

WHO's View on IVDs for Addressing AMR

Francis Moussy, Ph.D.
Lead for AMR Diagnostics
Secretary, SAGE IVD

19 June 2017



World Health Assembly 2015



GLOBAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE

the global action plan sets out five strategic objectives:

- to improve awareness and understanding of antimicrobial resistance;
- to strengthen knowledge through surveillance and research;
- to reduce the incidence of infection;
- to optimize the use of antimicrobial agents; and
- develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions.



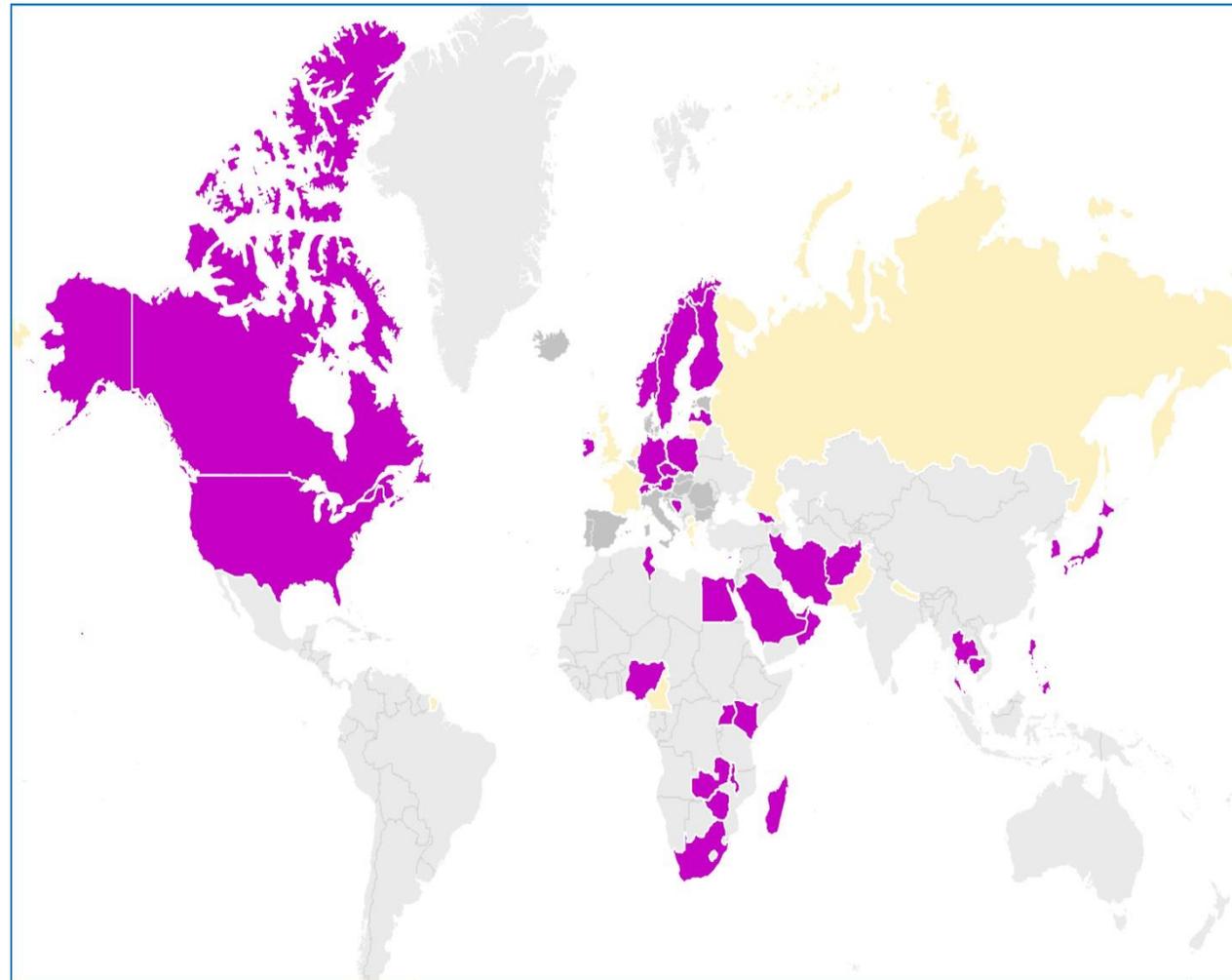
Implementation GAP: work streams

- Global communications campaign
- Global Antimicrobial Resistance Surv System
- Support measures to improve IPC
- Monitor use & enhance stewardship of antibiotic use
- Encourage R&D and explore new business models
- **Diagnostics for AMR**
- Address the environmental drivers
- Vaccines in order to prevent AMR



Status of countries enrolled in GLASS

As of 12 June 2017*



-  Enrolment completed (n=39)
-  Enrolment in progress (n=11)

* Call for country enrolment issued on 21 March 2016



Diagnostics and AMR

- Critical to **Improve Clinical / Community** use of antimicrobial drugs, for **surveillance** and monitoring as well as for conducting clinical **trials**.
- Large proportion of AM are **prescribed incorrectly** because health professionals cannot make a precise diagnosis in real time (e.g. acute respiratory infections, TB).

Diagnostics need to play a crucial role to change manner in which antibiotics are currently prescribed.



The need for rapid PoC diagnostics

- rapid PoC Dx are needed to help address AMR by quickly informing health professionals on exact nature of pathogen and the eventual presence of resistance.
- most effective treatment can then be determined during patient's visit
- will improve antimicrobial stewardship by **reducing use of broad spectrum** and often inappropriate antimicrobials which is often the rule when suitable and rapid Dx are not available.



Different types of rapid PoC Dx needed

1. Bacterial vs viral differentiation
2. Pathogen identification
3. Drug susceptibility testing



