CASE STUDY

THE UTILITY OF PHARMACY DISPENSING DATA FOR ART PROGRAMME EVALUATION AND EARLY IDENTIFICATION OF PATIENT LOSS TO FOLLOW-UP

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The rapid scale-up of antiretroviral treatment (ART) programmes in sub-Saharan Africa has challenged the capacities of ART services to monitor and retain large numbers of patients within programmes effectively. Many ART clinics in sub-Saharan Africa now have to cope with patient complements of several thousands,[1-3] all of whom require monitoring and tracking. Initially, programme emphasis was placed on the maintenance of high levels of adherence to therapy, particularly because of the concerns of widespread viral resistance that could develop as a result of expanded access to ART in low- and middle-income countries (LMICs).[4] The public health approach to delivery of ART therefore recognised the need for adherence strategies as an essential component of individual and programmatic treatment success.[5] The South African ART guidelines included protocol provision for adherence counselling strategies within clinics.[6] Despite initial scepticism, the feasibility of expanded access in LMICs has been justified by many early programmes reporting high levels of adherence[7,8] and viral suppression rates which were comparable with those achieved in industrialised settings.[9] While these results were encouraging, they represented the successful outcomes of individuals having been retained within the programmes, largely ignoring those individuals lost to each programme. However, overall programme performance and population impact may be more accurately reflected by intention-to-treat (ITT) rather than on-treatment analysis (OTA). The differences between ITT and OTA results may be considerable, and a recent meta-analysis has highlighted that the loss to follow-up after initiating ART is a major problem facing large-scale ART roll-out programmes in sub-Saharan Africa.[10]

RETENTION

The result of a systematic review of attrition within sub-Saharan African ART programmes on the proportion of adult patients remaining in care and on ART at 6 months or longer between 2000 and 2007 has been reported.[10] The analysis was based on data from 32 journal articles and conference abstracts describing 74 192 patients in non-research ART programmes in 13 countries. Retention was defined as the proportion of individuals known to be alive and receiving ART at the end of each follow-up period, and included those transferred to other programmes. Attrition was defined as the proportion of those not retained, and was a composite measure comprising losses owing to death of 40%, losses to follow-up of 56%, and discontinuation of ART within the programme of 4%. Weighted mean retention rates, as reported, were 79.1%, 75.0% and 61.6% at 6, 12 and 24 months, respectively. Of those reporting 24 months of follow-up, the best programme retained 85%, and the worst retained 46%, of patients. Attrition was higher in those studies with shorter reporting periods, with monthly weighted mean attrition rates of 3.3%, 1.9% and 1.6% per month for studies reporting to 6, 12 and 24 months, respectively. As those programmes reporting high attrition were least likely to provide data beyond 6 months, this was felt by the authors to indicate that overall patient retention had been overestimated in the published reports. The main conclusion was that overall attrition in African ART programmes was very high (40%) and was predominantly the result of loss to follow-up and, to a lesser degree, death. The authors concluded that there was a need for better patient trac-

ing procedures, increased understanding of loss to follow-up, and earlier initiation of ART in order to reduce mortality. As retention varied widely across programmes, it was felt that those programmes that had achieved higher retention rates might serve as models for future improvements.

CONVENTIONAL DATA SOURCES

Conventional approaches to data collection are 'doctor-centred', relying on patient information captured on data capture forms which are subsequently entered into a computerised database by a data entry clerk for subsequent use for programme evaluation (Fig. 1). More sophisticated versions incorporate direct entry of medical information into an electronic medical record (EMR) where the data are available for both patient care and programme evaluations. However, EMRs require computer networks and ongoing IT support which is frequently not available in many peripheral and community ART clinics. The rapid scale-up of ART to millions of patients, the scarcity of doctors and pharmacists, a poor computer infrastructure and involvement of nurses and lay counsellors in patient care both inside and outside of formal clinics, compound the difficulties of data collection and collation. Furthermore, doctor visits are typically scheduled 6-monthly,[6] which does not allow early detection of attrition from the programme as patients might have been off therapy for several months before being identified.

