






Global Action Plan on HIV Drug Resistance:

Response to comments & modifications

12-13 December 2016



Strategic Objectives

	1. PREVENTION AND RESPONSE	<ul style="list-style-type: none">• Use all available evidence in a timely manner to inform public health actions to prevent and control HIVDR.
	2. STRENGTHEN SURVEILLANCE AND ROUTINE PROGRAMME DATA	<ul style="list-style-type: none">• Obtain quality data from periodic HIVDR surveys while expanding the coverage and quality of routine VL and HIVDR testing to inform continuous HIVDR surveillance;• Monitor quality of service delivery and collect and analyze data recorded as part of routine patient care for the purpose of evaluating programme performance to prevent HIVDR.
	3. RESEARCH	<ul style="list-style-type: none">• Encourage relevant and innovative research leading to interventions which will have the greatest public health impact in minimizing HIVDR;• Fill existing knowledge gaps on the risk of HIVDR for newer antiretroviral drugs and the impact of service delivery interventions to increase viral load suppression and contain HIVDR.
	4. LABORATORY CAPACITY	<ul style="list-style-type: none">• Strengthen laboratory capacity and quality to support and expand use of viral load and resistance testing in low- and middle-income countries
	5. GOVERNANCE AND ENABLING MECHANISMS	<ul style="list-style-type: none">• Ensure that enabling mechanisms (awareness/advocacy, country ownership, coordinated action and sustainable funding) are in place to support action on HIVDR

STRATEGIC OBJECTIVES UP CLOSE





SO1. Prevention and response

1. Response

Use all available evidence in a timely manner to inform ART programme and public health actions

- Use all available evidence in a timely manner to **inform public health actions to prevent and control HIVDR.**



SO1. Consultation feedback

- **Rename SO to 'Prevention and Response'**
- **Need for greater focus on actions to address the drivers of HIVDR and preventing HIVDR**
 - Adherence and retention
 - Stigma reduction
 - Implement treat all and service delivery models
 - Importance of appropriate treatment regimens, including for children and 2nd/3rd line.
 - To eliminate drug stock outs and commodities (VL)
 - Training of healthcare workers



SO1. Consultation feedback

- **Clearly distinguish between surveillance activities and responding to levels of HIVDR**
- **Response actions**
 - PDR/ADR surveillance activities and EWI monitoring
 - WHO recommendations to guide response
 - Timely sharing of HIVDR at national, regional and global level
 - Real time database accessible to countries (in addition to biennial reports)



SO1: Action framework

Prevention		
Actions for countries	Actions for national and global partners	Actions for WHO
Regularly monitor EWI and use them at clinic and programme level to make adjustments where needed to minimize HIVDR.	Encourage countries to conduct regular monitoring of EWI using existing M&E systems	Encourage countries to conduct regular monitoring of EWI using existing M&E systems
Ensure national HIV guideline recommend appropriate ART regimens	Support timely switch of individuals failing ART to second and third line	Ensure normative guidance on the use of ARVs for prevention and treatment incorporates emerging evidence on HIVDR, new drug classes and service delivery approaches
Eliminate drug stock outs to ensure continuous supply of ARVs	Support country initiatives to characterize effective practices and their scale up	Develop a clear structured approach to prevention of HIVDR
Adopt service delivery models to support retention and adherence	Ensure adequate resources are allocated to strengthen the quality of care provide for people living with HIV on ART	
Implement interventions to address stigma and discrimination		



SO1: Action framework

Response		
Actions for countries	Actions for national and global partners	Actions for WHO
Ensure timely reporting of HIVDR data to inform national and global public health actions	Encourage countries to triangulate data from surveillance, programme data and research to inform decision making	Regularly report global and national levels of HIVDR
Triangulate data from surveillance, programme data and research to inform decision-making		Develop a decision framework for countries to respond to HIVDR
Ensure health care worker and laboratory staff are trained to prevent, monitor and respond to HIVDR		



SO1: HIVDR prevention and response

WHO's Guidelines on HIVDR management

- 1) What level of pre-treatment NNRTI resistance in a country should trigger a public health action?
 - 10%? 15%?

