Control and Implementation Research

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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]
Oppportunities

• 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

Optimize current tools, pursue universal health coverage and social protection

Current global trend: -2%/year

Average -10%/year

Introduce new vaccine, new prophylaxis

Average -17%/year

Average -5%/year
Post-2015 Global TB Strategy
Proposed Pillars and Principles

- Integrated, patient-centered TB care and prevention
- Bold policies and supportive systems
- Intensified research and innovation

- Government stewardship and accountability, with monitoring and evaluation
- Building a strong coalition with civil society and communities
- Protecting and promoting human rights, ethics and equity
- Adaptation of the strategy and targets at country level, with global collaboration

World Health Organization
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

Launched in Delhi, India, on 29th August 2011
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

1.1 Situation analysis

1.4 Evaluation of the scale-up and impact of a new test or new package of tests and algorithms

1.2 Identification of new programmatic approaches

1.3 Piloting implementation of a new diagnostic tool or package of tools in various settings:
   1.3.1 Through existing diagnostics services
   1.3.2 Through active case-finding

OR priorities to improve TB care and control. WHO 2011
From tools to strategies

GLOBAL TB PROGRAMME

TEST 1
- no further TB diagnostics
+ TEST 2
  - +
  - -
  + treat
  - further TB diagnostics
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

GLOBAL TB PROGRAMME

World Health Organization
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?
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.
Structured Operational Research and Training Initiative

Improving health systems through research

Knowledge management and planning of capacity building

Dialogue with countries
Research prioritization
Plans for capacity-building

Integrated Operational Research and Training

Influencing policy and practice
Influencing future research
Building sustainable capacity

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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