Supervision, monitoring and evaluation of nationwide scale-up of antiretroviral therapy in Malawi*
Edwin Libamba, Simon Makombe, Eustice Mhango, Olga de Ascurra Teck, Eddie Limbambala, Erik J Schouten, & Anthony D Harries

Objective To describe the supervision, monitoring and evaluation strategies used to assess the delivery of antiretroviral therapy during nationwide scale-up of treatment in Malawi.

Methods In the first quarter of 2005, the HIV Unit of the Ministry of Health and its partners (the Lighthouse Clinic; Médecins Sans Frontières–Belgium, Thyolo district; and WHO's Country Office) undertook structured supervision and monitoring of all public sector health facilities in Malawi delivering antiretroviral therapy.

Findings Data monitoring showed that by the end of 2004, there were 13 183 patients (5274 (40%) male, 12 527 (95%) adults) who had ever started antiretroviral therapy. Of patients who had ever started, 82% (10 761/13 183) were alive and taking antiretrovirals; 8% (1026/13 183) were dead; 8% (1039/13 183) had been lost to follow up; < 1% (106/13 183) had stopped treatment; and 2% (251/13 183) had transferred to another facility. Of those alive and on antiretrovirals, 98% (7098/7258) were ambulatory; 85% (6174/7258) were fit to work; 10% (456/4687) had significant side effects; and, based on pill counts, 96% (6824/7114) had taken their treatment correctly. Mistakes in the registration and monitoring of patients were identified and corrected. Drug stocks were checked, and one potential drug stock-out was averted. As a result of the supervisory visits, by the end of March 2005 recruitment of patients to facilities scheduled to start delivering antiretroviral therapy had increased.

Conclusion This report demonstrates the importance of early supervision for sites that are starting to deliver antiretroviral therapy, and it shows the value of combining data collection with supervision. Making regular supervisory and monitoring visits to delivery sites are essential for tracking the national scale-up of delivery of antiretrovirals.

Keywords HIV infections/drug therapy; Acquired immunodeficiency syndrome/drug therapy; Anti-retroviral agents; National health programs/organization and administration; Program evaluation; Malawi (source: MeSH, NLM).

Mots clés Infection à VIH/chimiothérapie; SIDA/chimiothérapie; Agents antirétroviraux; Programme national santé/organisation et administration; Evaluation programme; Malawi (source: MeSH, INSERM).

Palabras clave Infecciones por VIH/quimioterapia; Síndrome de inmunodeficiencia adquirida/quimioterapia; Agentes antirretrovirales; Programas nacionales de salud/organización y administración; Evaluación de programas; Malawi (fuente: DeCS, BIREME).

Introduction Malawi is facing a severe human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) epidemic. It is a small and impoverished country in central–southern Africa with a population of 11 million. There are an estimated 900 000 adults and children living with HIV/AIDS; there are more than 85 000 AIDS deaths per year, and up to 170 000 people are thought to need antiretroviral therapy. At the beginning of 2004, only 4000 patients in nine public health facilities had access to antiretroviral drugs.

With so few patients on antiretroviral therapy, scaling-up treatment became an urgent national priority, and a two-year national plan for scaling-up delivery services in 2004–05 was developed and finalized in February 2004. The main elements of the plan for the public health sector included: the selection of 60 hospitals and clinics to scale-up the delivery of antiretroviral therapy to provide broad geographical coverage throughout Malawi; the provision of antiretrovirals free of charge; the use of the first-line antiretroviral treatment regimen only for scale-up

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* Since acceptance of this paper, the set of guidelines for potential authors of "Lessons from the Field" have been updated. Please see http://www.who.int/bulletin/contributors/en/current_guidelines.pdf
activities involving new facilities, with alternative first-line and second-line therapy provided when health facilities had shown the ability to properly deliver antiretroviral therapy; and the provision of antiretrovirals to facilities only if they had been formally assessed by the clinical HIV Unit of the Ministry of Health as being ready to deliver treatment.