- 2) What is the most appropriate public health action?
 - HIVDR testing for all patients starting ART ?
 - Moving away from NNRTI-based first line ART and using a non –NNRTI based first line ART?
 - Review of evidence through Grade Process
 - CE analysis
 - Expert opinion (for the threshold)



SO2. STRENGTHEN SURVEILLANCE AND ROUTINE PROGRAMME DATA

- Obtain quality data from **periodic HIVDR surveys** while expanding the coverage and quality of routine VL and HIVDR testing to inform **continuous HIVDR surveillance**;
- **Monitor quality of service delivery** and collect and analyze data recorded as part of routine patient care for the purpose of evaluating programme performance to prevent HIVDR.

WHO's recommendations for HIVDR Surveillance and monitoring of routine programme data



WHO HIVDR surveillance recommendations for each UNAIDS fast-track country:

Early Warning Indicators

Annual monitoring at all ART clinics

PDR – adults starting first-line ART

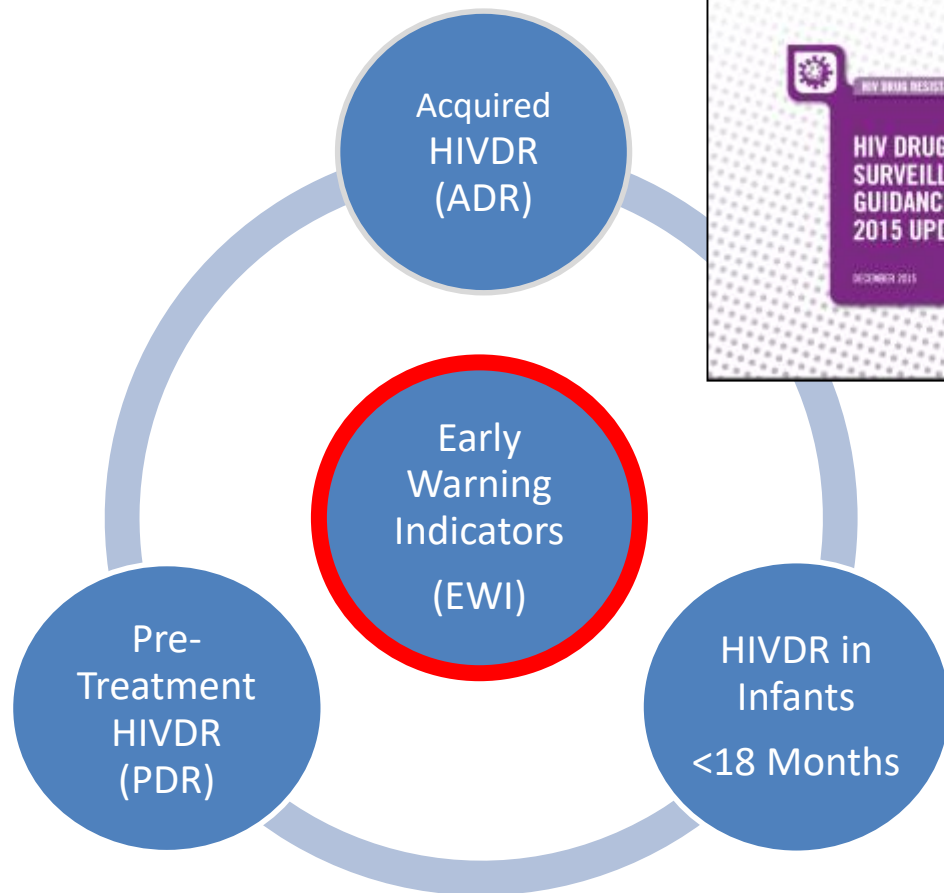
Routine surveillance, every 3 years

ADR – adults and children on treatment

