Implementation of Diagnostics

Value-based translation of innovative diagnostics into routine use to optimize Abx and reduce AMR

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Brussels ● June 19, 2017
Challenges & Hurdles

- **Business Case**
  - Value of Dx is under-appreciated (Low cost of Abx versus Dx)
  - Reimbursement is not value driven

- **Regulatory Framework complexity is increasing**

- **Especially in primary care, lack of**
  - Evidence of utility/outcome benefit and cost-benefit studies
  - Economic incentives
  - Alignment of stakeholder interests
Key Value Drivers

Demonstrate the value of diagnostics
- Optimize the antimicrobial therapy
- Reduce a driver of AMR
- For individual patients and public health

Design and implement a framework
- Extensive consultation with key stakeholders
- Sustainable infrastructure for the evidence based translation of innovative diagnostics into routine care

Kurt Lewin’s Change Theory

Key Success Factors Implementation

1. Cooperation of relevant Stakeholders
   - Who and how to ensure commitment?

2. Build on existing activities
   - Identify and motivate for cooperation

3. Evidence base - scientific and economic data
   - Patient benefit
   - Public Health impact

4. Description of an integrated solution
   - Proven to work
   - Sustainable business model
Key Tasks for Implementation

- **Establish a consulting network**
  Physicians, European IVD regulators, HTA programs, reimbursement experts, third-party payers, health economists, medical educators and psychosocial experts

- **Systematically drive evidence based implementation**
  Describe key hurdles and propose actions to implement innovative diagnostics into standard of care in LRTI

- **Connect with existing activities and establish cooperation**
  Systematic review of the existing (peer-reviewed) literature and ongoing European AMR-related activities

- **Standardized Care Network**
  Infrastructure for rapid evidence based implementation of innovative diagnostics into routine

- **Implementation**
  Facilitate decisions to implement the framework into routine with stakeholders
Implementation – Deliverables

- **Opportunities for improvement and prioritize the most promising**
  - Clinical evidence generation
  - Regulatory environment

- **Requirements (evidence) for the adoption of new Dx**
  - Defined measurable clinical outcome and success parameters
  - Best practices to shorten time to market

- **Health Economics Model for reimbursement**
  - Funding considering their impact in reducing antimicrobial prescribing and AMR
  - Model acceptable to payers for establishing value-based reimbursement

- **Change management and implementation**
  - Description of psychological barriers and outline of an implementation process for new devices
  - Publication of the framework in a peer-reviewed journal
  - Draft guideline recommendations for the optimal use of antimicrobials
  - An education and dissemination program for the implementation of the framework

- **Sustainable infrastructure**
  - Describe a business plan for future rapid benchmarking and translation of diagnostics
Outcome of Implementation

- Description of efficient and sustainable methods for implementing diagnostics to:
  - Establish clinical utility
  - Optimize the use of antimicrobial therapeutics
  - Demonstrating the value in health economics using acceptable quality markers / surrogate endpoints

Tested solution for accelerating the approval and use of innovative diagnostics to support optimal antimicrobial usage