OPERATIONAL RESEARCH

What, Why and How?

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“What” is operational research

Research into interventions, strategies, tools or knowledge that can enhance the quality or coverage of disease control programs, health services or health systems

Historical roots:

Military & industrial modelling

defined as “the application of analytic methods to help make better decisions”

Example: Military sector: anti-aircraft artillery efficiency
Examples: Commercial sector

• England « Penny Post » – 1840

• Improved scheduling of airline crews

• Better design of waiting lines at Disney theme parks
Guiding principles in setting operational research agendas

• Define program / health system objectives

• Identify constraints to meeting objectives

• Ask research questions around constraints
RESEARCH QUESTIONS

Three themes:

• Lack of knowledge?

• Lack of a tool or intervention?

• Inefficient use of a tool or intervention?
Theme – “lack of knowledge” about patients lost to follow up

• **Objective** = Achieve an 85% treatment completion (TB) or excellent retention on therapy (ART, asthma, smoking cessation tool)

• **Constraint** = high loss to follow up rates (30%) from therapy
  \( \Rightarrow \) Treatment completion = 70%

• **Research question** = why are people lost? (payment? side effects? transport costs to clinic? unreported death?)

• **Answer the question and find solutions** to decreasing losses from therapy
Theme – “inefficient use of a tool” sputum smears for diagnosing PTB

- **Objective** of NTP = high quality sputum smear diagnosis using three sputum smears per patient

- **Constraint** = three smears per patient are demanding for the laboratory technicians (shortages, high caseloads)

- **Research question** = are *two smears* as efficient as three smears for diagnosing smear-positive pulmonary TB

- **Answer the question in a number of different ways**
Research methodology

- Descriptive or cross-sectional studies
- Case-control studies
- Cohort studies (prospective, retrospective)

Research is performed within the routine system; within a sound ethics framework; follows STROBE guidance

(Lancet 2007; 370: 1453-57)
What is not operational research:

- Basic science research

- Randomised controlled trials [RCT] – where research is conducted in a strictly controlled environment, with inclusion and exclusion criteria – **efficacy is the end point**
The need for RCT and operational research: a necessary continuum

- RCT
- Operational research
- Patients and communities

Generates knowledge (Trial conditions)

How to apply the knowledge? How the knowledge is applied? (Real world conditions)

Benefits +
Routine data monitoring system

SYNERGY

Data used for operational research
Why is operational research relevant?
Three broad reasons:

• Improve programme outcomes in relation to medical care or prevention

• **Assess feasibility** of new strategies or interventions in specific settings or populations

• Advocate for policy change
Improve program outcomes:
Voluntary counselling, HIV testing and adjunctive cotrimoxazole reduces mortality in TB patients in Thyolo, Malawi

*AIDS* 2003; **17**:1053-1061

⇒ Country-wide, expansion of HIV testing and cotrimoxazole for TB patients
HIV Testing and CPT in TB patients in Malawi: progress

<table>
<thead>
<tr>
<th>MALAWI</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
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<tbody>
<tr>
<td>TB patients</td>
<td>26836</td>
<td>26136</td>
<td>26019</td>
<td>26659</td>
<td>25767</td>
<td>25688</td>
<td>24356</td>
<td>22536</td>
</tr>
<tr>
<td>HIV tested</td>
<td>15%</td>
<td>26%</td>
<td>47%</td>
<td>66%</td>
<td>83%</td>
<td>84%</td>
<td>86%</td>
<td>88%</td>
</tr>
<tr>
<td>HIV positive</td>
<td>69%</td>
<td>72%</td>
<td>69%</td>
<td>66%</td>
<td>69%</td>
<td>63%</td>
<td>64%</td>
<td>64%</td>
</tr>
<tr>
<td>Start CPT</td>
<td>87%</td>
<td>97%</td>
<td>92%</td>
<td>98%</td>
<td>97%</td>
<td>96%</td>
<td>94%</td>
<td>94%</td>
</tr>
<tr>
<td>Start ART</td>
<td>0%</td>
<td>&lt;10%</td>
<td>29%</td>
<td>38%</td>
<td>32%</td>
<td>38%</td>
<td>45%</td>
<td>54%</td>
</tr>
</tbody>
</table>
# National TB treatment outcomes in new smear-positive PTB

