Control and Implementation Research

EDCTP Stakeholder Meeting

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World Health Organization
Geneva, Switzerland

GLOBAL TB PROGRAMME

World Health Organization

Classical notion of Operational Research

Research to improve programme performance and outcomes

- Focus on *service delivery*
  - goal is to assess deficiencies in TB control and identify causes that are amenable to improvement using technical or managerial interventions
  - intended to provide locally relevant solutions to locally defined problems (but may be useful to similar settings elsewhere)

→ Priorities generally locally defined

Examples

- Deficiencies in TB-HIV referral
- Causes of diagnostic delays
- Reasons for defaulting or non-adherence

Improving Global TB Control
– what do we need ?

1. *Better functioning TB programmes:*
   - assess deficiencies and identify causes that are amenable to improvement by technical or managerial intervention

2. *New interventions to improve TB control:*
   - effective and efficient use of new tools & strategies
   - determination of the conditions/requirements under which they can be effectively implemented

3. *Inform Policy recommendations*
   - provide evidence on what can be expected from new interventions in real-life settings
     - increasingly important for international policy decisions and funding
     - e.g. GRADE process for policy recommendation

Paradigm shift

From program performance to new interventions

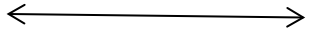
From tools to strategies

From TB focus to context

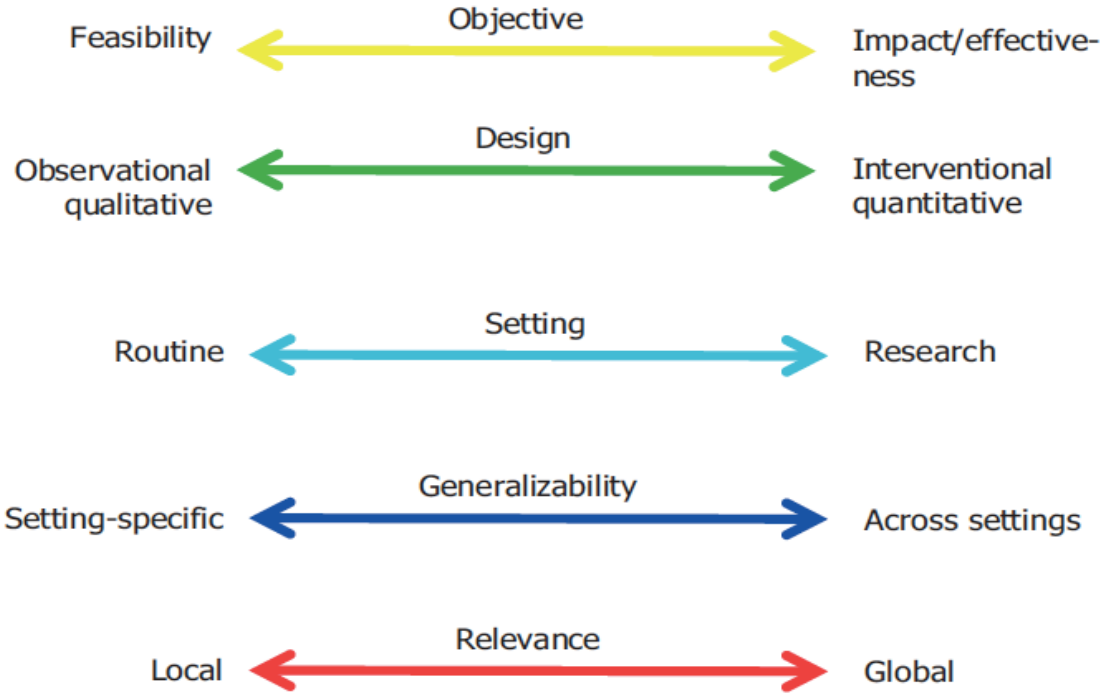
→ address the perspective of *needs*

OR covers a broad spectrum defined by the needs

Research to improve TB programme performance and outcomes



Research to develop and scale up new interventions to improve TB control



Lienhardt & Cobelens, IJTLD 2011

Opportunities

- Effectiveness studies embedded in TB programmes
- Use of routinely collected data (eg. notifications, treatment outcomes) and increasing availability/use of individual patient-based recording systems
- Recent methodological developments (pragmatic randomised controlled trials, phased implementation)
- Increasing awareness and interest with funding bodies
- Increased countries' involvement in OR (India, Brazil, SA)
- Proposed Post 2015 Global TB Strategy

