In 2002, the World Health Organization (WHO) first published guidelines for a public health approach to scaling up antiretroviral therapy (ART) in resource-limited settings. These guidelines were simplified in 2003 and revised in 2006. In October 2009, WHO led a multidisciplinary committee of HIV treatment experts to further revise the guidelines. Their recommendations were packaged as Rapid Advice: Antiretroviral Therapy for HIV Infection in Adults and Adolescents and were disseminated in late November 2009 (WHO 2009).

The key messages that emerged from these recommendations are earlier initiation of ART, the use of less toxic treatment regimens, and an expanded role for laboratory monitoring, including both CD4 testing and viral load (VL) monitoring (WHO 2010). Table 1 lists eight key Rapid Advice recommendations. The full revised guidelines, Antiretroviral Therapy for HIV Infection in Adults and Adolescents: Recommendations for a Public Health Approach, were released in July 2010 (WHO 2010).

The WHO committee of experts that developed the recommendations agreed on a set of guiding principles for countries developing or revising their national HIV treatment guidelines. Principal consideration was given to the need for public health interventions that “secure the greatest likelihood of survival and quality of life for the greatest numbers of people living with HIV” (WHO 2009, 4). The guidelines also specify that “the individual rights of people living
with HIV should not be forfeited in the course of a public health approach” (WHO 2009, 4). The four guiding principles for countries revising their treatment guidelines are as follows:

- **Do no harm**: When introducing changes, preserve access for the sickest and most in need.

- **Ensure access and equity**: All clinically eligible people should be able to enter treatment services (including ART) with fair and equitable distribution of treatment services.

- **Promote quality and efficiency**: Ensure delivery of the highest standards of care within a public health approach so as to achieve the greatest health impact with the optimal use of available human and financial resources.

- **Ensure sustainability**: Understand the long-term consequences of change with the vision of providing continued, life-long access to ART for those in need.

Many countries plan to revise their national guidelines to reflect the recent WHO recommendations. Côte d’Ivoire, Malawi, Nigeria, Tanzania, and Zambia have undertaken feasibility studies, including cost analyses, to assess the impact of adopting such recommendations (PlusNews 2010). These studies have demonstrated that many countries face significant challenges as they move to incorporate the recommendations into their national treatment protocols, including ensuring the availability of resources to support increased patient loads, improving supply chain management capacity, ensuring sufficient human resources, and building in-country consensus around protocol changes.

### TABLE 1. WHO RAPID ADVICE KEY RECOMMENDATIONS (WHO 2009)

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Start ART in all patients with HIV who have a CD4 count of less than 350 cells/mm³, irrespective of clinical symptoms.</td>
</tr>
<tr>
<td>2.</td>
<td>• Start one of the following regimens in ART-naïve individuals eligible for treatment.</td>
</tr>
<tr>
<td></td>
<td>• Zidovudine (AZT) + lamivudine (3TC) + efavirenz (EFV)</td>
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<td></td>
<td>• AZT + 3TC + nevirapine (NVP)</td>
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<tr>
<td></td>
<td>• Tenofovir (TDF) + 3TC or emtricitabine (FTC) + EFV</td>
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<tr>
<td></td>
<td>• TDF + 3TC or FTC + NVP</td>
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<tr>
<td>3.</td>
<td>Start ART in all individuals living with HIV with active tuberculosis, irrespective of CD4 cell count.</td>
</tr>
<tr>
<td>4.</td>
<td>Start ART in all individuals living with both HIV and hepatitis B virus (HBV) who require treatment for their HBV infection, irrespective of CD4 cell count or WHO clinical stage.</td>
</tr>
<tr>
<td>5.</td>
<td>Start ART in all pregnant women with HIV and a CD4 count of less than 350 cells/mm³, irrespective of clinical symptoms.</td>
</tr>
<tr>
<td>6.</td>
<td>Where available, use VL to confirm treatment failure.</td>
</tr>
<tr>
<td></td>
<td>• Where routinely available, use VL every six months to detect viral replication.</td>
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<tr>
<td></td>
<td>• A persistent VL above 5,000 copies/mL confirms treatment failure.</td>
</tr>
<tr>
<td></td>
<td>• When VL is not available, use immunological criteria to confirm clinical failure.</td>
</tr>
<tr>
<td>7.</td>
<td>A boosted protease inhibitor (PI/r) plus two nucleoside analogues are recommended for second-line ART.</td>
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<tr>
<td></td>
<td>• For second-line ART, atazanavir/ritonavir (ATV/r) and lopinavir/ritonavir (LPV/r) are preferred.</td>
</tr>
<tr>
<td>8.</td>
<td>National programs should develop policies for third-line therapy that consider funding, sustainability, and equitable access to ART.</td>
</tr>
</tbody>
</table>
Since 2006, the National AIDS Programme in Guyana has been implementing WHO’s 2010 recommendations of a CD4 threshold of 350 cells/mm$^3$ for initiation of ART and a TDF-based first-line treatment regimen. Strong political will and leadership from the government, collaborative partnerships between local and international agencies, low patient loads, effective supply chain management, and resource availability are key factors contributing to Guyana’s successful implementation of WHO’s new recommendations.