In March 2004, all selected hospitals were briefed at three regional meetings about the plan and the national guidelines on antiretroviral therapy. Following the briefings, training sessions on antiretroviral therapy were conducted for clinicians and nurses in each of the 60 health facilities. (These briefings continued to be conducted throughout 2005.) From the latter half of 2004, the HIV Unit carried out a structured assessment of all health facilities to determine their readiness to deliver antiretroviral therapy, and by the end of March 2005 all facilities were assessed as being ready. There was a gradual increase in the number of health facilities delivering antiretroviral therapy. By the end of 2004, the number had increased from 9 to 24. In January 2005, another 10 facilities began delivering the therapy. During 2004, as part of an interim arrangement, the regional officers of the national tuberculosis control programme visited health facilities and collected data on the number of patients starting antiretroviral therapy and on their outcomes. Between January and March 2005, the HIV Unit conducted the first (of what are to become quarterly) supervisory and monitoring visits to sites delivering antiretroviral therapy.

This paper describes how the supervision and monitoring of sites delivering this therapy are conducted, the lessons learned and the results of the national expansion of the delivery of antiretroviral therapy up to the end of 2004.

Methods
Registering and monitoring patients
The details of the methods have been previously described. In brief, the tools for monitoring antiretroviral therapy include the patient master card (the front of the card is used for case registration and monthly outcomes and the back is used for the indicator diseases by which the patient is staged for therapy), the register of patients (where the left-hand page is used for case registration and the adjacent page for outcome data), and the quarterly and cumulative cohort analysis forms. The cards, registers and forms are kept in the clinic; the patients’ cards and cohort analysis forms are filed in sequence within polypropylene sheet protectors. Patients keep an identity card, on which is recorded their unique registration number and other vital information pertaining to their therapy. Patients’ details, which are entered on the master card and register, include age, sex, date and place of HIV test, reason for starting antiretroviral therapy and the drug formulation.

Every month patients attend the clinic for review, and their master card is completed. Standardized treatment outcomes are recorded, as well as ambulatory status, work status, side effects of drugs and pill counts (to determine whether patients are taking the drugs correctly). At the start of every new quarter, patients’ master cards are inspected, and the data from the last month of the previous quarter are used to update the patient register. Once the register is updated, its data are used to conduct quarterly and cumulative cohort analyses.

Supervisory and monitoring visits
Between January and March 2005, the HIV Unit and its partners the Lighthouse Clinic; Médecins Sans Frontières–Belgium; Thyolo district; and WHO’s Country Office prepared a plan and visited all 34 public sector health facilities delivering antiretroviral therapy. At any one time, two members of the unit were in the field. A checklist was developed to assist them in providing structured supervision; the checklist focused on determining whether the referral system to the clinic worked, the cleanliness of the clinic, the filing system, completion of the antiretroviral monitoring tools and the stock of antiretroviral drugs in the pharmacy. For the 10 facilities that started delivering antiretroviral therapy in January 2005, an assessment was made of their progress in recruiting patients.

For the 24 facilities delivering antiretroviral therapy up to 31 December 2004, quarterly and cumulative cohort analyses were performed. The quarterly assessment used details of new patients registered between 1 October and 31 December 2004 and their outcomes at the end of the year. The cumulative assessment used details of all patients who had ever started antiretroviral therapy up until 31 December 2004 and their outcomes at the end of the year.

Findings
Supervision and monitoring
All 34 facilities delivering antiretroviral therapy at the time of the supervisory visit had a proper referral system; the clinic rooms were tidy; and filing arrangements were in order. The registers and patients’ master cards were examined at all sites. Many registers and master cards were missing data, and the supervisory team helped clinic staff complete them while emphasizing the importance of accurately recording the data. Some of the other problems identified in the organization and entry of data are shown in Table 1.

The process of cohort analysis was examined for the 24 health facilities that were delivering antiretroviral therapy at the end of 2004. Six health facilities had not performed their own cohort analysis; four had performed the analysis but the number of patients’ outcomes did not add up to the number of patients who had started treatment. There were also some mistakes made in the understanding of definitions of outcomes, such as default (which was defined as “not being seen in the clinic for three months”) and stopping treatment. Proper cohort analyses were undertaken by the visiting team in conjunction with clinic staff, and the identified mistakes were all corrected during the site visits.

Antiretroviral stocks
Stock counts on antiretroviral drugs were performed in the pharmacies. Satisfactory stocks were present in all but one health facility where an impending shortage was identified. This resulted in an emergency order of drugs being placed to avoid a shortage.