DRAFT Post-2015 TB Strategy at a glance

VISION:

- **A WORLD FREE OF TB**
  Zero deaths, disease and suffering due to TB

GOAL:

- **End the Global TB Epidemic**

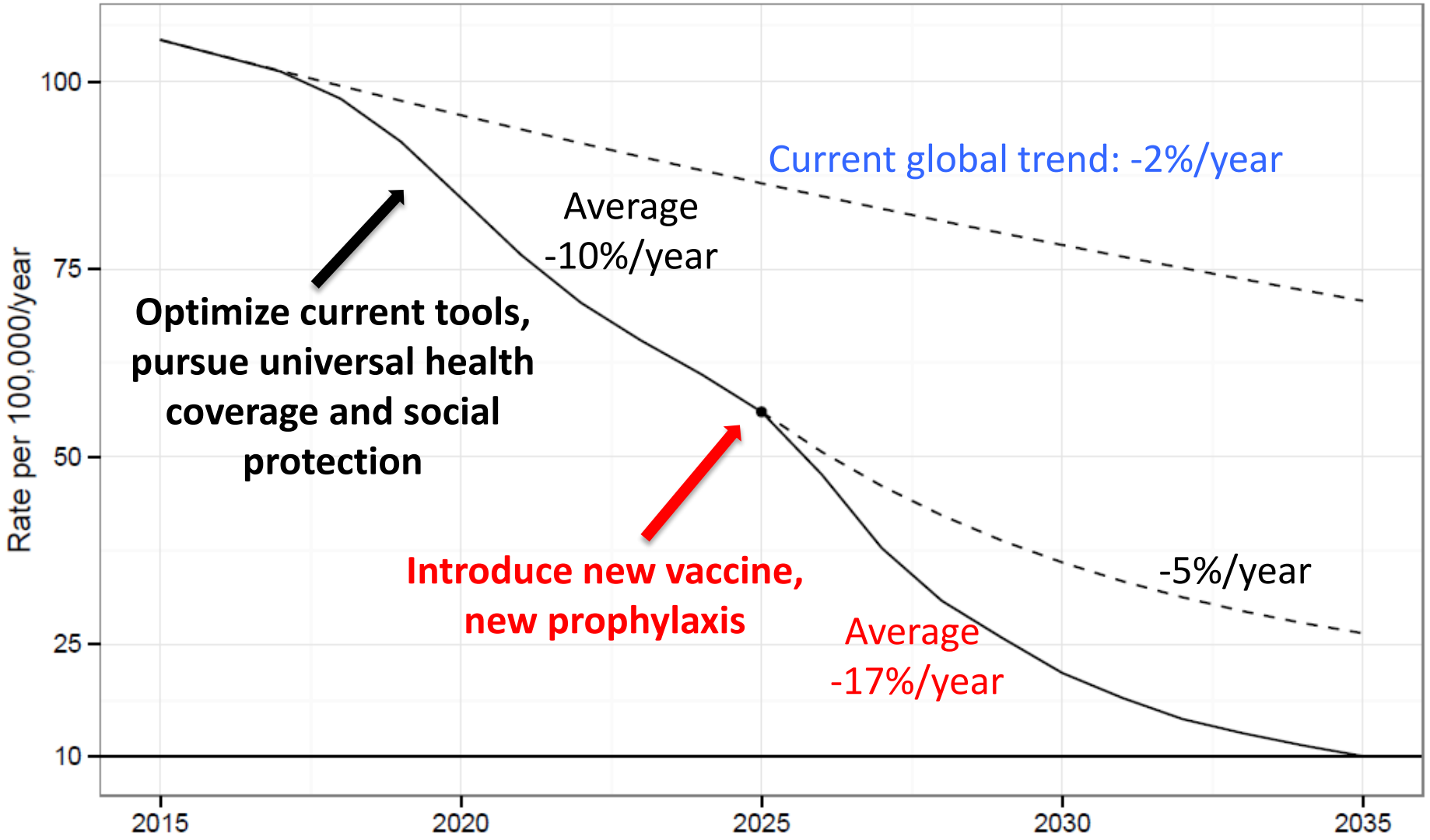
TARGETS FOR 2035:

- **95% reduction in TB deaths (compared with 2015)**
- **90% reduction in TB incidence rate (≤10/100,000)**

MILESTONES FOR 2025:

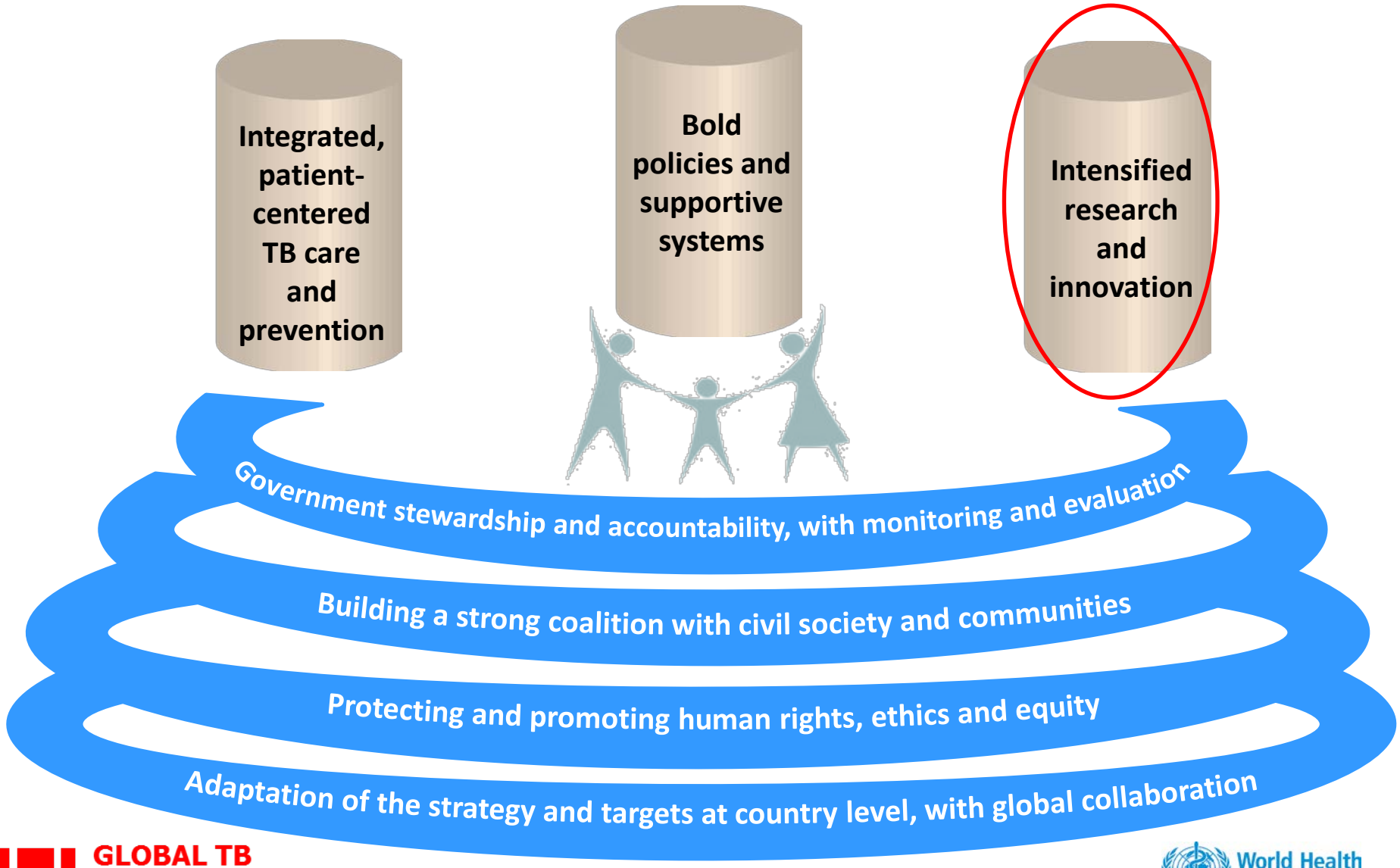
- **75% reduction in TB deaths (compared with 2015)**
- **50% reduction in TB incidence rate (< than 55/100,000)**
- **No affected families face catastrophic costs due to TB**

