Lessons from the Field

Hybrid data capture for monitoring patients on highly active antiretroviral therapy (HAART) in urban Botswana

Hermann Bussmann, a C William Wester, a Ndwapi Ndwapi, b Chris Vanderwarker, a Tendani Gaolathe, b Geoffrey Tirelo, b Ava Avalos, a Howard Moffat, c & Richard G Marlink d

Abstract Individual patient care and programme evaluation are pivotal for the success of antiretroviral treatment programmes in resource-limited countries. While computer-aided documentation and data storage are indispensable for any large programme, several important issues need to be addressed including which data are to be collected, who collects it and how it is entered into an electronic database. We describe a patient-monitoring approach, which uses patient encounter forms (in hybrid paper + electronic format) based on optical character recognition, piloted at Princess Marina Hospital in Gaborone, Botswana’s first public highly active antiretroviral therapy (HAART) outpatient clinic. Our novel data capture approach collects “key” data for tracking patient and programme outcomes. It saves physician time and does not detract from clinical care.

Keywords Medical records; Medical records systems, Computerized; Data collection; Automatic data processing; Botswana (source: MeSH, NLM).

Mots clés Dossier médical; Dossier médical informatisé; Collecte données; Informatique; Botswana (source: MeSH, INSERM).

Palabras clave Registros médicos; Sistemas de registros médicos computarizados; Recolección de datos; Procesamiento automatizado de datos; Botswana (fuente: DeCS, BIREME).

Introduction In recent years the international community has responded with unprecedented attention and commitment to the human immunodeficiency virus (HIV)-1 pandemic. Several antiretroviral treatment (ART) initiatives have recently been initiated in sub-Saharan Africa and other areas hardest hit by the HIV/acquired immune deficiency syndrome (AIDS) epidemic in an effort to significantly improve the quality of life for the millions of persons with HIV/AIDS who urgently need ART.1–3 With the rapid scale-up of these programmes, large numbers of patients will require comprehensive care which includes the lifelong provision of highly active antiretroviral therapy (HAART). While issues of antiretroviral (ARV) affordability, ARV production and procurement, training needs and manpower constraints have received most of the attention in the past years,4–7 the need for reliable documentation and tracking of patient outcomes for ascertaining overall programme success have only recently begun to receive attention.5, 6 There is a paucity of data on the lessons learned and best method to monitor and evaluate the outcomes of patients initiated on HAART in sub-Saharan Africa.8–11

Well-designed and integrated “longitudinal” data capture and tracking systems are vital for the successful and sustainable implementation of ART programmes at the level of the patient and in the broader public health perspective. We developed a concise hybrid “paper–electronic” patient documentation system, which makes use of optical character recognition (OCR) technology, at Princess Marina Hospital in Gaborone, Botswana’s largest tertiary referral hospital and the first public HAART outpatient clinic. While imposing minimal burden on physicians this system provides critical data documenting patient outcomes that can be used for monitoring both at the clinic and national programme level.

Background The Botswana medical record system, used countrywide, has proven to be an

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Ref. No. 04-019307
Submitted: 3 December 2004 – Final revised version received: 10 October 2005 – Accepted: 17 October 2005
efficient and reliable means of maintaining documentation. It primarily uses paper-based, patient-held outpatient department (OPD) cards that contain all pertinent medical data, including outpatient visits, hospitalization summaries, specialist notes, prescriptions and diagnostic results, arranged in chronological order. Medical records on hospital admissions are maintained at the individual district and referral hospitals. Parallel health programmes, such as directly observed anti-tuberculosis therapy, antenatal/obstetric care and family planning services, use additional patient-held documents.

In January 2002, medical staff at the outpatient HIV clinic of Princess Marina Hospital (referred to as the adult Infectious Disease Care Clinic (IDCC)) officially began Botswana’s national ART programme by providing HAART to qualifying Botswana citizens in accordance with Botswana National Antiretroviral Treatment Guidelines. Botswana’s ART programme estimated that 6000 patients would need to be placed on HAART in Gaborone alone during the first year.

