3 million by 5 2005

Expanding Access to HIV/AIDS Treatment

Operational Research to Scale up Antiretroviral Treatment in the South-East Asia Region

World Health Organization
Regional Office for South-East Asia
New Delhi
2004

SEA–AIDS–148
Distr..: General

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Operational Research to Scale up Antiretroviral Treatment in the South-East Asia Region

Report of an Informal Consultation
New Delhi, 1-3 September 2004

World Health Organization
Regional Office for South-East Asia
New Delhi
2004

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Printed in India

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1. Background

In the South-East Asia Region (SEAR), nearly 900 000 people living with HIV/AIDS (PHAs) urgently need antiretroviral treatment (ART) but barely 7% of them are receiving it. Four countries, namely India, Indonesia, Myanmar and Thailand account for an overwhelming majority of the antiretroviral treatment gap.

Following the announcement of the "3 by 5" initiative (i.e. to provide ART to three million by 2005 to those who need it the most), important beginnings have been made in Member States of the SEA Region to scale-up ART programmes. Thailand which began large-scale ART programme in 2000 is on its way to provide universal access to treatment by 2005. A free ART programme by the Government of India was launched in April 2004 and plans for phased scale-up have been prepared. In Indonesia and Myanmar, there is high political and administrative commitment to start ART, and plans are being prepared for the ART scale-up.

To date, evidence about the success of HIV/AIDS treatment is available mostly from industrialized countries and more recently from Brazil, Thailand and some sites in Africa. In South-East Asia, a nearly 10-fold scale-up is required to close the treatment gap. However, the evidence base on how to scale up is unavailable. The urgency for closing the treatment gap calls for a "learning by doing" approach.

In November 2003, national AIDS programme managers of Member States of the SEA Region met in New Delhi and endorsed a five-pronged strategic framework for ART scale-up in the Region. Monitoring, evaluation and operational research were listed as one of the five elements of this strategic framework. As a follow-up to the

recommendations of this meeting and to promote evidence-based approach to scaling up ART, an informal intercountry consultation on operational research for scaling up ART was organized at SEARO, New Delhi, from 1 to 3 September 2004 with the following objectives:

(i) To identify current gaps in knowledge for scaling up ART programmes by review and exchange of available information;

(ii) To identify key programmatic constraints and, correspondingly, research priorities for scaling up ART programmes; and

(iii) To discuss the process of taking the research agenda forward and to identify next steps for implementation at the country level.

2. Research Priorities

Expanding ART programmes poses an immense challenge to the host countries. As ART programmes are accelerated, several questions are likely to emerge–Is the programme working? How can we make it work more efficiently? What can we do to increase access, especially to vulnerable groups? Is the health sector burdened or strengthened by treatment activities? Prioritizing research questions is an important first step towards generating relevant strategic information for guiding ART scale-up.

For the purpose of the consultation, research questions were discussed under four broad categories:

(i) socio-behavioural research addressing issues related with improving access to treatment and long-term treatment adherence, and reducing risky behaviours;

(ii) strengthening health systems dealing with human and financial resources and quality of services;

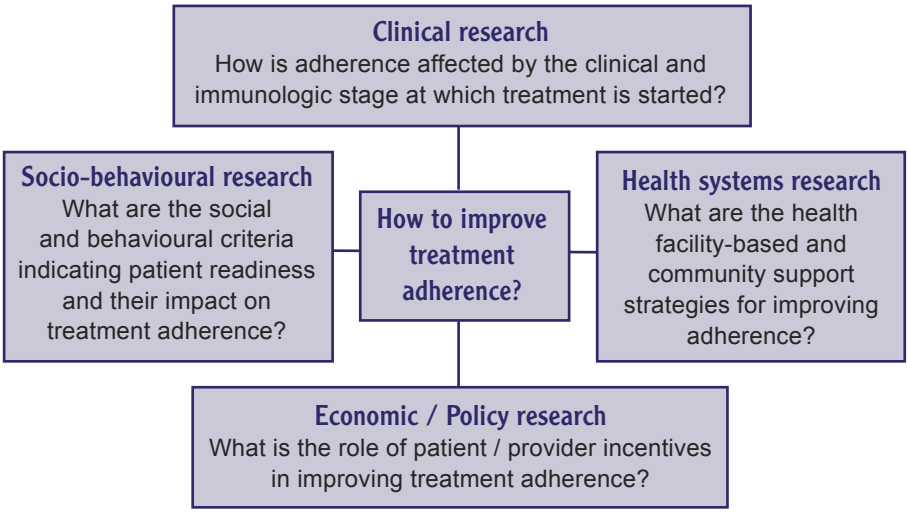
(iii) clinical and laboratory research; and

(iv) health policy and economic research questions addressing macro-level and policy issues of ART delivery. However, research themes cannot be restricted to the above distinct categories but are interconnected. This is illustrated in the figure below using treatment adherence as an example.

