The rapid scale-up of HIV treatment with antiretroviral therapy (ART) in sub-Saharan Africa (SSA) brought with it many challenges, including the need for EMRS in settings with no prior experience. In response to this need, there have been a diverse set of approaches to EMRS implementation in SSA. Each program's unique experiences and approaches provide valuable learning opportunities, and sharing these solutions, along with their challenges, can benefit other programs with similar needs, preventing the cycle of "reinventing the wheel". Our system is unique in that it was developed with a commercially available database program, was relatively simple to design and implement, did not require constant internet connectivity, and was created to scale up as a sustainable system.

1.1. *Background*

Nigeria is the most populous African country, with an estimated 170 million people living there as of mid-2013, and covers approximately 924,000 km^2. It is comprised of 36 states and a Federal Capital Territory, where the capital city, Abuja, resides. Nigeria is diverse, with more than 200 ethnic groups [1]. The country is 50% Muslim and 40% Christian, with concentrations in the northern and southern parts of the country, respectively [2]. Despite being the largest economy on the continent with a $1052 GDP per capita (USD), the majority of the population live on <$1.25 per day [3]. There is also a sharply uneven distribution of wealth—the poverty rates are strikingly higher in the northern two-thirds of the country than in the south [4]. Health care coverage is similarly uneven, with measurable health outcomes lower in the northeast and northwest regions than in the rest of the country [5]. Infrastructure is also better in the more population-dense, wealthier southern tip of the country; but everywhere in Nigeria, power supply is a severe challenge, despite relatively high rates of electrification. As much as 35% of the installed power supply is not functioning and power outages are so common that the majority of businesses own back-up generators [4]. Internet coverage is sparse in many places and often unreliable, although GSM coverage is growing rapidly [6].

The first cases of AIDS in Nigeria were identified in 1986; by 2000, 5% of the adult population was infected with HIV. Implementation of large-scale prevention, care, and treatment programs reduced the national HIV prevalence estimate to 4.1%; but with a population of over 160 million, the burden of disease is the second highest worldwide. In response to the epidemic, the Government of Nigeria established the National ART Program in 2002 to treat 10,000 adult HIV patients. In 2004, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) provided additional funding to scale up and further support the HIV program. The Harvard School of Public Health and AIDS Prevention Initiative in Nigeria (Harvard/APIN) PEPFAR program in Nigeria began with six centers in 2004 and expanded to 33 by 2012, distributed over a broad geographic area (Fig. 1). We partnered with existing medical institutions to expand their HIV

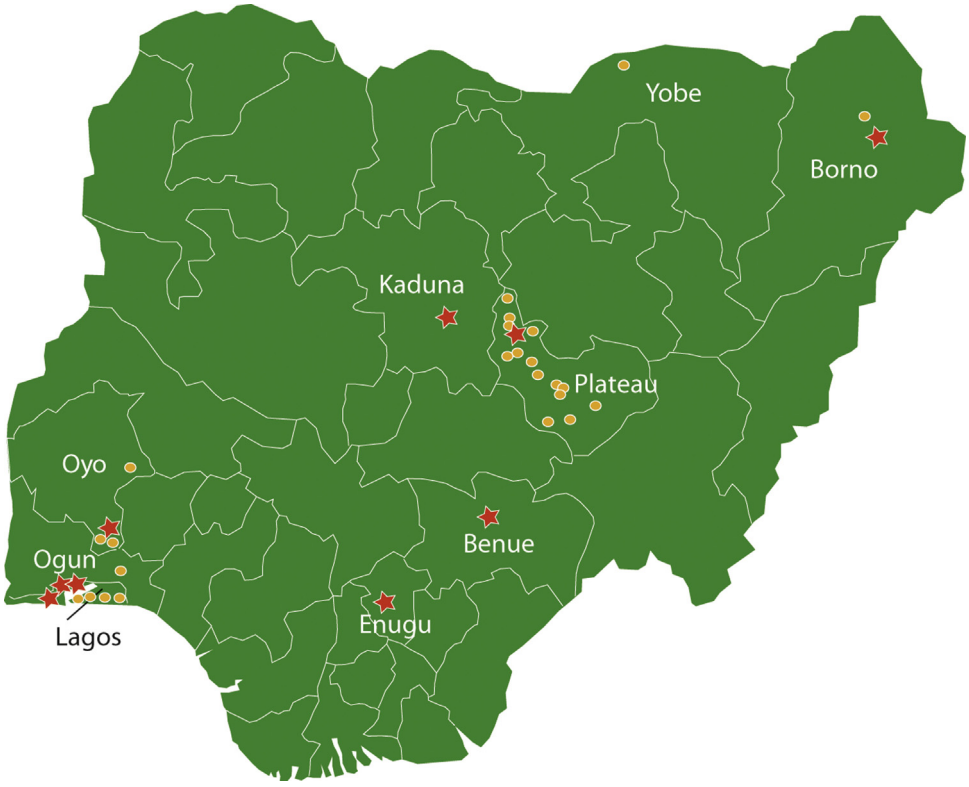


Fig. 1 – Map of Nigeria, showing Harvard/APIN facilities, 2004 through 2012. Larger tertiary sites are represented as stars; secondary and primary sites are represented as circles.

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

care and treatment programs. By February 2012, a cumulative total of 105,228 patients had received ART [7,8].

1.2. Program needs

In 2004, prior to the start of the PEPFAR program, all of the partner institutions in Nigeria were maintaining paper-based medical records [9–11]. As Harvard/APIN collaborated with medical institutions to scale-up HIV prevention, care and treatment activities across clinics in Nigeria, the program team determined that patient data would be collected using an EMRS. Lifelong ART and associated clinical management requires recording of clinical exams, laboratory results, and medications prescribed and dispensed on a monthly basis; this constitutes requisite patient information that must be available during clinical visits to guide physicians in counseling patients and making choices regarding complex drug regimens. In addition, it was anticipated that detailed reports for the Government of Nigeria and the U.S. government funding partners, as well as internal and external quality control audits, would be required. Given the expected large volume of information to be collected and the need for constant and efficient monitoring, it was clear that an EMRS would offer significant benefits for both patient care and program management. Furthermore, the creation of an EMRS would allow for operational monitoring and evaluations that would be useful for quality improvement.

Due to the infrastructure problems throughout the country and the number of clinics that had to be up and running at the start of our program, we could not, pragmatically, guarantee an always-on internet connection or even ensure an uninterrupted electrical supply. In addition, other considerations that weighed heavily in the design of the EMRS included: user-friendliness, congruent with a wide variety of end users (e.g., data entry clerks to laboratory and clinic staff who were accustomed to paper-based log books and forms); significant differences in clinics and the physical distance to laboratories, pharmacies, and data management office space; and, adaptability and sustainability over time.

