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Barriers to ART scale up, and potential solutions

By Theo Smart

"[To] reverse the tide of the HIV/AIDS epidemic, we must think differently. The scale of the solution has to match the scale of the problem from the outset," Dr Ernest Darkoh, Chairman of BroadReach Healthcare, told the crowd attending the opening plenary session of the 2nd South African Conference on HIV/AIDS on Tuesday evening in Durban. Dr Darkoh detailed several steps to "unlock" capacity based on real lessons learned in the field.

Dr Darkoh has a wealth of first hand experience. From 2001 through December 2004, he was the Operations Manager for Botswana's flagship Masa programme— the first comprehensive national HIV/AIDS programme in southern Africa to roll-out antiretroviral therapy. He was responsible for guiding the overall implementation of the ARV program that achieved countrywide rollout in 36 months. When he finally handed over leadership of the program to a local counterpart, Masa was treating over 30,000 patients and there were an additional 7,000 patients in the private sector.

But Masa still has a long way to go to meet the overwhelming need for treatment in Botswana. Dr Darkoh's lecture provides some insight into the challenges he faced getting the programme up and running, and the barriers that keep treatment programmes from expanding more rapidly.

Supply-side challenges

"The demands that are being placed on our health care systems, greatly overwhelm our capacity to supply," Dr. Darkoh began. He explained the key work streams with the various steps involved in implementing a national antiretroviral treatment programme, starting with the process of getting someone ready to be tested for HIV (testing campaigns, pre-test counselling) with various steps involved through to treatment and long-term follow-up.

He highlighted a few key areas "that are particularly troublesome, where we still do not have good solutions: pre-test counselling, lab logistics (which in itself represents dozens of steps), post-test processing (screening viral loads/CD4), monitoring of HIV positive patients who are not yet eligible for treatment, follow up and adherence management as well as management of long-term side effects."

The programme must be supported by a number of interrelated systems including programme development, management and logistics; community mobilization; staff recruitment and retention; training; data and financial management; referral; psychosocial and wellness support, procurement of space and equipment; monitoring, evaluation (M&E) and operational research; and enforcement of accountability — there must be a someone accountable for each function, in order to fix things that aren't working.

"And if that wasn't challenging enough," said Dr. Darkoh, ART programmes are confronted by a number of additional challenges. First, Dr. Darkoh noted, there is a stubborn "adherence to healthcare delivery models which intrinsically lack ability to scale." In most developing countries, health care systems are built around centrally located tertiary and secondary referral hospitals.

"This is a model that was by definition set up to manage low prevalence conditions — not public health emergencies where sometimes up to 40% of the population is infected. And unfortunately, a lot of proposals still focus on building this capacity — as opposed to developing community-based capacity" (such as a network of community-based facilities that reach people where they live).

Plus, "when it comes to testing, we are trapped in the pre-HAART mindset," said Dr. Darkoh. He believes that voluntary counselling and testing (VCT) which was devised to protect privacy rights is now actually preventing people from accessing care and services — "and," he said, "often promotes stigma by creating the sense that HIV is so different that you have to go through this special process."

Programmes are also plagued with effort fragmentation, and too many vertical programmes. Dr. Darkoh said: "As the operations manager in Botswana that became my living nightmare. Dealing with a multitude of partners, all doing their own different things — and yet knowing that in toto we had the capacity in our hands that we needed, however it was fragmented. Vertical programmes are not necessarily bad — what makes them bad is when there is poor integration and coordination between these programmes."

Demand-side challenges

On the demand side, Dr. Darkoh noted that the HIV/AIDS epidemic is "unprecedented in [scale with] a massive burden of disease" that outstrips the capacity of national health care systems to scale-up and effectively respond.

Public health systems simply aren't designed to deal with such large numbers. "If you had this many people with sprained ankles, you would have a crisis. But when upwards of 35% of the adult population have a condition that must be addressed, the logistics of addressing that condition alone — no matter how simple it is — are daunting. And HIV is not simple."