Recruitment of new patients
Progress recruiting new patients was assessed at the 10 sites that had started delivering antiretroviral therapy in January 2005. These facilities had been classified as either low burden or medium burden, and had been given enough drugs to place either 25 or 50 new patients, respectively, on antiretroviral therapy each month.

At the time of the visit, there should have been 584 patients started on antiretroviral therapy: in fact, 347 patients
had started (59% of capacity). Discussions took place about how to improve recruitment. By the end of March, there should have been 1200 patients started on antiretroviral therapy: there were 1017 (84% of capacity), which was a significant improvement compared with the beginning of the quarter.

Quarterly and cumulative cohort analyses
Case-registration data for the quarterly and cumulative cohort analyses in the 24 health facilities delivering antiretroviral therapy are shown in Table 2. In both datasets, females outnumbered males by approximately 6:4, and the majority of patients were adults. The commonest reason for starting antiretroviral therapy was because patients were classified as being in WHO clinical stage 3 (1640/3261 in the quarterly analysis and 5407/13183 in the cumulative analysis). In both datasets, slightly more than 10% of patients were started on antiretroviral therapy because they had tuberculosis.

Patients’ occupations were systematically recorded in 12 hospitals (5 government and 7 mission) for patients who had ever started antiretroviral therapy. Of 826 patients for whom these data were available, 189 (23%) were housewives; 185 (22%) were subsistence farmers; 116 (14%) were in the military or police force; 86 (10%) either owned a small business or worked for one; 70 (8%) were teachers; 38 (5%) were health-care workers; and the remainder held other jobs.

The main treatment outcome data are shown in Table 3. Outcomes at three months were very good. The outcomes of those who had ever started treatment were also good, with 82% (10 761/13 183) of patients alive and on antiretroviral therapy, and another 2% (251/13 183) who had transferred to another facility were thought to be alive. Of those who had died and for whom the month of death was known, 73% (315/431) died within the first three months of starting antiretroviral therapy. Two of the largest facilities in the country, which had started delivering antiretroviral therapy in 2001–02, contributed 91% (948/1039) of patients recorded as dead or lost to follow-up. In one facility, this was because patients had to pay for antiretroviral therapy up until June 2004, and many defaulted from therapy because of the cost; in the other facility many patients came from districts where there were no other public delivery sites. The number of patients who stopped treatment was small. The main reasons for stopping treatment were not quantified but mainly resulted from side effects and beliefs that traditional medicine and prayer could cure AIDS.

Additional outcomes for patients alive and on antiretroviral therapy are shown in Table 4. These outcomes were not counted for all patients either because recording was poor or because in busy facilities the supervisory team did not have enough time to manually count the outcomes from patients’ master cards. The majority of patients on antiretroviral therapy were ambulatory, and a large percentage was able to work. In the cumulative analysis, about 10% of patients had side effects at the end of the year, the most common side effect being peripheral neuropathy. Adherence to the treatment regimen, as determined by pill counts, was very good.

Discussion
Supervisory and monitoring visits were conducted to support facilities in their new venture of delivering antiretroviral therapy and to collect routine data. In Malawi it is assumed that once staff have been trained in a new intervention it can then be implemented satisfactorily in the field. We think this is not the case. Our supervisory visits, conducted soon after the delivery of antiretroviral therapy was implemented, showed that mistakes were being made in the completion of registers and patients’ master cards. If not corrected early, such mistakes will be perpetuated and lead to inaccuracies in case-finding and treatment-outcome data. Rwanda has developed a system for collecting monthly data on antiretroviral therapy from peripheral sites; these data are sent to a central unit through bilingual telephones and a web interface (D Lowrance, personal communication, 2005). However, if there is no concurrent supervision, errors in data collection will not be identified and cannot be corrected.
Value of quarterly supervision

Our quarterly supervisory visits enabled mistakes in registration and monitoring to be corrected. We also learned about common misunderstandings held by clinic staff. Just before 25 additional sites assessed as ready to deliver antiretroviral therapy were to receive their antiretrovirals in June 2005, we conducted a refresher training day for staff on how to register and monitor patients, and we emphasized the areas where mistakes had been previously made. Since our last visits during January–March 2005, we have also developed a better-structured tool that can be used to assess the quality of the registration and monitoring systems.