1.3. Software choice

One of the goals of the Harvard/APIN PEPFAR program was to support and develop systems for sustained HIV prevention, care and treatment activities; accordingly, the EMRS was designed with the recognition that the program would eventually transition to local Nigerian leadership. The choice of software was critical.

At the inception of the Harvard/APIN partnership, it was determined that the system would need to capture information in a variety of types of clinic settings. While the ideal approach to EMRS development would have been to create and test the system in the context of one hospital or clinic and then gradually phase it in, this was not possible due to the rapid scale-up of the PEPFAR program. Rather, the EMRS needed to be quickly implemented in a variety of well-established existing institutions of varying sizes and geographic locations throughout a large country. The goal was to avoid a platform that required highly specialized training or expensive software developers for modifying the databases or had barriers, such as high cost or maintenance fees. The software had to scale well and be stable and reliable enough to store patient data. The system needed to function well at clinics and hospitals with minimal hardware and no connectivity, but also support a server and multiple users where appropriate. As of 2004, the Harvard team had been using FileMaker Pro (FileMaker, Inc., Santa Clara, CA) for maintaining patient data since 1991 in a 20-year-long prospective study of HIV in Dakar, Senegal [12]. While there were a number of solutions that other groups subsequently successfully deployed [13–21], the FileMaker Pro cross-platform relational database application was the logical choice for the Harvard/APIN PEPFAR program.

2. Methods

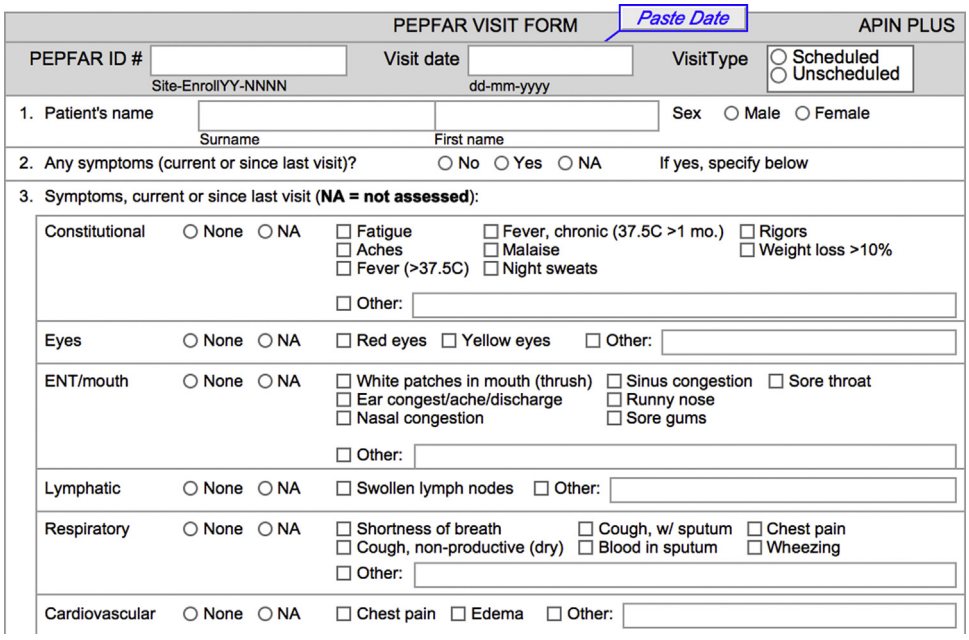
Time pressures necessitated a rapid development of the initial system. The PEPFAR grant was awarded to Harvard/APIN in late January 2004, exploratory meetings including key clinical personnel from all participating program sites to design the standardized clinical forms and parallel EMRS to be used across sites began in May 2004, and the system was launched in August 2004. Given the time constraints, it was understood from the beginning that the clinical forms and corresponding databases would continue to change and evolve, almost immediately upon being put into use.

A key consideration was that we were not creating clinic environments *de novo* and the system needed the flexibility to adapt to a range of circumstances, including the arrangement and functionality of the available physical spaces and the associated personnel. More specifically, at many hospitals, the centers of patient activity (*i.e.*, pharmacies, patient clinics, and labs) were physically separated. To design a system that was adaptable across all project hospitals, a collection of separate, stand-alone databases were developed to record different phases or elements of patient care. Each database was related to a specific paper case report form (Fig. 2) onto which information was manually recorded. The paper records were retained in patients' files and utilized in parallel with the electronic system, a practice that is not uncommon in resource-limited settings [22–25].

In managing a system based on stand-alone databases, design principles such as uniformity, simplicity, and transparency facilitated the adaptation to changing program requirements. For example, design and user interface was standard across all databases, maintaining a consistent experience for those entering or retrieving information. Transparency and simplicity meant that the organization and operation of the databases was readily discernible, allowing for modification as needed; this also facilitated the eventual transfer of the EMRS system management to APIN in 2012.

For the adult HIV care and treatment program, the approach of creating separate stand-alone databases resulted in the development of five primary and four auxiliary databases, each dedicated to a specific aspect of patient care or an event (Table 1). Once confirmed HIV-positive, a patient's first encounter with the care and treatment program was at his/her preassessment visit, where the clinical staff determined if the patient met the criteria to begin ART, based

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006


PEPFAR VISIT FORM Paste Date APIN PLUS

PEPFAR ID # Site-EnrollYY-NNNN Visit date dd-mm-yyyy VisitType ○ Scheduled ○ Unscheduled

1. Patient's name Surname First name Sex ○ Male ○ Female

2. Any symptoms (current or since last visit)? ○ No ○ Yes ○ NA If yes, specify below

3. Symptoms, current or since last visit (**NA = not assessed**):

Constitutional	○ None ○ NA	☐ Fatigue ☐ Fever, chronic (37.5C >1 mo.) ☐ Rigors ☐ Aches ☐ Malaise ☐ Weight loss >10% ☐ Fever (>37.5C) ☐ Night sweats ☐ Other:
Eyes	○ None ○ NA	☐ Red eyes ☐ Yellow eyes ☐ Other:
ENT/mouth	○ None ○ NA	☐ White patches in mouth (thrush) ☐ Sinus congestion ☐ Sore throat ☐ Ear congest/ache/discharge ☐ Runny nose ☐ Nasal congestion ☐ Sore gums ☐ Other:
Lymphatic	○ None ○ NA	☐ Swollen lymph nodes ☐ Other:
Respiratory	○ None ○ NA	☐ Shortness of breath ☐ Cough, w/ sputum ☐ Chest pain ☐ Cough, non-productive (dry) ☐ Blood in sputum ☐ Wheezing ☐ Other:
Cardiovascular	○ None ○ NA	☐ Chest pain ☐ Edema ☐ Other:

Fig. 2 – Example of a part of the Visit form, filled out at each clinical visit.