The Response to HIV in Guyana

Guyana is a small, English-speaking Caribbean country located on the northeast coast of South America, with a population of 748,486 (Central Intelligence Agency 2009). According to 2008 national HIV estimates, HIV prevalence in Guyana is 1.9 percent and the country’s estimated population of adults living with HIV (over 15 years of age) is 16,900, disaggregated into 8,900 males and 8,000 females (Presidential Commission on HIV and AIDS, Government of Guyana 2009). The first case of AIDS in Guyana arose in 1987 within the men who have sex with men community. Since then, the number of reported cases has increased steadily, and the epidemic is considered to be generalized (Presidential Commission on HIV and AIDS, Government of Guyana 2009).

In response to the burgeoning HIV epidemic, the Government of Guyana established the National AIDS Programme (NAP) under the Ministry of Health (MOH) in 1989. In 1992, the National AIDS Programme Secretariat (NAPS) was formed and charged with coordination of the national response to the HIV epidemic (Presidential Commission on HIV and AIDS, Government of Guyana 2009). By mid-2001, despite a flourishing epidemic, there was still no public access to ART in Guyana because of the prohibitive cost of antiretrovirals (ARVs) in the global market.

In 2001, Cipla Ltd., the generic pharmaceutical manufacturer, began marketing a generic fixed-dose combination (FDC) of stavudine (d4T)/3TC/NVP to Guyana. After negotiating with Cipla in 2001, the MOH was able to secure significant price reductions in the cost of first-line ART to U.S.$250 per patient per year. Additionally, both Cipla and Ranbaxy, another leading generic pharmaceutical company, offered technical assistance to build the capacity of a local pharmaceutical company, Georgetown Pharmaceutical Corporation (GPC), to manufacture ARVs in-country. Through these capacity-building efforts, by the end of 2001, GPC was able to produce first-line FDCs at a price of U.S.$140 per patient per year, allowing the government to announce its support of HIV treatment through the public health care system. In December 2001, the distribution of first-line therapy began free of charge at the national sexually transmitted infection referral center, then called the Genitourinary Medicine Clinic, in Georgetown, Guyana’s capital.

With additional support from the U.S. President’s Emergency Fund for AIDS Relief (PEPFAR) and the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), treatment services expanded to 16 sites by 2008. Second-line treatment was made available free of charge through the public system in 2006. Local capacity for CD4 testing was established in 2003 and VL capacity in 2010 (Presidential Commission on HIV and AIDS, Government of Guyana 2009). Currently, ART services are available in all regions, and all medical care offered by the public system, including HIV care and treatment, is free of charge.
By the end of 2009, a total of 2,832 persons were actively receiving ART through the NAP. Of those persons receiving treatment in 2009, 178 were children. Females made up 55.6 percent of all persons on treatment in 2009. In 2008, patients on second-line treatment accounted for 6.8 percent of all persons on treatment. At 12 months, average survival on treatment was 72 percent (Presidential Commission on HIV and AIDS, Government of Guyana 2009).