The quarterly visits enabled us to check drug stocks and prevent one potential shortage. An interruption to the antiretroviral drug supply is a catastrophe because it destroys the confidence of clients in their providers and promotes drug resistance. We have also realized the importance of quarterly drug stock-taking for determining future drug needs for facilities and ensuring drug security. Useful discussions were conducted in the new facilities about how to recruit the required number of patients for treating facilities and ensuring drug security.

Lessons from the Field

Table 2. Quarterly and cumulative analyses of patients starting antiretroviral therapy in Malawi, 2004

<table>
<thead>
<tr>
<th>Parameters of treatment</th>
<th>Quarterly analysis</th>
<th>Cumulative analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>3 261</td>
<td>13 183</td>
</tr>
<tr>
<td>No. of males</td>
<td>1 266 (39)</td>
<td>5 274 (40)</td>
</tr>
<tr>
<td>No. of females</td>
<td>1 995 (61)</td>
<td>7 909 (60)</td>
</tr>
<tr>
<td>No. of adults aged ≥ 13 years</td>
<td>3 080 (94)</td>
<td>12 527 (95)</td>
</tr>
<tr>
<td>No. of children aged ≤ 12 years</td>
<td>181 (6)</td>
<td>656 (5)</td>
</tr>
<tr>
<td>Reason for starting antiretroviral therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO clinical stage 3</td>
<td>1 919 (59)</td>
<td>6 610 (50)</td>
</tr>
<tr>
<td>WHO clinical stage 4</td>
<td>828 (25)</td>
<td>2 789 (21)</td>
</tr>
<tr>
<td>Low CD4 count (&lt;200)</td>
<td>510 (16)</td>
<td>3 748 (29)</td>
</tr>
<tr>
<td>Reason not given</td>
<td>4 (&lt;1)</td>
<td>36 (&lt;1)</td>
</tr>
<tr>
<td>Tuberculosis*</td>
<td>351 (11)</td>
<td>1 468 (11)</td>
</tr>
</tbody>
</table>

* The quarterly analysis includes all new patients starting antiretroviral therapy between 1 October 2004 and 31 December 2004.

Table 3. Quarterly and cumulative analyses of main treatment outcomes for patients starting antiretroviral therapy in Malawi, 2004

<table>
<thead>
<tr>
<th>Main outcomes</th>
<th>Quarterly analysis</th>
<th>Cumulative analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>3 261</td>
<td>13 183</td>
</tr>
<tr>
<td>No. alive and on antiretroviral therapy</td>
<td>3 117 (96)*</td>
<td>10 761 (82)</td>
</tr>
<tr>
<td>No. dead</td>
<td>117 (4)</td>
<td>1 026 (8)</td>
</tr>
<tr>
<td>No. lost to follow-up</td>
<td>2 (&lt;1)</td>
<td>1 039 (8)</td>
</tr>
<tr>
<td>No. who stopped antiretroviral therapy</td>
<td>14 (&lt;1)</td>
<td>106 (&lt;1)</td>
</tr>
<tr>
<td>No. permanently transferred to another facility</td>
<td>11 (&lt;1)</td>
<td>251 (2)</td>
</tr>
</tbody>
</table>

* The quarterly analysis includes all new patients starting antiretroviral therapy between 1 October 2004 and 31 December 2004.

Collection and interpretation of routine data

Once the qualitative supervision was completed, routine data were collected. In this way, data are cleaned on-site, which allows the national database to be accurately developed. Quarterly reports are written and submitted to the Ministry of Health, stakeholders and donors; and reports are also made to the facilities themselves during their next quarterly supervisory visit. Feedback to the facilities is unique to this supervisory system. It is highly appreciated by peripheral staff, and allows staff to see how they are performing in relation to their peers.

The information we obtained about which patients were receiving antiretroviral therapy is reassuring. In contrast to earlier fears that antiretroviral therapy might have a gender bias towards men, we found that this was not the case. Preliminary data suggest that more than half the patients accessing antiretroviral therapy are housewives, farmers and people in small-scale business. However, there are some areas that need to be examined. Few children were placed on antiretroviral therapy, which is similar to reports from Mozambique. This reflects difficulties in diagnosing HIV/AIDS in young children and the lack of paediatric drug formulations. Information obtained from this analysis prompted the convening of an international consultative meeting between WHO and UNICEF in October 2005 to discuss how to improve the delivery of antiretrovirals to children.

