In focus

WHO's HIV/AIDS strategy under the spotlight

Dr Jim Yong Kim, Director of WHO's HIV/AIDS Department, talks to the *Bulletin* about "3 by 5" — the global strategy which aims to provide three million people in developing countries with antiretroviral treatment by 2005



About "3 by 5":

Since its introduction in 1996, highly active antiretroviral therapy (ART) has enabled people with HIV/AIDS in industrialized countries to live healthier, longer lives and to continue to contribute to the social and economic well-being of their families and societies. However, although 95% of the world's 40 million HIV-positive people are living in developing countries, only about 400 000 of the six million people requiring treatment actually received it in 2003.

To address this treatment gap, at the UN General Assembly Special Session on HIV/AIDS in 2001, UN Member States unanimously committed to scaling up ART within their national HIV/ AIDS programmes. In late 2003, WHO and UNAIDS declared the inequity in access to HIV/AIDS treatment a global public health emergency and launched the initiative, dubbed "3 by 5", which aims to treat three million people living with HIV in developing countries by the end of 2005. In a special interview with the Bulletin, WHO's Director of HIV/ AIDS explains the principles behind the strategy, describes the challenges to its success and recounts the progress made towards achieving the target to date.

Bulletin: Why has WHO chosen HIV/AIDS for the signature initiative of the current Director-Generalship?

JK: "There are many reasons. One of the reasons is that for certain areas of the world the threat of HIV/AIDS is more severe than almost any other disease that we've seen for many hundreds of years. This is not to say that other diseases are

not important but HIV/AIDS is clearly the disease that could define our generation. It is killing a particular portion of the population which is the most important for social viability: young men and women in the prime of their lives, people who are key to a community's social and economic structure. It is an enormously serious problem, as the World Bank points out, when a country loses people in whom so much has already been invested and who must in turn invest in the next generation, if societies are to be sustained.

"By choosing to focus on the HIV/ AIDS treatment gap, WHO's Director-General, Dr LEE Jong-wook, recognized that WHO has an important role to play in combating this epidemic. This is because scaling-up treatment for HIV in developing countries requires a public health approach. Until now, the only way HIV could be treated was in a very clinical, hospital-based, first-world type approach, where physicians were the only ones who could treat HIV patients. In order to quickly and equitably roll out HIV treatment in resource-poor settings, we could not take a one doctor, one patient approach. We had to develop ways of treating many thousands

of people within a population using standardized regimens and simple treatment algorithms.

"WHO has been saying for years that we need to invest more in health and in some ways, we have been successful — the world is investing more in health but almost all of the new investment is for HIV. The world has voted — presidents and prime ministers have voted — to put their money into the fight against HIV/AIDS. For WHO to turn its back on HIV/AIDS would therefore be tantamount to a dereliction of duty. It's an opportunity we cannot afford to miss. WHO must therefore help the world achieve its goals but at the same time make sure that those goals contribute to broader social development."

Bulletin: Is there more to "3 by 5" than treatment?

JK: "Yes. In providing HIV treatment, we can achieve many other things at the same time. For example, by increasing access to ART, we have learnt that we can reduce the stigma associated with HIV infection. In the first world, the availability of ART — which can dramatically



Dr Jim Yong Kim, Director of WHO's HIV/AIDS Department

transform dying people back into healthy, productive individuals — was a critical factor in reducing the stigma associated with HIV and in enabling people to resume their lives.

"Secondly, providing HIV treatment also strengthens prevention. For example, when effective HIV treatment was offered in the first world, resistance to being tested dropped fairly quickly. One of the most powerful ways to prevent HIV is by quickly expanding the number of people who know their status so that they can protect themselves and others.

"Thirdly, by providing HIV treatment we can also strengthen health systems. To deliver HIV treatment, countries need systems that can provide chronic care and follow a patient throughout their life. The system must also, at least at a basic level, provide for their general health-care needs. I believe that WHO should intervene in countries in a way that can help ensure the long term development of health-care systems that will function not only for HIV but also for other chronic illnesses, such as diabetes and hypertension."

Bulletin: So "3 by 5" isn't just another "vertical" programme?

JK: "We have to make sure that it doesn't become one. There are so many aspects of caring for an HIV patient that we clearly need to integrate HIV care into a broader primary health-care system. That is what was done in Thailand and in Haiti. Unless HIV treatment is integrated into the overall health-care system, I think it will fail in the long run."

Bulletin: Who is responsible for achieving "3 by 5"?

