



Operations Research to Advance Scale-Up of HIV/ AIDS Programmes: What is the Way Forward?

Report of a special session
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3rd IAS Conference on HIV Pathogenesis and Treatment

Meeting Summary

Rapid scale up of AIDS services in resource limited countries is one of the most ambitious and complex undertakings in public health history. With more than six million people in immediate need of AIDS treatment, the mission is urgent. But the challenge of scale up is one of sustainability and efficiency as well as immediacy. AIDS is a chronic condition requiring a lifetime of care. Every day 14,000 people join the 40 million people already living with HIV. The AIDS service systems now being created in many less developed countries (LDCs) will need to serve a steadily increasing number of people in the coming years and decades.

Operations research (OR) will be crucial if the world is to accomplish accelerated, large scale, and sustainable delivery of AIDS treatment and prevention services. OR allows providers and policy makers to “learn by doing” and refine their programs as they grow. The World Health Organization (WHO) recognized “the rapid identification and reapplication of new knowledge and successes” as one of the five pillars of its AIDS treatment strategy.

Yet several hurdles stand in the way of more productive utilization of OR to advance AIDS service delivery. These include limited dedicated funding for OR, a lack of emphasis on OR by researchers, providers and donors, and absence of overall coordination of research that could promote standardization of research protocols and more efficient dissemination of results. In fact, the very definition of OR is the subject of some debate.

What is needed to promote OR and wide application of its results? At the 3rd IAS Conference on HIV Pathogenesis and Treatment a special session examined the status of OR and discussed challenges and priorities for the more effective use of this research. Representatives of three organizations made presentations on their OR programmes:

* WHO is supporting OR studies on AIDS service delivery in five African countries. Each country research plan has a different emphasis, including improving the uptake of HIV testing and treatment and improving adherence to treatment regimens. WHO is also pursuing development of generic tools to facilitate OR.

* The Thai Ministry of Public Health is building OR into the country’s healthcare system by adapting information systems and developing new staff training approaches. One priority is to more closely link OR researchers and program implementers and to ensure that OR generates results that are applicable to policy making and program design.

* The Brazilian National Program on STD-AIDS uses OR in many ways, including improving health interventions and optimizing services for particularly

vulnerable populations. An ongoing challenge is incorporating the findings of OR into policy and decision-making at all levels of the National Health System.

Several important issues emerged from the discussion that followed the presentations, including the importance of expanding financial support for OR, developing a widely accepted definition of this research, ensuring OR is driven by national priorities, creating common research tools, and doing a better job of applying research findings.

As a next step it may be useful for sponsors of OR research to host a consultation with major stakeholders to better define the research agenda, promote expanded support for OR, and ensure OR becomes integral in AIDS programme scale up.

Session Presentations

The meeting was opened by Helene Gayle (IAS President and Director for HIV, TB and Reproductive Health at the Bill & Melinda Gates Foundation) and Bernhard Schwartlander (Director of Strategic Information and Evaluation at the Global Fund to Fight AIDS, Tuberculosis and Malaria). Dr. Gayle said she hoped the meeting would increase awareness about the important role of OR in scale up of AIDS services and help funding organizations identify opportunities for support of OR.

Dr. Schwartlander said that the Global Fund is ready to support OR and implementation of this research through its grant making, but that there have been few proposals requesting support for OR activities. He pointed out that more attention is needed to the institutional, training, and other structures required to support expanded OR studies and application of results from this research.

Yves Souteyrand Strategic Information and Research World Health Organization

OR will be a critical part of an expanded response to the epidemic. The urgent need to scale up AIDS treatment and prevention services means that programs will often need to be implemented in the absence of extensive experience or a comprehensive evidence base of what works. But the ultimate success and sustainability of widespread AIDS treatment and prevention delivery depends on “learning by doing” -- the rapid identification of strategic evidence and application of new knowledge.

Several challenges must be tackled if we are to have a comprehensive and collaborative OR program. Today there are multiple players involved in the AIDS response, and coordination of scale up and evaluation efforts is limited. We have no unified framework for doing OR. Many policy makers and funders are comfortable with “top down” approaches in which the experiences and research needs of people at the site level are not adequately considered.

