The WHO PQ Programme and its Updated Role after the Outbreaks of Ebola and Zika Virus

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World Health Organization

The evolution of a new role for the PQ Programme

- 2014 Ebola virus crisis highlighted the need for an emergency assessment procedure for vaccines, medicines and IVDs

- The procedure would need to be different from PQ in four major ways
  - Faster assessment process
  - Decision based on minimal evidence of safety and performance, given that few products would be at a mature stage in the development cycle
  - Rolling submissions acceptable as more data (evidence) is collected by the manufacturer
  - Need to be flexible

- WHO Prequalification Programme already had experience with other assessment mechanisms
  - Lab evaluation only
  - Expert Review Panel for innovative products
    - QMS and limited dossier
- Emergency Use Assessment and Listing (EUAL) Procedure
  - To apply when there is a Public Health Emergency of International Concern
  - A procedure that can be adapted to the circumstances of the emergency
  - Based on good regulatory practice

- The Listing provides guidance including product-specific technical information to
  - UN procurement agencies,
  - WHO product utilization advisory committees,
  - national regulatory authorities (NRAs),
  - and others involved in efforts to control an epidemic.

The EUAL Procedure

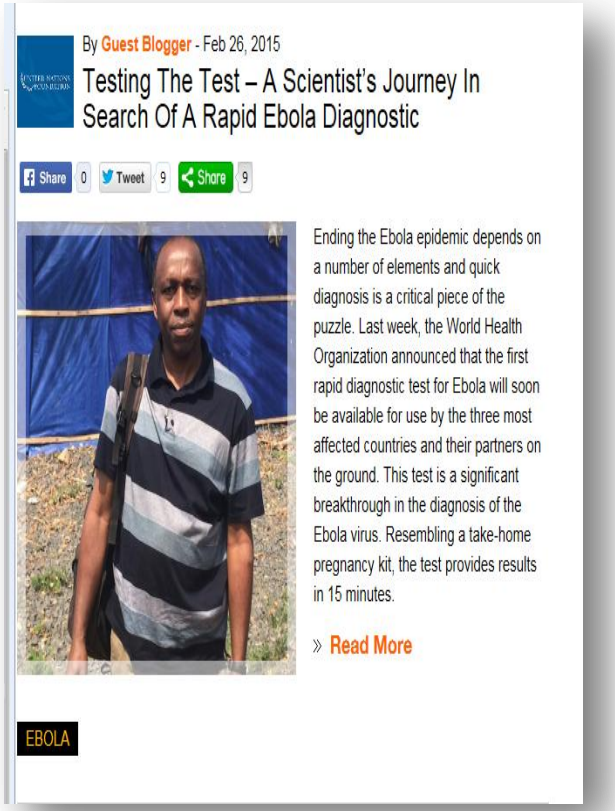
- Where possible, the EUAL for IVDs procedure consists of:
  - A desktop review of selected manufacturing and QMS documentation
  - A review of any existing documentary evidence of safety and performance
  - A limited laboratory evaluation of relevant performance and operational characteristics of the product
- Possibility to abbreviate any of the steps if evidence of sufficient scrutiny by a stringent regulatory authority

EUAL: The Ebola Experience

- Few manufacturers had started to develop NAT and antigen detection assays
- Most had very little technical documentation
- Some had rudimentary QMS (ISO 13485) but not manufacturing capacity
- Clinical blood samples were not available for validation
  - restriction in transportation of clinical samples outside W Africa
- Testing required BSL-4 laboratories
- Therefore the manufacturers had minimal analytical and clinical performance data

Ebola EUAL and International Collaboration

- International support in the provision of EVD IVD expertise for Dossier and QMS review
  - Dossier requirements and review
  - Adoption of US FDA requirements for dossier (provided alignment and harmonised approach)
  - USA, Belgium, Australia, Switzerland
- International Support for WHO based Lab and Field evaluations
  - BSL4 lab and LOD studies (Bernhard Nocht Institute, Germany)
  - Sierra Leone clinical performance study (Nigerian and PHE Labs)


By Guest Blogger - Feb 26, 2015

Testing The Test – A Scientist's Journey In Search Of A Rapid Ebola Diagnostic

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Ending the Ebola epidemic depends on a number of elements and quick diagnosis is a critical piece of the puzzle. Last week, the World Health Organization announced that the first rapid diagnostic test for Ebola will soon be available for use by the three most affected countries and their partners on the ground. This test is a significant breakthrough in the diagnosis of the Ebola virus. Resembling a take-home pregnancy kit, the test provides results in 15 minutes.