In addition, he added: "the epidemic is mostly invisible. Yes we have queues and yes they are long, but those queues are nowhere near as long as they need to be." The lack of testing and long periods free of severe symptoms makes it difficult to recognise the scale of the local problem until patients come in for care with serious disease.

As a result, the first patients that a new ART programme will serve are "devastatingly resource intensive." For example, the early cohorts in Botswana were usually quite ill, with an average CD4 cell count of around 50. "[These patients] required a lot of time and resources at a time when those facilities are short-staffed and when the health care workers are less experienced," said Dr. Darkoh.

"If you spend all your time and capacity on the very sick people, you can never get to those who are not yet sick, and unfortunately, that sets up a loop of perpetually insatiable demand."

Another impending challenge is that once on treatment, programmes will have to continue to monitor potentially millions of "well" people requiring "lifetime" follow-up in the community. Hospitals, Dr. Darkoh noted, have never been well equipped to do this. "The demand is in the community — we are building our solution in hospitals."

Then there are environmental, social, cultural and economic challenges limiting access and reach into rural areas. Dr. Darkoh focused on staffing: "In Botswana, I was [able to write] a blank check to whomever I needed to recruit to support our programme. But it does not work! Even when I did find a doctor willing to come to the country, [he or she] wasn't willing to live in remote rural areas.

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These are areas where I would not live. So the answer must be that we use already existing people who are living in these communities — in new and creative ways."

Finally, some of the special risk groups that must be reached are challenging. These include truck drivers, commercial sex workers and children. For example, commercial sex work is illegal in many countries, which makes it difficult to identify and service this population in need.

Dr. Darkoh focused on the difficulties reaching children. "You only have one shot at finding a child and that is when they are born," he said. "If you do not have across the board routine screening of pregnant women you are only going to find these children when they are sick or dying. And a massive number of these children die by 18 months."

Reversing the tide - unlocking capacity

"We do have within ourselves and in our environment a lot of latent capacity to respond to this epidemic — we just need to find effective ways of tapping into it," said Dr. Darkoh. "We must prevent new infections. We must test those who do not already know their status. We must treat *millions* of people already infected and we must support millions of "well" people in the community."

He suggested several ways to accomplish this.

Increasing testing rates

It's possible to "dramatically increase testing rates and decrease "resource intensity" per patient." He gave two examples of how this might be done. In Uganda, pilot studies have had significant success with a household-by-household campaign.

But in Botswana, testing uptake improved from below 20% to above 90% with introduction of a national policy of routine opt-out testing in health facilities.

Said Dr. Darkoh: "We have tried to routinise testing by making it a part of the regular medical exam. We said to ourselves, that in a country where 40% of adults are HIV positive, and 60% of the people in a health facility are HIV-positive, and 90% of the patients in an in-patient ward are HIV-positive, if you let somebody walk out of a health facility without strongly encouraging them to have a test and have done everything possible — it is malpractice."

Leveraging rare expertise: remote decision support

It is also possible to spread the expertise of one specialist over numerous non-specialist providers in the field with remote decision support. In South Africa, three private sector companies have shown it is possible to spread the expertise of a few specialists over thousands of generalist providers. From one remote location, which housed the specialist, they support the providers in the field with clinical decisions. They also provided patient support through call centres and education programmes.

"With these models they achieved ratios of 13,000 patients to one doctor," said Dr. Darkoh. "That ratio is unprecedented."

Harnessing and utilising cross-sectoral skills and capacity

Botswana has shown that public private partnerships can help jump-start implementation. These novel partnerships with businesses also increase the availability of skill sets to which the public sector rarely has access including management and planning skills, social marketing, financial skills, recruitment and human resources management, dealing with actuarial risk assessments, computers and data management, telecommunications, logistics and supply chain management, transportation and delivery services and insurance and claims management.

