

IDENTIFYING AND DESCRIBING COMPONENTS IN COMPLEX INTERVENTIONS

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WHO Hails Advance in Tuberculosis As Milestone

TB: World Health Organization Hails a Treatment That Could Save Millions of Lives

By Alan Cowell
New York Times Service

GENEVA — Claiming "the biggest health breakthrough of this decade," the World Health Organization forecast Wednesday that millions of lives could be saved over the next 10 years through a tuberculosis treatment that has been field-tested in such disparate places as New York City and rural Tanzania.

Researchers said the benefits of the system, known as Directly Observed

health radar screen" in the 1960s and 1970s amid widespread assumptions it was under control.

Only in the early 1990s, when "huge increases" in tuberculosis cases began to be identified in New York City, did health officials focus anew on the disease, Dr. Nunn said.

He added that tuberculosis claims 2 to 3 million deaths per year from a reported 6 to 8 million cases.

In an interview, Dr. Nunn said that several factors explained the worldwide

and asphyxiation. Patients also display wasting as muscle tissue is eaten away.

According to the World Health Organization, the disease dates back about 6,000 years and was once known as the "white plague."

It was so much part of the fabric of 19th century European society that it inspired poets and musicians in works including Puccini's opera "La Boheme."

In the early 20th century, richer patients were confined to sanatoriums

Directly observed therapy for TB

“Most exciting invention
Since the discovery
of penicillin” (Nakajima 1997)



Papers

Systematic review of randomised controlled trials of strategies to promote adherence to tuberculosis treatment

BMJ 1997 ; 315 doi: <https://doi.org/10.1136/bmj.315.7120.1403> (Published 29 November 1997)

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Responses

Jimmy Volmink, director (cochrane@eagle.mrc.ac.za)^a, *Paul Garner, division head*^b

Directly observed treatment has been successfully implemented in several settings and found to be associated with substantial improvements in rates of adherence and drug resistance.^{6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22}
²³ However, it has usually been introduced as part of a comprehensive effort to improve tuberculosis services. The most common accompanying interventions are improved accessibility of services, increased availability of drugs, changes in drug regimens, patient incentives, tracing of patients who default, and outreach efforts.²⁴ Directly observed treatment may, therefore, simply be a marker for a more serious commitment to tuberculosis control. Carefully designed randomised trials evaluating the independent effects of directly observed treatment are awaited.

Directly observed therapy (short course)

- Political commitment
- Laboratory improvement
- Drug supply improvements
- Better reporting
- Direct observation (“may or may not”)

**WORLD HEALTH ORGANIZATION
COMPLEX INTERVENTION TRANSFORMER**


Politics, money,
improved health systems



Watching people take
their drugs

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Directly observed therapy and treatment adherence

Jimmy Volmink, DPhil   • Patrice Matchaba, FRCOG • Paul Garner, MD

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| Reference | WHO strategy | | | | |
|-----------|----------------------|------------------------|--------------------|-------------|------------------|
| | Political commitment | Laboratory improvement | Direct observation | Drug supply | Reporting system |
| 6 | No | Yes | Yes | Yes | Yes |
| 7 | No | No | Yes | Yes | No |
| 8 | No | No | Yes | No | Yes |
| 9 | Yes | No | Yes | Yes | Yes |
| 10 | No | No | Yes | No | Yes |
| 11 | No | No | Yes | No | No |
| 12 | No | No | Yes | No | No |
| 13 | No | No | Yes | No | No |
| 14 | No | Yes | Yes | Yes | Yes |
| 15 | No | Yes | Yes | Yes | Yes |
| 16 | No | Yes | Yes | No | No |
| 17 | No | No | Yes | Yes | No |
| 18 | No | Yes | Yes | No | No |
| 19 | No | No | Yes | No | No |
| 20 | No | No | Yes | No | No |
| 21 | Yes | No | Yes | No | No |
| 5 | Yes | No | Yes | No | Yes |
| 22 | Yes | Yes | Yes | Yes | Yes |