2004 and 2006 Guideline Revision Processes

**Developing initial HIV treatment guidelines:** Following the Government of Guyana’s announcement at the end of 2001 that there would be universal access to HIV treatment, practitioners received a two-page brief that offered very limited guidance on prescribing. By 2003, Guyana had developed the capacity to conduct in-country CD4 testing, which prompted robust discussion among stakeholders about clinical protocols. In 2003, WHO guidelines recommended a minimum CD4 cell count initiation threshold of 200 cells/mm$^3$, irrespective of clinical disease stage, while guidelines in the United States and Europe were changing to reflect earlier ART initiation, up to CD4 cell counts of 350 cells/mm$^3$. The Minister of Health, the Honorable Dr. Leslie Ramsammy, aware of the treatment protocols being followed in the United States and Europe, has strongly advocated for guidelines aligned with the treatment protocols in resource-rich settings because he does not believe in setting a different standard for the developing world.

I believe that the restrictive protocol of using CD4 cut-offs for eligibility for ARV treatment is a backward protocol and an immoral one and we should pursue earlier treatment with ARVs. It is still my wish to place persons who are HIV-positive on ARV treatment as early as possible… Treating people even though we don’t know their CD4 is better than them dying.

–The Honorable Dr. Leslie Ramsammy, Minister of Health, Guyana

The Minister argues that, as with other diseases, clinicians should be given the discretion to manage their patients based on their best clinical judgment. He believes “HIV diagnosis [is] good enough” to start treatment and “they [health care providers] should not wait for somebody to get sick” before providing treatment. He wants patients to get early treatment to maintain their health, but also because he views widespread early treatment as an important component of an effective HIV prevention strategy.

After negotiations within the Government of Guyana and with other international organizations, the MOH launched the treatment access program with an initiation threshold of 200 cells/mm$^3$, but...
emphasized that the national program would be working toward a threshold of 350 cells/mm³. Formal guidelines recommending a CD4 initiation threshold of 200 cells/mm³ and a first-line regimen of d4T/3TC/NVP were finalized and disseminated in 2004. As the NAP expanded, the Minister mandated and approved membership of a Technical Working Group (TWG) for HIV Care and Treatment to be chaired by NAPS with participation from key technical partners. The TWG was to serve as an advisory board to NAPS and meet on a quarterly basis to discuss emerging issues facing the NAP, with the goal of strengthening Guyana’s national HIV response.

Developing the 2006 HIV treatment guidelines revision: Supported by local clinicians and key international partners, when the WHO released its revised 2006 guidelines advocating more strongly for a CD4 initiation threshold of 350 cells/mm³, the Minister of Health mandated a revision of Guyana’s national HIV treatment guidelines. The TWG identified additional technical experts to join the group and invited them to become members of the guideline revision committee. The committee was composed of: staff from various departments of the MOH, including NAPS, disease control, maternal and child health, and tuberculosis; local public and private sector clinicians; and partners including the François-Xavier Bagnoud Center (FXB)-USA and FXB-Guyana (University of Medicine and Dentistry of New Jersey), the Canadian Society for International Health, the Centers for Disease Control and Prevention (CDC), the AIDS Relief Consortium (Institute for Human Virology [IHV], University of Maryland), Dartmouth Medical School, and the Guyana HIV/AIDS Reduction and Prevention Program (MOH 2006).

Technical consultations funded by international partners were conducted with experts in the United States through in-person meetings, conference calls, and emails. When the draft guidelines were complete, WHO and the Joint U.N. Programme on HIV/AIDS also reviewed the document and provided comments. FXB-USA and IHV, both implementing partners under PEPFAR, conducted a full external review of the guidelines prior to their finalization.

Both global scientific research and local anecdotal evidence were considered by the guideline revision committee during their discussions, a process detailed later in this case study (see “Evidence Considered”). Following technical approval of the 2006 revised guidelines, some time passed before they were officially endorsed as policy and disseminated by the government. Meanwhile, to foster adoption of the revised guidelines as quickly as possible, NAPS “piggybacked” on already planned national and regional training efforts, such as those on prevention of mother-to-child transmission, by adding brief, informal training on the new treatment guidelines to the agenda.

Implementation and roll-out: Once the revised guidelines were formally endorsed and disseminated, NAPS conducted official training led by MOH staff and partners, which was rolled out nationally to all 360 health facilities. They employed a combination of training approaches

To foster adoption of the revised guidelines as quickly as possible, NAPS “piggybacked” on already planned national and regional training efforts.
depending on the circumstances, so that some training sessions for health workers from different regions took place in Georgetown, while others were conducted in the regions with support from the regional health offices. Implementers and health workers from the field were invited to the quarterly TWG meetings on an ongoing basis and were asked to give feedback on the progress and challenges facing implementation of the new guidelines. The MOH maintained and cultivated the TWG as a forum for troubleshooting.

