International Union Against Tuberculosis and Lung Disease

MEDECINS SANS FRONTIERES

LuxOR Luxembourg Operational Research

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

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

Zachariah et al, Lancet Infect Dis 2009; 9: 711- 717

Historical roots:

Military & industrial modelling

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

Example: Military sector: anti-aircraft artillary efficiency

Examples: Commercial sector

- **England « Penny Post » – 1840**

POST OFFICE REGULATIONS.

ON AND AFTER THE 10th JANUARY, a Letter not exceeding HALF AN OUNCE IN WEIGHT, may be sent from any part of the United Kingdom, to any other part, for ONE PENNY, if paid when posted, or for TWO PENCE if paid when delivered.

THE SCALE OF RATES,

If paid when posted, is as follows, for all Letters, whether sent by the General or by any Local Post,

Not exceeding ½ Ounce	.....	**One Penny.**
Exceeding ½ Ounce, but not exceeding 1 Ounce		**Twopence.**
Ditto 1 Ounce	..... 2 Ounces	**Fourpence.**
Ditto 2 Ounces	..... 3 Ounces	**Sixpence.**

and so on; an additional Two-pence for every additional Ounce. With but few exceptions, the WEIGHT is limited to Sixteen Ounces.

If not paid when posted, double the above Rates are charged on Inland Letters.

COLONIAL LETTERS.

If sent by Packet Twelve Times, if by Private Ship Eight Times, the above Rates.

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The Packet Rates which vary, will be seen at the Post Office. The Ship Rates are the same as the Ship Rates for Colonial Letters.

As regards Foreign and Colonial Letters, there is no limitation as to weight. All sent outwards, with a few exceptions, which may be learnt at the Post Office, must be paid when posted as heretofore.

Letters intended to go by Private Ship must be marked "*Ship Letter.*'

Some arrangements of minor importance, which are omitted in this Notice, may be seen in that placarded at the Post Office.

No Articles should be transmitted by Post which are liable to *injury* by being stamped, or by being crushed in the Bags.

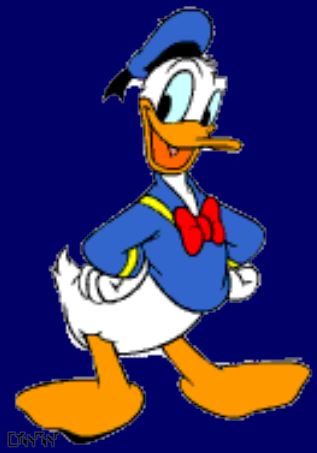
It is particularly requested that all Letters may be *fully* and *legibly addressed*, and *posted as early* as convenient.

January 7th, 1840.

By Authority:—J. Hatteril, London.

- **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

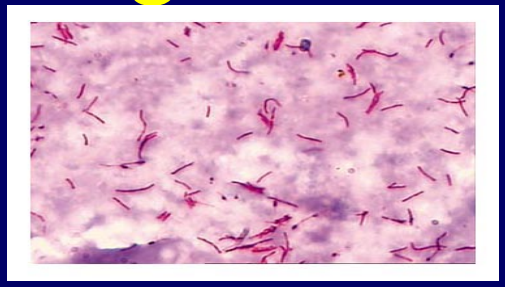
Three themes:

- 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
  (⇨ 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

Generates knowledge
(Trial conditions)

Operational research

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

Patients and communities

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

MALAWI	2003	2004	2005	2006	2007	2008	2009	2010
TB patients	26836	26136	26019	26659	25767	25688	24356	22536
HIV tested	15%	26%	47%	66%	83%	84%	86%	88%
HIV positive	69%	72%	69%	66%	69%	63%	64%	64%
Start CPT	87%	97%	92%	98%	97%	96%	94%	94%
Start ART	0%	<10%	29%	38%	32%	38%	45%	54%

Harries *et al*. BMC Public Health 2011; 11:593

National TB treatment outcomes in new smear-positive PTB

Year	Treatment Success	Death	Other
2002	71%	19%	10%
2004	71%	16%	13%
2006	79%	13%	8%
2008	85%	8%	7%
2010	88%	8%	4%