The IDCC medical staff were able to rapidly expand HIV/AIDS services and provide care to approximately 1000 qualifying adults by the end of the first six months of the programme using the paper-based data capture method. This consisted of (1) a registration sheet with baseline demographics and contact information collected by clinic administrative staff, (2) a clinic appointment database maintained by clinic administrative staff, (3) medical data on past illnesses and newly emerging problems such as toxicities and incident opportunistic infections collected by the physician/nurse, (4) laboratory data, and (5) ARV prescription (physician) and dispensing data (pharmacy staff).

However, as the number of patients grew, it became evident that efficient monitoring of this huge patient base would be possible only with the help of a computer-based patient tracking system. Recognizing this need and the difficulty of using OPD cards for HIV care and ART due to the regular multiple clinic visits, the Government of Botswana in April 2003 installed a computerized data capturing system in the then four operating sites of Botswana’s national ARV (“MASA”), including IDCC, Gaborone. Later in April 2004, the above system was replaced by an integrated patient management system (IPMS) to centralize health data. This new comprehensive state-of-the-art health-care information technology system, based on “real-time” health-provider data entry on to a computer workstation in their consulting room, is planned to eventually include all 32 ART sites of Botswana’s national ARV treatment programme.

Hybrid data forms based on optical character recognition technology for patient tracking and data capture

Before the introduction of the government’s computerized data capturing system, we developed and piloted a novel data capture and patient tracking system at Princess Marina Hospital to address the need for electronic documentation. Our system monitored ARV tolerability, ARV drug switches, as well as the occurrence of opportunistic and HIV-related illnesses; was a component of visit tracking activities (missed visits); provided data on follow-up statistics (including deaths and transfers); and ARV drug procurement projections from August 2002 through to March 2003.

Objectives

Our primary objective was to develop a patient tracking system that met the following criteria: (1) captures only key ART-related data, (2) requires very little physician time, (3) does not involve direct “real time” physician data entry, thereby not hindering the patient-physician relationship, (4) requires only one concise sheet to be completed at the baseline and at all subsequent patient visits, (5) has minimal “free text” thus minimizing errors and the need for data queries, and (6) allows data to be summarized on a one-page patient visit summary allowing providers unfamiliar with a patient’s medical history to be quickly and comprehensively updated.

Our secondary objective was to use our database (1) for individual patient care (site level) and (2) as a programme monitoring and evaluation tool (national level).

Patient tracking

During their first clinic visit each patient was given a unique patient identification number, and an administrative assistant directly entered each patient’s contact and demographic information (name, date of birth, gender, national identification/passport number, contact address, phone number and next of kin) into a confidentially maintained electronic database. At this visit, the medical officer completed a one-page “Baseline History” form (Annex A, web version only, available at: http://www.who.int/bulletin) which contained a list of major opportunistic infections, other major concomitant illnesses, and the WHO clinical stage. At this and all subsequent visits, a one-page “Longitudinal Visit Form” (Annex B, web version only, available at: http://www.who.int/bulletin) was completed capturing (1) status of ART, (2) toxicity information, (3) information on the presence of any opportunistic infections and medications used to treat them, (4) adherence assessment, (5) any ART modifications, and (vi) the currently prescribed ARV regimen.

Data entry clerks directly entered laboratory data on haematology, viral load and CD4, using the original laboratory result sheets as source documents. These data appeared in summarized tabular format in our “Patient Visit Summary” form (described later). An additional form, called “Patient Disposition” form (not shown), was designed to capture events such as death, transfer to other treatment sites and lost to follow-up and would only be completed when such an event occurs. This form is important for transparent patient disposition both for clinic as well as programme monitoring and evaluation.

The forms were scanned into an electronic database, and the original paper versions were retained at the clinic as source documents with individual patient medical charts. Any additional information that the physician deemed important could be added as free text at the back of the Longitudinal Visit form and be readily retrieved from the chronologically arranged patient medical charts.