What is needed to facilitate the development of these tests

- Coordinate the necessary mapping of existing diagnostic tools for AMR
- Assess the needs and develop consensus TPPs, with very clear definitions of point of care
- With various organizations, initiate (a) partnership(s) to develop priority AMR based on the TPPs
- De-risk the development of new DXs for AMR for companies (e.g. coordinate market analysis for diagnostics in response to the TPPs, advance market commitments, prizes, grants,...).

The issues of access and use of the newly developed tests will also need to be addressed.

Other barriers to overcome

- A lack of standardized diagnostic methods/techniques
- Lack of supplies and equipment
- Insufficient or outdated training (lack of experts)
- Difficulties in quality control/assurance stemming from paucity of training, logistical and capacity issues, and cost barriers
- Lack of buy-in from national, regional and hospital authorities
- Often poorly functioning infrastructure
- Poorly functioning accreditation
- Reimbursement and cost issues
- Overload of laboratories

Role of WHO

- WHO has a key role to play in **raising awareness of AMR (and IVDs' role)**, targeting the public, health workers, and investors.
- WHO can help better define the needs for IVDs for AMR.
- WHO can coordinate the mapping of existing diagnostic tools for AMR
- Develop TPPs for needed IVDs for AMR
- Contribute to initiatives to de-risk the development of IVDs for AMR
- Facilitate the implementation of the IVDs in countries

Role of WHO, cont.

- WHO should also raise awareness of the fact that discussion around **diagnostic priorities** relates to many of WHO's other accepted strategic priorities (for example, the right diagnostics are fundamental to the discussion around essential medicines).
 - WHO Model List of Essential In Vitro Diagnostics (EDL). First version of the list will focus on TB, malaria, HIV and hepatitis. Will then expand to other priority areas such as AMR, NCDs... → strong interest in having a focus/section in the list for diagnostics that will help slow down AMR

THANK YOU

Contact: Dr Francis Moussy (moussyf@who.int)