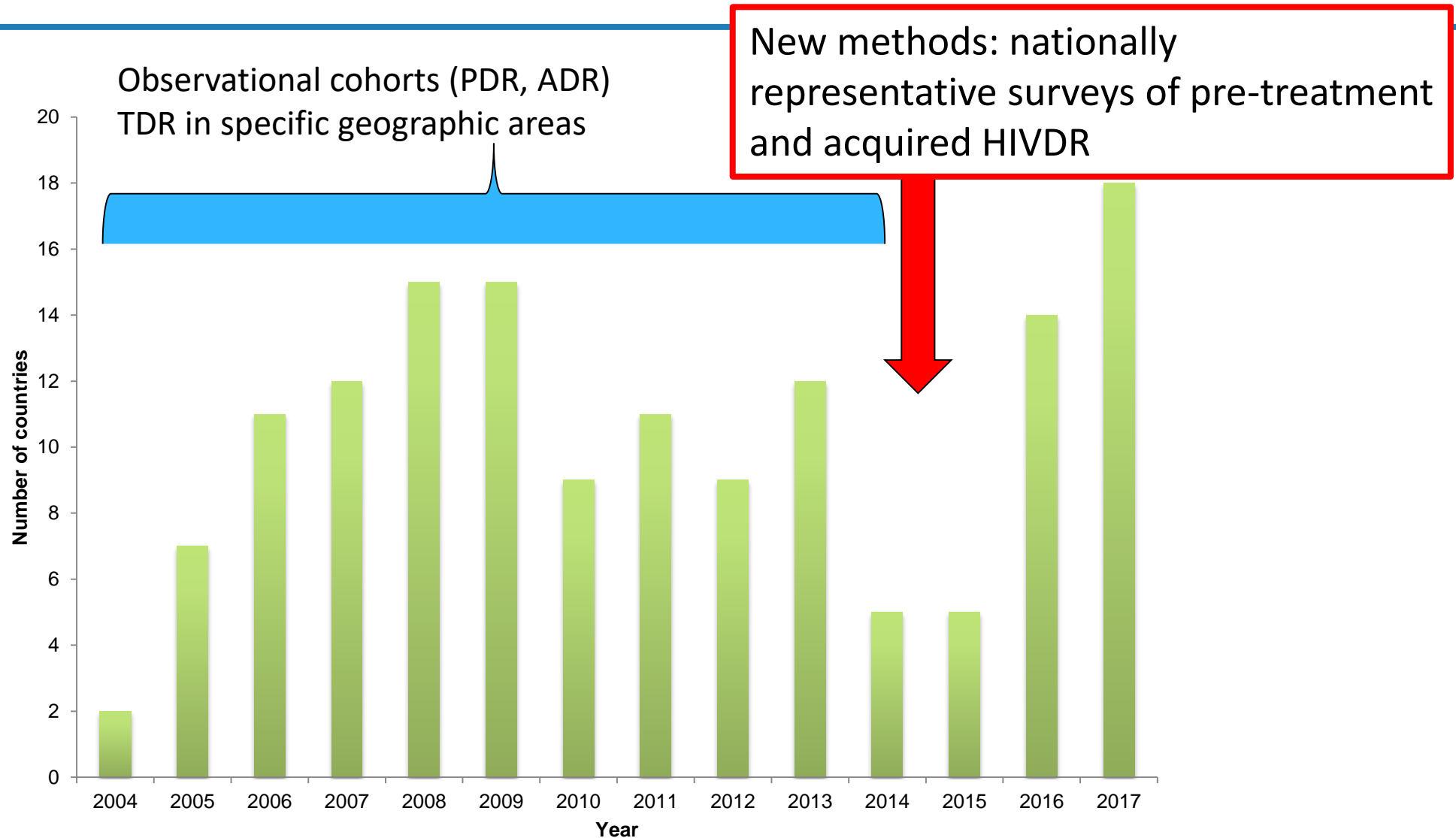
Routine surveillance, every 3 years

HIVDR in Infants less than 18 months

Surveillance at least once between 2017 and 2021



Number of countries implementing HIVDR surveys (2004-2016)



Toward using routine VL and HIVDR programme data

Routine HIVDR testing in LMIC, December 2015

At ART start



1st line failure





SO2. Consultation feedback

- Expand the focus to **include monitoring of service delivery (EWI + other quality of care indicators) and develop framework to move towards use of VL/DR programme data**
- Consideration of **monitoring HIVDR in vulnerable populations** (pregnant women, post-delivery women, children, adolescents) and key populations (IDUs, MSM, sex workers, prisoners)
- Actions to support disaggregation of **routine programme data to inform national ART guidance and programme response**
- Provide technical support to countries to ensure quality of data
- Link surveillance results to programmatic actions
- **Monitor HIVDR emerging from PrEP scale up and from introduction of DTG** (including HIVDR to DTG-backbone)