The newly revised 2006 guidelines were disseminated to all ART sites in different formats. NAPS made packages for distribution at the TWG meetings, sent packages to regional health offices with instructions to distribute the guideline materials throughout the region, and distributed packages at quarterly immunization meetings. NAPS followed up with each of the ART sites through the regional health offices to ensure they had received and were implementing the new guidelines.

Additionally, the new guidelines were announced at the Minister’s News Conference, a regularly scheduled meeting between the media and the Minister of Health, which was covered by both print and television news outlets. The total timeframe for the 2006 revision process was approximately one year, beginning with the Minister’s mandate to update the guidelines to the government’s endorsement of the final revised guidelines. However, it took an additional year before all of the health workers were trained and actively implementing the guidelines.

Evidence Considered

The guideline revision committee considered both global scientific research and local anecdotal evidence as they deliberated on the updates to make. The evidence they considered regarding each of the key 2006 revisions is summarized next.

**Initiation thresholds for antiretroviral therapy:** Clinicians from the National Care and Treatment Centre (NCTC), the center of excellence for management of HIV and sexually transmitted infections in Guyana, were members of the guideline revision committee. They, along with other private and public sector clinicians, were concerned about how sick and weak their patients were by the time their CD4 count reached 200 cells/mm\(^3\). They completed informal assessments via patient chart reviews in which patient CD4 levels were plotted against their health outcomes, beginning at ART initiation and continuing over time, to show the change in CD4 levels and how those changes affected overall health. From these informal assessments and their clinical observations, they reported increased morbidity, opportunistic infections, and longer recuperation periods in those patients who started treatment when their CD4 count was at or below 200 cells/mm\(^3\).

Citing the findings of their informal assessments and clinical observation, these local clinicians began advocating strongly for earlier initiation of ART. There were varying views within the revision committee about the sustainability of increasing the initiation threshold to 350 cells/mm\(^3\), with some members advocating for maintaining 200 cells/mm\(^3\) and others supporting a more tempered increase to 300 cells/mm\(^3\). PEPFAR-supported local treatment partners FXB and IHV were especially supportive of revising the guidelines to initiate patients at less than 350 cells/mm\(^3\), based on cohort data in the United States and Europe showing improved clinical outcomes with earlier ART initiation. Both organizations provided remote technical assistance from the United States through a combination of in-person meetings, conference calls, and emails.

**Tenofovir-based first-line regimen:** The local clinicians on the TWG also provided anecdotal evidence of d4T-related neuropathy and lipodystrophy
and advocated for a more patient-friendly first-line regimen. There was extensive debate about which nucleoside reverse transcriptase inhibitors (NRTIs) to use. Data supporting the superiority of TDF-FTC NRTI backbones in virologic suppression and CD4 response were released in 2006 (Gallant et al. 2006). In addition, fewer side effects, such as nausea and anemia, were noted with TDF than with regimens including AZT. In the face of mounting concerns about including d4T in the first-line regimen, the revision committee agreed to alter the first-line regimen.

To help determine which drugs should be included in the first line, NAPS asked the PEPFAR-supported Supply Chain Management System (SCMS) Project in Guyana to complete a cost analysis comparing the old d4T-based first-line regimen to regimens containing TDF. SCMS-Guyana studied actual invoices, made assumptions about annual ART patient targets, and used the new treatment initiation threshold of 350 cells/mm$^3$ to determine the cost of first-line therapy, including branded TDF/FTC. Although the TDF/FTC-based regimen proved more costly, the MOH believed that this regimen was superior to the other options considered. After exhaustive discussion, the revision committee came to a consensus that a TDF-based first-line regimen was the best option for patients and would be cost-effective in the long-term. While cost was an important factor in all of the discussions, the efficacy and quality of the treatment regimen were the priorities. All new patients initiating ART began TDF/FTC in combination with a non-NRTI, specifically NVP or EFV. Guidance for the management of existing patients on d4T-based therapy recommended an immediate switch to a TDF-based regimen in the absence of contraindications.