<table>
<thead>
<tr>
<th>Year</th>
<th>Treatment Success</th>
<th>Death</th>
<th>Other</th>
</tr>
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<tbody>
<tr>
<td>2002</td>
<td>71%</td>
<td>19%</td>
<td>10%</td>
</tr>
<tr>
<td>2004</td>
<td>71%</td>
<td>16%</td>
<td>13%</td>
</tr>
<tr>
<td>2006</td>
<td>79%</td>
<td>13%</td>
<td>8%</td>
</tr>
<tr>
<td>2008</td>
<td>85%</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td>2010</td>
<td>88%</td>
<td>8%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Harries et al. BMC Public Health 2011; 11: 593
Assess feasibility: HIV treatment in a conflict setting: Experience from Bukavu, DRC

*PloSMed, 2007 5:e129*

⇒ Knowledge on offering HIV/AIDS care and ART in chronic conflict settings
Advocate for policy change

Advocacy for “Free-ART” in Nairobi, Kenya

Payment for antiretroviral drugs is associated with a higher rate of patients lost to follow-up than those offered free-of-charge therapy in Nairobi, Kenya

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Received 23 May 2007; received in revised form 13 December 2007; accepted 13 December 2007

KEYWORDS
HIV; AIDS; Antiretroviral therapy; Payment; Loss to follow-up; Kenya

Summary: This retrospective analysis of routine programme data from Moi Teaching District Hospital, Nairobi, Kenya shows the difference in terms of loss to follow-up between a cohort that paid 500 shillings/month (approximately US$2) for antiretroviral drugs (ART) and one that received medication free of charge. A total of 435 individuals (mean age 31.5 years, 66% female) were followed-up for 140 person-years. 246 were in the “payment” cohort and 189 in the “free” cohort. The incidence rate for loss to follow-up per 100 person-years was 47.2 and 20.5, respectively (adjusted hazard ratio 2.27, 95% CI 1.21–4.24, P = 0.01). Overall risk reduction attributed to offering ART free of charge was 56.6% (95% CI 20.0–76.5%). Five patients diluted their ART regimen to one tablet (instead of two tablets) twice daily in order to reduce the monthly cost of medication by half. All these patients were from the payment cohort. Payment for ART is associated with a significantly higher rate of loss to follow-up, as some patients might be unable to sustain payment over time. In resource-limited settings, ART should be offered free of charge in order to promote treatment compliance and prevent the emergence of drug resistance.

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Key elements

- Research questions are generated by identifying constraints and challenges of implementation.

- The answers to these questions should have direct, practical relevance to solving these problems and improving health care delivery.
Operational research – How?

The enabling factors
1. Direct Programme relevance

- Programme staff and general health staff are busy

- Research question must be relevant to programme implementation & connected to health service delivery

- Coordination mechanism to provide clear strategy about setting of research priorities
# Malawi TB Programme: 1999-2004

**Six principal objectives**

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<tr>
<td>1.</td>
<td>Positively influence health seeking behaviour of suspects</td>
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<tr>
<td>2.</td>
<td>Improve and sustain equity in process of TB care</td>
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<tr>
<td>3.</td>
<td>Improve diagnostic practices</td>
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<tr>
<td>4.</td>
<td>Improve capacity of NTP to deliver effective treatment</td>
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<td>5.</td>
<td>Increase collaboration – e.g., with HIV/AIDS; private sector</td>
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<td>6.</td>
<td>Strengthen supervisory and monitoring systems</td>
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Identify constraints for each objective and ask research questions around these constraints.
2. Partnerships

- Tendency to outsource research to academic institutions (annexed sites)
- Research findings passed to busy programme managers (implementation not a mandate)

- Paradigm shift: a “partnership model” that promotes better *involvement*, *co-ownership* and *responsibility* of programme staff with researchers

- Thus, build funding and resources for operational research into a national programme
  - Foreign institutions have funding, time and mandate for research and the associated power of decisions
International Expertise
- WHO
- The Union
- LSHTM

Malawi Institutions
- Medical School
- NGOs (MSF..)
- National AIDS Programme

Research Ideas

TB Programme Management Group

Implementation of research by the various groups
(Oct 2011) Stakeholders

International
World Diabetes Foundation
The Union
WHO

National
NTP (RNTCP) / MOH
National program - Cancer, Diabetes, CVD & Stroke
National experts

(Jan 2012)
Screening of TB patients for diabetes
(8 tertiary & 60 peripheral centres)

(Sept 2012)
Results presented back to stakeholders
Screening of patients with tuberculosis for diabetes mellitus in India

India TB-Diabetes Study Group*
3. Build research capacity / time

- Research Question
- Protocol development, including ethics approval
- Secure funding
- Implementation, collection of data, cleaning of data
- Data analysis and interpretation
- Paper writing, submission, peer review, re-writing

“The Hard Work” to translate findings into policy and practice
4. Develop and support trained researchers

- Are existing models working?