Guiding principles for research

- **Relevance:** Top priority should be given to research that is practical and relevant and feeds directly into programme scale-up.
- **Urgency:** Closing the treatment gap is an emergency and correspondingly, the urgency to initiate research and disseminate the use of the new knowledge generated for better design and implementation of ART programmes is of paramount importance.
- **Phased approach:** It is practical to start with small research studies at a few sites, which could then lead to a process of peer learning and a phased extension to other sites.
- **Flexibility:** Research needs at national and local levels should be examined periodically and the research agenda revised accordingly to reflect the changing programmatic requirements.
- **Use of existing sources of information:** There is a need to fully utilize existing sources of information, such as data generated from routine monitoring and evaluation (M&E). M&E data can help in flagging problem areas which can be examined in depth through well-designed research studies.
- **Quick dissemination of information:** Information generated and lessons learned from research studies should be quickly fed back into policy and practice.

An example to illustrate that research themes cut across disciplines



Key research questions that emerged from the discussions are listed below:

2.1 Socio-behavioural Research

Improving the equity and access to care, particularly for vulnerable populations

- What is the socioeconomic profile of patients accessing ART?
- What are the essential criteria for selection of patients and are these applied appropriately at the local level?
- With existing criteria, is treatment accessible to the most vulnerable population sub-groups (e.g. short-term labour, ethnic groups, women, the poor, sex workers, drug users)?
- Why are some vulnerable groups not accessing the programme? What are the barriers within the system that affect access of such groups to ART? Are the health providers sensitive to the needs of such vulnerable groups?
- What is the current demand for ART? What are the health-care seeking behaviours of different population groups?
- To what extent does stigma affect the access to treatment?

Improving adherence to treatment

- What are the determinants of treatment adherence? What strategies are in place to support adherence?
- Does directly-observed treatment improve treatment adherence?
- What are the determinants of acceptance and adherence to ART in the prevention of mother-to-child-transmission programme?
- What is the extent of treatment compliance and barriers to adherence among drug users?
- What is the role of peer support groups and NGOs to support treatment adherence in specific groups, such as transportation workers and drug users?

- What is the impact of patient-provider interactions on treatment adherence?
- What are the effective counselling messages and strategies used to increase adherence?
- What strategies are available at health facilities to support adherence? Are patients aware of the support for adherence?
- What role does disclosure play in establishing positive/negative support for adherence?
- What is the role of family support in increasing adherence? What kind of support does the family require?
- How to measure and standardize adherence and improve patient/health-care worker reporting of adherence?

Reducing risky behaviours among patients on ART

- What are patients' attitudes towards ART?
- What are the short- and long-term effects of treatment on sexual practices (frequency, partner types, and condom use)?
- What is patients' understanding of the effect of ART on HIV transmission?

2.2 Health Systems Research

- What are the resources needed to deliver ART?
- What are the entry points for patients to the ART programme?
- What is the current infrastructure available to deliver ART?
- What are the human resources and capacity at ART delivery points?
- How well is the ART programme integrated within the health-care delivery system?
- What are the perceptions of health care workers about stigma and discrimination?

- What is the essential package of services necessary for delivering ART at various levels within the health systems, i.e. primary, secondary and tertiary?

- What is the proportion of patients receiving ART in the private sector? How can we improve referral and networking with the private sector?

- What is the quality of services from patient and provider perspectives?

2.3 Clinical and Laboratory Research

- What is the impact on adherence, morbidity and survival of using different clinical and immunologic criteria that are appropriate at primary, secondary and tertiary levels of health care?

- What clinical and/or immunologic criteria can be used to diagnose treatment failure?

- Are there cheaper and simpler diagnostic tests for opportunistic infections?

- Are there cheaper and simpler diagnostic tests for monitoring HIV disease progression?

- What is the impact of single-dose nevirapine administration used for prevention of mother-to- child transmission on the future therapeutic options for mothers and babies?

- What are the effective approaches used to diagnose TB in HIV-infected children?

- Can we use nevirapine-based ART in intermittent tuberculosis treatment?

- What is the pattern of ARV drug resistance by geographical location, age groups, and gender and population sub-groups?