Actions for countries	Actions for Global and National Partners	Action for Civil society	Action for WHO
<p>Regularly monitor levels of HIVDR following a standardized approach and validation methods.</p> <p>Promptly disseminate HIVDR results</p>	<p>Ensure that HIVDR monitoring and programme evaluation are regularly funded</p>	<p>Advocate for HIVDR surveys, monitoring of quality of care indicators, and expanded coverage of VL & HIVDR testing</p>	<p>Develop guidelines for HIVDR surveillance (periodic and continuous); periodically review recommended methods based on new evidence and lessons learned from implementation.</p>
<p>Monitor the quality of service delivery through the collection of a subset of internationally agreed indicators that are highly predictive of HIVDR (EWI for HIVDR). Collect EWI through available M&E systems using routine programmatic data.</p>	<p>Ensure HIVDR surveys are a core component of the ART programme; and that MoH are driving monitoring of HIVDR. Strengthen quality of programme data</p>		<p>Set the standard and develop a framework to assess the use of routine VL and HIVDR programme data to inform national HIVDR prevalence and trends and support programme decision-making.</p>
<p>Perform quality assessment of available routine VL and HIVDR programme data</p>	<p>Streamline data sharing</p>		<p>Include assessment of DLG-based ART when rolled out and HIVDR emerging as a consequence of new interventions (PrEP).</p>
<p>Establish mechanisms to link programme VL and HIVDR data to epi & clinical data</p> <p>Disaggregate routine HIVDR programme data by age groups and by subpopulations or key populations where feasible.</p>	<p>Streamline implementing partners' scientific and ethical review</p>		<p>Strengthen national and global repository of HIVDR surveillance data to support national and high-level global health recommendations; Regularly report global and regional levels of HIVDR and trends</p>



SO3. RESEARCH

3. Research and strengthened programme data

Strengthen programme data and encourage relevant and innovative research leading to greatest impact; fill the gaps in knowledge on risk of HIVDR for newer molecules and impact of service delivery interventions on viral load suppression and HIVDR

- Encourage **relevant and innovative research** leading to interventions which will have the greatest public health impact in minimizing HIVDR;
- **Fill existing knowledge gaps** on the risk of HIVDR for newer antiretroviral drugs and the impact of service delivery interventions to increase viral load suppression and contain HIVDR.



SO3. Consultation feedback

- Create **distinct strategic objective for research** (remove strengthen programmatic data)
- Develop **priority research agenda for HIVDR** as an action
- **Reinforce importance of research;**
 - developing innovative approaches to VL and HIVDR testing
 - POC VL testing
 - HIVDR at second line failure to inform third-line regimens
 - Operational research on community engagement
 - Trans disciplinary research to avoid development of drug resistance
 - Cost effectiveness studies can support advocacy
 - Research on techniques to capture data



SO3: Action framework

Actions for countries	Actions for global and national partners	Actions for WHO
Encourage researchers to prioritize and address research questions of public health importance to the local context.	Prioritise support for research questions with public health importance including assessment of impact of service delivery interventions	Drive the global discussion on the research agenda for HIVDR including research prioritization.
Collate all country level HIVDR research in national repository	Invest in basic science research to answer evolving questions in HIVDR including new diagnostics for HIVDR testing at the point of care.	
	Promptly report research data	

Actions for the research community
Conduct implementation science research, including cost effectiveness of service delivery approaches to prevent and minimize HIVDR
Conduct research to develop affordable, user friendly approaches for HIVDR testing at the point of care.
Evaluate the use of alternative regimens for first-, second- and third line failure
Develop mathematical models to determine which public health actions are optimal at different levels of HIVDR.
Ensure planning and conduct of research supports priorities of prevention, monitoring and response to HIVDR