The three concise yet comprehensive one-page data capture forms developed using OCR technology (Cardiff TELEforms™ version 8) primarily used a check box format and had minimal free text fields, thus minimizing handwriting errors. These forms took less than a minute to complete, and therefore only minimally detracted from the overall patient-physician relationship. The baseline and longitudinal patient tracking forms are extremely versatile and can be easily modified to capture information deemed as “essential” by the treating medical clinic staff and/or national ARV programme managers to adapt to the

Lessons from the Field

Hybrid data capture approach for monitoring HAART patients

Hermann Bussmann et al.
varying levels of ART monitoring capacity across different sites within sub-Saharan Africa.

**Clinic- (site) and programme- (national) level monitoring and evaluation**

For site-level monitoring, we designed a concise Patient Visit Summary form (Annex C, web version only, available at: http://www.who.int/bulletin). This form efficiently summarized individual patient outcomes and contained all key aspects of patient care collected from the Baseline History and Longitudinal Visit forms, as well as CD4+ cell count and plasma HIV-1 RNA data. This form would be consistently updated after each scheduled visit. The Patient Visit Summary form, which is retained by the patient until the next scheduled clinic visit, helps to provide patient information to other health workers at the local clinic who may help provide care for the patient, or those at another ART site if the patient gets transferred.

For programme monitoring and evaluation, we opine that aggregated patient data could be summarized in report formats and regularly reviewed by the clinic’s senior medical staff and/or programme managers at the national ART programme level. We could not test this due to the short duration of our pilot study.

We believe that these aggregated reports would help provide the following “key” information: (1) total number of patients newly initiated on ART, (2) total number of patients receiving ART, (3) breakdown of patient numbers on various HAART regimens, (4) number of patients with individual ARV toxicities, (5) mortality statistics, (6) adherence estimates based on plasma HIV-1 RNA levels and patient adherence to clinic visits, and (7) lost to follow-up or transfer statistics. Each aggregate summary could easily be modified and tailored to match the local infrastructure and operations specific for each individual ART site.

**Methodology**

We piloted this data capturing approach in a setting in which the ART clinic and data management centre were in close proximity to each other. Baseline History and Longitudinal Visit forms were dispatched at the end of each clinic day to the data management centre where they were scanned and verified by an experienced medical student trained in the procedure. These forms were then sent back to the site and filed alongside the patients’ medical charts to be available during their next clinic appointment. Patient visit summaries with updated clinical data, ARV prescription and laboratory data (CD4+ cell count and plasma HIV-1 RNA levels) were available within one month (before the next scheduled visit) of the visit.

The software program for our tracking system was developed using the basic features of Microsoft Access®.

**Personnel needed**

At the clinic level, an administrative assistant with basic skills in computer use was trained to manage the registration of new patients, to book future patient appointments and to oversee the “housekeeping” of individual patient charts. Support staff (students, volunteers) were trained to assist in updating the patient charts, filing of Baseline History, Longitudinal Visit, and Patient Visit Summary forms, carrying the forms to and from the nearby data management centre, and providing the first level of quality assurance by responding to queries not requiring physician supervision and involvement. Treating physicians received training in completion of forms as well as basic information technology skills to readily access and print on demand the individual Patient Visit Summary forms.

At the data management centre, an experienced medical student verified all scanned forms for completeness and legibility. Trained volunteers and/or treating physicians answered any questions that the medical student had.

The length of our pilot was approximately seven months and we effectively managed about 3000 patients (who are seen by a physician five times a year on average) using our core staff. We envisage that to sustain a patient volume of up to 6000, 1 or 2 full-time data entry clerks (who could scan 150–200 one-page data capture forms/day) and a part-time (0.5 full-time-equivalent) data manager to oversee their work and provide the necessary quality assurance would be required. A person may also be required for maintenance of the central database to ensure effective functioning of the data-capture system.

**Costing analysis**

To effectively and efficiently provide care for approximately 6000 patients using our system, the start-up costs would include the purchase of a scanner (US$ 7000), one PC workstation (US$ 1000) and software licence (US$ 1500). Ongoing costs would include salary for support staff indicated above, US$ 300 for about three toner (printer) cartridges per year as well as approximately US$ 500 per year for paper/photocopying expenses.

**Lessons learned**

Which data should be collected?