WHO is an important facilitator and catalyst of country-led OR activities. The Organization brings several comparative advantages to this work, including its presence in heavily affected countries, close collaborative relationships with Ministries of Health and national programmes, extensive programme implementation experience, and a network of stakeholders in the field.

In July 2004, WHO and the Tropical Disease Research programme (TDR) held a consultation to

discuss the OR agenda. The consultation identified four main areas as priorities for OR: improving treatment and ensuring access; dispensing ARVs and supporting adherence; optimizing consequences of treatment; and, ensuring overall health systems strengthening. The group also voiced support for multidisciplinary approaches to cross cutting research questions, such as socio-behavioural, economic, health system and clinical research studies.

Finally, the consultation identified five central questions for OR studies:

- * What effect do different models of antiretroviral (ART) delivery and financing have on quality, efficiency and sustainability?
- * How can we increase workforce capacity in the health sector and optimize communities' participation in delivering treatments?
- * What are the main obstacles to significantly increasing access and uptake of testing and counselling, and how can these obstacles be alleviated?
- * How can we make sure that scaling up ART accelerates prevention and reduces stigma?
- * What process will minimize negative economic consequences of ART on individuals and households?

Country ownership is essential to the success of OR. In 2004, the US Institute of Medicine issued recommendations for OR to facilitate delivery of AIDS treatment in LDCs. It called for beginning this research “at the initiation of scale up” activities and emphasized that research priorities should be lead by national programs and informed by the perspectives of local researchers, health workers and community representatives.

WHO/TDR efforts on OR thus far have focused on five African countries: Burkina Faso, Malawi, Tanzania, Uganda, and Zambia. Each country has developed a proposal for OR related to scale up of its AIDS services, and these proposals were evaluated in May 2005. Each proposal has a different emphasis:

- * Burkina Faso: strengthening coordination between stakeholders to improve the continuum of care
- * Malawi: improving uptake of voluntary counselling and testing, care and treatment among healthcare providers
- * Tanzania: assessing adherence and evaluating its determinants
- * Uganda: identifying best practices to integrate adherence support and HIV prevention in ART programs

* Zambia: utilizing TB and prevention of mother to child transmission services as entry points for ART

WHO and TDR now want to develop generic tools to facilitate OR in these and other countries, and the agencies are planning a consultation in October 2005. Generic tools would help standardize collection, measurement and analysis of OR data and would facilitate comparisons across settings in order to draw general lessons. Some of the research areas that run across research sites and are particularly well suited for generic tools include: links between treatment and prevention, promotion of adherence, cost-effectiveness, and evaluation of the economic impact of ART.

Ultimately we need a global approach to OR that builds on the pilot programs noted above. Development of a global effort is going to require the active involvement of multiple partners and donors. It will also mean confronting several challenges, including sustaining adequate funding for this research, strengthening research capacity in countries, providing continuous technical support, promoting knowledge sharing and utilization, and, finally, developing a culture within national programs that appreciates the powerful role of OR in improving program outcomes.

Petchsri Sirinirund **Department of Disease Control** **Ministry of Public Health, Thailand**

When we think about improving AIDS services, the first thing we should ask is: what are the needs of people living with HIV and AIDS? The type of care that is appropriate is different at different stages of the disease. If you start your OR at delivery of ARVs and forget about care needs earlier in the course of disease you are missing part of HIV-related care.

It is also essential to understand the social and economic context of AIDS care and the importance of adequate living conditions, legal rights, social interaction, mental health, and a healthy environment to the overall wellbeing of patients.

We want people living with HIV to have the best quality of life possible, not just receive ARVs.

The goal of OR is to base policy, planning and program implementation on solid evidence. In Thailand we are trying to build OR into the health service system by adapting our information systems and updating our staff training. We need more qualitative data about patient care, and we are working to more fully integrate the qualitative and quantitative data we are receiving. We also need to do a better job of linking researchers and program implementers.

It is important to ensure OR yields results that are useful in a policy context, and that research is more closely tied to policy making. There also needs to be a closer connection between OR and biomedical, social, cultural, and economic research.

OR is central to improving HIV/AIDS care, but participating in this research should not become

a burden for people working in the response to AIDS. Right now people providing for the needs of people living with HIV/AIDS are overburdened and more manpower is needed. We need to motivate people to learn as they practice and to utilize new technologies to maximum effect. And researchers need to be encouraged to work more closely with other professionals and providers.