SO4. Laboratory

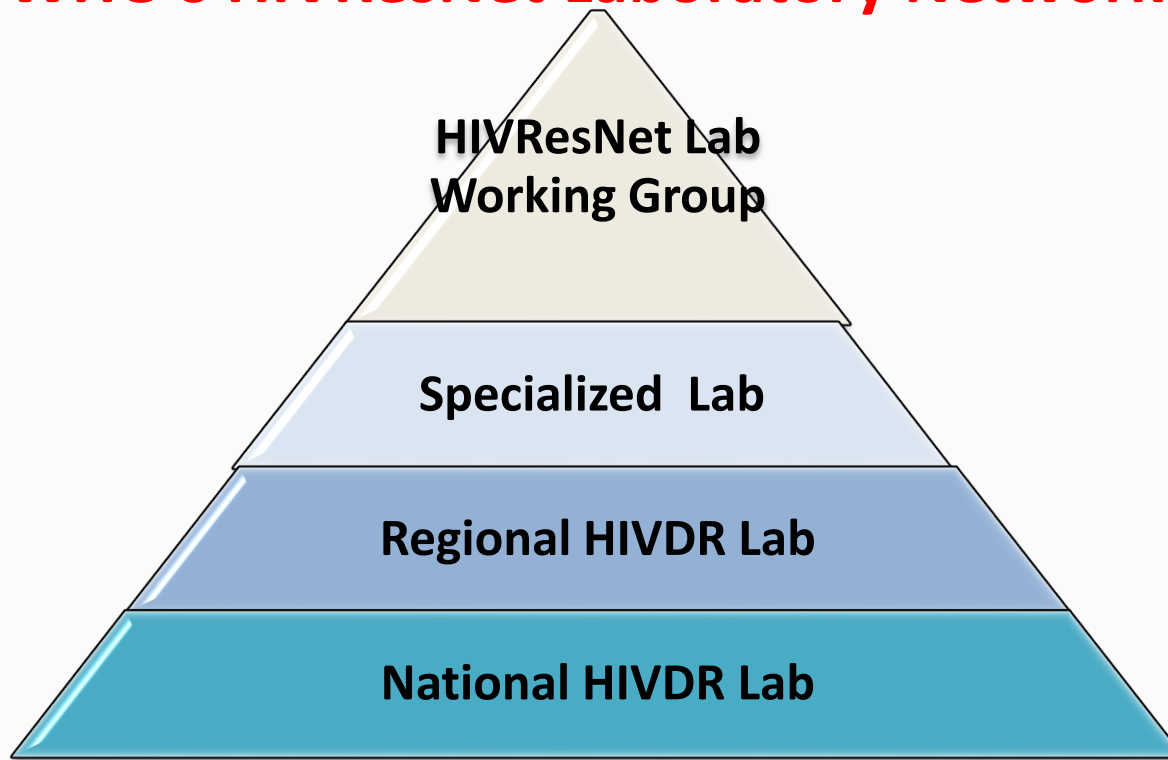
4. Laboratory

Strengthen laboratory capacity and quality to ensure the availability of a comprehensive global laboratory network that supports viral load and resistance testing in low and middle income countries

- **Strengthen laboratory capacity and quality to support and expand use of viral load and resistance testing in low- and middle-income countries**

SO4: Laboratory Strengthening

WHO's HIVResNet Laboratory Network



Free DR testing possible!

Region	National	Regional	Specialized	TOTAL
AFRO	5	4*	-	9
SEARO	4*	-	-	4
WPRO	4	2*	-	6
EURO	-	-	4*	4
AMRO	1	4*	3*	8
Total	14	10	7	31

*One or more labs designated for DBS genotyping



SO4. Consultation feedback

■ Suggested actions

- **Capacity building** of laboratory staff including M&E supported by NAP
- Expand capacity to perform HIVDR testing, including DBS and **testing for newer drug classes (integrase inhibitors)**
- Simplify tools
- Support **expansion of VL testing** to monitor viral response
- Investment to develop POC kits for VL
- Increase access to HIVDR testing
- Research to identify alternative clinical or biomarkers to provide VL measurement
- Quality assurance mechanisms for laboratory
- **WHO HIVResNet** to support countries for 1 country laboratory to be accredited for HIVDR genotyping



SO4: Action framework

Actions for countries	Actions for national and global partners	Actions for WHO
Strengthen country laboratory services and quality assurance for VL testing including POC	Support countries to develop national capacity for VL testing and HIVDR	Support countries to expand laboratories for designated genotyping (WHO HIVResNet)
Designate 1 national laboratory for WHO accreditation for HIVDR testing	Build capacity on HIVDR testing in designated laboratory including application for WHO accreditation	Develop a framework for 1) generating quality assured VL and HIV testing results 2) standards on the interpretation of HIVDR test results
Establish country laboratory services on HIVDR testing using DBS	Commit to greater investment for developing POC VL technologies	Develop policy for countries to identify individuals most in need of HIVDR genotyping.
Expand coverage of and quality of VL and HIVDR testing to ensure that people failing therapy are identified and promptly switched	Support countries to strengthen use of VL and HIVDR testing including user-friendly approaches	Integrate integrase inhibitor drug resistance testing into the HIVDR surveillance strategy



SO5. ENABLING MECHANISMS

5. Enabling mechanisms

Ensure that enabling mechanisms (advocacy, country ownership, coordinated action and sustainable funding) are in place to support action on HIVDR.

