



The GAP for AMR: from Action Plan to operations

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Overall perspectives

- Ground up efforts in parallel with international and regional strategies: developing countries
- GAP is another step
- Who (WHO?) coordinates and supports?
- Do we want a donor driven model?
- Where does the money come from?
- Country level prioritisation
- Health security v Global Health

Diagnostic Tests

- Crucial for implementation of the GAP (surveillance, to update clinical guidelines, antibiotic stewardship, enrolment in clinical trials, infection control)
- Receives less attention as need for new drugs
- Many promising tests (ie, Maldi-tof, full genome sequencing) but not adapted for LMIC
- While waiting for new tests for LMIC, need to build microbiological capacity
- Algorithms to manage fever & febrile syndromes

Antibiotic Issues in MSF

- Old narrow spectrum antibiotics like Penicillin that can be used for treatment of some infections like syphilis:
lack of quality approved supply
- Revival of old antibiotics for very resistant bacteria
Polymyxin: *old antibiotic largely abandoned 20-30 years ago because of AEs, approved at a time with different regulatory oversight, no standardization of dosing and indications.*
- Access to later generation antibiotics like Imipenem:
not available in countries or expensive
- Dry antibiotic pipeline: *i.e. fixing whats wrong with Beta lactams, regulatory shortcuts*
- Continued high mortality from infections
- Access still an issue

Access Cascade

- Development of strategies for interventions & tools
- Research and Development
- Registration, marketing / access plans
- Policy to recommend use (international and national)
- Prioritization and resources (cost a factor)
- Quality assured supply (more than 1)
- Procurement to ... distribution to local level
- Rational use (link to policy, regulation, HSS, diagnostics)
- Appropriate uptake, compliance
- Monitoring & surveillance

Global Action Plan: gaps

- **Objective 2: Strengthen the knowledge and evidence base through surveillance and research**
- Focusing on the most vulnerable to infections caused by resistant bacteria, there is a need for surveillance in highly susceptible patients such as HIV, neonates, malnourished and war/burn injuries.
- In the development of the framework to monitor the consumption of antibiotics, it is important to collect data on appropriate and inappropriate use. Aside from collecting information on excessive and inappropriate use, it is equally important to collect information on access to antibiotics for patients who truly need them.

- **Objective 3: Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures**
- Resources to implement infection control measures should be provided at all levels of health care beyond education and training.
- Access to vaccines is critical in order to reduce the burden of disease, morbidity and mortality and need for and use of antibacterial drugs. Key vaccines such as those against pneumococcus must be made more affordable for all low and middle income countries to have optimal access and realize their potential to help address AMR. Vaccines must also be fit to resource constrained areas, including by improving their labelling for extended thermostability and use in the controlled temperature cold chain and through making their packaging as small in volume as possible.

- **Objective 4: Optimize the use of antimicrobial medicines in human and animal health**
- Access to diagnostic tools is an essential but often less emphasized part. There is a need for point of care and rapid diagnostic tests designed and developed for resource limited settings. These diagnostic tests should meet international standards of quality and regulatory approval.

- WHO should push regulatory authorities to revise registration policies for old antibiotics that are being reviewed for treating multidrug resistant infections, harmonize their recommended dosing and indications and promote manufacturing of quality assured antibiotics.
- WHO should also continue to address reports of substandard antibiotics that maybe contributing to antibiotic resistance. Moreover, strengthening pharmacovigilance in countries is important, as stringent regulatory authorities have recently made amendments to speed up the approval of new antibiotics with less clinical data.

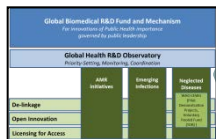
- **Objective 5: Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions**
- We are convinced that the solution to the current market failure in the medical research in AMR lies in de-linking the cost of R&D from the volumes of sales and the sales revenues both to ensure conservative use of antimicrobial agents and affordable access for those in need.
- MSF supports the immediate establishment of a new entity which can encourage the development of new, effective antibiotics through de-linked models of R&D, promote conservation, access not excess.

What next?

- Political commitment at country level to implement the GAP
- Resources need to be available for countries and WHO
- UK's Govt Fleming fund (195 million pounds) to help response capacity in LMIC
- WHO's role:
 - More than just Health Security
 - Innovation, Policy of rationale use, EML, PQ, Regulatory strengthening, HSS..
- Do we need a Global fund like structure?
 - Good governance
 - Should not undermine the role of WHO on priority setting, coordination, policy making
 - Not merely about market shaping, procurement or purchasing of commodities
 - Not convinced if current GHAs can meet this task

Establish a **complementary, sustainably-financed global R&D fund and mechanism to cover R&D components of three priority areas: AMR, emerging infections & neglected diseases**

Funding for R&D initiatives



BILL & MELINDA GATES foundation

BNDES
The Brazilian development bank

DFID Department for International Development

UNITAID

EUROPEAN COMMISSION

EDCTP

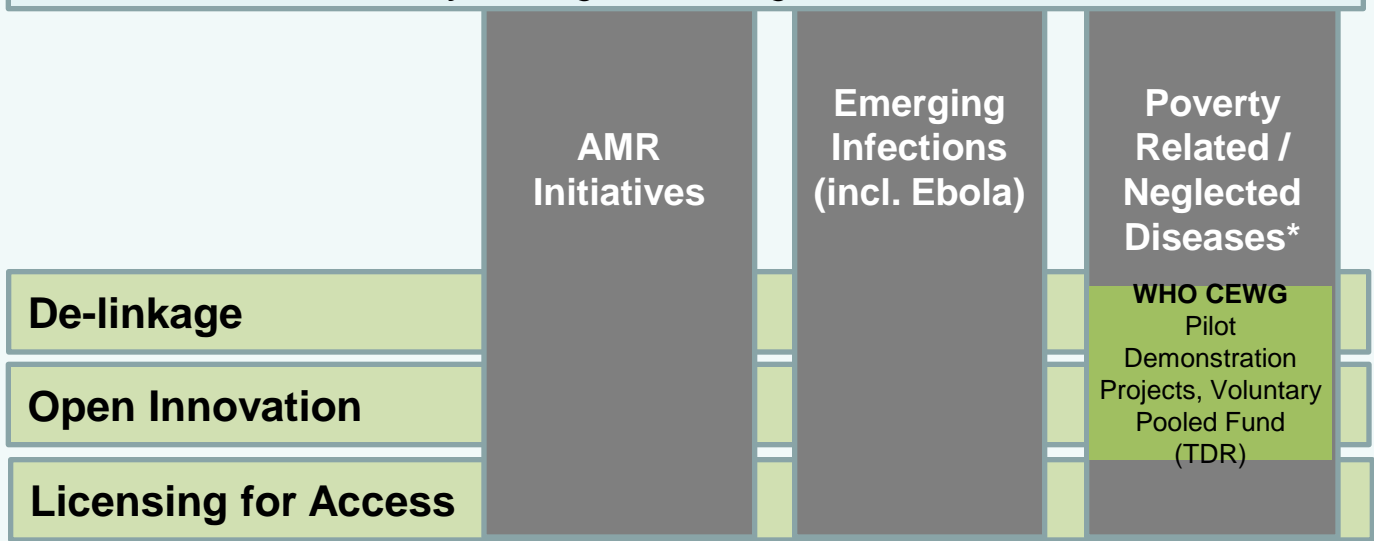
...and others

Global Biomedical R&D Fund and Mechanism

For innovations of Public Health importance governed by public leadership

Global Health R&D Observatory

Priority-Setting, Monitoring, Coordination



* Type II and III diseases, and the specific R&D needs of developing countries in relation to Type I diseases”