MINIMUM DATA REQUIREMENTS FOR ITT ANALYSES

Data for programme evaluation of retention differs from that required for individual patient management and is therefore not just a consolidation of individual responses to ART. ITT analysis of programme performance necessitates knowledge of the numbers of individuals initiating therapy, remaining on therapy, and lost (attrition) to the programme. Further classification of attrition into known deaths, transfers and remaining loss to follow-up requires additional active follow-up procedures. Establishment of vital status may be difficult to achieve within a normal clinic, and may be better achieved in those services that have established interactions with patients at a community level.

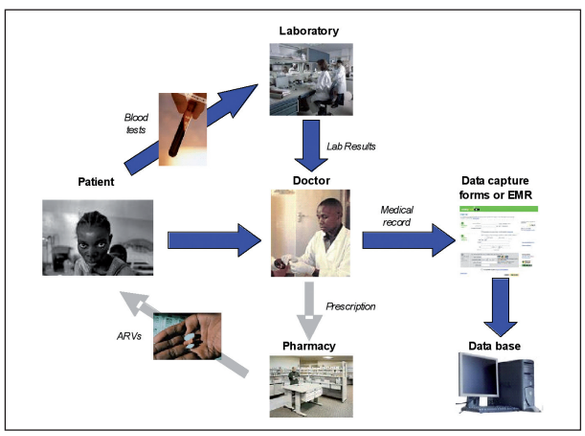


Fig. 1. The data collection cycle.

PHARMACY-BASED DATA SOURCES

Pharmacy-based records have previously been reported to be a simple and effective population-level tool for monitoring adherence within scaling-up African HAART programmes.[11] Pharmaceutical dispensing already requires the capturing of date information, patient identifiers such as age, and gender and contact details together with specifics of the prescription instructions from the health care provider. ART programmes may also easily add a requirement for justification of regimen changes classified into simple categories such as intolerance, toxicity or virological failure. If the date and time of patient receipt of ARVs could be captured, the pharmacy-based records could be expanded to capture programme retention data as well as adherence information. Most of these data are required to be collected as part of routine pharmacy functioning in all treatment sites and can be made available for programme evaluation without adding to the workload of busy clinics.

iDART SYSTEM

As an extension of the concept of using pharmacy information as a programme evaluation tool, the intelligent dispensing of ART system (iDART) has been developed as a non-proprietary programme. iDART is a pharmacy application developed on open-source software that allows dispensing of ART both on site and from a remote pharmacy. The system has been developed in response to a need to manage large numbers of patients on ART simply and effectively. The key benefits of the iDART system are accurate tracking of patient treatment and providing comprehensive patient treatment history. Operationally, iDART aids accurate ARV stock control management and faster pharmacy dispensing through faster processing. It reduces and identifies loss of ARVs, and it operates through clearly identifiable, multilingual bar-coded labels which are created for each and every drug and patient package. iDART provides a pharmacy management tool incorporating stock-control, drug deliveries and drug-dispensing information designed to allow a central pharmacist to provide services to multiple satellite clinics (Fig. 2). Demographic details, regimen dispensed and date and time of receipt of ART by the patient are captured without the need for additional data clerks (Table I). Standardised programme reports can be generated for funding agencies (e.g. PEPFAR) and health authorities (Fig. 3), together with updated lists of patients who have failed to pick up their prescriptions and who are defaulting from the programme. The programme has already been successfully used in 7 large ART clinics in North West, Gauteng, Western Cape and Northern Cape provinces and has been integrated with other data systems (e.g. EMR, lab-based) and the Western Cape provincial health record system (eKAPA). One of the most important