- Much investment in training [MSF, JATA, Union, CDC, WHO], but what about the products from the field?

- What happens to researchers who have completed Masters or PhD? Where are they?
  - Appointed to senior management
  - No budgets or infrastructure
  - No opportunities
Programs: Need for a critical mass!

• Build a “critical mass” of research staff
  • Competent Research Officer working with Programs
    ⇒ Coordinates and sets research priorities
    ⇒ Builds a “critical mass” of research staff

• “Practical skills” to conduct and publish research

• Resources for work and research dissemination
  • Annual meetings (field and partners)
  • Presentation at conferences
Scientific Publications-Trend (MSF-OCB)

Introduction of a "critical mass" of support staff: a research coordinator, a data manager and a medical editor

Start of MSF-Union operational research courses and OR fellows
5. Role of non-governmental organizations (NGOs-MSF)

- Work in conflict settings and with vulnerable groups (e.g. prisoners, commercial sex workers)

- By mandate, NGOs (e.g. MSF) are implementers and engage in translating research into policy and practice

- NGOs well resourced
6. Regularly evaluate success (or not) of research

- Have research activities completed and published?
- Has it influenced policy / practice?
- Provide feedback and disseminate
Framework for evaluation

Studies approved

\[\xrightarrow{\text{Studies completed}}\]

Papers submitted

\[\xrightarrow{\text{Papers published}}\]

Research findings disseminated

\[\xrightarrow{\text{Changes in policy and practice}}\]

Programme performance improves
Provision of Antiretroviral therapy in Malawi: 2004-2008
ART Scale Up in Malawi “DOTS” system

- Free ART to HIV-positive eligible patients
- One first-line ART regimen only “Triomune”
- One second ART line regimen
- Standardized system of monitoring/reporting
- Quarterly cohort analysis
- Quarterly structured supervision
Strong focus on monitoring, evaluation & supervision
Figure 3: Patients alive on ART in public and private sector clinics in Malawi
ART and Operational Research

Started in 2006
Support from an anonymous donor
Malawi Health Care Workers on ART: 38 in 2004 to 2398 in 2008

Health care workers on ART - survival

Survival Probability

- 85.1% at 6 months
- 81.3% at 12 months
- 78.2% at 18 months

months since ART initiation

Malawi Defence Force – access to ART and deaths in the army

Banda et al, PloS One 2008: e1445
Measuring Impact of ART scale up in Thyolo District

Mortality Reduction Associated with HIV/AIDS Care and Antiretroviral Treatment in Rural Malawi: Evidence from Registers, Coffin Sales and Funerals

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Abstract

Background: To report on the trend in all-cause mortality in a rural district of Malawi that has successfully scaled-up HIV/AIDS care including antiretroviral treatment (ART) to its population, through corroborative evidence from a) registered deaths at traditional authorities (TAs), b) coffin sales and c) church funerals.

Methods and Findings: Retrospective study in 5 of 12 TAs (covering approximately 50% of the population) during the period 2000–2007. A total of 210 villages, 24 coffin workshops and 23 churches were included. There were a total of 18,473 registered deaths at TAs, 15,781 coffins sold, and 2762 church funerals. Between 2000 and 2007, there was a highly significant linear downward trend in death rates. sale of coffins and church funerals (X² for linear trend: 538.4 P<0.0001, 989 P<0.0001 and 197 P<0.0001 respectively). Using data from TAs as the most reliable source of data on deaths, overall death rate reduction was 37% (95% CI 33–40) for the period. The mean annual incremental death rate reduction was 0.52/1000/year. Death rates decreased over time as the percentage of people living with HIV/AIDS enrolled into care and ART increased. Extrapolating these data to the entire district population, an estimated 10,136 (95% CI: 9760–10,529) deaths would have been averted during the 8-year period.

Conclusions: Registered deaths at traditional authorities, the sale of coffins and church funerals showed a significant downward trend over a 8-year period which we believe was associated with the scaling up HIV/AIDS care and ART.

PLoS One 2010, 5, e10452
Registered deaths at traditional authorities

Death per 1000 population/year

Year

Deaths/1000 population 95% CI

Registered church funerals

Church funerals/1000 members

Year

Church funerals/1000 members 95% CI

Coffin sales

Coffin sales/1000 population

Year

Coffin sales/1000 population 95% CI