Recently, several opinions on the minimum level of patient information needed for effective patient tracking and programme evaluation have been published.5-14 An electronic medical record system developed and implemented in Kenya used an eight-page initial visit encounter form and a two-page return visit encounter form.5 Our concise one-page Baseline History and Longitudinal Visit forms were well received by treating physicians and significantly reduced costs on consumables (reduced photocopying costs) and quality assurance as they had minimal free text thus generating fewer queries and requiring less data manager supervision. In addition, the majority of the queries were not complicated as they could be handled at the data keying and physician level. We refrained from collecting extensive data on physical examination, signs and symptoms, and diagnostic tests, and instead chose to focus on ARV-associated toxicity, virological failure, adherence assessment and incident opportunistic infections. At our clinic, where individual physicians were routinely examining 25–40 patients per day, the collection of any additional data not considered to be “key” for tracking major patient outcomes was perceived as a burden and was likely to not be reliably collected. We strongly feel that if additional data collection is required, designated research teams should collect it separately as they typically have fewer manpower constraints and therefore can spend more time per patient encounter.

How best to capture the data?

While addressing the question of how best to enter individual and aggregate patient data in electronic format, we focused primarily on developing a physician independent approach by using optical character recognition (OCR) technology.
Why is a physician independent approach necessary?
We believe that an optimal data capture system should be “physician independent”, as physicians are often a scarce resource in busy ART clinics, and their time should be reserved for day-to-day clinic administrative duties, patient management and staff education. Many physicians in the ART clinics have competing outpatient clinic and medical ward responsibilities and do not have time during any given work-day to complete multiple-page forms and answer multiple queries that incomplete filling out of these numerous forms would generate. Even for the newer more expensive IPMS, “physician-driven” data entry is not only time consuming but also likely to detract from the patient–physician relationship as the treating physician spends less time examining and talking to individual patients because they have to constantly look at the workstation on their desk to ensure simultaneous correct data entry.

How does optical character recognition technology help in data capture?
To best accomplish our above-mentioned objectives, we decided to capitalize on existing OCR software technology (Cardiff TELEforms version 8) to scan forms into the central database. Our one-page OCR forms, created mostly in check box format (rather than having “free text” fields), allowed us to daily scan these forms into the central database while still being instantly accessible for review in the patient folder, thereby avoiding multiple data entry. The Longitudinal Visit forms could also assist in maintaining a high standard of care and in strengthening adherence to existing national ART guidelines. Another advantage of the OCR format is the possibility of conveniently linking peripheral sites with phone access to a central site via fax.

Other data entry options
Advances in information technology offer a wide array of data capturing methods, which could be considered for specific settings. Innovative technologies such as personal digital assistants, touch-screen computer technology or web-based medical record systems, are promising avenues that potentially combine ease of data entry and minimal interference with physicians’ work. Their use in resource-limited settings, however, has yet to be studied.

Limitations
Our experiences were limited by the relatively short time available for piloting our data capture system because the government launched computerized data capture and IPMS. We, however, believe that the large number of patients that we followed up compensated for this shortcoming. We also could not extend our pilot study to involve one or more peripheral sites but such a system should be tried in more geographically isolated areas where many rural clinics feed into one or more central clinics.

In addition, now that more is being reported on the specifics of patient monitoring and evaluation, any future development of our or other related novel data capture systems would need to harmonize with guidelines that are now available which emphasize standardization of data dictionaries and health data programming as set forth by the HL7 and WHO working groups.

Conclusion
The number of HIV-1-infected persons receiving lifelong HAART in sub-Saharan Africa is expected to grow exponentially in the next few years. Infrastructure limitations and manpower shortages will constitute major challenges in efficiently and effectively documenting individual patient care and overall ART programme outcomes. While, the traditional method of paper to electronic data transfer by data entry clerks often compromises on the format because it has to suit the health-care provider’s need for ease of completion and the data entry clerk’s need for quick and reliable entry into the electronic database, direct electronic data input by physicians detracts from patient–physician encounters and also requires a reliable power supply and on-going technical assistance, which may be scarce in resource-limited settings. We believe that the newly implemented integrated patient management system in Botswana would be costly, requiring multiple computer stations at each ART site, as well as be highly provider-dependent as it requires health-care providers to enter data “real-time” directly onto the workstation in their consultation room and may therefore only be feasible in a few countries offering ART. We recommend the use of our concise one-page OCR-based forms in hybrid paper–electronic format, which collects “key” data for individual and overall patient outcomes, combining ease of data entry and saving of limited physician time while not disrupting the patient–physician encounter.