Cristina de A. Possas

Research and Development Unit

Brazilian National Program on STD-AIDS

In Brazil we have a health system that provides care to all citizens. We have found that OR is a necessity in the successful implementation of national AIDS programs. Our OR focuses on optimizing interventions, processes and products, such as ARV drugs. We also use OR to understand cost-effectiveness and the impact of interventions. OR can help us improve care for vulnerable populations, develop tools to address stigma and discrimination, and better serve difficult-to-reach populations. We have found that one major challenge is incorporating research data into policy and decision-making at all levels of the National Health System.

The International Cooperation Technological Network was founded at the Bangkok International AIDS Conference, and it now includes Brazil, Thailand, China, Ukraine, Russia, Nigeria, Cuba and Argentina, and other countries are expected to join. This is a network for cooperation on drug development, laboratory issues, and research on treatments and prevention technologies. It may also facilitate collaboration on OR.

Brazil is providing dedicated funding for OR, in part through support from the World Bank. OR has been included in several calls for research proposals. The country has a comprehensive OR agenda that focuses on:

- * Evaluative studies: program performance at different government levels
- * Cost-effectiveness studies: how to make the most cost-effective use of limited resources
- * Randomized controlled trials: on existing and new processes and products
- * Modeling and scenarios: demand for services, processes and products to support informed policy decisions

A priority for OR in Brazil is to test simplified and standardized tools for patient care and monitoring. The National Program requires that research efforts be coordinated and we promote use of common research protocols at multiple sites. We also insist that civil society, NGOs and health services personnel are involved in selecting research proposals and in discussions on access to the benefits of research, intellectual property and ethical issues in clinical studies.

To maximize the impact of OR it is important to build sustainable links between academic research, governments and local health service providers. There needs to be a continual flow of information from service sites to researchers and back. Finally, we have to work on building staff capacity for OR.

Remember that OR is science - the fact that some scientists think it is not is an issue we have to address.

Gregg Gonsalves

Treatment and Prevention Advocacy

Gay Men's Health Crisis

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GMHC co-hosted a think tank on OR some time ago, but many of the issues raised there have still not been answered. People living with HIV want to know how their medical care can be optimized. There are a whole host of questions like when to start therapy, when to switch drugs, and how to maximize adherence, that need to be addressed by researchers. We need to understand the success of the current WHO treatment guidelines and know more about toxicity and side effects of drug regimens. Fixed dose combinations and blister packs need to be more thoroughly evaluated as well.

These are all highly important research areas but it seems no one makes them a priority. The US National Institutes of Health shy away from this kind of research, and one senior staff person has said that OR is “not science”. PEPFAR says it does not want to be involved in research in general.

The research agenda needs to be set from the ground up, not top down. There is an OR agenda, but there is no support to do the work. We need capacity building efforts to support researchers, and funders need to provide more resources for country-based treatment research efforts. The Doris Duke Charitable Foundation recently issued a request for proposals on OR and got 77 applications. That is an example of a relatively small amount of money potentially catalyzing a lot of change.

As a person living with HIV, I know more research is the only way we are going to get answers about how to improve care. Right now we are managing care without the evidence to make those decisions wisely.

Key Points from Group Discussion

In the group discussion that followed the presentations a variety of perspectives were raised about the definition of OR, priorities for study, and next steps for advancing the research agenda.

Defining OR

Many speakers emphasized the importance of expanding the use of OR in the scale up of AIDS services. There is not one universally accepted definition for OR, but several meeting participants offered their own perspectives. One said that OR concerns “improving program performance in a timely fashion”. Another said that it “has to do with what works and doesn't work on the ground”. The US Institute of Medicine has defined OR as “the use of advanced analytical techniques to achieve better outcomes, define optimal processes of service delivery, and develop more cost effective systems¹.”

One speaker noted that strategic clinical trials are needed to address the issues raised by Mr. Gonsalves in his presentation. “We have practical questions about giving drugs to kids, and those

kinds of questions need their own trials.” Mr. Gonsalves agreed, but said that interest in this kind of research is limited. One speaker cautioned against confusing clinical research and OR, stating that OR has to do with program implementation issues. Others noted that OR is sometimes equated incorrectly with program evaluation.