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

Transactions of the Royal Society of Tropical Medicine and Hygiene (2008) 102, 288–293

available at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevierhealth.com/journals/trst

ELSEVIER

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

Summary This retrospective analysis of routine programme data from Mbagathi District Hospital, Nairobi, Kenya shows the difference in rates of loss to follow-up between a cohort that paid 500 shillings/month (approximately US$7) for antiretroviral drugs (ART) and one that received medication free of charge. A total of 435 individuals (mean age 31.5 years, 65% female) was followed-up for 146 person-years: 265 were in the ‘payment’ cohort and 170 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.

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

1. Positively influence health seeking behaviour of suspects
2. Improve and sustain equity in process of TB care
3. Improve diagnostic practices
4. Improve capacity of NTP to deliver effective treatment
5. Increase collaboration – e.g., with HIV/AIDS; private sector
6. Strengthen supervisory and monitoring systems

Identify constraints for each objective and ask research questions around these constraints

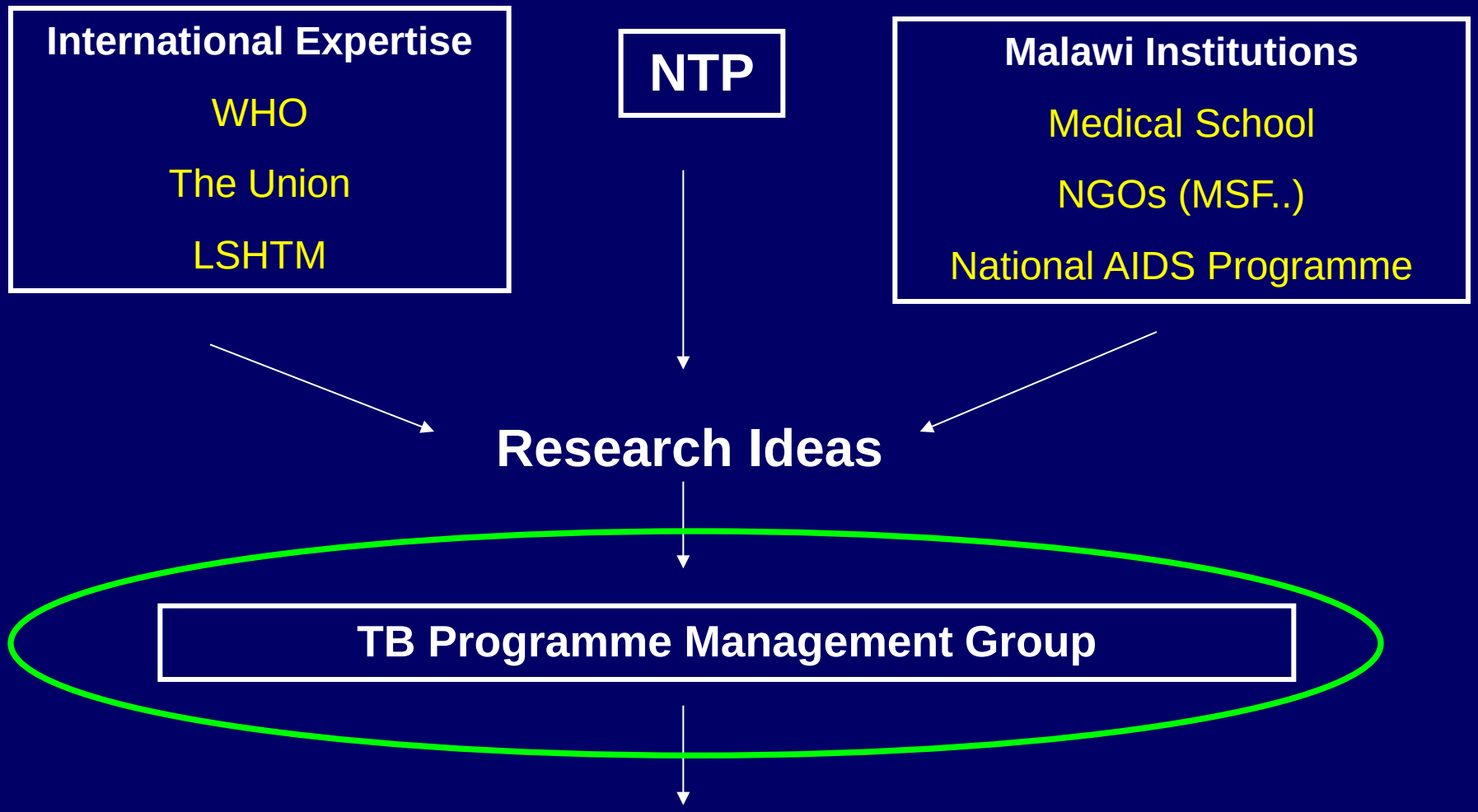
2. Partnerships

⇒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