Acknowledgements
We would like to thank the Ministry of Health, Botswana, Adult Infectious Disease Care Clinic (IDCC) staff of Princess Marina Hospital, Botswana–Harvard School of Public Health Partnership Adult Antiretroviral Treatment, and the Drug Resistance (“Tshepo”) study staff for their support and assistance.

Competing interests: none declared.
Recogida de datos mixtos para el monitoreo de pacientes sometidos a terapia antirretroviral de gran actividad (TARGA) en zonas urbanas de Botswana

La atención individual a los pacientes y la evaluación de los programas son fundamentales para el éxito de los programas de tratamiento antirretroviral en los países con pocos recursos. Aunque la documentación y el almacenamiento de datos asistidos por ordenador son imprescindibles para cualquier programa de amplio alcance, hay varias cuestiones importantes que es necesario abordar, como por ejemplo qué datos deben reunirse, quiénes deben reunirlos, y cómo deben introducirse en la base de datos electrónica. Describimos aquí un sistema de monitoreo de los pacientes que, basado en formularios de encuentro con el enfermo (en formato mixto: papel y versión electrónica) procesados mediante un sistema de reconocimiento óptico de caracteres, se ha aplicado experimentalmente en el Princess Marina Hospital de Gaborone, primera clínica pública de Botswana para pacientes ambulatorios sometidos a la terapia antirretroviral de gran actividad (TARGA). Este novedoso sistema de recopilación de datos reúne datos «clave» para seguir de cerca la evolución de los pacientes y los resultados de los programas. El sistema supone un ahorro de tiempo para el médico y no afecta a la atención clínica.

References

## Annex A

### BASELINE HISTORY

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<th>PID</th>
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<th>INITIALS</th>
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**INSTRUCTIONS:** Shade the bubble when applicable. For other fields, enter the value as required.

**Pulmonary Tuberculosis (Most Recent)**
- □ SMO +
- □ SMO -
- □ UNKNOWN

**Pulmonary Tuberculosis (Previous)**
- □ SMO +
- □ SMO -
- □ UNKNOWN

**Extrapulmonary Tuberculosis**
- □ CNS
- □ GI
- □ Cardiac
- □ Other

**Cryptococcal Meningitis**
- □ Yes
- □ No

**Kaposi’s Sarcoma**
- □ Cutaneous
- □ Diffuse with lymphatic obstruction
- □ Palatal only
- □ Diffuse without lymphatic obstruction
- □ Palatal and cutaneous
- □ Presumed visceral disease

**Current peripheral Neuropathy**
- □ Yes
- □ No

**Wasting Syndrome (>10% net loss from baseline)**
- □ With chronic diarrhea
- □ Without chronic diarrhea

**Chronic Diarrhea (>1 month duration)**
- □ Yes
- □ No

**AIDS Dementia Complex**
- □ Yes
- □ No

**CMV Retinitis**
- □ Yes
- □ No

**Candidiasis**
- □ Esophageal
- □ Oral
- □ Both

**Chronic dermatitis**
- □ Seborrheic dermatitis
- □ Other
- □ Papular pruritic dermatitis

**PCP Pneumonia**
- □ Proven
- □ Suspected

**Recurrent genital ulcers**
- □ Yes
- □ No

**Herpes Zoster**
- □ Cutaneous
- □ Ophthalmic

**Other**
- □ Yes
- □ No

**Best Weight (kg)**
- □ Yes

**Karnofsky score**
- □ Yes

**Height (cm)**
- □ Yes

**Active/Previous medical history:**
- □ Carcinoma
- □ Malignancy
- □ Hypertension
- □ Diabetes mellitus
- □ Renal Disease
- □ Traditional Medicine use
- □ Psychiatric illness requiring treatment

**WHO clinical stage (Specify):**
- □ Stage 1
- □ Stage 2
- □ Stage 3
- □ Stage 4

**Clinician’s Signature:**
Lessons from the Field

Hybrid data capture approach for monitoring HAART patients

Hermann Bussmann et al.

