Improved Diagnostics to fight AMR: Barriers to Development and Uptake
Diagnosis is the first step to appropriate treatment & improved clinical outcomes

- Reduce antibiotic use
  - Bacterial vs non-bacterial differentiation
  - Pathogen identification (e.g. fever panels)

- Guide antibiotic choice
  - Susceptibility profiling

- Fill knowledge gaps & Target interventions
  - Resistance monitoring
Overcoming challenges on the way to essential AMR diagnostics

1. Few tests in development or don’t make it to market...
   - Gaps in science & knowledge sharing
   - Limited understanding of needs / priorities
   - Low market incentives given high dev’t risks
   - Lack of supporting infrastructure for innovators

2. Slow LMIC market penetration...
   - Fragmented regulatory and policy pathways, e.g. need for redundant trialing
   - Unclear financing/procurement pathway
   - Complex delivery channels, e.g. public/private sector

3. Impact stifled...
   - Access to antibiotics
   - Linkage of testing and care (adherence)
   - Weak health and lab systems
   - Logistics and support in primary health care

4. ... and prioritization of diagnostics low
   - Limited understanding of dx value and thus minimal investment
   - Since 2007, R&D funding for Dx has stagnated at 3-4%
Guiding R&D through Target Product Profiles, e.g. TB

Meeting Report

High-priority target product profiles for new tuberculosis diagnostics: report of a consensus meeting

http://apps.who.int/iris/bitstream/10665/135617/1/WHO_HTM_TB_2014.18_eng.pdf?ua=1

28–29 April 2014
Geneva, Switzerland

Caveat: + Market report and grant or investor funding
Facilitating R&D, e.g. Data sharing, Access to specimens and sites

Specimen collection, Tanzania

Fever trial preparation, Vietnam

CURATED AND AGGREGATED DATA
- Genotypic Data
- Phenotypic Data
- Clinical Data
- Drug Resistance Data
- SNP Reports

ANALYTICS TOOLS
- “R” Statistical Analysis
- Misc. Integrated Analysis

RECOGNITION
- Individual Recognition
- Institutional Recognition
- Global Impact
Landscape analysis identified >113 unique biomarkers for detecting bacterial infections from 59 clinical evaluation studies in 24 countries between 2010 and 2015.

Fever biomarkers included host proteins, gene transcript signatures, and biochemical reactions or cellular processes associated with infection.

Performance of biomarkers varied widely from 17-100% sensitivity and 31-100% specificity as markers of bacterial infection.

Several commercially available products incorporating these biomarkers and combinations of biomarkers have shown promising performance in early clinical trials and are currently undergoing validation in larger trials.

Gaps in clinical dx biomarker research: Lack of large, high quality trials (n>500), very few clinical trials in developing countries, lack of standardized reporting, lack of data sharing (a lot of knowledge kept within companies).
Mapping antibiotic use, disease etiology and resistance essential to inform R&D, and measure impact of testing.
Defining implementation models early

V. Dacremont et al.

Recommendation for treatment and/or admission

Oximeter
Glucometer
Hemoglobinimeter

Algorithm
\( \rightarrow \) disease probability

RR device

Swiss TPH
Ingredients for successful delivery

- Policy & Regulatory guidance
- Quality assurance scheme
- Easy to use diagnostic
- Support and supply chain
- Financing mechanism
- Models for uptake

WHO

Collecting evidence for scale-up
Scale-up

Price intervention
Annual implementers & donor meetings
Endorsement (Roadmap, guidelines)
STAG Meeting & Global consultation
Expert Group Meeting