Building community-based monitoring and support

It is also possible to create support and monitoring mechanisms for millions of "well" people in the community. Dr. Darkoh believes that numerous functioning and under-utilised organizations already exist through which targeted interventions can be channelled and monitored. These include PLWHA support groups, workplaces, academic institutions, faith-based groups and institutions, cooperatives and trade unions, state institutions (e.g. military and police), traditional authority structures and families.

"The key thing," said Dr. Darkoh, "is to find ways of harnessing this so that we can provides services at scale."

Community workers as ART providers

Dr. Darkoh suggests greater reliance of community health workers to provide non-complex maintenance and adherence support for ART under supervision. For example, experience in Haiti has shown success with supervised community health workers providing direct observed therapy with antiretrovirals. This programme has adherence rates over 90%, and has reduced patient visits (and lengths of stay) to the hospital.

In Khayelitsha, South Africa, MSF has pioneered community based programs that have demonstrated better than 90% adherence rates, with more than 90% of patients with optimal viral suppression at 6 months and a more than 70% reduction in opportunistic infections.

Rapidly grow supply to exceed demand

"We can put together all of these elements into a big enough unit that we can effectively deal with the demands put upon us by HIV," said Dr. Darkoh. "But we have to agree on a certain set of principles:

- "In resource limited settings we must agree to the principle that no job should be done by a person if someone less qualified can do it (or be easily trained to do so).
- "We must organise, and utilise all existing supply-side resources to create required scope and reach.
- "We must organise the demand-side and capacitate it to do as much as possible in the community.
- "We must centralise and leverage rare expertise as well as any backroom functions that are not necessary to replicate.
- "We must build systems that manage simple and complex cases (e.g. resistance related issues).
- And finally, we must pursue integrated approaches that strengthen overall health systems to support other health needs as well — not just HIV."

Three remaining challenges

Even if a programme incorporating all these elements could be put in place, Dr. Darkoh believes three key challenges will continue to limit rapid expansion of treatment capacity.

First, there is an urgent need for technological break-throughs in laboratory technology (CD4, viral load, haematology, chemistry, resistance) to extend to community and home level monitoring. "The current technologies are just too bulky, too expensive and require too much expertise," said Dr. Darkoh. He'd like to see

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semi-quantitative tests which provide instant results that are simple (can be operated by non-specialist staff), highly portable, either solar or battery operated, easy to maintain and deployable in remote community settings.

There is also a need for simplified "failure management" protocols that can work at district and clinic level to monitor and manage resistance-related issues. He asked researchers present to try to come up with protocols that are simple and practical, operable on a population level, with minimal dependence on expensive technology, and which are adaptable across a wide range of staff. Finally, there is a need to make linkages between prevention and treatment truly operational. Models have been proposed where individuals who are tested are either entered into prevention services or into treatment and care programmes, but these have not really been well explored in large-scale practice.

Conclusion

"The core of a successful ART programme is not physical infrastructure," said Dr. Darkoh, in conclusion, "but it's systems and processes which allow people to take drugs on a prescribed and consistent basis in the community over a lifetime. The emphasis must be on early identification and maintaining wellness- this is a significant paradigm shift from current health delivery models that we are used to.

"We must avoid re-inventing the wheel and use "winning" models, existing expertise and multi-sectoral capacity. And finally, we must have the courage to cross boundaries and join hands in the spirit of true jointly accountable partnerships where every stakeholder down to the individual has a distinct, monitored and enforced role.

News coverage from the 2nd South African AIDS Conference

News Headlines - Including exclusive news coverage of the Second South African AIDS Conference, Durban

Meta-analysis highlights wide variation in success of developing world HIV treatment

http://www.aidsmap.com/en/news/D5BDFA9D-5222-450D-8575-1B79F33B79C5.asp?hp=1

A meta-analysis of studies of antiretroviral treatment in resource-limited settings shows large variations in the success of treatment. The findings are published in the July 15th edition of the journal Clinical Infectious Diseases.