Annex B

LONGITUDINAL VISIT FORM

<table>
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</table>

INSTRUCTIONS: Shade the bubble when applicable. For other fields, enter the value as required.

1. Is the patient on ART? [ ] Yes [ ] No [ ] Initiated at this visit

2. Indicate any ARV-related toxicities since the last visit:
   - ZDV-Aemia moderate (Hb between 7.7-9g/dL)
   - ZDV-Aemia severe (Hb between 6-9g/dL)
   - ZDV-Aemia life threatening (Hb < 6 g/dL)
   - Peripheral neuropathy moderate (discomfort requiring Rx)
   - Peripheral neuropathy severe (incapacitated, disabled)
   - NVP rash moderate (maculopapular)
   - NVP rash severe (blistering, mucosal involvement)
   - EFV CNS symptoms
   - Minor ZDV-related symptoms (headaches/nausea)
   - ddI-related clinical pancreatitis
   - ddI-related chemical pancreatitis
   - Lipatrophys/Lipohypertrrophy
   - Hepatotoxicity
   - Other:

3. Indicate any new HIV-related diagnosis since the last visit:
   - Herpes Zoster
   - Pulmonary Tb
   - Extrapulmonary Tb
   - Candidiasis (oral)
   - Candidiasis (esophageal)
   - OMV retinitis
   - PCP pneumonia
   - HIV encephalopathy
   - Wasting Syndrome
   - Cryptococcal Meningitis
   - Diarrheal illness (>7 days duration)
   - Recurrent genital ulcers (>1 month)
   - Diffuse Lymphadenopathy
   - Other:

4. Indicate OI preventative / therapeutic medication prescribed at this visit or since last visit:
   - Amitriptyline
   - Cotrimoxazol (treatment dose)
   - Cotrimoxazol (prophylaxis dose)
   - Ketoconazole
   - Fluconazole
   - ATT
   - IPT
   - Benzathine Penicillin
   - Gancyclovir
   - Acyclovir
   - Nystatin
   - Other:

5. Are there any new drug allergies, previous unreported? [ ] Yes [ ] No

Specify:

6. In your opinion, is the patient at least 90% adherent to ART? (Clinician) [ ] Yes [ ] No

7a Are there any changes in ART at today’s visit? [ ] No changes [ ] Modified

7b If dose modification:
   - Reduced
   - Increased
   - Held
   - Resumed
   - Drug switch

7c Please give the primary reason for change:
   - Toxicity
   - TB Treatment
   - Virologic failure
   - Dose escalation
   - Pregnancy
   - Other:

8. What is the prescribed regimen today?

NRTIs
- CBV BD
- ZDV 300 BD
- ZDV 200 BD
- 3TC 150 BD
- ABC 300 BD
- ddI 400 OD
- ddI 300 OD
- ddI 200 OD
- d4T 40 BD
- d4T 30 BD
- d4T 20 BD

NNRTIs
- NVP 200 OD
- NVP200 BD
- NVP 400OD
- EFV 600OD
- EFV 800 OD

PIs
- NEL 1250 BD
- IDV 800 TDS
- RT/IDV 100/800 BD
- RT/SQV 400/400 BD
- RT/SQV 100/1000 BD
- RT/SQV 100/1600 OD

DATE OF NEXT VISIT: 20

Clinician’s Signature:

B Bulletin of the World Health Organization  February 2006, 84 (2)
Annex C

02406  Patient Initials:  KS  Gender:  F  Date of Birth:  16/01/1975
Allergies:  NONE  Pre-enrolment ARV History (If any):

Baseline History:  Wasting Syndrome without chronic diarrhea
Herpes Zoster (cutaneous) 2000
Pulmonary TB, smear+ 2002

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