According to WHO staging parameters, all HIV-positive people with tuberculosis are potentially eligible for treatment, but only 11% of those classified as eligible for antiretroviral therapy had tuberculosis. This might reflect a problem with record-keeping, but is also a genuine problem highlighting the difficulties of drug interactions between nevirapine and rifampicin, particularly the effect that rifampicin has in reducing plasma concentrations of nevirapine and therefore potentially creating the risk of drug resistance. In Malawi, there is also an administrative problem in that...
antiretroviral drugs are administered by hospitals while tuberculosis drugs are administered in a decentralized fashion from health centres. Expecting HIV-positive patients with tuberculosis to travel long distances from rural areas to collect antiretroviral drugs is unrealistic, and possibly accounts for the small number of patients with tuberculosis who also take antiretroviral therapy. Treatment for tuberculosis has been decentralized in many African countries, and we suspect that other programmes are facing the same problems. Solutions need to be found if antiretroviral therapy is to benefit HIV-positive patients who also have tuberculosis.

Malawi has developed its own standardized treatment outcomes for assessing the effectiveness of antiretroviral therapy, although these are in line with those developed by WHO. What may be unique to Malawi is the emphasis on quarterly and cumulative cohort analyses. These analyses have several advantages. The quarterly analysis allows for regular collection of data to determine the number and characteristics of patients starting antiretroviral therapy. It provides accurate data on how many patients are alive and on treatment at any given moment, which, when used together with drug-stock assessments, enables rational drug procurement policies. As the antiretroviral therapy programme matures these analyses will also allow routine national cohort survival analyses to be undertaken, a method that is normally used only in trials.

In general, cumulative treatment outcomes were good. The high early death rates, which are seen in other parts of the region, may reflect the fact that some patients are starting antiretroviral therapy too late, and this needs to be investigated in more detail. One of the facilities contributing the largest number of patients who defaulted from treatment is embarking on an operational study to identify what has happened to these patients. The monitoring of secondary outcomes, such as side effects and pill counts, requires a tedious manual check of patients’ cards, and in busy facilities this is difficult to accomplish, given the time constraints of the visits. In future, this type of data may be sampled at selected sites.

### Sustaining quarterly supervision and monitoring

During the three-month supervisory period, three HIV Unit personnel were out in the field for 20 working days and nights, at a total cost of US $4 200 for accommodation, daily subsistence and fuel. As the number of facilities delivering antiretroviral therapy grows, the time needed to accomplish these visits will increase. Plans are being developed to have only one member of the HIV Unit out at a time, to work more closely with its established partners and to encourage new partners to become involved, such as the Taiwan Medical Mission in the north of the country, to use specific dedicated supervisors recruited and employed at central hospitals and to use the services of yet-to-be-established administrative health offices.

We believe that it is essential to visit sites soon after they have started to deliver antiretroviral therapy and to ensure that these visits are conducted at quarterly intervals, similar to supervisory activities used by Malawi’s national tuberculosis control programme. Supervision is thought to be generally helpful in maintaining the performance of health workers. For antiretroviral therapy, supervision is probably the only way to ensure that standards set in guidelines and imparted to staff during training are maintained, and this, in turn, is essential if the efficacy of antiretroviral therapy is to be safeguarded for AIDS patients in resource-poor countries like Malawi.

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### Competing interests

none declared.
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Résumé

Supervision, suivi et évaluation de l’élargissement du traitement antirétroviral à l’ensemble du Malawi

Objectif Décrire les stratégies de supervision, de suivi et d’évaluation utilisées au Malawi pour évaluer la délivrance du traitement antirétroviral dans le cadre de l’élargissement de ce traitement à l’ensemble du pays.

Méthodes Au cours du premier trimestre 2005, l’Unité chargée du VIH au Ministère de la Santé et ses partenaires (la Lighthouse Clinic ; Médecins sans Frontières Belgique ; le district de Thyolo ; et le Bureau de l’Organisation mondiale de la Santé au Malawi) ont entrepris une supervision et un suivi structurés de tous les établissements publics de santé du Malawi délivrant un traitement antirétroviral.

