

***Report and Recommendations of HIVResNet Steering Committee Meeting
Geneva, 4-5 November 2008***

This document serves as a report and summary of recommendations from the HIVResNet Steering Committee Meeting, which took place on 4-5 November 2008 in Geneva, Switzerland. For reference, the agenda and list of participants for this meeting are attached. The presentations are available from WHO upon request.

The Steering Committee of HIV ResNet considers that the programme meets an essential need and should be further strengthened. A synopsis of recommendations to WHO and potential donors, including the current major donor, i.e. the Gates Foundation, is as follows:

The Committee considers that the progress achieved to date does indeed meet the milestones established by the Gates Foundation. However, there is a need for greater feedback to interested parties and participants and dissemination of available information to guide programmatic decisions e.g. to the local Drug Resistance working groups and Ministries of Health. [\[communication\]](#)

In addition, it is recommended that WHO:

- a. Intensify the focus on drug resistance (DR) issues in paediatric populations [\[paediatric\]](#)
- b. place more emphasis on the issue of resistance among treated patients [\[survey implementation\]](#)
- c. Establish greater clarity on how various activities are prioritized [\[communication\]](#)

It was also suggested that HIV ResNet should maintain its focus on high prevalence countries, but also try to develop a toolkit (by forming a writing group with selected partners) in different national/local languages to provide basic information on HIV drug resistance. [\[communication\]](#) For low prevalence countries, the focus should be on monitoring of EWIs instead of embarking on monitoring or threshold surveys, due to difficulties in reaching the required sample size. [\[survey implementation\]](#)

Efforts should also be made to consider more cost-effective options for drug resistance assays for Regional/National labs to serve antiretroviral treatment (ART) programmes in developing countries. [\[laboratory\]](#)

It was also felt that efforts be made to improve communication on and understanding of aspects of the strategy. Incentives that could be considered include:

- fast track approval at the country level (e.g. of protocols for monitoring surveys) [\[survey implementation\]](#)
- involvement in existing protocols [\[survey implementation\]](#)
- potential publications [\[communication\]](#)

A statement from a high level of WHO on human subjects issues could help to expedite approval of HIV DR strategy protocols. [\[communication\]](#)

In regard to pediatric issues, it was felt that WHO should advocate for and provide guidance for use of dried blood spots (DBS) in pediatric surveys. [\[laboratory\]](#) Efforts should also be made to address the issue for children who are infected through breast feeding. Monitoring surveys for children should follow the same protocols as for adults. [\[paediatric\]](#)

Research into alternative genotyping assays should be encouraged and might focus on a small number of target mutations to be analyzed by real-time PCR in comparison with population sequence genotyping. The use of DBS should be fully validated and efforts should be made to make resistance genotyping cheaper. A better understanding of subtype sequence variability in regard to detection of drug resistance mutations using such methods is also urgently needed. [\[laboratory\]](#)

Other recommendations are that WHO use countries that have already implemented the strategy to assist other countries that are planning to start (e.g. sharing documents and experience). [\[survey implementation\]](#) There should be a focus on providing support to labs in regions that are under-served [\[laboratory\]](#), accompanied by advocacy from WHO to encourage partners to integrate early warning indicators into routine monitoring. [\[survey implementation\]](#) Adherence should be added as an assessment element to the strategy. [\[survey implementation\]](#) There should be provision of finalized translated documents (French, Portuguese, Chinese, Arabic, Russian, Spanish) on the WHO website. [\[communication\]](#)

Well-resourced countries should co-operate with WHO and submit novel data on cost and technical improvements in regard to resistance testing to WHO. [\[laboratory\]](#)

WHO should also consider accrediting diagnostic/commercial labs as appropriate in some settings and should identify key HIV operational research questions. There should be efforts to link clinical, epidemiological and laboratory personnel in order to properly implement surveys. [\[laboratory, survey implementation\]](#)

The use of mathematical modeling may be useful in determinations of when transmitted resistance may be first likely to appear and for assessments of the durability of first-and second-line regimens in different settings. Efforts should be made to better understand the impact of HIVDR on viral genetic diversity as well as on prevention efforts. An important subject is whether DR will develop as a consequence of pre-exposure prophylaxis and whether this will potentially result in more transmitted resistance. [\[epidemiology\]](#)

Finally, annual country reports should be 5 pages or less. Community and other advocacy groups should be included in WHO-decision-making. [\[communication\]](#)

The Committee reemphasizes the importance of drug resistance surveillance and monitoring in developing countries, in light of the fact that both secondary drug resistance and transmitted drug resistance will be inevitable consequences of the use of anti-retroviral drugs (ARVs) and ARV roll-out programmes. We consider that the HIVResNET efforts are well-conceived in regard to both programme elements and protocols, and that these efforts constitute an essential component of the WHO response to the HIV epidemic. We believe that donor countries and agencies that are commonly involved in ARV roll-out programmes should also recognize the importance and essential nature of HIVResNET efforts. They should accordingly accompany their support for purchase and distribution of ARVs by also directly helping to support WHO programmes such as HIVResNET aimed at monitoring the problem of drug resistance. [\[survey implementation\]](#)

We believe that WHO efforts should not be restricted by limitations or milestones that have been put into place under the conditions of the grant from the Gates Foundation. Rather, there needs to be a realization that WHO efforts in the field of drug resistance surveillance must,

by definition, be an expanding effort that also involves the need to build capacity in developing countries so as to enable scientists and clinicians in such settings to feel directly invested in these efforts and to participate fully in them. We also believe that data that are generated within developing country settings must be quickly disseminated in the scientific literature through presentations at conferences, publications in scientific journals, etc.

[communication] Local Ministry of Health Officials should be encouraged to facilitate these efforts by working together with WHO and other organizations within HIVResNET that will be able to provide important guidance in this regard. We also believe that the use of a newsletter to promote HIVResNET activities should be expanded as should the use of reports that emanate from the WHO and that will inevitably impact on the use of ARVs.

[communication] In short, it is clear that the use of ARVs in developing country settings must be judicious as well as broad scale and that availability of ARVs in every jurisdiction in the world must be accompanied by establishment of programmes that are able to effectively monitor for the presence of drug resistance.

An efficient WHO HIVResNET programme will inevitably need to accelerate the standardization of cost-effective genotyping assays throughout the developing world as well as accelerate the use and validation of such methods as use of dried blood spots for resistance testing. [laboratory] WHO will also need to accelerate its efforts aimed at laboratory accreditation, quality assurance through proficiency testing, and capacity building in developing country settings. [laboratory] It is clear that both donor countries and Foundations must be prepared to contribute to these efforts as an essential component of providing ARVs to HIV-infected individuals in developing country settings.

We call on WHO to take urgent measures to alert donor countries and donor agencies as to their responsibilities in the areas outlined above. We also call on donor countries and donor agencies to provide suitable additional funding to WHO in order to enable the progress that has already been accomplished to be accelerated and consolidated.

Respectfully submitted,

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