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, 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). 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. The South African ART guidelines included protocol provision for adherence counselling strategies within clinics. Despite initial scepticism, the feasibility of expanded access in LMICs has been justified by many early programmes reporting high levels of adherence and viral suppression rates which were comparable with those achieved in industrialised settings. 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.
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 network 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, 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.

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. 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. 1. The data collection cycle.
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.

CAPE TOWN iDART CONFORMANCE

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.
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/>.

REFERENCES