Résultats Il ressort de l’examen des données qu’à la fin de 2004 13 183 malades (dont 5274 (40 %) sujets de sexe masculin et 12 527 (95 %) sujets adultes) avaient commencé un traitement antirétroviral. Parmi les malades ayant entamé un traitement de ce type, 82 % (10 761/13 183) étaient encore en vie et prenaient des antirétroviraux ; 8 % (1026/13 183) étaient décédés ; 8 % (1039/13 183) étaient perdus de vue ; moins de 1 % (106/13 183) avaient abandonné le traitement ; et 2 % (251/13 183) avaient été transférés à un autre établissement. Parmi les patients vivants et sous traitement antirétroviral, 98 % (7098/7258) bénéficiaient de soins ambulatoires, 85 % (6174/7258) étaient en mesure de travailler, 10 % (456/4687) présentaient des effets secondaires importants et, d’après le décompte des comprimés, 96 % (6824/7114) avaient pris correctement leurs médicaments. Des erreurs concernant l’enregistrement et le suivi des patients ont été relevées et corrigées. Les stocks de médicaments ont été contrôlés ce qui, dans un cas, a permis d’éviter une rupture de stock. A la suite des visites de supervision, on a constaté, fin mars 2005, que le nombre de patients affectés à des établissements devant commencer à délivrer un traitement antirétroviral avait augmenté.

Conclusion Le rapport démontre l’importance d’une supervision à un stade précoce des établissements qui commencent à délivrer des traitements antirétroviraux et l’intérêt d’associer cette supervision à une collecte de données. Des visites régulières à des fins de supervision et de suivi des établissements délivrant le traitement sont indispensables pour suivre l’élargissement à l’échelle nationale de la distribution d’antirétroviraux.

Resumen

Supervisión, seguimiento y evaluación de la expansión de la terapia antirretroviral a nivel nacional en Malawi

Objetivo Describir las estrategias de supervisión, seguimiento y evaluación utilizadas para valorar el suministro de terapia antirretroviral durante las actividades de expansión nacional de dicha terapia en Malawi.

Métodos En el primer trimestre de 2005, la Unidad de VIH del Ministerio de Salud y sus asociados (Lighthouse Clinic; Médicos Sin Fronteras - Bélgica, distrito de Thyolo; y la oficina de país de la Organización Mundial de la Salud) emprendieron una supervisión y vigilancia estructuradas de todos los centros de salud del sector público de Malawi que aplicaban el tratamiento antirretroviral.

Resultados La vigilancia de los datos mostró que al final de 2004 había 13 183 pacientes (5274 (40 %) hombres, 12 527 (95 %) adultos) que habían iniciado en algún momento la terapia antirretroviral. Entre los pacientes que habían empezado a tratarse, el 82% (10 761/13 183) estaban con vida y tomaban antirretrovirales; el 8% (1026/13 183) habían muerto; otro 8% (1039/13 183) se habían perdido durante el seguimiento; menos del 1% (106/13 183) habían dejado de medicarse; y un 2% (251/13 183) habían sido transferidos a otro centro. Entre los que seguían vivos y tomando antirretrovirales, el 98% (7098/7258) eran pacientes ambulatorios; el 85% (6174/7258) estaban en condiciones de trabajar; un 10% (456/4687) presentaban efectos secundarios importantes; y, a juzgar por el número de píldoras, el 96% (6824/7114) habían tomado los medicamentos correctamente. Los errores de registro y seguimiento de los pacientes fueron detectados y corregidos. Se vigilaron las reservas de medicamentos, y se evitó así un posible agotamiento de las existencias. Como resultado de las visitas de supervisión, al final de marzo de 2005 había aumentado en los centros de salud la captación de pacientes programados para iniciar la terapia antirretroviral.

Conclusión Este informe demuestra la importancia de la supervisión temprana en los sitios que están comenzando a aplicar la terapia antirretroviral, y pone de manifiesto la utilidad de combinar la recogida de datos y la supervisión. La realización de visitas regulares de supervisión y vigilancia a los sitios que ofrecen tratamiento es esencial para seguir de cerca la expansión del suministro de antirretrovirales a escala nacional.
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