Projected acceleration of TB incidence decline to target levels



Post-2015 Global TB Strategy

Proposed Pillars and Principles



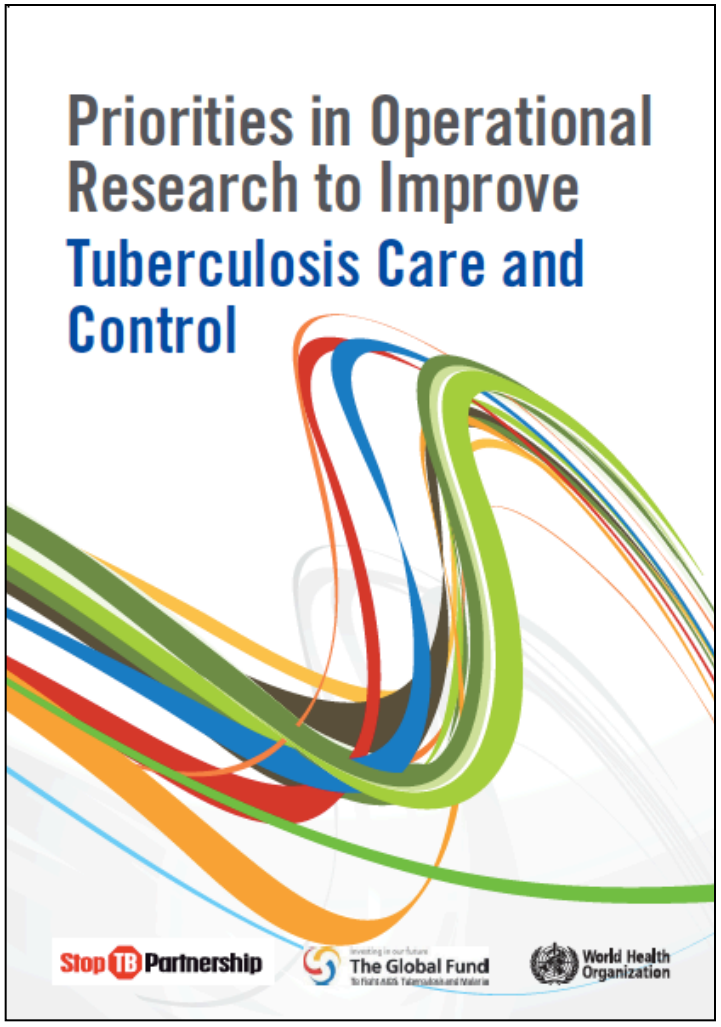
Priorities in Operational Research to Improve Tuberculosis Care & Control

Objective:

to assist countries/NTPs in conducting OR to improve TB care and control and applying for grants for OR

Contents:

- Description of *five priority OR areas* and rationale for research questions
- Determination of research cycles describing a logical timeline of successive research projects
- For each research question, development of a *standard research template*