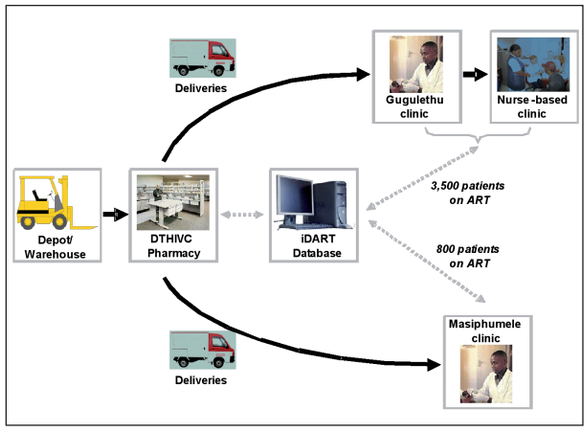
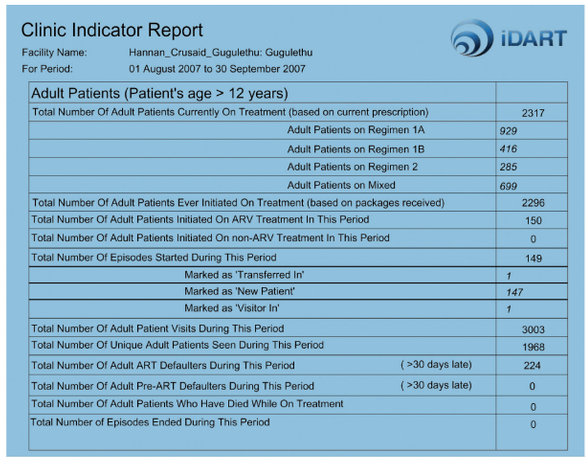


Fig. 2. The iDart system as applied to Gugulethu and Masiphumelele clinics.



Clinic Indicator Report

iDART

Facility Name: Hannan_Crusaid_Gugulethu: Gugulethu
For Period: 01 August 2007 to 30 September 2007

Adult Patients (Patient's age > 12 years)		
Total Number Of Adult Patients Currently On Treatment (based on current prescription)		2317
Adult Patients on Regimen 1A		929
Adult Patients on Regimen 1B		416
Adult Patients on Regimen 2		285
Adult Patients on Mixed		699
Total Number Of Adult Patients Ever Initiated On Treatment (based on packages received)		2296
Total Number Of Adult Patients Initiated On ARV Treatment In This Period		150
Total Number Of Adult Patients Initiated On non-ARV Treatment In This Period		0
Total Number Of Episodes Started During This Period		149
Marked as 'Transferred In'		1
Marked as 'New Patient'		147
Marked as 'Visitor In'		1
Total Number Of Adult Patient Visits During This Period		3003
Total Number Of Unique Adult Patients Seen During This Period		1968
Total Number Of Adult ART Defaulters During This Period	(>30 days late)	224
Total Number Of Adult Pre-ART Defaulters During This Period	(>30 days late)	0
Total Number Of Adult Patients Who Have Died While On Treatment		0
Total Number of Episodes Ended During This Period		0

Fig. 4. An iDart clinic report.

functions of iDART lies in the various reports that the software makes available. These range from basic stock control management and monitoring reports to specific patient defaulter lists, which facilitates easy management and follow-up of patients. iDART also keeps the entire patient history of a patient in its database, providing accurate tracking of patients receiving treatment from ART sites (Fig. 4). The iDART system also allows the decanting of packages to remote clinics and dispensaries that do not hold stock of ARVs; a central pharmacy prepares packages for patients belonging to remote clinics and the system will trace the entire process until the patients collect their drugs. Feedback is then provided via the network or other data transfer systems to the central pharmacy to signal that the package was collected, and the pharmacist is then allowed to package drugs for the patient in the next month. Minimum system requirements are a single computer, barcode printer and barcode reader. Data transfer can utilise a flash memory stick, cell phone, email or internet connection.

Fig. 3. An iDart programme report.

CAPE TOWN iDART CONFORMATION

The Cape Town central pharmacy receives and manages drug deliveries and supports peripheral clinics (Fig. 2). A single pharmacist and pharmacy assistant dispense ARVs to 2 peripheral clinics. Gugulethu is a busy doctor-based ARV clinic servicing >3 500 patients, which incorporates a nurse-led decanting clinic for patients established on stable ARVs. Masiphumelele is a smaller public-sector community polyclinic providing >800 patients with ARVs with both doctor- and nurse-led services. Gugulethu and Masiphumelele are approximately 20 and 40 kilometres distant from the pharmacy, respectively, with data transfer between peripheral site networks and central database via a virtual private network (vpn).