Much of the advanced expertise in OR is found in business schools, companies and the military, one speaker said. These are the types of organizations that have extensive experience applying the lessons of OR. The speaker argued that the public health sector has not made sufficient use of OR and that to maximize the use of this research we need to look outside of public health institutions.

¹. Institute of Medicine, Scaling Up Treatment for the Global AIDS Pandemic: Challenges and Opportunities, National Academies Press, Washington, D.C., 2005

There is a natural bias in OR, one speaker said, because people working on the ground do not have an incentive to reveal implementation problems. As a result, in promoting OR we need to make it easier for people to come forward with problems they experience in delivery AIDS-related services.

Setting the research agenda

The OR agenda must be set at the country level and “not directed completely from Geneva,” according to one speaker. Countries may need more support, however, if they are to take the lead on setting their own research agendas.

Another person raised the concern that it is sometimes difficult for groups not aligned with their national government to get funding for their research proposals. He said funders need to consider funding research which is not supported by government authorities because it might produce results not favorable to government-sponsored programs. One panelist agreed, saying that was why donors need to be able to fund independent analyses of service delivery. Dr. Schwartlander said that it is important that national-level planning involves all stakeholders, and that the international community appreciates its important role in empowering broad stakeholder involvement at the national level.

Developing common tools

Several people spoke to the need for the development of standardized tools and methodologies in OR. It was acknowledged this will be a challenge given that the scope of OR and the central issues in treatment delivery differ from setting to setting. One speaker said a priority should be to develop systems to systematically compile information and improve knowledge management once OR results are in. Another person raised a concern about the effect of new bilateral trade agreements and their potential negative impact on sharing of data.

Monitoring the monitor

One speaker said OR should study the multiple systems involved in management the AIDS response, including Global Fund Country Coordinating Mechanisms and the monitoring and evaluation agencies themselves. A panelist agreed that “monitoring the monitor” should be key component of the OR agenda.

Expanding support for OR

Funding agencies must provide more resources for OR and encourage grantees to propose their own OR studies, according to several speakers. Dr. Gayle agreed that not enough resources have been dedicated to OR. Dr. Schwartlander said the Global Fund is committed to expanding OR. “We need to have the platforms available,” he said, “so we are not always recreating how OR is done, and we need to be able to make real time corrections in how it is done”.

Mr. Gonsalves said he thought the burden of paying for OR should be on agencies with the greatest resources, such as the US Government. Another person said that, “donors have the power to say what they want,” and should be asking for more OR, and then broader application of OR findings. She suggested that “South to South” cooperation is one way to address the significant language barriers that exist between researchers and funders in the North and providers and researchers in the South.

One member of the audience from Africa commented that, “evidence-based decision making is key...every funder should realize that without it we won’t make a lot of headway on the challenge of AIDS”.

Next Steps

There was universal support at the conference session for expanded use of OR in the scale up of AIDS-related services. Several next steps are suggested by comments and presentations at the session:

* Improve collaboration among programs: WHO, the Global Fund, several national AIDS programs, and other agencies are engaged in OR on AIDS service scale up, but these studies are not coordinated and there is no comprehensive plan to standardize research questions or share lessons learned. WHO, UNAIDS, the Global Fund or another agency should sponsor a consultation of major funders, provider agencies, researchers and community stakeholders in order to facilitate coordination of the OR agenda, discuss research methods, and ensure dissemination and application of research results.

* Define OR: Policy makers, providers and others involved in the response to AIDS need to have a clearer sense of what OR is, how it can be used to improve service delivery, and how it is distinguished from applied clinical research and monitoring and evaluation programs. The consultation recommended above should develop a consensus definition of OR and identify key players in the funding, coordination, and information dissemination of this research.

* Significantly expand resources: There is a clear and immediate need for additional resources to support OR as AIDS services are scaled up. Funders should provide increased resources for OR and encourage grantees to propose research studies. Funders should also ensure that grantees develop strategies to utilize results of OR.

* Strengthen links to policy: Several speakers at the session identified the importance of more closely linking research results to policy making and program design. Attendees at the consultation recommended above should identify models and develop guidelines to promote knowledge management of OR findings and application of OR results in service delivery and policy making.

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