REVIEW

| Reference | Study | Study type and size | Interventions offered in addition to direct observation | | |
|--------------------------------------|---|--|--|---|---|
| | | | Patients | Staff | Other |
| Agutu ⁶ | Somalia, Hospital-based DOT by medical staff | Retrospective, n=213 | Health education, free drugs, follow-up | Intense supervision | External funding, improvement of microscopy services and record-keeping |
| Alvarez-Gordillo, et al ⁷ | Mexico, DOT by health workers at health facilities or patients' homes | Retrospective comparison of DOT group with semi-supervised and self-supervised controls, n=461 | Social support | Training, intense supervision | Drug supply, support from local authorities |
| Neher, et al ²⁵ | Nepal, clinic-based DOT by medical staff | Prospective, n=771 | Relaxed atmosphere and friendly behaviour by staff, education, defaulter tracing | Motivation | External funding |
| Norval, et al ²⁶ | Cambodia, DOT not fully described, patients in hospital for 2 months | Retrospective, n=4164 | Free food and drugs | Motivation, training and supervision, monetary incentives | External funding, improved drugs supply, and logistics, integration of tuberculosis management into general health services, improved laboratory services |
| Pozsik, et al ²⁷ | SC and NY, USA, clinic and community-based DOT by nurses | Retrospective, SC n=1521, NY n=9200 | Free food, clothing, books, transport, treatment for substance abuse, court-mandated DOT, incarceration | No information | No information |
| Ruben, et al ²⁸ | Pennsylvania, PA, USA, community-based DOT by nurses | Retrospective, n=404 | Free food and cigarettes | No information | No information |
| Schluger, et al ²⁹ | New York, NY, USA, hospital-based DOT by nurses | Retrospective, n=113 | Contracts, defaulter tracing, taxi fare, food, subway tokens, social-worker assistance with housing, public assistance and health insurance, access to substance-abuse programmes, relationships | Weekly conferences | External funding |

| Trial ID | DOT | | | | | Self administered therapy | | | |
|--------------------------------------|-------------------------|--------|-----------------|---------------------|------------------------------------|---------------------------|--|------------------------------------|---------------|
| | Who observed? | Where? | How often? | | Adherence recorded at each contact | Cure | Frequency of contact with health service | Adherence recorded at each contact | Cure |
| | | | Intensive phase | Consolidation phase | | | | | |
| Kamolratanakul 1999 THA ¹ | Healthcare worker | Clinic | Daily | Daily | Yes | 76% (315/414) | Monthly | Unclear | 67% (283/422) |
| | Community health worker | Home | Daily | Daily | | | | | |

Cochrane Database of Systematic Reviews | [Review - Intervention](#)

Directly observed therapy for treating tuberculosis

✉ [Jamlick Karumbi, Paul Garner](#) Authors' declarations of interest

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Worm Wars



A debate has been raging over the last month about the benefits of mass deworming projects. Hugely popular with the UN and charities, the evidence behind the practice has come under attack. Are the criticisms...

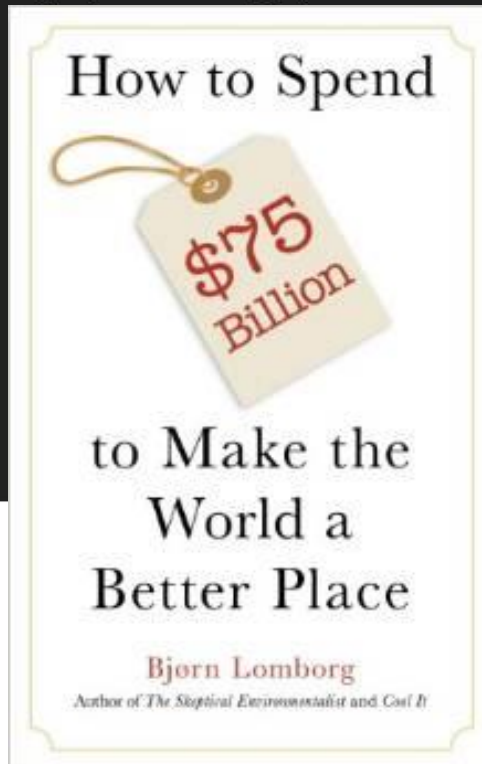
Available now

🕒 10 minutes



Copenhagen Consensus

“ Providing facts on how to do the most good for the world.