SIZOPHILA COMMUNITY ADHERENCE PROGRAMME

The Gugulethu ARV service is supported by a network of adherence counsellors who are recruited from the community, openly live with HIV and are trained and employed to carry out both clinic- and community-based services (Fig. 5). On any weekday, there are counsellors who report to the clinic in the morning and perform the clinic duties which include treatment readiness sessions for new recruits, adherence trouble-shooting for established patients and day-to-day clinic operations.

TABLE I. INFORMATION CAPTURED FROM PHARMACY AND DISPENSING INPUTS TO iDART AND INDIVIDUAL PATIENT AND CONSOLIDATED PROGRAMME REPORT OUTPUTS

iDART inputs	Information captured	Outputs
ARVs delivered ARV returns ARV expirations ARVs dispensed ARVs transferred to clinics	ARVs in stock ARVs dispensed	Pharmacy stock control ARV regimens used
Registration of patient Date receipt of 1st ARVs Date of repeat ARVs Failure to pick up ARVs	Demographic details Start date on ART Duration of treatment List of defaulters	Programme reports Individual adherence Individual retention

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HIV & aids

P O R T F O L I O

VIDEX™: S4 **Proprietary Name and Composition:** VIDEX™ tablets 25 mg, VIDEX™ tablets 50 mg, VIDEX™ tablets 100 mg, VIDEX™ tablets 150 mg, VIDEX™ paediatric powder 2 g. Tablets contain didanosine 25, 50, 100 and 150 mg, respectively. Paediatric powder contains 2 g didanosine per bottle. **Pharmacological Classification:** A 20.2.8 Antiviral Agents. **Indications:** VIDEX™ should be used as part of or in combination with other antiretroviral agents for the palliative treatment of adult and paediatric patients with advanced HIV infection. **Dosage and Directions for Use:** To be taken on an empty stomach, at least 30 minutes before, or 2 hours after a meal. Adults: Weight-dependent dosing, for patients with a baseline body weight ≥60 kg the recommended dose is 200 mg 12-hourly or 400 mg once a day; <60 kg the recommended dose is 125 mg 12-hourly or 250 mg once a day. Children: Dosing in accordance with body surface area (BSA), for patients with a BSA of 1.1 to 1.4 m^2 the recommended dose is 100 mg 12-hourly, for patients with a BSA of 0.8 to 1.0 m^2 the recommended dose is 75 mg 12-hourly, for patients with a BSA of 0.5 to 0.7 m^2 the recommended dose is 50 mg 12-hourly, for patients with a BSA of ≤0.4 m^2 the recommended dose is 25 mg 12-hourly. **Contraindications:** VIDEX™ is contraindicated in patients with known hypersensitivity to any of its ingredients, including didanosine. There are insufficient data to recommend the use of VIDEX™ in patients with impaired hepatic function. Safe use in pregnancy has not been established and it is recommended that women who take didanosine do not breastfeed. **Warnings:** Fatal and non-fatal pancreatitis, lactic acidosis, liver failure, toxic peripheral neuropathy, retinal changes and optical neuritis. **Precautions:** Lactic acidosis, liver disease, magnesium overload in renal impairment, geriatric use, hyperuricaemia, phenylketonurics, drug interactions. **Side-effects:** Adults: Diarrhoea, peripheral neurological symptoms / neuropathy, rash / pruritis, abdominal pain, pancreatitis, nausea, vomiting, headache. Children: Similar to those reported for adults. **Registration Numbers:** VIDEX™ 25 mg tablets 27/20.2.8/0040; VIDEX™ 50 mg tablets 27/20.2.8/0041; VIDEX™ 100 mg tablets 27/20.2.8/0042; VIDEX™ 150 mg tablets 27/20.2.8/0043; VIDEX™ 2 g paediatric powder 27/20.2.8/0045. **Holder of the Registration Certificate:** Bristol-Myers Squibb (Pty) Ltd, 47 Van Buuren Road, Bedfordview, 2008. **Date:** July 2006. For full prescribing information refer to the approved package insert.