Tenofovir may linger up to 3 weeks in body: discontinue with caution

http://www.aidsmap.com/en/news/5FABE543-4174-486B-B30D-91B788CB42E3.asp?hp=1

Sub-optimal levels of tenofovir (Viread) that could lead to drug resistance may linger in the body for at least three weeks after the drug is discontinued, according to a report in the May edition of Antimicrobial Agents and Chemotherapy. The findings, published by a French and Spanish research group, call into previous assumptions about the safety of discontinuing tenofovir treatment, say the researchers.

Traditional healers being integrated into HIV care and treatment in Kwazulu-Natal

http://www.aidsmap.com/en/news/E24CE61D-B50C-4FE1-BC21-20E8E4BEDD30.asp?hp=1

Efforts to improve the care and treatment of South Africans with HIV/AIDS are often hampered by misunderstandings and poor relations between Western healthcare workers, and the community-based African traditional healers (or sangomas) that many people first turn to when they have a medical complaint. However, a new project launched in the Nelson R. Mandela School of Medicine/University of KwaZulu-Natal (UKZN) in Durban is trying to build bridges and improve collaboration with traditional healers caring for people with HIV/AIDS.

PEPFAR-funded NGOs present progress at 2nd South African AIDS Conference

http://www.aidsmap.com/en/news/0B7338AE-5DBB-43CC-9ABA-9D37F516F012.asp?hp=1

A diverse group of non-governmental organizations (NGOs), funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR), presented their first year's progress at a satellite conference of the 2nd South African AIDS Conference in Durban. Funded projects focused on providing aid to orphans and vulnerable children, `faith-based` HIV prevention services, voluntary counselling and testing services, collaborations with traditional healers, operational research into the long-term success of PMTCT programmes, nurse-driven antiretroviral therapy, and antiretroviral treatment delivery in an antenatal clinic.

PEPFAR working closely with South African government to support HIV treatment and care

http://www.aidsmap.com/en/news/B414BAEA-07D5-4EFF-B67E-555669ECAF95.asp?hp=1

Before the official start of the 2nd South African AIDS Conference, representatives from the United States President's Emergency Plan for AIDS Relief (PEPFAR) held a satellite conference to review the challenges faced and progress made by the programme's South African partners during the first year of the plan's implementation.

Rifampicin resistance linked to dosing schedule in HIV-positive TB patients

http://www.aidsmap.com/en/news/C251CD10-402E-48B4-A9D6-98610CFBEC33.asp?hp=1

Resistance to the anti-tuberculosis (TB) drug rifampicin (Rifadin / Rimactane) in HIV-positive patients is most likely to develop if the drug is taken intermittently during the first two months of treatment, according to a retrospective study published in the 1st July edition of Clinical Infectious Diseases. The study also showed that the risk of resistance was not affected by whether the patients took rifampicin or the similar drug rifabutin (Mycobutin).

Standard tests underestimate resistance in mothers who received nevirapine when giving birth

http://www.aidsmap.com/en/news/A3C49CD6-6951-4B70-B872-887600D5C1D3.asp?hp=1

Highly sensitive resistance tests that can detect very small populations of drug-resistant virus have shown that in women exposed to single-dose nevirapine (Viramune) at the time of delivery,