2.4 Economic and Policy Research

- What is the feasibility, costing and cost-effectiveness of different models of ART delivery?

- How are the ongoing free/subsidized ART programmes being implemented at different sites?
- How much are patients of different socioeconomic strata paying for ART?
- What are the alternative mechanisms for financing of ART, e.g. out-of-pocket expenses, insurance?
- What are the principles for subsidizing ART for all patients?

3. Taking the Research Agenda Forward

Given the pressing need for strategic information to guide ART scale-up, clear processes need to be outlined for the implementation of the research agenda. While conventional methods remain necessary to generate strategic information for scale-up, new and innovative techniques are required to fulfil the immediate information needs of the programme.

The key processes for implementing research activities in the context of "3 by 5" are listed below:

3.1. Ownership and Leadership for Research

Research should be an integral part of the framework of national plans for scaling up ART. The ownership of the research agenda and findings must remain with the national AIDS programmes. With the involvement of key stakeholders, the national programmes should provide leadership in prioritizing and endorsing a research agenda based on country needs and availability of funds. This will create an environment where relevant research is undertaken and the research findings are translated into policy and programme practices.

3.2. Partnerships

Partnerships are required at multiple levels – international, national and local. At the international level, donors, technical agencies and national programme managers can help build a facilitating environment for research. At the national level, partnerships between implementing bodies and research councils should help in developing, monitoring and using the research findings for ART scale-up. At local ART sites, programme managers could link up with research institutes, medical colleges, NGOs and PHA groups to identify, prioritize and operationalize research agenda. PHAs can play a role not only as subjects of the study

but also as stakeholders. There is a need to involve them in the process of design, implementation and use of research findings.

3.3 Development of Research Protocols and Tools

Short-term and medium-term approaches may be used to develop research protocols and tools. A rapid situational analysis may be undertaken at sites where ART is ongoing with involvement of programme managers and partner research institutes. Using a participatory approach, protocols and tools can be developed that address local operational research questions. Such situational analysis can be conducted at a few sites and then expanded with revised tools based on the lessons learned. In parallel, for the medium-term, other approaches to protocol development can be undertaken, such as inviting research proposals and subjecting them to technical peer review and commissioning research protocols developed by expert groups and shared with the countries and adapted by them.

3.4 Capacity-building

Research capacity in Member States is limited. Participation of the local ART programme managers in development of research protocols and tools, data collection, analysis and documentation will contribute to increasing the capacity for research over time. It would be useful to identify existing institutions, NGOs and other agencies with research capacity and strengthen them so that they can provide technical assistance and mentorship to ART sites.

3.5 Knowledge Management

The findings of research need to be communicated without delay. A plan for dissemination of findings should be part of research plans. Mechanisms should be in place for setting up research studies and incorporating feedback into policy and programme practices. Innovative mechanisms should be developed for knowledge management and sharing with key stakeholders.

3.6 Funding for Research

There is a need to identify and mobilize funds for undertaking research. There is also a need to ensure that fund allocation is decentralized to avoid bottlenecks in research implementation, and to help local

programmes and partner research organizations to access these funds easily so as to undertake research.

3.7 Monitoring Progress in Research

It is important to track how research activities are guiding ART scale-up. The key indicators that may be developed to monitor progress in research include the following:

- Is there a national research agenda?
- How many research studies have been initiated?
- How many conferences have been organized or papers published to disseminate research findings?
- Are there examples of changes in policy and programme practice from research findings?

4. Summary and Next Steps

An informal consultation to discuss research priorities for scaling up ART programmes, held at SEARO, New Delhi from 1-3 September 2004, underscored the need and urgency to undertake priority research to guide ART scale-up and suggested the following next steps:

(A) Member States to:

- Promote operational research as an integral component to guide the scale-up of ART;
- Institute a national research committee to guide and monitor ART activities;
- Involve key stakeholders to develop and endorse a national research agenda;
- Identify local ART research priorities; allocate and decentralize funds to local research sites;
- Undertake situational analysis at selected ART sites to understand how the programme is functioning at different ART sites; and
- Develop mechanisms to quickly incorporate research findings into policies and programme practices.

(B) WHO to:

- Provide leadership and build an environment to promote the national ART research agenda;
- Facilitate coordination among stakeholders to plan and develop research protocols, data collection tools, analysis and documentation of operational research findings;

- Provide technical expertise and mentorship to ART sites to ensure that high quality research can be integrated into the scale-up process;

- Facilitate knowledge management and sharing of information through periodic meetings, conferences and other mechanisms; and

- Monitor the quality and progress of ART research in Member States.

