Implementation of Diagnostics

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

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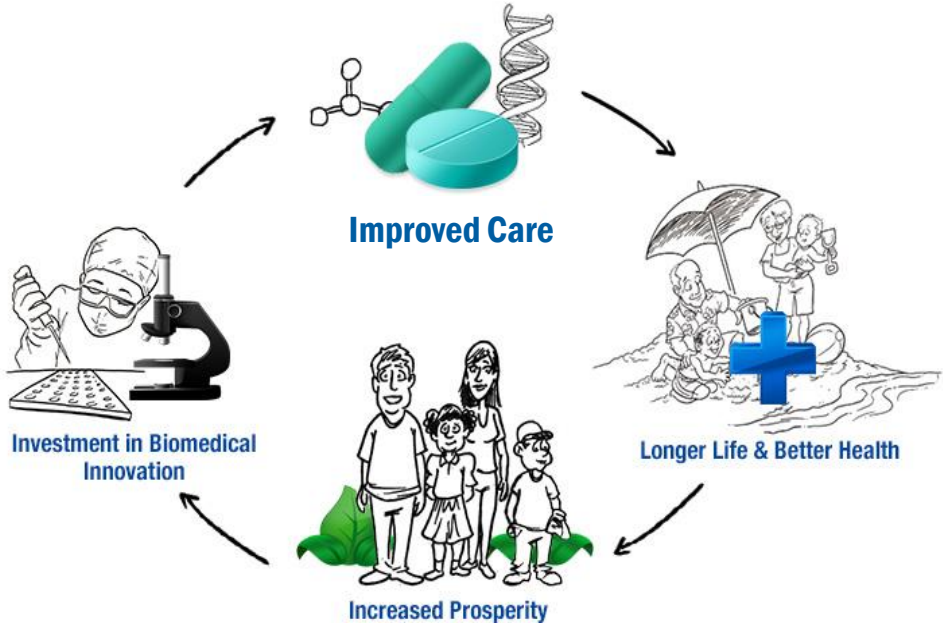
Challenges & Hurdles



- **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

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Key Value Drivers

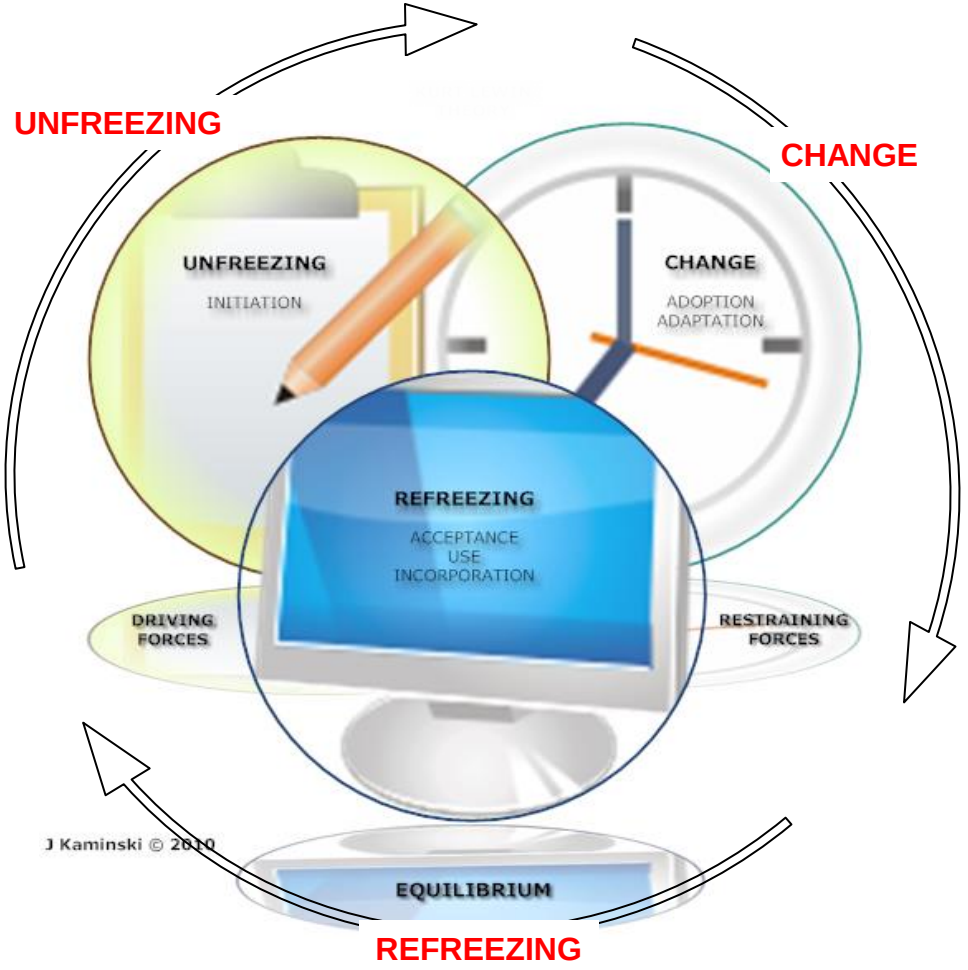
Demonstrate the value of diagnostics

- 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



Src: Kaminski, J. (Winter, 2011). *CJNI: 6* (1), Editorial.

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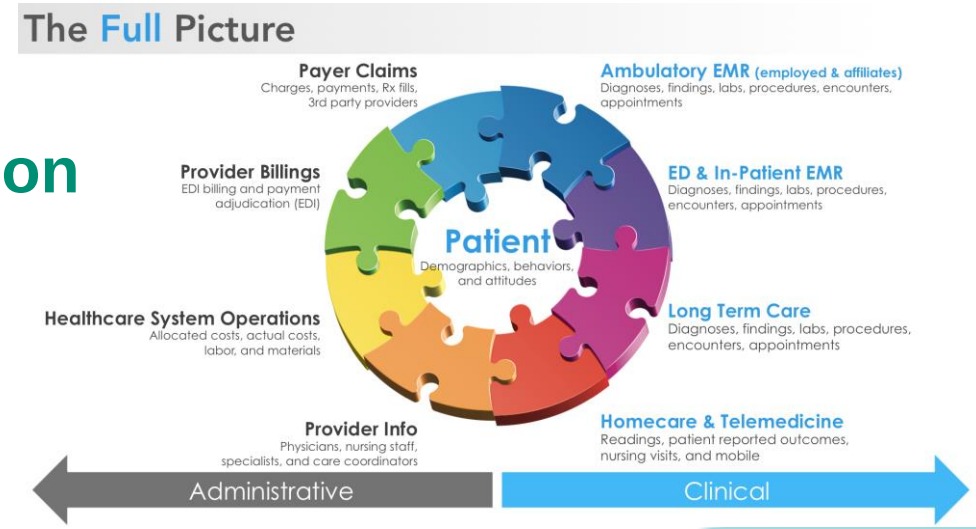
Key Success Factors Implementation

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



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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

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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

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