Factors Supporting Successful Implementation

Important supply chain management factors in Guyana along with financial resource availability enabled the implementation of the 2006 revised guidelines.

Supply chain management: With the advent of the SCMS Project in Guyana in 2006, the supply chain in Guyana was significantly strengthened, enabling it to effectively support the national HIV program. A satellite MOH Materials Management Unit Farm Annex Warehouse was established to provide suitable storage conditions for ARVs procured by major HIV donors, including PEPFAR and GFATM. A fleet of two trucks delivered ARVs directly to 13 of the 15 fixed ART sites, with the two main private sector sites managing their own pick-up (SCMS Project-Guyana 2008).

SCMS-Guyana supported NAPS to complete a forecasting and quantification of ARV requirements according to the new treatment guidelines using the software package Quantimed, which was the standard quantification tool for the country. Using Quantimed, CDC-Guyana and NAPS worked with SCMS-Guyana to forecast and quantify CD4 testing supplies to support earlier initiation of ART through routine CD4 testing. Finally, NAPS used the ARV and laboratory forecasts in the software package PipeLine to develop a procurement and supply plan to help manage the supply chain of ARVs according to the new treatment guidelines.

Registration and importation of the new ARVs were significantly expedited by the fact that in 2001 the government established a policy allowing the Food and Drug Department (FDD) to issue registration waivers for new ARVs upon request from the MOH’s Chief Medical Officer. A registration waiver was requested by the Chief Medical Officer for the new ARVs and promptly issued by FDD, allowing for importation of ARVs recommended by the new guidelines.

Resources available: In 2006, Guyana’s NAP was in the enviable and relatively unique position of having multiple donors supporting the MOH in covering the costs of all its public sector
HIV services. Guyana was receiving substantially greater money per patient than any other PEPFAR-supported country at that time. GFATM was providing funds for procurement of ARVs to cover all first-line adult patients, post-exposure prophylaxis, and prevention of mother-to-child HIV transmission. PEPFAR procured ARVs for all adult second-line and pediatric patients through the end of 2006, at which point the Clinton Health Access Initiative (CHAI) took over coverage for all pediatric patients. Since 2007, GFATM has provided all first-line ARVs. Currently, PEPFAR covers second-line ARVs and CHAI provides pediatric treatment. However, CHAI funding will be entirely phased out by 2011. Fortunately, Guyana has recently secured a Rolling Continuation Channel under GFATM Round 9, which secures funding for all first-line and pediatric treatment from 2010 through 2015. Given this funding landscape, the availability of resources to support more patient-friendly regimens and earlier initiation of ART was not a major concern of the 2006 revision committee.

Results

Following implementation of the 2006 revised guidelines, all patients had access to ART once they entered the national program and were deemed eligible for treatment. With strong donor and ministry support, funding for HIV treatment was able to match scale-up plans, so an ART waiting list never developed. Anecdotial reports from local clinicians showed that patients were generally less sick because they sought services sooner and treatment was initiated earlier. Decentralization of services to primary health centers further fostered access to treatment, with the potential to lessen the stigma around HIV infection.

The Minister of Health believes that the sense of hopelessness in Guyana prior to universal treatment access lifted as patients initiated ART earlier and were able to live healthier, longer lives. He feels this, in turn, gave confidence to health workers because they were better able to serve their patients, and thus improved overall morale at the health centers.

No formal study of the clinical outcomes of the 2006 guideline revision or Guyana’s national HIV program in general has been completed to date. However, NAPS has plans to conduct an outcomes study in collaboration with CDC-Guyana in the near future and is currently developing a database to analyze cohort data to determine clinical outcomes. An HIV drug resistance study is also planned to begin in early 2011.

What Worked Well

The key factors that contributed to the successful revision of Guyana’s treatment guidelines included strong political will and leadership from the government, collaborative partnerships between local and international agencies, and low patient loads.