Annex 1
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Annex 2
Programme

Day 1: Wednesday, 1 September 2004

08:30-09:00	Registration	
09:00-09:15	Welcome and opening remarks Objectives of the meeting Introduction of participants	*Dr Jai P. Narain*, Ag. Director Communicable Diseases WHO/SEARO
09:15-09:45	Operational research to scale-up treatment and accelerate prevention: Learning by doing, and highlights of an expert consultation Discussion	*Dr Carla Makhlouf Obermeyer* Strategic Information and Research Unit Department of HIV WHO Geneva
09:45-10:00	Scaling up ART in Thailand: Lessons learned	*Dr Sanchai Chasombot* Bureau of AIDS, TB & STIs Ministry of Public Health Thailand
10:00-10:15	Discussion	
10:15-10:30	Tea/Coffee Break	
10:30:10:45	Clinical and laboratory research needs for scaling-up ART in South-East Asia	*Dr R Gangakhedkar* Asst. Director National AIDS Research Institute Pune, India
10:45-11:00	Discussion	
11:00-11:15	Paediatric Antiretroviral Therapy: operational problems and research needs	*Dr Soumya Swaminathan* Deputy Director (HIV/TB) Tuberculosis Research Centre Chennai, India
11:15-11:30	Discussion	
11:30-11:45	Key issues in socio-behavioral research for scaling up antiretroviral therapy in South-East Asia	*Dr Virginia Loo* Epidemiologist Gates Foundation
11:45-12:00	Discussion	

12:00-12:15	Socio-behavioural research priorities to scale up ART with a focus on treatment adherence and risk behaviour	*Dr Avina Sarna* Global Coordinator Treatment Care & Support Population Council India
12:15-12:45	Discussion	
12:45-13:45	Lunch	

Operational research for improving health systems response to ART scale-up

13:45-14:00	Early experiences of implementing ART in a tertiary-care health care facility in Mumbai, India	*Dr Alka Gogate* Project Director Mumbai District AIDS Control Society
14:00-14:15	Discussion	
14:15-14:30	Planning for scaling up ART in Myanmar: building on lessons from the Waibagi pilot project, Myanmar	*Dr Htin Aung Saw* National AIDS Programme Waibagi Hospital Myanmar
14:30-14:45	Discussion	
14:45-15:00	Building partnerships for delivering ART to injecting drug users in Indonesia	*Dr Sudharto Ronoatmodjo* Faculty Member Dept. of Epidemiology University of Indonesia
15:00-15:15	Discussion	
15:15-15:30	Increasing co-ordination between DOTS and ART programmes	*Dr Rajasekharan Sikhamani* Deputy Director Govt. Hospital of Thoracic Medicine Tambaram
15:30-15:45	Discussion	
15.45-16.00	Public-private partnerships in scaling up antiretroviral treatment—Results of a study in Pune, India	*Dr Sheela Rangan* Scientist MAAS Pune, India
16.00-16.15	Discussion	
16:15-16:30	Key issues in health policy and economic research on ART	*Dr Indrani Gupta* Associate Professor Institute of Economic Growth India
16:30-16:45	Discussion	
16.45-17.00	Using data from routine Monitoring and Evaluation to guide ART Scale-up	*Dr Renu Garg* Epidemiologist HIV/AIDS WHO/SEARO
17.00-17.15	Discussion	
17:30-19:00	Reception	

Day 2: Thursday, 2 September 2004

09:00-09:30	Synthesis of operational issues, available evidence and research gaps	*Mr. Steve Morris* Medical Intern WHO/SEARO
09:30-12:30	Constitution of Working Groups (WG) to identify national research priorities	
	WG-1 Clinical and laboratory research	Group work
	WG-2 – Key research issues individual and community level factors in research	Group work
	WG-3 – Health systems research	
	WG-4 – Research on policy and economic aspects of ART scale-up	
12:30-13:30	Lunch	
13.30-14:30	Presentation by working groups on research priorities Discussion	Presentation by group representatives
14:30-16:30	Taking the research agenda forward Brain storming on the process of implementation of operational research	Discussion

Day 3: Friday, 3 September 2004

09:30-12:30 Discussion on the process of taking the research agenda forward

- Development of research protocols
- Capacity building in research
- Collaboration between programme managers, researchers and donors
- Dissemination of research findings
- Monitoring research quality
- Ethical issues in research
- Identification of next steps to implement priority research agenda
  - at country level
  - at regional/international level
- Summary and Recommendations

Closing

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