13 Nobel Prize Winners:

“Best way of advancing global welfare?”

“Deworming”

Table 7. Description of studies: accompanying health promotion activities[Open in table viewer](#)

| Accompanying intervention | Details from trial | Trials |
|----------------------------------|---|-------------------------|
| To both intervention and control | Quote: "The AWC workers, usually local women (plus assistants), give pre-school education, give nutritional supplements to malnourished children, and record births and pre-school deaths." | Awasthi 2013 (Cluster) |
| | Quote:"The parents of all children aged < 7 years were offered a range of health services at child health days, including vaccinations, vitamin A supplements, growth monitoring and promotion, and demonstrations of complementary feeding." | Alderman 2006 (Cluster) |
| | Quote:"The primary job responsibilities of the AWW [anganwadi worker] are to run a creche and provide primary | Awasthi 2001 |

...Total eight studies

| | | |
|--------------------------------|--|-----------------------|
| Only in the intervention group | Treatment schools received worm prevention education through regular public health lectures, wall charts, and the training of teachers in each treatment school on worm prevention. Health education stressed the importance of hand washing to avoid ingesting roundworm and whipworm larvae, wearing shoes to avoid hookworm infection, and not swimming in infected fresh water to avoid schistosomiasis. | Miguel 2004 (Cluster) |
|--------------------------------|--|-----------------------|

Health promotion inc.
deworming



Single tablet to whole
continents of children

WORLD HEALTH ORGANIZATION COMPLEX INTERVENTION TRANSFORMER

Rapid initiation of antiretroviral therapy for people living with HIV

✉ Alberto Mateo-Urdiales, Samuel Johnson, Rhodine Smith, Jean B Nachega, Ingrid Eshun-Wilson

Authors' declarations of interest

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<https://doi.org/10.1002/14651858.CD012962.pub2> 

Main results

We included seven studies with 18,011 participants in the review. All studies were carried out in low- and middle-income countries in adults aged 18 years old or older. Only one study included pregnant women.

In all the studies, the rapid ART intervention was offered as part of a package that included several cointerventions targeting individuals, health workers and health system processes delivered alongside rapid ART that aimed to facilitate uptake and adherence to ART.

Comparing rapid ART with standard initiation probably results in greater viral suppression at 12 months (RR 1.18, 95% CI 1.10 to 1.27; 2719 participants, 4 studies; moderate-certainty evidence) and better ART uptake at 12 months (RR 1.09, 95% CI 1.06 to 1.12; 3713 participants, 4 studies; moderate-certainty evidence), and may improve retention in care at 12 months (RR 1.22, 95% CI 1.11

Table 2. Interventions delivered alongside rapid antiretroviral therapy (ART) in the intervention arm[Open in table viewer](#)

| Study | Intervention target | | |
|---------------|--|--|--|
| | Individual ^a | Health system ^b | |
| | | Health-providers | Healthcare structures and processes |
| Amanyire 2016 | <ul style="list-style-type: none"> • ART initiation within 14 days of eligibility • Individualized counselling including assessment of ART readiness | <ul style="list-style-type: none"> • Opinion-leader-led training of healthcare workers on the benefits of early ART, including lectures, introduction of revised 'less strict' counselling approach, and ART readiness assessment • Feedback on ART initiation rates | <ul style="list-style-type: none"> • POC HIV diagnosis and CD4 count • No need for treatment supporters • Flexible number of pre-ART counselling sessions |
| Elul 2017 | <ul style="list-style-type: none"> • ART initiation at 1st visit after diagnosis • Counselling session on day of presentation • Mobile phone visit reminders • Non-cash FI^{c,d} | <ul style="list-style-type: none"> • Receptionists expedited PLWH appointments • Clinicians encouraged to start ART on 1st clinic visit | <ul style="list-style-type: none"> • POC HIV diagnosis and CD4 count • Paper-based referral to on-site HIV services • 1st consultation within 1 week from diagnosis |