VIDEX™ EC: S4 **Proprietary Name and Composition:** VIDEX™ EC capsules 250 mg, VIDEX™ EC capsules 400 mg. Each capsule contains the equivalent of 250 mg or 400 mg of didanosine as enteric-coated beadlets. **Pharmacological Classification:** A 20.2.8 Antiviral Agents. **Indications:** VIDEX™ EC should be used in combination with other antiretroviral agents for the palliative treatment of adults with advanced HIV infection. **Dosage and Directions for Use:** Due to the reduced absorption in the presence of food VIDEX™ EC should be taken on an empty stomach at least one hour before or two hours after a meal. Adults: Weight-dependent, once-daily dosing, for patients with a baseline body weight ≥60 kg the recommended dose is 400 mg once a day; <60 kg the recommended dose is 250 mg once a day. **Contraindications:** VIDEX™ EC is contraindicated in patients with known hypersensitivity to any of its ingredients, including didanosine. Safety and efficacy of VIDEX™ EC in children have not been established. There are insufficient data to recommend the use of VIDEX™ EC in patients with impaired hepatic function. Safe use in pregnancy has not been established and it is recommended that women who take didanosine do not breastfeed. **Warnings:** Fatal and non-fatal pancreatitis, lactic acidosis, liver failure, toxic peripheral neuropathy, retinal changes and optical neuritis, hyperuricaemia. **Precautions:** Lactic acidosis, geriatric use, hyperuricaemia, patients on a sodium restricted diet, drug interactions. **Side-effects:** Adults: Diarrhoea, peripheral neurological symptoms / neuropathy, rash / pruritis, abdominal pain, pancreatitis, nausea, vomiting, headache. **Registration Numbers:** VIDEX™ EC 250 mg capsules 36/20.2.8/0065; VIDEX™ EC 400 mg capsules 36/20.2.8/0066. **Holder of the Registration Certificate:** Bristol-Myers Squibb (Pty) Ltd, 47 Van Buuren Road, Bedfordview, 2008. **Date:** September 2003. For full prescribing information refer to the approved package insert.

ZERIT™: S4 **Proprietary Name and Composition:** ZERIT™ capsules 15 mg, ZERIT™ capsules 20 mg, ZERIT™ capsules 30 mg, ZERIT™ capsules 40 mg, ZERIT™ powder for oral solution 1 mg/ml. **Pharmacological Classification:** A 20.2.8 Antiviral Agents. **Indications:** ZERIT™ is indicated in combination with other antiretroviral agents for the treatment of adults and children (6 months of age and older) with HIV infection. **Dosage and Directions for Use:** Weight-dependent dosing. Adults: For patients with a baseline body weight ≥60 kg the recommended dose is 40 mg 12-hourly; <60 kg the recommended dose is 30 mg 12-hourly. Children: <30 kg the recommended dose is 1 mg/kg 12-hourly, ≥30 kg to < 60 kg the recommended dose is 30 mg 12-hourly, ≥60 kg the recommended dose is 40 mg 12-hourly. **Contraindications:** ZERIT™ is contraindicated in patients with known hypersensitivity to any of its ingredients, including stavudine. ZERIT™ is not recommended for use in children under 6 months of age. Safe use in pregnancy has not been established and it is recommended that women who take stavudine do not breastfeed. **Warnings:** Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of ZERIT™ alone or in combination, fatal and non-fatal pancreatitis, neurological symptoms, ZERIT™ in combination with 3TC. **Precautions:** Lactic acidosis, hepatic dysfunction, renal impairment, laboratory test abnormalities, geriatric use, diabetes mellitus, lactose intolerance, drug interactions (the use of stavudine in combination with zidovudine in particular, is not recommended). **Side-effects:** Adults: Abdominal pain, peripheral neurological symptoms, including peripheral neuropathy, depression, lipodystrophy, rash, pruritis, diarrhoea, nausea, dyspepsia, fatigue, dizziness, abnormal dreams, insomnia, somnolence. Children: Similar to those reported for adults. **Registration Numbers:** ZERIT™ 15 mg capsules 32/20.2.8/0264, ZERIT™ 20 mg capsules 32/20.2.8/0265, ZERIT™ 30 mg capsules 32/20.2.8/0266, ZERIT™ 40 mg capsules 32/20.2.8/0267, ZERIT™ 1 mg/ml powder for oral solution 32/20.2.8/0268. **Holder of the Registration Certificate:** Bristol-Myers Squibb (Pty) Ltd, 47 Van Buuren Road, Bedfordview, 2008. **Date:** July 2006. For full prescribing information refer to the approved package insert.