GLOBAL TB PROGRAMME

Launched in Delhi, India, on 29th August 2011

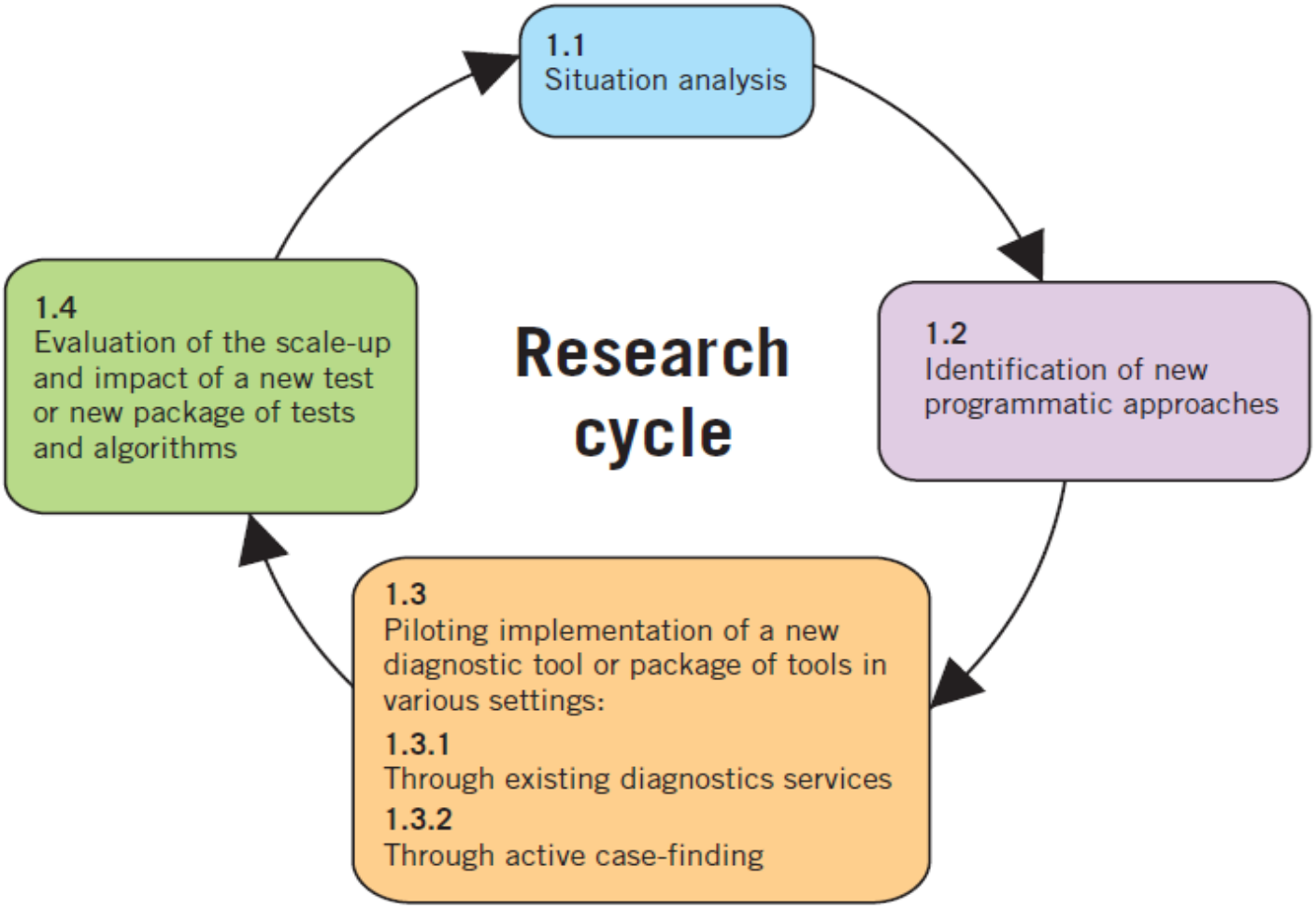
World Health Organization

Priorities in Operational Research to Improve Tuberculosis Care & Control

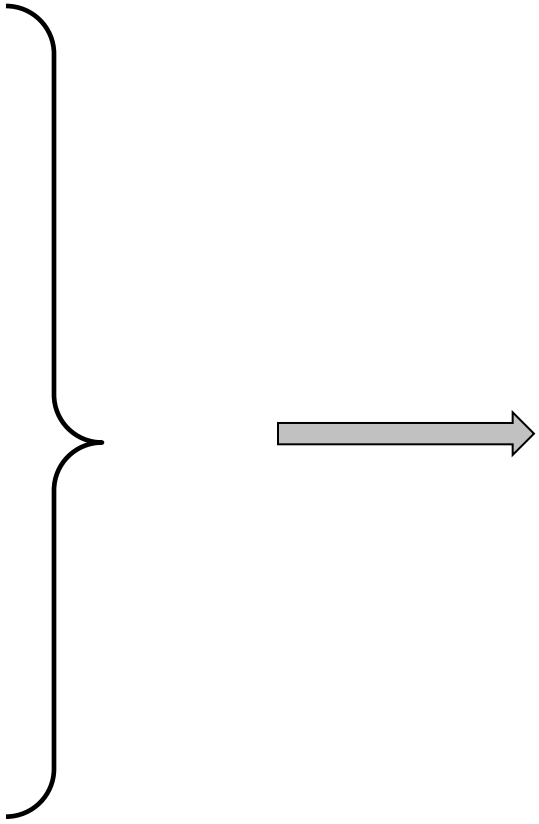
5 main areas:

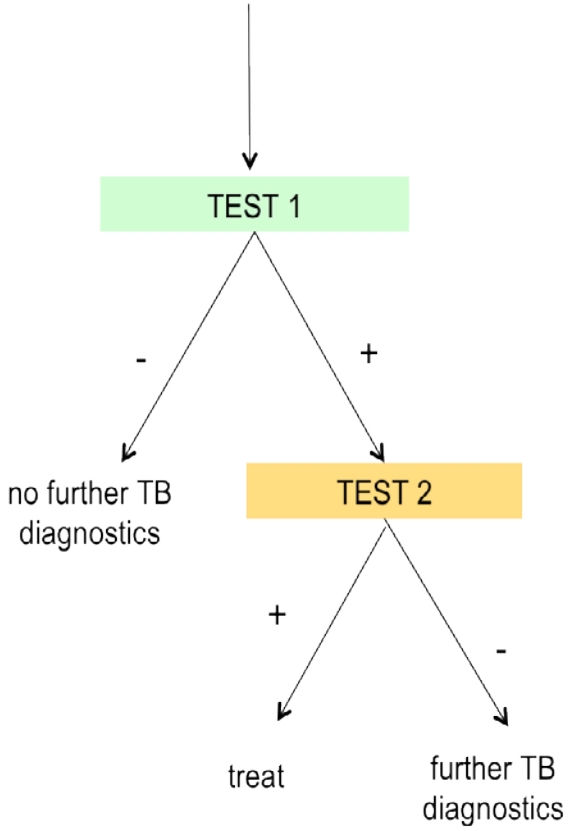
1. Improving access, screening and diagnosis of TB
2. Developing sustainable collaboration with all care providers for TB care and control
3. Prevention of TB in HIV-infected patients and joint treatment of TB and HIV
4. Treatment of Drug-susceptible and M/XDR-TB: optimal access, delivery and community participation
5. Capacity Building for Operational Research