Table 1 – Forms/databases by program area.

Database	Type	Function
Adult HIV care and treatment		
VCT	Primary database	Voluntary counseling and testing data
IDCard	Primary database	Identifying numbers issued to patients
Preassess	Primary database	Initial preassessment for ART eligibility
Entry	Primary database	Baseline information collected at start of ART
Pharmacy	Primary database	Antiretrovirals and other medications dispensed
Lab	Primary database	Laboratory results: viral load, CD4, ALT, etc.
Visit	Primary database	Results of clinical assessments
Outcome	Primary database	Drug-related toxicities and failure data
Discontinue	Primary database	Dropouts from program, transfers or deaths
Pediatric HIV care and treatment		
Ped Clinical	Primary database	Initial and follow-up pediatric clinical data
Ped Pharmacy	Primary database	Antiretrovirals and other medications dispensed
Ped Lab	Primary database	Laboratory results: viral load, CD4, ALT, etc.
Ped Discontinue	Primary database	Dropouts from program, transfers or deaths
Prevention of mother-to-child transmission of HIV		
PMTCT	Primary database	Antenatal, delivery and infant follow-up
Exposed Infant Clinical	Primary database	Initial and follow-up exposed infant clinical data
Exposed Infant Pharmacy	Primary database	Antiretrovirals and other medications dispensed
Exposed Infant Lab	Primary database	Laboratory results
Automated utilities/tools		
Regimen Report	Utility	Automates aggregation of ARV data from the Pharmacy database for use in reporting and inventory
Treatment Response	Utility	Aggregates data from Preassessment, Entry, Visit, Lab and Pharmacy databases to display and graph relevant patient data
QuIC Tool	Utility	Compiles quality indicators such as continuity of care, TB treatment, CTX prophylaxis, etc.
ID and Data Cleaning	Utility	Identify and correct problems with ID and dates across various databases
PEP ID Problem Finder	Utility	Locate patients with incorrect identifiers across multiple primary databases
Monthly Reporting Form	Utility	Used to collect aggregate patient data across sites and then aggregates for reporting to funder or national agencies
Follow-Up Utility	Utility	Used to generate a list of patients that need active follow-up because they are overdue for a clinical visit or pharmacy pickup

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

on Nigerian national guidelines, and assigned the patient a unique identifier (ID). For this initial visit, patient demographic data were collected using the preassessment form. Upon initiation of ART, baseline clinical data were captured using the combination of the entry and visit forms. For all follow-up clinical visits, which were scheduled every six months for healthy cases, data were recorded on the visit form. Typically, subsequent to each scheduled visit, there was a corresponding laboratory assessment. Test results, which included the patients' CD4+ cell counts, viral loads, chemistries, and hematologies, were recorded onto the laboratory form. In addition, a pharmacy form was used to document ARV drugs as they were prescribed and dispensed. Once completed, forms were transferred to the data rooms for on-site data entry; once electronically entered, paper forms were returned to patient charts for storage.

Auxiliary forms and databases documented consent for treatment and research, information from voluntary counseling and testing, adverse outcomes, and discontinuation (*i.e.*, termination from the program due to withdrawal, transferring or death). Databases for pediatric patients and prevention of mother-to-child transmission (PMTCT) were designed similarly, with the addition of content relevant to antenatal visits, delivery information, infant testing and laboratory values, and pediatric care and ART.

From the inception of the program, one critical and unchangeable factor was the ID assigned to each patient. The ID was important for linking information from separate files and for following patients over the course of their care and treatment. The ID contained ten characters separated into three segments by hyphens, including a two-digit facility code, a two-digit indication of the year a patient first enrolled at one of our program facilities, and a four-digit serial number unique for each new calendar year. The ID remained with a patient if they withdrew and re-started treatment, or transferred to a new facility within our program. At the larger facilities, plastic cards imprinted with the ID and other identifying details were provided to the patients to bring to each subsequent visit. The ID was included on every form and database and was crucial for linking the information between the separate files.

2.1. *Data workflow*

As described in Section 2, information was recorded first on paper forms and then entered into the databases by personnel dedicated to data management. At each location, the forms were transferred to the data room for electronic entry by trained data entry staff. Data were entered using stand-alone computers in empty clones of databases, which were merged weekly and stored on a secure server (Fig. 3).