NTP
Malawi Institutions
Medical School
NGOs (MSF..)
National AIDS Programme
Research Ideas
TB Programme Management Group
Implementation of research by the various groups

INDIA

International

World Diabetes Foundation

The Union

WHO

(Oct 2011)
Stakeholders

National

NTP (RNTCP) / MOH

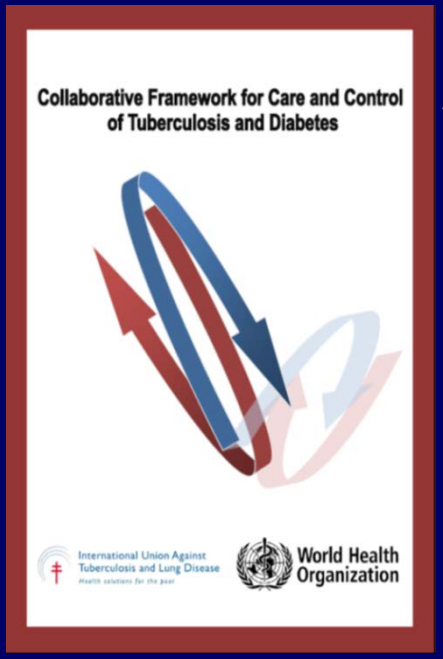
National program - Cancer, Diabetes, CVD & Stroke

National experts

(Jan 2012)

Screening of TB patients for diabetes

(8 tertiary & 60 peripheral centres)



(Sept 2012)

Results presented back to stake holders

Sl. no. 38

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Directorate General of Health Services
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health and Family Welfare
निर्माण भवन, नई दिल्ली - ११० १०८
Nirman Bhawan, New Delhi - 110 108

IMMEDIATE

D. O. No. Z-28015/64/2011-TB
Date: 21st September 2012

Subject: RNTCP – Screening of All TB patients for Diabetes Mellitus – Reg

Dear Dr. Jain,

Tropical Medicine and International Health doi:10.1111/tmi.12084

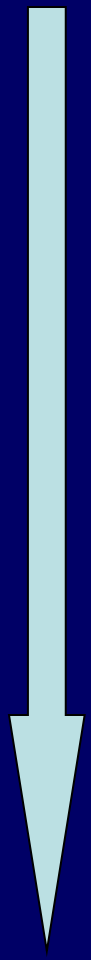
VOLUME 18 NO 5 PP 636–645 MAY 2013

Screening of patients with tuberculosis for diabetes mellitus in India

India Tuberculosis-Diabetes Study Group*

India TB-Diabetes Study Group

3. Build research capacity / time



TIME & Capacity

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!