The importance of political will: Dating back to the early days of the emergence of HIV in Guyana, there was very strong political commitment from the government to the fight against the epidemic. Ministry officials, including the Minister of Health, remained aware of the latest global research around HIV treatment, care, and support, and the public health community in Guyana remained receptive to changes and advances in the field.
Strong global partnerships: Guyana’s HIV program has also benefited enormously from a strong, collaborative partnership between local and international agencies. The Pan American Health Organization, WHO, the U.N. Children’s Fund, and U.S. Government partners have been important allies that worked closely with the MOH to understand and support its goals. Although there were varying opinions on technical issues at certain points throughout the revision process, the revision committee generally agreed that long-term cost effectiveness and a higher quality of patient care were the proper direction for the NAP.

Consistent leadership from the MOH: Different international partners bring different perspectives to the development of guidelines; therefore, molding the guidelines into a uniquely Guyanese approach required strong national leadership. The Minister of Health provided that leadership at all stages of the development of the national guidelines, resulting in a strategy that provides highly effective treatment for all eligible patients living with HIV.

The availability of funding to cover national treatment needs: Low patient load and funding availability in Guyana undoubtedly facilitated consensus around the 2006 guideline revisions. Although concerns about longer term funding were discussed by the revision committee, the extent of these concerns was less than it would have been in the African treatment context of limited funding for hundreds of thousands of patients.

Challenges

The key challenges that Guyana faced during the 2006 guideline revision process were patient understanding, adherence, human resource shortages, and supply chain management constraints related to the timing for dissemination of the new guidelines.

Patient concerns about switching regimens: Initial reports from implementers and health workers revealed that patients were concerned about moving from the simple dosing of one pill with the d4T-based FDCs in the old regimen to the more complicated dosing of two different pills in the new TDF-based regimens. The TWG discussed the issue with the implementers and, while a multidisciplinary approach to treatment counseling is the norm, everyone agreed to focus on the role of the social workers at the health centers to assuage patient fears. Social workers were mentored by MOH staff and encouraged to work very closely with ART patients to increase their understanding of the benefits of the new regimen and the reasoning behind the switch. Patients were told that the new drugs reduced their risk of treatment failure and adverse side effects and therefore increased the quality of care they received.

Fostering patient adherence to new guidelines: Patient adherence to treatment was an ongoing challenge faced by the NAP that was exacerbated by the new treatment guidelines. The NCTC, located in Georgetown, developed a Group Discussion Program to address this challenge. Before a patient was initiated on treatment at the NCTC, he or she was required to attend three compulsory treatment-related counseling sessions. The patient was asked to select and bring a “support buddy” to at least one of the three counseling sessions. Once a patient successfully attended the three counseling sessions and selected a support buddy, he or she began ART and was asked to attend the focus group discussions, which were held biweekly at the NCTC. The focus groups consisted of five members of the NCTC staff, including a doctor, pharmacist, nurse, social worker, and home-based care person, and all of the ART patients with their support buddies. The objective of the focus group discussions was for adherent HIV patients to talk about their successes and for non-adherent patients to share their struggles. The NCTC has
continued implementing this program and has made a formal recommendation to NAPS that the program be rolled out to ART sites nationally. Many clinics have begun implementing similar support activities but with variations based on clinic size and staffing levels.

Dealing with personnel shortages: An additional challenge for the NAP was a shortage of human resources to manage the increased patient load. Early in the epidemic’s history, Guyana worked to prevent the establishment of a parallel HIV service delivery system and leverage existing human resources by integrating HIV services into the public health infrastructure. Task-shifting ART away from the physicians to lower cadres of health care workers was also considered as a potential solution to the human resource challenge, especially in the remote hinterland areas. The NAPS decided to recruit 11 doctors from the U.N. Volunteer Program to provide additional support to the ART sites. While keeping ART initiation under the purview of physicians, NAPS did undertake some measures to better distribute the workload of clinicians and nurses who were managing the country’s HIV patients. NAPS introduced a new position, the lay counselor, to provide HIV counseling in the larger clinics and thus alleviate the bottleneck presented by long lines of patients waiting for counseling sessions with nurses.

Reaching remote communities: While HIV prevalence in remote areas of Guyana is relatively low, there was some concern that mining and logging activities, coupled with limited access to treatment facilities, could worsen the epidemic among those communities. As a result, NAPS has begun to provide HIV services through mobile ART clinics visiting remote areas quarterly. Mobile clinicians initiate patients on ART according to the new initiation criteria, and local medics monitor them on an ongoing basis. The mobile clinicians remain on call by radio and telephone communication to advise the local medics as needed. If an emergency arises, arrangements are made for the patient to travel to Georgetown with the support of the Ministries of Health and of Amerindian Affairs.