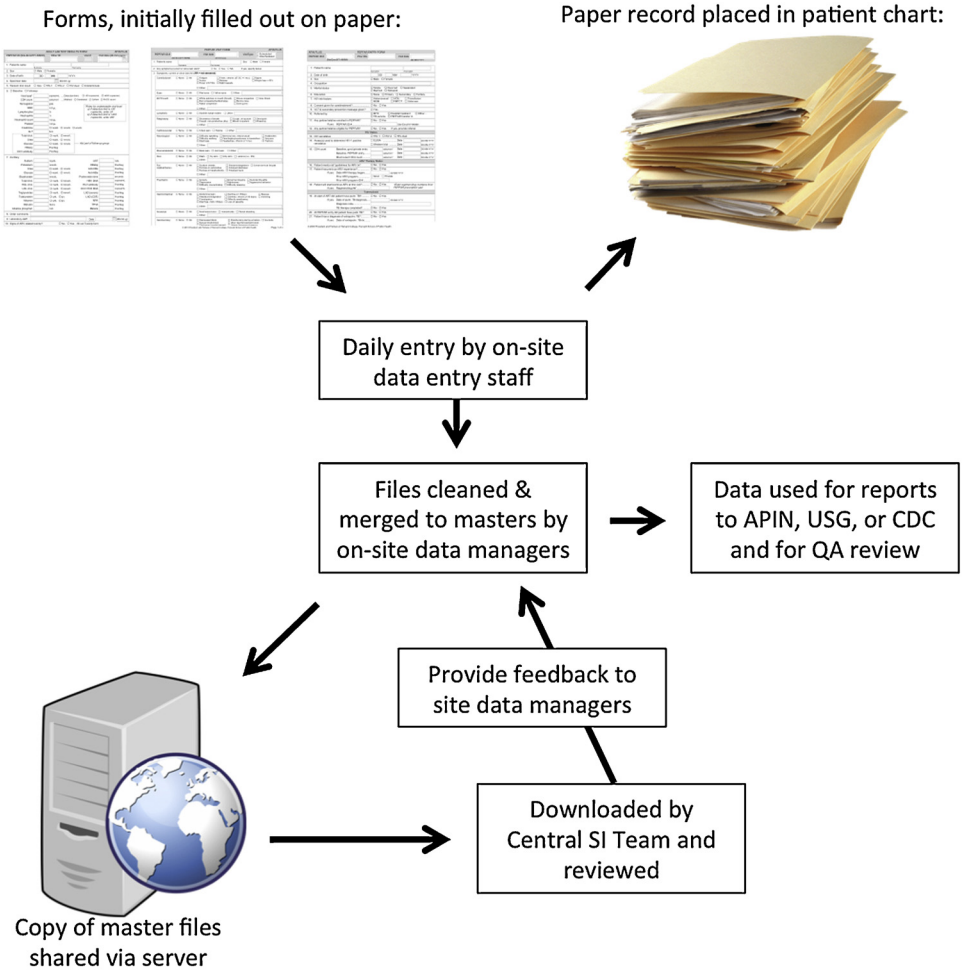


Fig. 3 – Schematic of data entry, management infrastructure and data flow.

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

ENTER/BROWSE DATA (PEPID TABLE) **PHARMACY DATABASE** **APIN PLUS**

Opening | Patient List | Pharmacy Table | **Enter New Data** | *Find* | *Sort* PepID | *Sort* Name | View Field Index | Refresh Statistics | Show All

PEPFAR ID (Site-EnrollYY-NNNN)	Surname	First name	Date of Birth DD	MM	YYYY	Sex	Drug Allergies Y/N	Specify	Total Records	Avg. Days Past Sched.	Avg. % Adherence
BO-08-4447	DOE	JANE	19	2	1966	F			8	6.7	83.6

Site error

DRUG DATA ENTR | DISPENSING STATISTIC

Rec. No.	Schedule Date	Dispense Date	Days Past Schedule	Dispense Interval	Percent Adherence	Weight (kg)	Reg. Change	Regimen	Reg. Code	Supply (months)
		22/05/2008				60.0	No			1
1		18/07/2008				64.0	No	EFV-Truv (TDF/FTC)-EFV	43.96.40	1
2	15/08/2008	20/08/2008	5	33	85	65.0	No	EFV-FDC (TDF/FTC/EFV)	40.116	1
3	17/09/2008	17/09/2008	0	28	100	66.0	No	EFV-FDC (TDF/FTC/EFV)	40.116	1
4	15/10/2008	18/10/2008	3	31	90	63.0	No	EFV-FDC (TDF/FTC/EFV)	40.116	1
5	15/11/2008	15/11/2008	0	28	100	63.0	No	FDC (TDF/FTC/EFV)-EFV	116.40	1
6	13/12/2008	18/12/2008	5	33	85	63.0	No	EFV-FDC (TDF/FTC/EFV)	40.116	1
7	15/01/2009	31/01/2009	16	44	64	63.0	No	EFV-FDC (TDF/FTC/EFV)	41.116	1
8	28/02/2009	18/03/2009	18	46	61	63.0	No	EFV-FDC (TDF/FTC/EFV)	40.116	1

Fig. 4 – Example of the pharmacy database, showing an overview of one patient's drug dispense and adherence history.

Over time, some adjustments were made to this workflow to increase overall efficiencies. As it became clear that laboratory results tended to arrive batched rather than on individual forms and that certain laboratory results were produced in a digital format that could be transferred to the databases directly, avoiding the errors and inefficiency of duplicate manual entry, data transfers were automated whenever it was feasible.

Additionally, the way pharmacy information was entered into databases also changed over time. As with other clinical forms, physicians would note the prescribed antiretroviral medications on a paper prescription pad, pre-printed with the available drugs and dosages. The patients would take the prescription to the dispensary, where the pharmacy personnel would provide the prescribed medications. Pharmacists at the larger centers were provided networked computers which allowed them to actively display the patient's ART history as they newly entered the drugs being dispensed. This system provided quality control to ensure that the current prescription was consistent with those dispensed prior. Viewing the file in real-time allowed for alerts on patients that might require adherence counseling due to missed or late prescription refills (Fig. 4).

At each program hospital or clinic, one data manager was responsible for maintaining the master databases and uploading them weekly to a central server that was accessible to programmatic staff at both Harvard and APIN. This process of data transfer ensured secure storage and ensured that the strategic information team at Harvard was able to provide technical support for the project and work in close partnership with APIN, addressing problems as they arose, exchanging ideas about improvements and refining the training programs.

2.2. Utilities

After the first few months of data collection, it became apparent that it would be useful to have additional electronic tools that would allow for automation of various routinely-performed activities. Furthermore, the volume of required program reporting grew rapidly and the subsequent need to ease the work burden for data staff as well as ensure consistent and accurate information-gathering throughout the program became a necessity.

In general, information was entered into primary databases and any analyses or extra functionality needed was integrated by means of external files that contained the appropriate programming. This meant that modification of the primary databases was limited, and separate utilities could be developed independently as add-on tools.

The ID number was critical for linking information from the various clinical files and enabled the effective use of utilities. The relational capabilities of the FileMaker Pro software allowed for use of a "match field" to display records labeled with a specific identifier from one database into another file, to perform calculations on these linked records, and to combine them in third party operations, such as graphing. In this way, the information could be entered and maintained in the main files and the utilities could pull from that original data as if it were in one integrated file, to satisfy a multitude of different reporting requirements, patient summary reports, and review of quality of care.

2.2.1. *Monitoring and reporting utilities*

We developed a number of different utilities that performed very specific functions. A regimen report utility generated unduplicated counts of ART regimens dispensed over time for programmatic as well as supply chain management. A quality improvement utility (QuIC Tool) reported on indicators that assessed patient care. A follow-up utility generated lists of patients that required follow-up because they were overdue for a clinical visit or prescription refill. We also developed a utility that aggregated data on national standard indicators that were being reported monthly by the clinics to quickly summarize program data for national monitoring and evaluation purposes (Table 1).