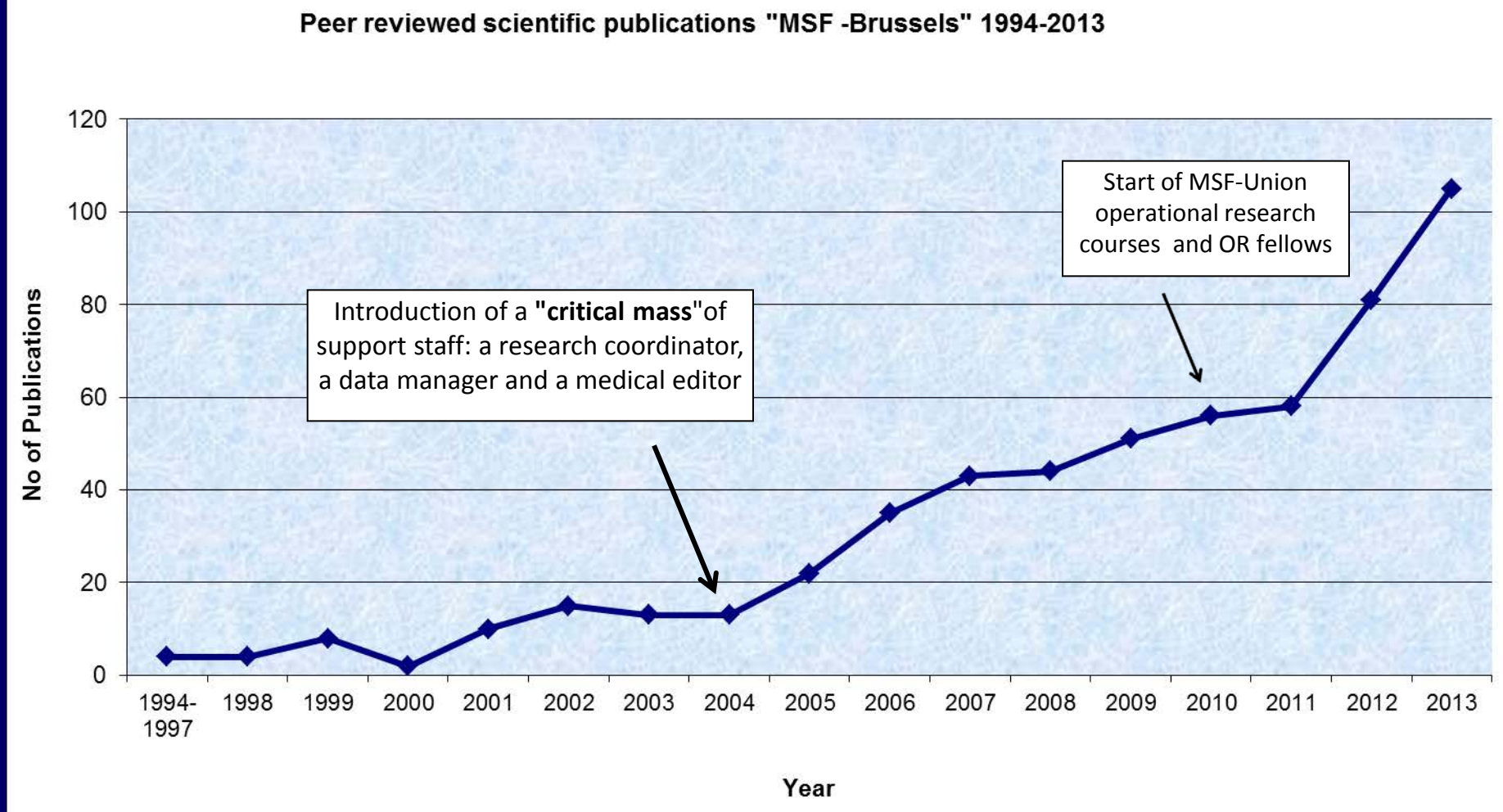
- **Build a "critical mass" of research staff**
  - Competent Research Officer working with Programs

  ⇒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)



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
  - Studies completed
    - Papers submitted
      - Papers published
        - Research findings disseminated
          - Changes in policy and practice
            - Programme performance improves