JK: "It is important to understand that "3 by 5" is not a WHO project. WHO cannot and never claimed to be able to do this by itself. We don't have money for drugs, we are not a funding agency and we are not even going to be the primary implementing agency on the ground. WHO has chosen to hold itself accountable to the "3 by 5" target because we feel it is the most concrete, transforming and appropriate goal around which to organize our activities at this point in the epidemic. Whether or not the world can achieve "3 by 5" will depend on many other actors. In proclaiming our commitment to the target, we are saying that we will do everything in our power to help countries reach their aspirations in treating their HIV-positive citizens."

Bulletin: What can WHO do to facilitate treatment scale-up?

JK: "Lots of things, including establishing technical norms and guidelines and providing direct technical support to ministries of health at the country level. We can also help ensure that national efforts are coordinated — that partners are working together on the ground."

Bulletin: WHO estimates that it will cost US\$ 5.5 billion to reach the "3 by 5" target over the next two years. Is this funding in place?

JK: "No, not right now. But there are many possibilities for increasing funding to get more people on treatment. First, the cost of antiretrovirals continues to go down. Secondly, redirecting some of the funds from the first three rounds of grants by the Global Fund to Fight AIDS, TB and Malaria could lead to more money available for treatment. Also, the World Bank is now moving much more quickly to fund treatment in the countries in which they are working. In addition, the US Government is now playing a major role and contributing resources. Canada has also made a substantial contribution to the "3 by 5" initiative. With all these possibilities, WHO can play an important role at the country level to help ensure the funds are spent sufficiently."

Bulletin: What is the US\$ 5.5 billion for?

JK: "It is for the many aspects of treatment and prevention scale-up — training health workers, paying for ART, providing medicines for opportunistic infections and all the different aspects of a comprehensive treatment programme that must be in place."

Bulletin: How will countries persuade their private health sectors to implement the pillars of "3 by 5"?

JK: "The private sector is already a major provider of HIV treatment in many countries. Our experience has been that the private sector is also looking for guidance on how to treat HIV patients because there are many choices. But governments need to play a stronger regulatory role and WHO is working to provide them with a framework by which they can establish procedures, rules and regulations to guide the treatment activities of not only the private sector but also of nongovernmental and faith-based organizations.

Strengthening health systems means strengthening the policy and regulatory capacity of governments in relation to the whole range of health-care providers."

Bulletin: WHO has committed to getting three million people on ART by 2005 and to keeping them on treatment for the rest of their lives. Is this target achievable?

JK: "The target is achievable but it depends on how much political will, money and resolve the world is willing to invest. Many people tell me that it's not achievable, but since very few have really tried to scale-up ART treatment, how could they possibly know with such certainty that it is impossible? I'm not interested in defeatist conclusions at the outset. We should be discussing the obstacles to achieving this target and working to develop ways of overcoming them, instead of citing reasons why it can't be done."

Bulletin: WHO has been accused of double standards because it has recommended drugs for developing countries that have not been approved by national drug regulatory authorities for use in developed countries such as the EU, Japan and the US. What is the justification for this?

JK: "The reason they are not approved in those specific countries is that selling generic medicines would breach national patents in those rich countries. Recent developments at the World Trade Organization have allowed poor countries — in the event of a pandemic like HIV/AIDS — to import generic drugs made under compulsory licensing, if they are unable to manufacture the medicines themselves. Several countries are doing this now. But how do those countries which may not have good drug regulatory authorities evaluate the quality of these imported generic drugs? The EU, Canada, Australia and the US have highly respected drug regulatory authorities but it is difficult for them to test these generic drugs for a number of reasons including the enforcement of patents.

"So we have a situation where the drugs are available, poor countries want them and they want them with quality assurance but they themselves may not have the regulatory capacity to give that kind of assurance. WHO, therefore, has developed its pre-qualification system which utilizes drug regulators from countries like Switzerland,

Canada, Australia, France and 16 other countries to assess the quality of the drugs. This allows the UN system and poor countries to import them with confidence."

Bulletin: How will WHO advise countries on how to make difficult ethical decisions such as who to begin treating first?

JK: "We are preparing very practical guidelines to help countries make these choices. But there is no way round the question of who to treat first. The goal is universal access but you have to start somewhere. Triage is part of every medical intervention and triage has always presented an ethical problem. But the situation in which we are living now — where a minute percentage of those who need treatment in Africa are receiving it — has much more serious ethical implications. Who to treat first is a far better ethical problem to deal with than not treating at all. Some people have suggested that launching "3 by 5" created an ethical problem but I see it very differently. The "3 by 5" initiative and the push for universal access will help us pull ourselves out of the gravest of ethical problems and organizations like Médécins Sans Frontières are showing how communities can successfully make these decisions for themselves."