Table 2a: Summary of intervention strategies

| Intervention strategies | | Amanyre 2016 | Chan 2016 | Coffey 2019* | Colasanti 2018 | Dai 2020 | Dijkstra 2020 |
|---|---|----------------------------|-----------------------------|--|----------------|----------|---------------|
| | | Accelerated ART initiation | Patient directed strategies | Reduce administrative requirements to initiate ART | | | y |
| Reduce pre-ART psychosocial requirements | y | | | | | | |
| Aim to improve pre-ART counselling content / delivery | y | | | | | | |
| Navigation during ART initiation visit | | | | | | | |
| Assist/accelerate insurance approval/financial aid | | | | | y | | |
| Promote shared decision making | | | | | | y | |
| Assign a case manager | | | | | | | y |
| DOTS ART first dose | | | | | | | |
| Provider directed strategies | Provider training on rapid ART initiation | | y | | | y | |
| | Provider training on counselling | | y | | | | |
| | Provider supervision/ coaching /mentorship | y | | | | | |
| | Provider performance feedback | y | | | | | |
| | Provide SOP/guidance document | | | | | | |
| | Provide decision support tool (checklist/algorithm) | | | | | | |
| | Reduce no. of pre-ART sessions | y | y | | | | |
| | First ART counselling on day of HIV testing | | | | | | |

| Cointerventions | | POC TB testing | Primary care physician to initiate ART | Collaborative clinical care | Linkage transport voucher | Linkage incentive (conditional) | Linkage navigation | Linkage LTFU tracing | Appointment reminders | Short term ongoing navigation/ support | Intensified post ART counselling | Increased duration post ART initiation clinical visit | Incentive to attend post ART initiation visits | Multi-month scripting for stable patients | Trace lost patients | Integrated NCD care | Patient centered services | Multidisciplinary team care | Service quality improvement efforts | Improve medical record systems | | |
|---|--|-----------------|--|-----------------------------|---------------------------|---------------------------------|--------------------|----------------------|-----------------------|--|----------------------------------|---|--|---|---------------------|---------------------|---------------------------|-----------------------------|-------------------------------------|--------------------------------|--|--|
| | | Cointerventions | Linkage strategy | | | | | | | | | | | | | | | | | | | |
| Immediate post ART retention strategies | | | | | | | | | | y | | | | | | | | | | | | |
| | | | | | | | | | | | | y | | | | | | | | | | |
| | | | | | | | | | | | | | y | y | | | | | | | | |
| | | | | | | | | | | | | | | | y | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |
| Long term retention strategies | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | |

Footnotes: *Coffey 2019 conducted in the same center with the same interventions as Pilcher 2017 therefore only one study represents centralized Lab; Maskew 2020 conducted urine TB LAM testing, ** Same day ART not offered in these studies

Hugely complex interventions to assure rapid start



Just give them drugs at time of diagnosis

WORLD HEALTH ORGANIZATION COMPLEX INTERVENTION TRANSFORMER

Does this mean we need an “ingredients approach”?

Certainly, in Cochrane reviews

Comparison 2: Two or more interventions versus no intervention

We found no improvements in **ANC coverage of four or more visits** (average OR 1.48, 95% CI 0.99 to 2.21; participants = 7840; studies = six; Heterogeneity: $\text{Tau}^2 = 0.10$; $I^2 = 48\%$; *low quality evidence*) or **pregnancy-related deaths** (average OR 0.70, 95% CI



“It’s all rule-based epistemology and no thoughtful ontology. We don’t know what we are studying”

Professor Sandy Oliver

Epistemology

the theory of knowledge, especially with regard to its methods, validity, and scope, and the distinction between justified belief and opinion.

Ontology

a set of concepts and categories in a subject area or domain that shows their properties and the relations between them.