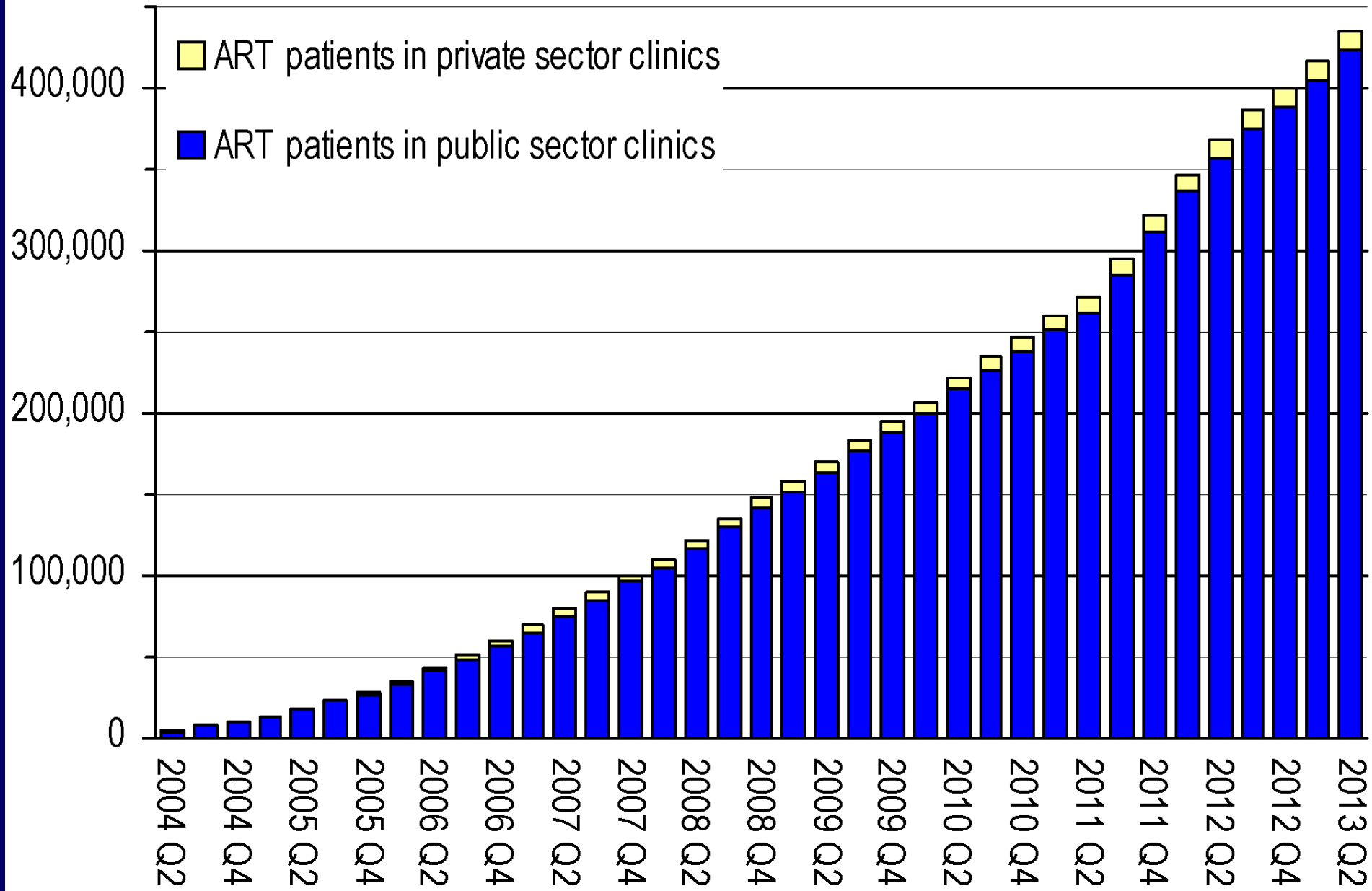
Provision of Antiretroviral therapy in Malawi: 2004-2008