2.2.2. *Treatment response utility*

Another program-wide need surrounded the clinician's ability to efficiently and accurately review a patient's medical history during follow-up visits. As chart volumes for patients grew, an automated method to generate a comprehensive digital "snapshot" of the treatment history and clinical response was needed and subsequently developed. This need was similarly

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

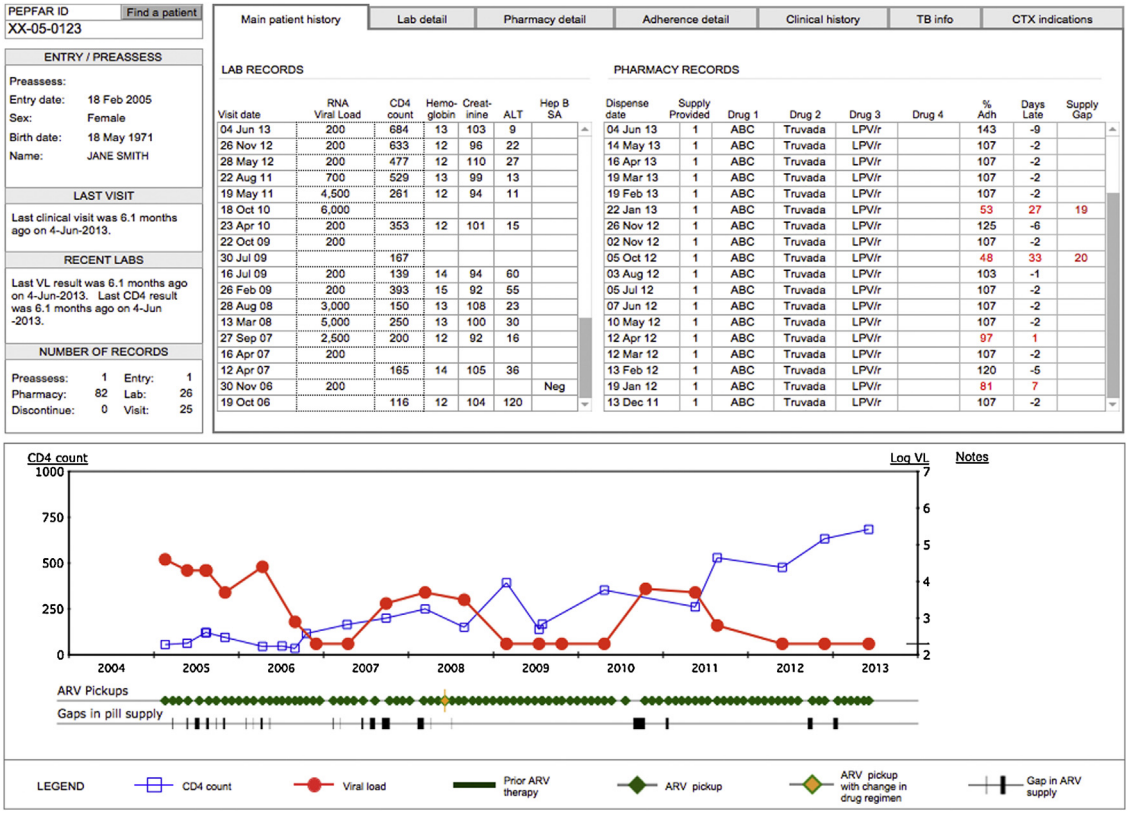


Fig. 5 – Treatment Response Utility, with a graphical display of each patient's CD4 cell counts, viral load and ARV adherence. Basic demographic information is shown on the left, with a tabbed pane displaying the most critical laboratory, pharmacy and clinical history, on the right.

echoed by Were et al., when they indicated that patient summaries allow physicians to spend more time in direct care [26].

An electronic tool, referred to as the Treatment Response Utility (TRU), was created using FileMaker's relational capabilities along with a third-party graphing plug-in (X2Max Software, http://www.x2max.com). TRU allowed the user to combine data in order to provide a snapshot of the most relevant clinical information. A tabbed one-page view showed a variety of data collected during clinical visits, drugs dispensed, adherence statistics, and laboratory results. The TRU included a graphical display of each patient's CD4+ cell counts, viral loads, and ART drug refill history over time (Fig. 5). The summaries of patient history were also used in decision-making concerning patients that needed to be switched to a new regimen, and as part of the process of information transfer for patients who moved from one facility to another. Over time, the TRU has been very well received by program staff as well as patients. Anecdotally, we have heard from physicians in our program that the ability to reference the most pertinent information and lab results on one screen is useful, and preferred over relying solely on patient charts.

2.3. *Training*

The first official data training for program staff was held in August 2004. Following that initial workshop, regular training sessions on various aspects of data entry, management and use have been conducted. Initially, the focus was on learning the basics of entry into the databases and maintaining and backing up files. Later workshops dealt with thornier issues of complex reporting and hands-on problem solving. Feedback from these sessions was crucial to understanding modifications and changes that were needed to the EMRS. As the program matured and new clinics were integrated, sites would often send the members of their data teams to more established facilities to learn the fundamentals of the system, and "step-down trainings", in which the team member who attended a workshop would transfer this information to colleagues upon returning, were encouraged. Eventually, training modules were established to ensure a structured process in which all the various levels of personnel dealing with electronic data were receiving a standardized education.

3. Results

In the early phase of the PEPFAR project, there was a certain amount of justifiable skepticism about the feasibility and value of an EMRS. Since most of the effort was devoted to fulfilling program reporting and monitoring requirements there was the perception that this detracted from serving the interests of clinical care. Additionally, since health centers had been using paper-based records for decades, there were concerns regarding a transition to a fully electronic system. For this reason, paper based forms were maintained in existing

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

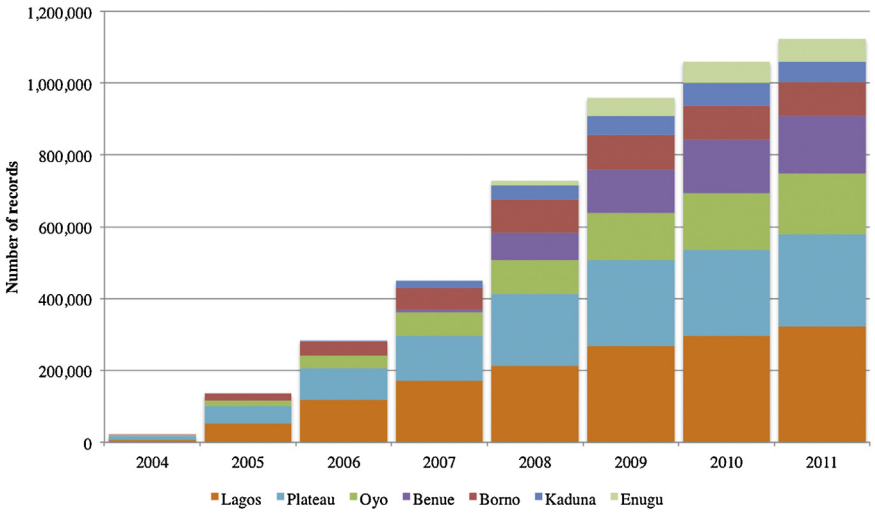


Fig. 6 – Number of records generated each year by the Harvard/APIN PEPFAR program, supporting adults, pediatric and PMTCT patients in care and receiving antiretroviral treatment.

records rooms in parallel with the electronic systems. This provided redundancy and was consistent with the manner in which staff expected to operate, promoting acceptance of the EMRS and allowed physician consults to proceed even during periods when the electricity failed.