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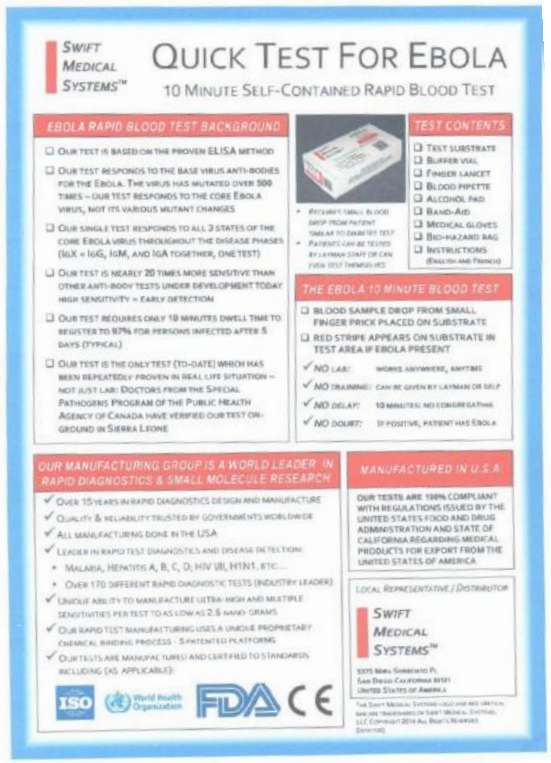
EBOLA

Ebola EUAL : Making a Difference

- WHO first listed a PCR, followed by a rapid antigen assay
- PCRs were able to be used in the internationally supported mobile laboratories
- Use of RDTs has proven sustainable



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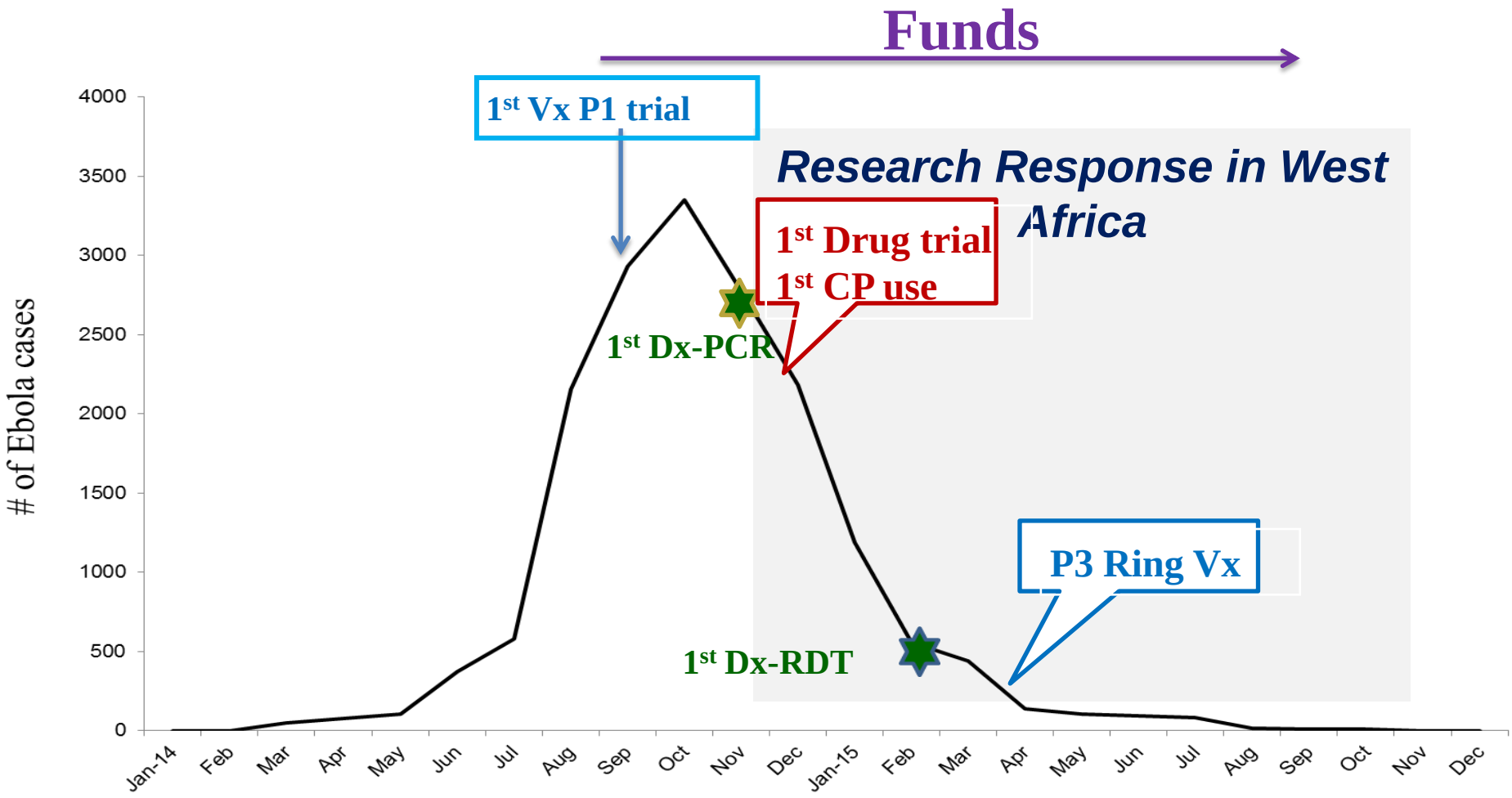
EUAL and the Zika Experience