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nevirapine resistance is more common than thought, and may persist for up to two years, according to findings from two studies published in the July 1st edition of the Journal of Infectious Diseases.
BMJ editorial: assess cardiovascular risk and consider delaying HAART until CD4s reach 200 cells/mm3

http://www.aidsmap.com/en/news/29BEBA80-8FA8-4404-B4E9-34A2B21146AF.asp?hp=1
An editorial published in the June 11th issue of the British Medical Journal argues that HIV clinicians should take cardiovascular disease risk into account, in addition to the risk of HIV progression, before suggesting that treatment-naive individuals begin highly active antiretroviral therapy (HAART).
Modest reductions in new cases of TB seen in South African isoniazid trial

http://www.aidsmap.com/en/news/A82A1807-EF2A-4188-A2F2-FECE67524FDF.asp?hp=1
A study from South Africa has shown that giving isoniazid to HIV-infected adults attending a workplace HIV clinic reduced the incidence of tuberculosis (TB) by over a third. However, the investigators, writing in the 8th June edition of the Journal of the American Medical Association warn that levels of TB diagnoses remained high even after preventive isoniazid treatment and that additional interventions are needed to reduce disease and death most effectively.
HIV-1 subtype in West Africa less susceptible to unboosted PIs

http://www.aidsmap.com/en/news/C58D67B2-86F7-4086-9FC5-C3DBDD0F64C7.asp?hp=1
The prevalent HIV-1 subtype in West Africa is less susceptible to some protease inhibitors, according to a study published in the July 15th edition of Clinical Infectious Diseases (now on-line). The investigators from Japan, Ghana and France, found that ritonavir (Norvir) had the strongest inhibitory effect and nelfinavir (Viracept) the weakest effect of any protease inhibitor included in their analysis and "propose that the combination of ritonavir and protease inhibitors other than nelfinavir is still clinically applicable" for the treatment of the HIV subtype prevalent in West Africa.
Leading South African health and social advocate calls for an end to denialism at South African Conference on AIDS

http://www.aidsmap.com/en/news/355ADF9D-3107-4D43-A188-B0F595D784B8.asp?hp=1
"The best way of honouring the memory of Nkosi Johnson and many other children who met premature deaths at the hands of HIV/AIDS is to end denialism now!", Dr Mamphela Ramphele told a cheering audience last night during the opening of the Second South African Conference on AIDS. She urged fellow South Africans to transcend their past and work together to ensure the human rights of people with AIDS.
South African AIDS Conference opens with call for unity

http://www.aidsmap.com/en/news/A4D019C5-5766-496E-B794-3E03755FE51E.asp?hp=1
"We must start working together," Professor Lynn Morris of South Africa's National Institute for Communicable Disease told the participants of South Africa's Second National AIDS Conference on the evening of June 6th in her welcoming address to the meeting. Professor Morris is also the chairperson for the conference being held this week (June 7-10) in Durban.

HIV-1 and HIV-2 coinfection: viral response to HAART differs

http://www.aidsmap.com/en/news/1EFDF0C5-5686-46FD-98EE-986CF81BC1CC.asp?hp=1
For patients coinfected with both HIV-1 and HIV-2, both viruses should be taken into account when selecting treatment regimes and measuring outcome, emphasise investigators writing in the July 15th edition of Clinical Infectious Diseases (now on-line). These cautions are included in a case report of an individual, coinfected with HIV-1 and HIV-2, who initially achieved good immunological and virological outcomes on commencing highly active antiretroviral therapy (HAART). However, the individual experienced an increase in HIV-2 viral load and fall in CD4 cell count after HAART was changed to a simpler regimen which kept HIV-1 undetectable.
Stevens-Johnson syndrome affects mother and son taking nevirapine

http://www.aidsmap.com/en/news/55E68DBB-4A17-4C8B-86CF-924C5D270735.asp?hp=1
Two cases of the rare side-effect of nevirapine, Stevens-Johnson syndrome, involving a mother and her son, are reported in the June 10th edition of AIDS. The investigators "are unaware of any previous familial clustering" of Stevens-Johnson syndrome associated with nevirapine treatment.
Risk of diabetes increased by being HIV-positive and on HAART

http://www.aidsmap.com/en/news/460E8178-0626-411B-AA43-3B588F458682.asp?hp=1
HIV-positive men who are taking highly active antiretroviral therapy (HAART) are more than four times more likely to develop diabetes than HIV-negative men, according to an analysis of data from the Multicenter AIDS Cohort Study (MACS). These findings were published in the 23rd May edition of the Archives of Internal Medicine.
Africa's HIV palliative care needs examination