As highlighted by Jimoh et al., there can be a disconnect between donor and end-user priorities for electronic patient data [6]. While the creation of our EMRS was driven by the goal to efficiently capture clinical data, it also had value in other areas. Overall, the reluctance to embrace the EMRS slowly shifted as the system proved its utility in patient management. Clinicians at the sites where the TRU data were regularly shared with patients started reporting that the patients came to expect seeing the graphical representation of their progress and were encouraged to improve their adherence, as they saw the direct effects on their own treatment outcomes. One outcome of this changing attitude toward use of EMRS was more space and better working conditions gradually being allocated for the data entry staff, which had a positive impact on the program. The value of the EMRS was further reinforced in September 2012, when a fire destroyed the Lagos University Teaching Hospital outpatient ART clinic. The paper records for over 8000 patients were destroyed; however, because the electronic data entry was up-to-date and stored on a secure web-based server, electronic versions of all patient records were still available.

Another challenge we encountered involved errors that accompanied the process of data entry. When the databases were first created, safeguards were built in to prevent errors. These included alerts when a malformed ID was entered, flags for missing information, data verification screens, and scripts that assisted data managers with the task of finding records with problems. However, these methods could not prevent all mistakes. Errors manifested in a variety of forms, such as incorrect patient ID numbers, transcription errors from the paper forms, or improbable laboratory or date values. Another major issue was the lag time in entry of certain laboratory tests, as some tests took longer to complete than others, interrupting the normal flow of data processing, and resulting in problems when laboratory values had to be added to existing records. The system of regularly uploading the databases to a shared server meant that a dedicated staff member could regularly examine the files for systematic problems and respond back to the data manager, establishing an interactive and iterative process that resulted in improved accuracy. Information collected through these data sharing activities continually informed the ongoing data training efforts. Standardized operating procedures, along with additional 'data-cleaning' utilities, were also developed to deal with these issues.

In keeping with the fundamental philosophy of the program, the focus of the EMRS has been on capacity building and an ultimate transition to local management. In-country APIN staff increasingly took on a leadership role in managing the program, with a formal transfer at the end of February 2012. By this time, a total of 4,947,433 adult, pediatric and PMTCT records had been created and continued to be available for use in patient care (Fig. 6). To date, APIN continues to develop and manage the program's EMRS with success.

4. Discussion

Software choice for a large-scale program necessarily involves compromise and is profoundly influenced by the environment and options available at the time of creation. Our group had in-house data management expertise from developing databases for HIV biomedical research in West Africa, and given the time constraints for having an operational EMRS up and running and the lack of strong existing options at the time we were establishing EMRS on ground, we chose to continue with the platform we had already successfully developed rather than testing a new EMRS at that time. As the PEPFAR program expanded into many countries with limited resources, OpenMRS emerged as another highly successful option that was adopted by many programs as a solution. This system was very new in early 2004 and we considered switching over from

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

FileMaker during the early stages of our EMRS implementation; however, the substantial investment in resources, time and effort involved in switching to new software was prohibitive. The in-house EMRS development allowed for control over the system, and could be tailored by program staff to fit the needs of the project rather than requiring the project to adapt to the EMRS. It could also be modified quickly. This factor was particularly important in terms of integration with reporting forms issued by the Government of Nigeria, as well as other funding agency reporting requirements. In addition, part of the PEPFAR project mandate was that we build infrastructure and developing an in-house EMRS was a step in fulfilling this goal. In our view, an off-the-shelf data management platform allowed the widest possible knowledge transfer, in contrast with alternatives with a steeper learning curve and high training costs.

In comparison with OpenMRS, currently the most compelling alternative since it is open source software, FileMaker Pro is commercial software with a price that is not trivial in a resource-limited setting. While OpenMRS is free, it is more complex to set up and modify, even with the substantial support system that has evolved around it [27]. Furthermore, at the time we were designing our system, the OpenMRS community was not developed to the extent that it is today. As Seebregts et al. describe, it was designed to be implemented without expertise/fluency in Java or other programming languages, but there are circumstances where programming experience is necessary. One solution that evolved was the OpenMRS Implementers Network, which provided collaboration tools and support along with valuable training for those in RLS. For our program, we preferred the approach of using commercial software that was simple enough to understand that the basics could be explained in a few hours, particularly given the number of staff that were being trained and sites that needed to be developed simultaneously.

Finally, the FileMaker software proved stable even when dealing with large amounts of data. At the tertiary facilities, such as Jos University Teaching Hospital, a larger database such as the one holding pharmaceutical records contained over 100,000 records in 2007 and over 400,000 by 2012, by which time it was accessed via a local server from multiple workstations, all entering data concurrently.

4.1. *Areas for improvement*

Using the FileMaker databases as a server, it would have been possible to create a real-time system for entering and accessing patient information. However, a real time system required that all clinic staff log information directly into the computer system. In the cultural context of Nigeria, where physicians are not accustomed to performing data entry and have serious time constraints, along with the fact that the clinical forms are lengthy, and the considerations of internet and power outages, entering most information on paper followed by data entry by specialized personnel was preferred. Given the schedule of visits, with most patients seen every few months, this was not usually a problem.

The EMRS we developed focused on our programmatic needs and many elements of the system are transferrable to different RLS healthcare settings, since many clinical, laboratory and pharmacy measurements are standardized. In a different context, depending on the location and the type and scale of the program, a similar system might need to be fully live. A networked system implemented in Malawi is noteworthy. Many adaptations, including strong electrical backup to keep the system running, low-power touch screen equipment, and software that guides the healthcare workers through the clinical encounter, allow it to perform well in a challenging environment [18].

Another limitation of our EMRS was its lack of integration with other systems. At the time the EMRS was in use from 2004 through 2012, the Nigerian healthcare system did not have any widely implemented electronic records. Had this existed, compatibility would have been a consideration in the choice of software. However, when information was requested, it was usually provided in the form of an aggregate report, and when information was required for research or analysis, it was exported via Excel or text files into other popular software programs. As tertiary hospitals in Nigeria embark on development of hospital-wide EMRS, we will work with the teams to integrate with our existing EMRS.