Bulletin: How will WHO help countries address the issue of patient confidentiality?

JK: "Protecting patient confidentiality is a problem that exists in all health-care systems including those in developed countries. The way to look at "3 by 5" is as an opportunity to improve the ability of developing country health systems to protect patient confidentiality. If it can be done for HIV then it can be done for other health problems. It won't be easy but since we have to do it anyway, why not use the political will behind HIV treatment to make a real effort to solve the problem?"

Bulletin: Are there systems in place for the monitoring and evaluation of patients on treatment, in particular for any potential side effects resulting from ART which may require a change in drug regimen?

JK: "Yes, there have to be systems in place to monitor and evaluate patients on treatment. Some patients will be monitored in rural areas mostly under the supervision of nurses and health workers but if they have serious side effects that require changing therapy,

then that is another issue. A major question is: how serious do the side effects need to be before a change in therapy is required? I would personally argue that in first world countries, drug regimens are often changed too quickly. We really have to work to develop a better understanding of the appropriate time to change regimens, especially when there is a limited pool of drugs."

Bulletin: Many argue that supervised therapy is necessary to prevent the emergence of drug resistant HIV strains. Does WHO recommend supervised therapy to countries scaling up treatment?

JK: "My personal view is that we should recommend supervised therapy. However, there are all kinds of issues involved relating to human rights, logistics, availability of resources and so on. So it is a difficult issue and it needs to be properly studied. I think in the end, we will conclude, as Partners In Health (my former organization) in Haiti did, that having treatment support workers to help people take their drugs is very cost effective and that it can help prevent drug resistance and improve patient outcomes overall.

"Currently, WHO strongly recommends countries to provide patients with treatment supporters where possible. Our responsibility is to work with countries and donors to conduct operational studies which will confirm the importance of treatment supervision in preventing the emergence of drug resistance. But one point I would stress is that WHO definitely does not suggest that countries should delay the initiation of therapy if a treatment support worker system cannot be established. Many programmes that don't use them have done extremely well and in fact, compliance rates have been quite high in these programmes.

"WHO, together with its partners, is building a monitoring and surveillance system called HIV Resnet through which we will be monitoring the emergence of drug resistance, through studies over time.

"Resistance is a challenge we need to anticipate but it is never used as an excuse not to provide treatment in rich countries and shouldn't be in poor ones."

Bulletin: The cost of second-line drug regimens are monumental by comparison to first-line regimens. How will countries care for patients who have failed to respond to first-line regimens?

JK: "This is a big challenge. There is no question that the cost is much higher. One of the top priorities of WHO's AIDS Medicines and Diagnostics Service is to look into this issue and try to bring these costs down to the level of first-line regimens in a very short period of time. I am hopeful that this issue can be resolved fairly quickly."

Bulletin: Countries have to become TRIPS (trade-related aspects of intellectual property rights) compliant by 2005. Is this going to drive up the cost of ART and how will this affect countries' abilities to provide treatment for "3 by 5"?

JK: "TRIPS compliance doesn't necessarily mean that the cost of ART will go up. If drug prices were to rise, I think that the HIV community including different civil society actors would respond by re-affirming the spirit of Doha and its relationship to public health. TRIPS confirms the importance of trade and intellectual property but it also says that these issues are not more important than public health disasters like HIV/AIDS. In 2005, we may have to negotiate again but we think and hope that the conclusion will be the same. Protecting public health in the face of emergencies and other disasters like HIV/AIDS must take priority."

Bulletin: What has been achieved since the launch of "3 by 5"?

JK: "WHO has sent teams to 37 countries and we now have a much better idea of what is and is not happening at the country level. As a result of that, we have been able to develop a clear and focused business plan and to define the specifics of WHO's role. We now know that WHO has more to offer in some areas but not in others and we know what has already been done by the countries themselves and by other partners. WHO is learning every day how to be a better partner.

"We have produced some very good tools: clinical guidelines, monitoring standards, training materials that are currently being used in countries. We need to do more, and we will. Right now, we are doing everything we can to help bring all the players together because the whole world needs to rally around this incredible challenge if we are going to reach "3 by 5"."

Sarah Jane Marshall, Bulletin