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

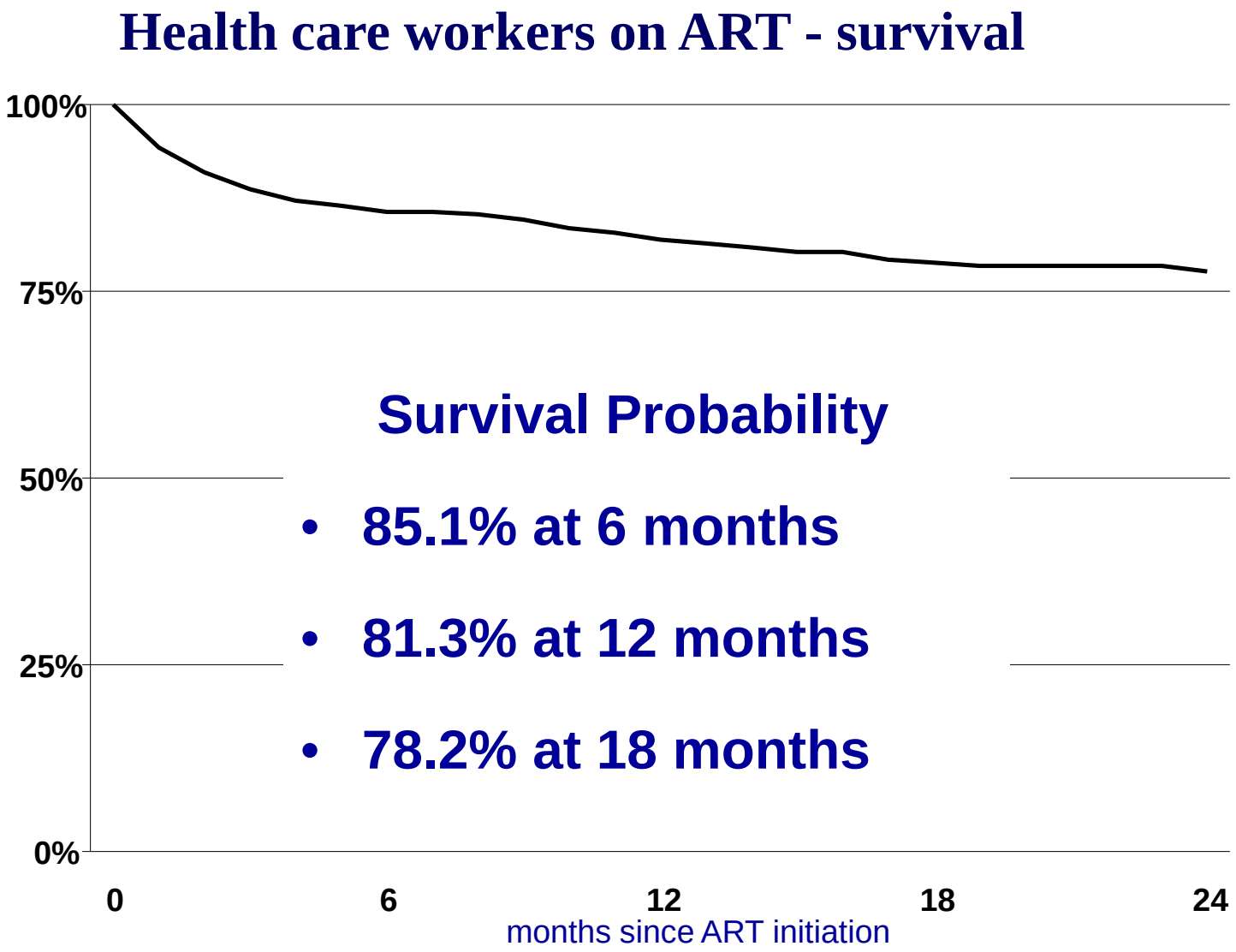


ART and Operational Research

Started in 2006

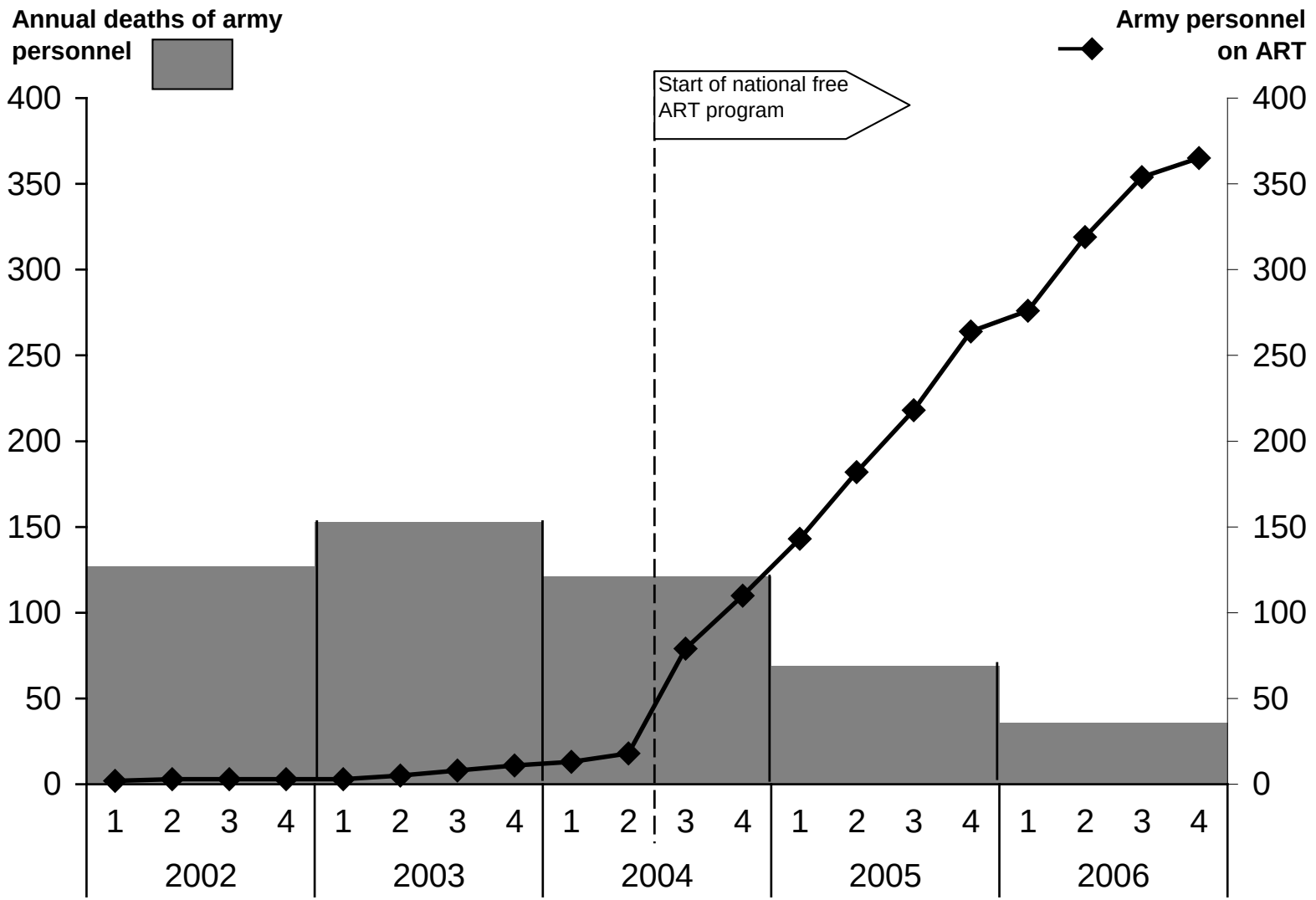
Support from an anonymous donor

Malawi Health Care Workers on ART: 38 in 2004 to 2398 in 2008



Makombe et al, Bulletin of WHO, 2007; 85: 851-857

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

OPEN ACCESS Freely available online

PLoS one

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