4.2. *Sustainability*

Sustainability and strengthening local capacity were important considerations throughout our process of building the EMRS. Depending on the patient burden at each clinic or hospital, the number of data entry and management staff varied greatly, from one or two at the primary clinics, to a dozen or more at the larger centers. As with all donor-funded health programs, there is a question about the level at which this program will be supported as it transitions to country ownership and support from the Government of Nigeria. However, the EMRS was designed to make minimal assumptions about hardware, training and staff skill sets, and is adaptable enough to continue as long as needed. FileMaker Corporation has demonstrated a commitment to the continued development of this software, but if it were to become unavailable, the information contained in the primary databases could certainly be transitioned to another backend. It is likely, in such a circumstance, that the add-on utilities would be created anew using the alternative software, based on the current programmatic and clinical needs. Additionally, a major aspect of establishing the EMRS at the sites involved the hiring and training of local data entry staff and data managers. The training they have received ensures sustainability of the EMRS we have established. If there is a switch to another EMRS, we envision the high level training that our staff have received renders them strong candidates to continue this work on other platforms.

Over the years, the Harvard/APIN PEPFAR EMRS has adapted to the changing needs of patients, physicians and program managers while remaining compliant with requirements of the Government of Nigeria. Flexibility was a major consideration in the design conventions established to guide the development of the EMRS. While the decision to employ a set of stand-alone files was influenced by the variability in infrastructure among the program clinics and hospitals, partitioning the database system into segregated files made it possible to modify them without revising the entire system at one time.

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006

5. Conclusions

Keeping information from these different phases of patient care in separate files may seem to complicate data management. However, not having one integrated data file had advantages in the ability to maintain and modify the system and the limitations could be overcome with utilities that joined the relevant information together.

The EMRS implemented by the Harvard/APIN PEPFAR program was beneficial to patient management. Because data were collected in the EMRS, they were easily manipulated using utilities to ensure clinical staff had efficient access to key information. For example, as it is well established that ART adherence is a strong predictor of virologic suppression [28,29] and known that the display of the patient's adherence history can be useful for counseling as medication is dispensed. By structuring the workflow such that pharmacists had real-time access to patients' refill history, pharmacists could more efficiently identify patients that required additional counseling.

The Harvard/APIN PEPFAR EMRS also enabled efficient reporting to the Government of Nigeria with a challenging infrastructure and a diversity of clinics distributed across Nigeria. The system also allowed program managers and staff to conduct quality control audits, which improved patient care. Finally, the EMRS has data on more than 100,000 patients evaluated over the past nine years. This represents a rich resource of data for future operational research studies [30–36] that will add to the knowledge extracted from a large-scale rollout of ART in a resource-limited setting.

With the benefit of hindsight, we would have increased the initial investment in the development of the system so that data instruments helpful for analyses were created earlier in the project. As the need for different types of aggregate reports and information became apparent, we realized that early and more detailed consideration of outcome data would have been more expeditious. Another key factor to the success of the EMRS, realized as the project progressed, was the training and feedback provided by the local data managers. Finally, to be viable and sustainable an EMRS cannot be static; with time and use, constant revision will be needed. Continued modification and use for both individual and collective evaluation of care will ensure its sustainability and contribution to optimal patient care.

Summary points

What is already known about the topic:

- The rapid scale-up of HIV care and treatment in resource-limited settings brought with it the need for implementation of electronic medical records systems (EMRS).
- Electronic data are necessary for managing complex, chronic diseases such as HIV.
- An EMRS must provide value for everyone involved in the data collection process in order to be widely accepted and maintained.
- The system chosen has to be appropriate for the setting in which it is implemented.

What this study has added to our knowledge:

- Showing HIV patients a graphic display of their adherence to antiretroviral medications and viral load stabilization can have a positive effect in counseling and education.
- Implementation of a sustainable EMRS is an iterative process, requiring feedback and training.
- It's important to think about outcome data needed, and to expect ongoing revision of the EMRS.

Author contributions

STM had a central role in the implementation of the data system structure at the sites. She worked closely with BB and JA to provide training and oversight of the data managers, advised on the creation of the databases and utilities, and managed the reporting of EMRS data to various funding agencies. BB served as the Clinical Officer overseeing monitoring and evaluation and quality assurance. JA worked in country with the data staff at the sites to implement and provide continuous training and quality improvement on data-related issues. STM was assisted by CC, CW, and HRN. GE designed and modified the primary databases. BC, CW, and HRN worked on the creation of utilities for the EMRS, as well as being involved with mentoring and training. PK was the PI of the program and PO was and is currently the CEO of APIN Ltd./Gte. Both oversaw all phases of the program, including the development, implementation and continued use of the EMRS.

Conflict of interest

None declared.

Funding

This work was funded, in part, by the US Department of Health and Human Services, Health Resources and Services Administration (U51HA02522). The contents are solely the responsibility of the authors and do not represent the official views of the funding institutions.

Acknowledgements

We would like to thank all the patients enrolled at the Harvard/APIN PEPFAR sites, as well as acknowledge the hard work and dedication of the data management, clinical, pharmacy and laboratory staff of the sites and APIN.

REFERENCES

[1] World Bank. http://data.worldbank.org/country/nigeria (accessed 10.18.14).