REYATAZ™: S4 **Proprietary Name and Composition:** REYATAZ™ capsules 150 mg, REYATAZ™ capsules 200 mg. Each capsule contains the equivalent of 150 mg or 200 mg of atazanavir as atazanavir sulfate. **Pharmacological Classification:** A 20.2.8 Antiviral Agents. **Indications:** REYATAZ™ is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. **Dosage and Directions for Use:** Adults: The recommended dose of REYATAZ™ is 400 mg once daily taken with food. When co-administered with ritonavir, it is recommended that REYATAZ™ 300 mg once daily be taken with ritonavir 100 mg once daily with food. REYATAZ™ without ritonavir is not recommended for treatment-experienced patients with prior virologic failure. Children: The optimal dosing regimen for use in paediatric patients has not been established. REYATAZ™ should not be administered to paediatric patients below the age of 3 months. **Contraindications:** REYATAZ™ is contraindicated in patients with known hypersensitivity to any of its ingredients, including atazanavir. **Warnings:** Diabetes mellitus and hyperglycemia, drug interactions. **Precautions:** Pregnancy and lactation, patients co-infected with hepatitis B and/or hepatitis C virus, haemophilia, fat redistribution, immune reconstitution syndrome, PR-interval prolongation, rash, hepatic impairment and toxicity, hyperbilirubinemia. **Side-effects:** Frequent: Dizziness, headache, insomnia, peripheral neurological symptoms, scleral icterus, abdominal pain, diarrhoea, dyspepsia, nausea, vomiting, jaundice, rash, asthenia, fatigue. **Registration Numbers:** REYATAZ™ 150 mg capsules A39/20.2.8/0088; REYATAZ™ 200 mg capsules A39/20.2.8/0089. **Holder of the Registration Certificate:** Bristol-Myers Squibb (Pty) Ltd, 47 Van Buuren Road, Bedfordview, 2008. **Date:** July 2006. For full prescribing information refer to the approved package insert.

Fig. 5. Adherence counsellors are recruited from the community, and are trained and employed to carry out clinic- and community-based services.

The majority of the team work daily from home, their clients having been assigned geographically. They attend to home visits for new recruits as well as regular visits for defaulters and patients with adherence problems (red alert patients). Patients who adhere poorly, as indicated by pill counts, and patients who are not virally suppressed, are classified as 'red alert' and referred to their relevant counsellor for increased attention. A defaulters list is also generated from the iDART pharmacy system, based on missed pharmacy pick-up dates, and these patients are followed up by their counsellors. Adherent patients are classified as 'green' patients and visited less frequently. They attend the clinic 2-monthly for new drug supply and are seen by a nurse practitioner or doctor every 4 months. Each counsellor is responsible for approximately 120 patients, of whom only the minority are 'red alert'. Clinic-based activities ensure that patients are well informed about the need for treatment and programme adherence and, together with the red alert system, this ensures patient adherence, excellent viral suppression rates and thus sustained therapy options. However, it is the field-based activities of the counsellors providing individualised support, home visits and regular follow-up that ensure ongoing adherence and excellent retention with reliable outcome data. iDART is an important trigger for the adherence/retention team that patients have defaulted treatment pick-up, resulting in immediate community follow-up by the relevant counsellor. This combination of clinic- and field-based counsellors together with iDART maintains excellent adherence and viral suppression rates as well as remarkably low loss-to-follow-up rates in this large community-based clinic in Gugulethu, Cape Town.

CONCLUSIONS

Pharmacy pick-up data by patients are well suited for identification of patients retained or those potentially lost to the programme. iDART is a flexible solution able to be implemented on a variety of IT platforms. Alone, it is a simple solution which can be implemented at peripheral clinic sites by pharmacy management, enabling standard report generation including early identification of programme losses, and it enables implementation of active community follow-up strategies.

As iDART has been developed on open source software which is free and requires no licence, the full pharmacy management system is available for implementation at any antiretroviral clinic and can be downloaded online at URL <http://www.cell-life.org/content/view/75/>.

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