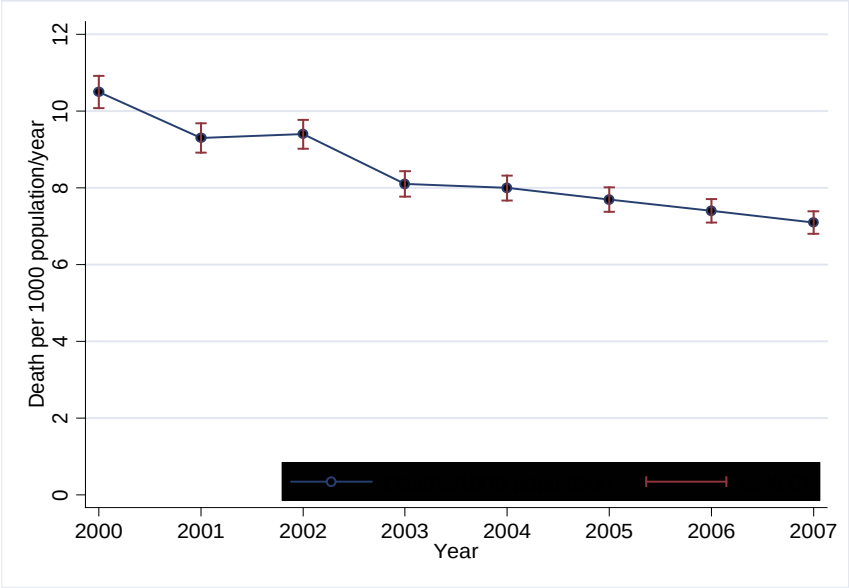
Background: To report on the trend in all-cause mortality in a rural district of Malawi that has successfully scaled-up HIV/AIDS care including antiretroviral treatment (ART) to its population, through corroborative evidence from a) registered deaths at traditional authorities (TAs), b) coffin sales 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, 15781 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 (X^2 for linear trend: 338.4 $P<0.0001$, 