[2] The World Factbook: Nigeria. https://www.cia.gov/library/publications/the-world-factbook/geos/ni.html (accessed 10.07.14).
[3] http://www.economist.com/news/finance-and-economics/21600734-revised-figures-show-nigeria-africas-largest-economy-step-change
[4] The World Bank, Nigeria's Infrastructure: a Continental Perspective, 2011 http://elibrary.worldbank.org/doi/book/10.1596/1813-9450-5686 (accessed 10.07.14).
[5] The World Bank: Improving Primary Health Care Delivery in Nigeria: Evidence from Four States, 2010, http://elibrary.worldbank.org/doi/book/10.1596/978-0-8213-8311-7 (accessed 10.07.14).
[6] L. Jimoh, M.A. Pate, L. Lin, et al., A model for the adoption of ICT by health workers in Africa, Int. J. Med. Inform. 81 (2012) 773–781.
[7] P. Kanki, R.G. Marlink, A Line Drawn in the Sand: Responses to the AIDS Treatment Crisis in Africa, Harvard Center for Population and Development Studies, Cambridge, MA, 2009.
[8] P. Kanki, S.T. Meloni, C. Wen, in: Health HSoP (Ed.), Harvard School of Public Health/AIDS Prevention Initiative in Nigeria: Reducing the Burden of AIDS, 2012.
[9] A. Thompson, E. Castle, P. Lubeck, et al., Experience implementing OpenMRS to support maternal and reproductive health in Northern Nigeria, Stud. Health Technol. Inf. 160 (2010) 332–336.
[10] I.T. Adeleke, A.O. Adekanye, K.A. Onawola, et al., Data quality assessment in healthcare: a 365-day chart review of inpatients' health records at a Nigerian tertiary hospital, J. Am. Med. Inform. Assoc. 19 (2012) 1039–1042.
[11] A. Garrib, N. Stoops, A. McKenzie, et al., An evaluation of the District Health Information System in rural South Africa, S. Afr. Med. J. 98 (2008) 549–552.
[12] P. Kanki, S. M'Boup, R. Marlink, et al., Prevalence and risk determinants of human immunodeficiency virus type 2 (HIV-2) and human immunodeficiency virus type 1 (HIV-1) in west African female prostitutes, Am. J. Epidemiol. 136 (1992) 895–907.
[13] A. Nucita, G.M. Bernava, M. Bartolo, et al., A global approach to the management of EMR (electronic medical records) of patients with HIV/AIDS in sub-Saharan Africa: the experience of DREAM software, BMC Med. Inform. Decis. Mak. 9 (2009) 42.
[14] B.H. Chi, B. Vwalika, W.P. Killam, et al., Implementation of the Zambia electronic perinatal record system for comprehensive prenatal and delivery care, Int. J. Gynaecol. Obstet. 113 (2011) 131–136.
[15] W.M. Tierney, M. Achieng, E. Baker, et al., Experience implementing electronic health records in three East African countries, Stud. Health Technol. Inform. 160 (2010) 371–375.
[16] C. Allen, D. Jazayeri, J. Miranda, et al., Experience in implementing the OpenMRS medical record system to support HIV treatment in Rwanda, Stud. Health Technol. Inform. 129 (2007) 382–386.
[17] J. Dawson, M. Clark, L. Peloso, Developing a medical records system at the Ola during Children's Hospital, Freetown, Sierra Leone, Stud. Health Technol. Inform. 164 (2011) 174–179.
[18] G.P. Douglas, O.J. Gadabu, S. Joukes, et al., Using touchscreen electronic medical record systems to support and monitor national scale-up of antiretroviral therapy in Malawi, PLoS Med. 7 (2010).
[19] E. Waters, J. Rafter, G.P. Douglas, et al., Experience implementing a point-of-care electronic medical record system for primary care in Malawi, Stud. Health Technol. Inform. 160 (2010) 96–100.
[20] H. Fraser, J. Blaya, Implementing medical information systems in developing countries, what works and what doesn't, AMIA Annu. Symp. Proc. (2010) 232–236.
[21] E.J. Manders, E. Jose, M. Solis, et al., Implementing OpenMRS for patient monitoring in an HIV/AIDS care and treatment program in rural Mozambique, Stud. Health Technol. Inform. 160 (2010) 411–415.
[22] P. Braitstein, R.M. Einterz, J.E. Sidle, et al., Talkin' about a revolution: how electronic health records can facilitate the scale-up of HIV care and treatment and catalyze primary care in resource-constrained settings, J. Acquir. Immune Defic. Syndr. 52 (Suppl. 1) (2009) S54–S57.
[23] W.M. Tierney, J.K. Rotich, T.J. Hannan, et al., The AMPATH medical record system: creating, implementing, and sustaining an electronic medical record system to support HIV/AIDS care in western Kenya, Stud. Health Technol. Inform. 129 (2007) 372–376.
[24] C. Allen, P. Manyika, D. Jazayeri, et al., Rapid deployment of electronic medical records for ARV rollout in rural Rwanda, AMIA Annu. Symp. Proc. (2006) 840.
[25] S.F. Noormohammad, B.W. Mamlin, P.G. Biondich, et al., Changing course to make clinical decision support work in an HIV clinic in Kenya, Int. J. Med. Inform. 79 (2010) 204–210.
[26] M.C. Were, C. Shen, M. Bwana, et al., Creation and evaluation of EMR-based paper clinical summaries to support HIV-care in Uganda, Africa, Int. J. Med. Inform. 79 (2010) 90–96.
[27] C.J. Seebregts, B.W. Mamlin, P.G. Biondich, et al., The OpenMRS implementers network, Int. J. Med. Inform. 78 (2009) 711–720.
[28] D.R. Bangsberg, Preventing HIV antiretroviral resistance through better monitoring of treatment adherence, J. Infect. Dis. 197 (Suppl. 3) (2008) S272–S278.
[29] A.S. Ernesto, R.M. Lemos, M.I. Huehara, et al., Usefulness of pharmacy dispensing records in the evaluation of adherence to antiretroviral therapy in Brazilian children and adolescents, Braz. J. Infect. Dis. 16 (2012) 315–320.
[30] H.E. Rawizza, B. Chaplin, S.T. Meloni, et al., Immunologic criteria are poor predictors of virologic outcome: implications for HIV treatment monitoring in resource-limited settings, Clin. Infect. Dis. 53 (2011) 1283–1290.
[31] N.G. Ladep, P.A. Agaba, O. Agbaji, et al., Rates and impact of hepatitis on human immunodeficiency virus infection in a large African cohort, World J. Gastroenterol. 19 (2013) 1602–1610.
[32] M.O. Akanbi, C.J. Achenbach, J. Feinglass, et al., Tuberculosis after one year of combination antiretroviral therapy in Nigeria: a retrospective cohort study, AIDS Res. Hum. Retrovir. 29 (2013) 931–937.
[33] E.O. Idigbe, T.A. Adewole, G. Eisen, et al., Management of HIV-1 infection with a combination of nevirapine, stavudine, and lamivudine: a preliminary report on the Nigerian antiretroviral program, J. Acquir. Immune Defic. Syndr. 40 (2005) 65–69.
[34] O. Agbaji, C.L. Thio, S. Meloni, et al., Impact of hepatitis C virus on HIV response to antiretroviral therapy in Nigeria, J. Acquir. Immune Defic. Syndr. 62 (2013) 204–207.
[35] A.P. Okwuraiwe, R.A. Audu, O.B. Salu, et al., Immunological and virological response to haart in HIV-1 patients co-infected with hepatitis B and C viruses, West Afr. J. Med. 31 (2012) 124–128.
[36] B.J. Brown, R.E. Oladokun, G.N. Odaibo, et al., Clinical and immunological profile of pediatric HIV infection in Ibadan, Nigeria, J. Int. Assoc. Phys. AIDS Care (Chic.) 10 (2011) 49–53.

Please cite this article in press as: B. Chaplin, et al., Scale-up of networked HIV treatment in Nigeria: Creation of an integrated electronic medical records system, Int. J. Med. Inform. (2014), http://dx.doi.org/10.1016/j.ijmedinf.2014.09.006