Anticipating supply chain difficulties: When the 2006 revised guidelines were formally endorsed and disseminated to health facilities, the MOH had a national overstock of ARVs for the old, d4T-based first-line therapy. They were not comfortable allowing all the old ARVs to expire, so they were forced to delay distribution of the ARVs for the new TDF/FTC-based first-line therapy until more of the old ARVs had been consumed. This resulted in some confusion among health workers who had been trained to use the new guidelines because the corresponding ARVs were not available to them at the health facilities. To address this challenge, ongoing updates were provided to the clinicians at the treatment sites regarding stock-on-hand of the old ARVs and ordering new ARVS.

Recommendations

National health leaders must build consensus: The success of Guyana’s 2006 guideline revision was due in large part to strong leadership from the MOH and collaborative partnership with both local and international agencies. A country’s MOH must work to build consensus among the various players while at the same time clearly articulating its vision and guiding the revision committee to develop guidelines that will most effectively achieve their vision.

Keep the committee small and flexible: Countries should closely review the latest HIV research with a small group of technically competent stakeholders who are open to new ideas and approaches. A smaller revision committee will keep the process focused and efficient. Once consensus has been reached within the revision committee and the updated guidelines have been drafted, the guidelines can then be circulated for comments to a larger group of stakeholders. To
LESSONS LEARNED FROM GUIDELINE REVISION PROCESS IN GUYANA

- Ensure top MOH policymakers remain abreast of HIV global research, WHO recommendations, and emerging local evidence so that ongoing revisions are made to the national HIV treatment guidelines as appropriate.
- Issue a mandate from the MOH to revise national HIV treatment guidelines when deemed necessary.
- Establish a small, technically competent guideline revision committee, led by the MOH, which has clear terms of reference through which consensus can be achieved.
- Garner financial and technical support from strong local and international partners and arrange for an external third party review of the draft revised guidelines.
- Plan around current ARV supply: It is recommended that countries look carefully at their ARV supply and procurement plans before rolling out new guidelines. Ongoing updates should be provided to the clinicians at the treatment sites regarding stock-on-hand of old ARVs and ordering new ARVS. Timing of the roll-out should be managed so that drugs from a previous protocol are consumed before the revised guidelines are fully rolled out. Proper timing will foster rapid uptake of the new guidelines by ensuring that health workers and patients receive clear messages and immediate distribution of the new ARVs is possible.
- Assess supply chain management implications of guideline revisions including drug forecasting and quantification, procurement, storage and distribution, importation requirements, etc.
- Assess resource availability to support guideline revisions including robust cost analyses.
- Consider the impact of guideline revisions on patient loads and implement locally appropriate human resource interventions including rollout of lay counselors, phlebotomists, and/or task-shifting.
- Review ARV supply and procurement plans before rolling out revised guidelines so that drugs from a previous protocol are consumed before the guidelines are fully rolled out.
- Officially endorse the revised guidelines as policy by having MOH leadership hold a public press conference announcing them.
- Collaborate with the local health offices to train health care workers nationally and distribute hard copies of the revised guidelines.
- Establish a feedback mechanism, such as quarterly implementer meetings, for local health officers and health care workers to relay any challenges with implementation of the revised guidelines back to the central level so that appropriate interventions can be developed.

Future Plans

Recently, Guyana has gone through another process of revising its national HIV treatment guidelines. In 2009, the Minister of Health convened a similar revision committee to plan for the addition of VL monitoring, potential initiation of ART for all patients diagnosed with HIV irrespective of CD4 level, revision of the pediatric ART regimens to include abacavir (ABC) in first-line therapy, and further guidance on ART initiation in tuberculosis/HIV co-infection. Currently, the 2009 guidelines remain in draft form and are being reviewed by various local and international partners. In addition, an in-depth costing of the new guidelines is underway to explore the resource implications for different guideline scenarios. Following incorporation of the comments resulting from these reviews, the MOH plans to officially endorse and disseminate the revised
guidelines through a process similar to the one used for rollout of the 2006 guidelines.

REFERENCES


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