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 10,156 (95% CI: 9786–10259) deaths would have been averted during the 8-year period.

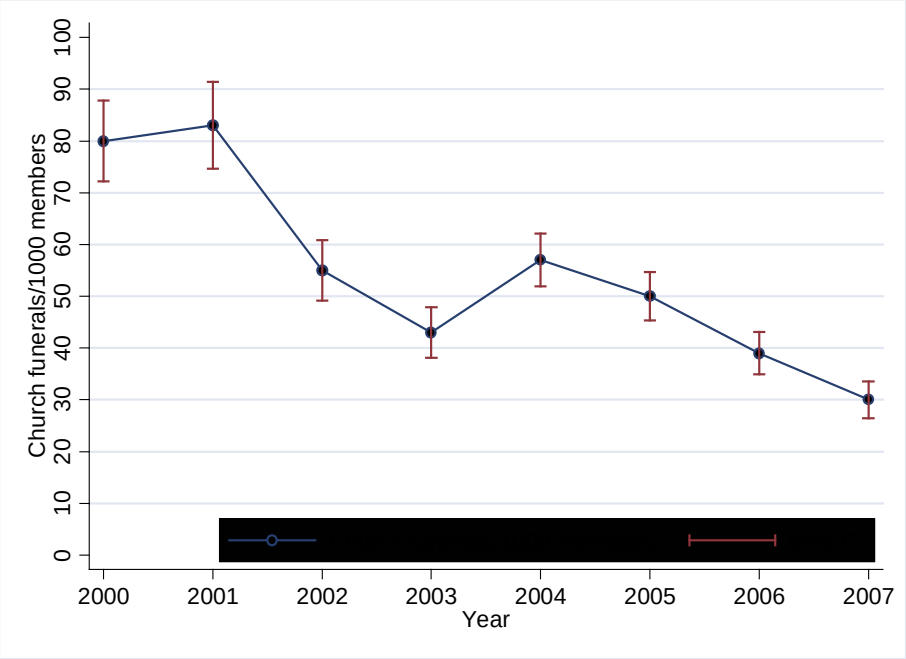
Conclusions: Registered deaths at traditional authorities, the sale of coffins and church funerals showed a significant downward trend over a 8-year period which we believe was associated with the scaling up HIV/AIDS care and ART.

PLoS One 2010, 5, e10452

Registered deaths at traditional authorities



Registered church funerals



Coffin sales