Adherence systematic reviews of RCTs

Lets' get into the patient's heads with a QES

Adherence to antiretroviral drugs in LMIC

Table 2. The nine emergent themes.

HIV-positive people navigate a complicated world

- 1: Poverty, competing priorities and an unpredictable microworld
- 2: Social identity and gender norms can have a profound impact on care-seeking behavior
- 3: Alienation makes it hard to take ART
- 4: People with HIV receive conflicting information, messages and views

The health system is punishing and uninviting

- 5: “Bad patients” are an unhelpful construct of an authoritarian health system
- 6: Poor clinic services for patients and inadequate support for health workers

It is difficult to adapt to and incorporate ART into life

- 7: The new normal requires daily drugs
 - 8: Self-efficacy, social responsibility and support helps
 - 9: The tipping point
-

<https://doi.org/10.1371/journal.pone.0210408.t002>



Supporting re-engagement with care

Dr Claire Keene
Médecins Sans Frontières: Khayelitsha
Technical Consultation on HIV Linkage
March 3rd 2019
Seattle, USA



Summary of the Welcome Service differentiated service delivery model for patients struggling with ART adherence and engagement



The Welcome Service is a differentiated service delivery (DSD) model for HIV care to support clients who are not coping with treatment, including those who have difficulty with adherence to antiretroviral therapy (ART) resulting in a high viral load (VL) and clients who struggle with clinic attendance (missed appointments or complete disengagement, i.e. loss to follow up). In a systematic review of qualitative literature, Eshun-Wilson *et al* explore how different factors influence adherence and long-term retention in HIV care¹. They describe how clients experience a multitude of competing stressors that combine to a point at which clients are unable to cope and “tip over” into disengagement (i.e. stop taking treatment or miss appointments).

The Welcome Service, developed on this theory, aims to build patient resilience and long-term retention through improved identification and management of barriers to engagement with ART.

Mass drug administration for filariasis

Cochrane QES

| | |
|--|-----------|
| Theme 1: Historical narratives and experiences shape community trust in government programmes | 2 |
| Subtheme 1: People believe the programme has an ulterior motive..... | 2 |
| Subtheme 2: Colonial legacies influence the credibility of the programme..... | 2 |
| Subtheme 3: Past traumas influence the credibility of the programme | 2 |
| Theme 2: People may suffer as a result of MDA. | 4 |
| Subtheme 1: Side effects are a frightening and unwelcome experience | 4 |
| Subtheme 2: The role of media and rumour generates mass panic..... | 4 |
| Subtheme 3: When people do suffer, there is no one around to help..... | 4 |
| Theme 3: The expectation that everyone complies may become coercive and blaming..... | 6 |
| Subtheme 1: Health workers may use an authoritarian approach to ensure people comply | 6 |
| Subtheme 2: Communities buy-in to mass drug treatment | 6 |
| Subtheme 3: Outward compliance, private rejection..... | 7 |
| Theme 4: Knowledge is not evenly shared or distributed. | 8 |
| Subtheme 1: Communities have different narratives of disease where LF has been around a long time ... | 8 |
| Subtheme 2: People seek clarification and rationale, but do not always receive it | 8 |
| Theme 5: People perceive benefits of the programme differently. | 10 |
| Subtheme 1: The potential benefits relate to the suffering, stigma and costs of disease..... | 10 |
| Subtheme 2: Theoretical benefits do not always mesh with their experiences and understanding so far | 10 |
| Theme 6: People do not value or respect their distributors. | 12 |
| Subtheme 1: Authority is derived from status rather than knowledge | 12 |
| Subtheme 2: Inappropriate behaviour reinforces the negative perceptions people have of CDDs. | 12 |
| Subtheme 3: CDD have a muddled role in the distribution | 12 |

In summary

- We need thoughtful structured approaches to describe complex interventions
- Often the effects and heterogeneity can be explained by the core components and co-interventions
- WHO use QES as adjunct to linear planning (guidelines)
- QES underused in designing, refining, and implementing complex interventions

Thanks to FCDO

Thanks to READ-It collaborators and staff