FIGURE 2. CYCLE OF RESEARCH ACTIVITIES FOR IMPROVED ACCESS, SCREENING A DIAGNOSIS OF TB



From tools to strategies





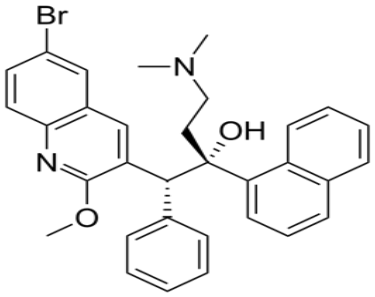
From tools to strategies

Implementation Study of Xpert®MTB/Rif for diagnosing pulmonary tuberculosis in Brazil

- A pragmatic trial to evaluate the effect of replacing two-sample smear examination by one-sample Xpert on PTB notification and treatment initiation in routine practice.
- Rio de Janeiro and Manaus
- Covering 8 million people >200 clinics
- Stepped-wedge cluster-randomized design
- Conducted by the Brazilian NTP

From tools to strategies

New drugs/treatments of TB/MDR-TB



- Evaluation of feasibility, effectiveness and impact

- Further tests of resistance?
  - which ones ?
  - how ?
  - where ?
  - for whom ?

-> various strategies regarding
- eligible patient population
- single- or multistep DST

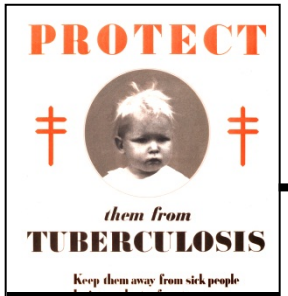
-> pharmacovigilance and monitoring

From focus to context

Difficulty in accessing health care

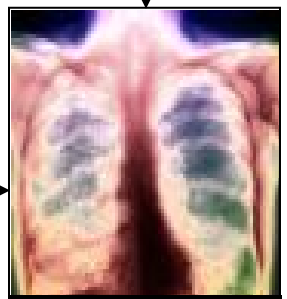
Ineffective prevention

Delayed diagnosis



Uninfected

Latent



Active

Differences in economic factors

Changing risk factors for TB

Delayed/insufficient/ inappropriate treatment

From focus to context

Access to care:

- **The Health system environment**

  - Availability and quality of services
  - Reimbursements of costs
  - Insurance schemes
  - Social protection

- **Patients costs**

  - Health seeking behaviour
  - Adherence
  - Incentives, enablers

Evidence for scale-up of new interventions

1. Is it scalable?

Retain effectiveness when brought to scale?

- Real-life conditions
- Adverse consequences?

2. Is it worth scaling up?

Cost-effectiveness and affordability when applied at scale?

- Monetary, non-monetary costs
- Compare various ways of scale-up (e.g. algorithms)

3. How should it be scaled-up?

- What are its key delivery aspects?
- Operational bottlenecks?
- Access?

Capacity Building for Operational Research

1. Creation of an **enabling environment** for performing OR research is key to the potential for improvement at NTCP levels

2. Theoretical background in research methods:

    - knowledge training

    - practical experience with fieldwork ("*hands-on*")

3. Protocol development, ethical approval, data collection, data analysis, paper writing, publication.

SORT IT

Structured Operational Research and Training IniTiative

Improving health systems through research

Knowledge management and planning of capacity building

World Health Organization

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

MEDECINS SANS FRONTIERES

http://www.who.int/tdr/capacity/strengthening/sort/en/

Union / MSF mentorship course to build OR capacity

Purpose: To teach the practical skills for conducting operational research and publishing results

Approach:

- Product –oriented [a submitted research paper]
- Modular approach [3 modules over 10 months]
- Participants go through whole research process ["Hands-on"]
- Milestones must be achieved to stay in course
- Trained participants should become facilitators

Conclusions –*"Operational Research 2.0"*

- Need for Operational Research
- Focus on development and scale-up of new or improved interventions
- Integrated use of new tools and new approaches (strategies)
- Involve context, e.g. risk groups, risk factors, economic aspects

→ Need for pilot/demonstration studies of new interventions

→ Collect “evidence for scale-up”

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Thank you for your attention !