- Ensure that enabling mechanisms (**awareness/advocacy, country ownership, coordinated action and sustainable funding**) are in place to support action on HIVDR



SO5. Consultation feedback

- **Suggested actions**
 - **Country specific action plans**
 - **Advocacy to include business case** for the GAP on HIVDR
 - Increase investment in the research and development of new non ARV based HIV prevention tools, including vaccines that can reduce the number of new HIV infections
 - Include **HIVDR in HIV/AIDS performance indicators**
 - Link HIVDR strategic plans with **TB, Malaria and Hepatitis programmes**
 - **Treatment literacy**

- **Acknowledgment of diagnostic industry as key partner**

- **Alignment of partners**

Advocacy and communication

Actions for countries	Actions for national and global partners	Actions for WHO
Strengthen country ownership and coordination through national HIVDR working groups	Build community engagement for preventing and responding to HIVDR and to create demand for viral load and drug resistance testing.	Support countries to develop the business case for GAP on HIVDR.
Engage stakeholders, including civil society, for implementing country-level communication strategies to improve understanding and awareness of the risk of HIVDR emergence at all levels	Build HIVDR language into all relevant technical material, guidance documents and tools used in routine communications with supported countries.	Develop a communication and advocacy strategy, including targeted messages to different audiences to increase HIVDR awareness and commitment for national programme managers, stakeholders and funders, civil society and communities.
Ensure country-level communication synergies with AMR, Health Sector Strategy, consolidated ART Guidelines and Global Health Security Agenda	Support a central role of the national programmes in the development of national HIVDR strategy, HIVDR surveillance implementation, analysis and interpretation.	Encourage collaboration between countries, partners and communities_
Build capacity at national and sub-national levels to implement HIVDR awareness, oversight and stewardship, knowledge.		Report global estimates and trends of HIVDR in a timely manner

S05: Action framework





Sustainable resources

Actions for countries

Identify and allocate resources to fund HIVDR activities as a routine part of ART scale-up

Include costing of all elements of HIVDR prevention, monitoring and response in national HIV strategic plans, PEPFAR cooperative agreements, and Global Fund grant applications.

Actions for global and national partners

Mobilise sustainable funding for the response to HIVDR as part of ART scale up

Support price reduction of alternative 2nd and 3rd line regimens and innovative diagnostics to increase access

Ensure that adequate resources are allocated for national HIVDR prevention, monitoring and response in all countries' HIV grants from the **Global Fund**; list HIVDR strategy as a separate activity and budget within the modular framework, to allow tracking countries' requests and progress.

Ensure that adequate resources are allocated for HIVDR national strategies from **PEPFAR's COPs**

Actions for WHO

Identify opportunities with WHO HIVResNet and other partners to leverage funding to support the global coordination and response to HIVDR.

Publish biennial global reports, including an assessment of countries and organizations with plans and progress on implementation and financial support received

S05: Action framework





S05: Action framework

Coordination, integration, alignment and country ownership

Actions for countries	Actions for global and national partners	Actions for WHO
Develop a 5-year national HIVDR strategy and integrate it into the national HIV plan, with milestones and a funding plan	Ensure and adopt cohesive and aligned recommendations on HIVDR assessment and response.	Provide technical support to countries to develop and implement national HIVDR strategies
Create linkages and leverages with National AMR, TB, Malaria and Hepatitis programmes	Support implementation of the Global Action Plan for HIVDR, including providing resources and sharing data for global reports.	Promote and foster alignment with <u>MoH</u> and key implementing partners for coordinated technical support.
Include key performance indicators on HIVDR in the national HIV/AIDS performance indicators	Encourage and support country ownership to ensure appropriate response to HIVDR	