- Lessons learnt
  - Optimise international cooperation ✓
  - Agree and publish requirements ✓
  - Ensure requirements aligned ✓
  - Abbreviate where possible ✓
  - Alignment /cooperation with other WHO/PAHO led initiatives
    - Input into testing strategies ✓
    - WHO reference materials ✓
    - TPP development ✓

EUAL for Zika virus

- Challenges
  - Access to collaborating centres
  - Products validated in Europe (Flavivirus-naive populations)
  - WHO resources
  - Changing evolution of the disease
    - Outbreaks in other parts of the world
      - Different lineage

WHO Research Response EBOLA



Response to the Ebola outbreak

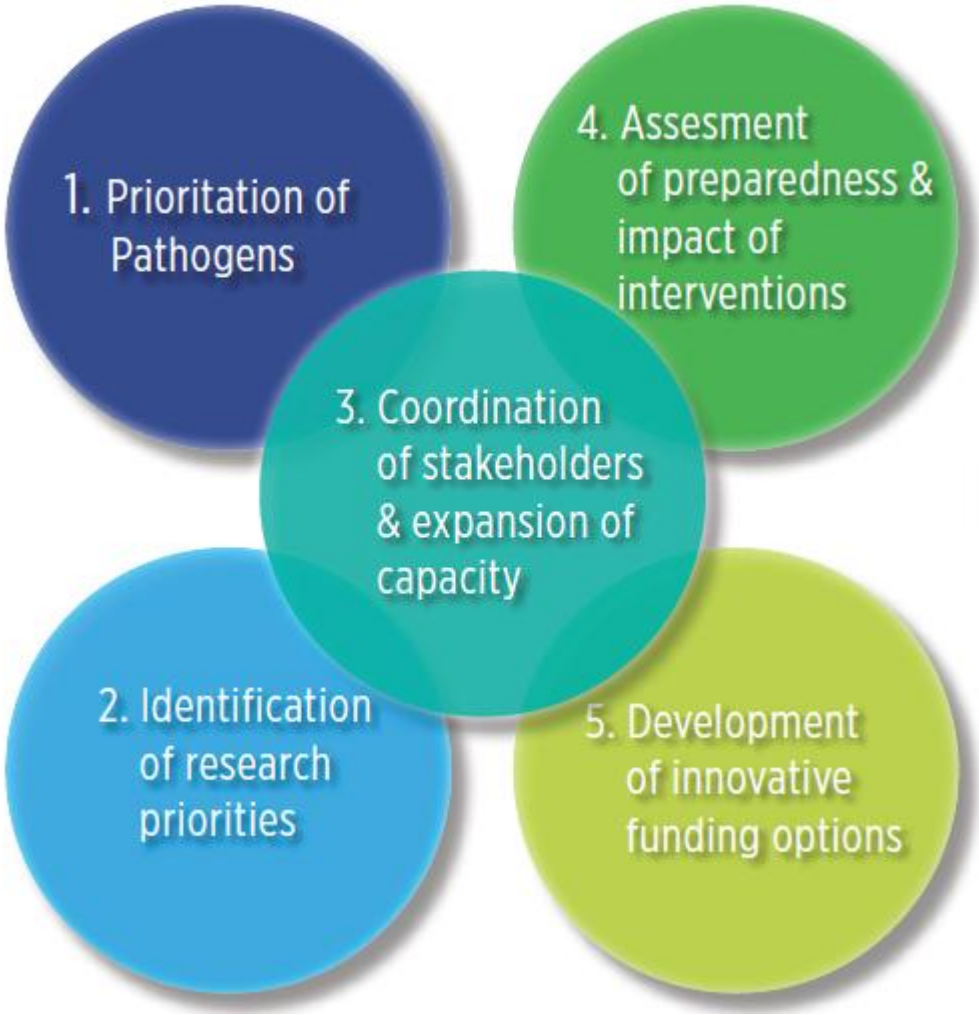
World Health Organization

WHO Response to Outbreaks

- Global strategy for epidemic preparedness:
  - R&D Blueprint for Action to Prevent Epidemics
- WHO coordination for
  - Improved preparedness
  - Rapid response
- Ratified at the 68th WHA2015 and G7 Health Ministers, 2015

Development of the Blueprint

- Building on the efforts of others
- A collaborative effort with Member States and other relevant stakeholders
- Consultations
- Scientific Advisory Group



Blueprint activities of note

- Assessing epidemic threat and defining priority pathogens
  - Methodologies
  - Monitoring
- Outlining funding processes
- Building an effective coordination framework based on global cooperation
- Developing R&D roadmaps
  - Priority pathogens
  - Technology platforms

Blueprint activities of note

- .Facilitate open access to research resources
  - Publication of CT protocols for blueprint priority diseases
  - Develop a concept of biobanking linked by an information sharing platform
  - Facilitate discussions on best practices for testing vaccines, drugs and diagnostics
- Efforts to strengthen national regulatory and ethics bodies
- Connecting the Blueprint with other international efforts

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