http://www.aidsmap.com/en/news/F2A267D9-C935-45EB-9937-3BA270A97B2B.asp?hp=1
HIV palliative care in southern Africa is being provided by family members and local communities, who are "often inadequately trained in clinical skills and lack access to essential drugs," according to a review article published in the June 4th edition of The Lancet. The investigators also argue that palliative care will continue to be important in Africa even when antiretrovirals become available.
Zambia: provinces left behind in ARV rollout

http://www.aidsmap.com/en/news/5DA4446D-0148-4BD0-905C-68848C3C73BD.asp?hp=1
In the remote district of Zambezi, near the Zambian border with Angola, getting hold of anti-AIDS drugs is a major struggle for those living with the virus.
New research questions link between African food crisis and AIDS

http://www.aidsmap.com/en/news/ACA5DF7C-7CB3-4D7B-87E4-0B5B9219E9EE.asp?hp=1
The link between HIV/AIDS and hunger in rural communities has received a great deal of attention in Southern Africa, where HIV/AIDS seems to have added a new dimension to the region's four-year-long food crisis. But a new report has argued that although HIV/AIDS constitutes a humanitarian catastrophe, the impact of the

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epidemic was not a major cause of the region's food crisis during 2001 and 2004.

Pancreatitis risk studied in 20 US HIV drug trials

http://www.aidsmap.com/en/news/42191A1D-70AE-4526-A9FE-9138A6E0E2FA.asp?hp=1

Overall rates of pancreatitis were similar for patients taking single or dual nucleoside analogue (NRTI) regimens, according to a review of 20 United States clinical trials published in the June 1st edition of the Journal of Acquired Immune Deficiency Syndromes. However, as would now be expected, the combination of ddI/d4T was associated with the highest incidence of pancreatitis of any nucleoside analogue combination, with the HAART regimen of indinavir/ddI/d4T "associated with particularly high rates of pancreatitis, reminiscent of high-dose ddI-monotherapy trials."

Total lymphocyte count, anaemia, add to symptoms in pinpointing who needs treatment in Thailand

http://www.aidsmap.com/en/news/6793640B-E0B9-41DA-9E32-F1B3B7B9AC50.asp?hp=1

Current WHO advice on the detection of severe immunosuppression in the absence of sophisticated laboratory tests may result in a significant underestimate of the number of people who would benefit from immediate antiretroviral therapy, according to findings from a joint US/Thai study published in the June 1st edition of the Journal of Acquired Immune Deficiency Syndromes.

Tattooing associated with HIV risk in Chennai, India

http://www.aidsmap.com/en/news/9C786221-5D9F-496C-91C4-1A5659ACC5EA.asp?hp=1

Around 30% of the intravenous drug users (IVDUs) in Chennai, India, are infected with HIV, and around one out of six of these has passed the infection onto their regular sex partners, according to a cross-sectional study published in the May 1st edition of the Journal of Acquired Immune Deficiency Syndrome. Once HIV prevalence among a high-risk IVDU population becomes so high, the paper says "HIV epidemics can become self-perpetuating, with even modest levels of risk behaviour leading to substantial rates of infection. And yet very few of the participants in this study, including those who were infected, thought that they were at any risk of contracting HIV."

Lipodystrophy on first-line ARV regimens common in Indian patients

http://www.aidsmap.com/en/news/B15C0D05-95D8-42BF-ABEF-E51EF79E10BE.asp?hp=1

Lipodystrophy appears to be just as common in Indian patients receiving antiretroviral treatment as it is in the United States and Europe, according to a report from an HIV clinic in Pune, Western India, published in the June 1st edition of the Journal of Acquired Immune Deficiency Syndromes.

about **HATiP**

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The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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