

Tuberculosis: a persistent global health challenge

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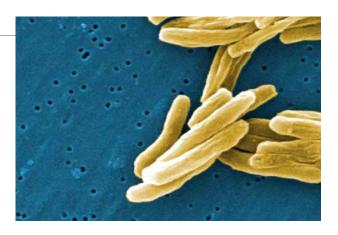
What is TB?

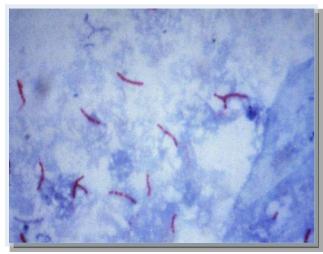
Tuberculosis is an infectious disease caused by *Mycobacterium tuberculosis*

Active TB: sick and contagious

Most infected people do not develop the disease

- These people are <u>not</u> contagious
- We call this 'latent infection'





Clinical manifestations of TB

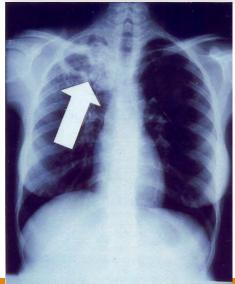
General

- Fever, weight loss, weakness
- "Consumption", "Phthisis"

Organ specific

- Lungs: cough, spitting up blood
- Others:
 - Scrofula: swollen lymph nodes
 - Spine: 'hump-back'
 - Etc.





"Youth grows pale and spectre thin and dies"



TB killed Keats at the age of 25.

TB was nearly always fatal before the advent of anti-TB drugs



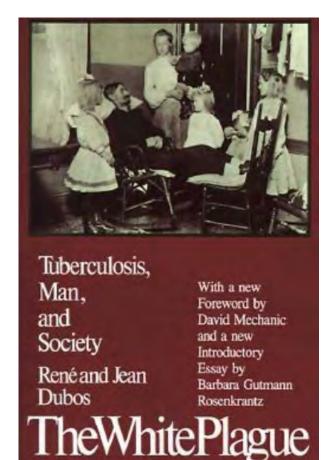


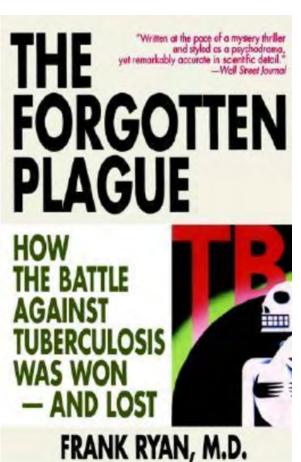


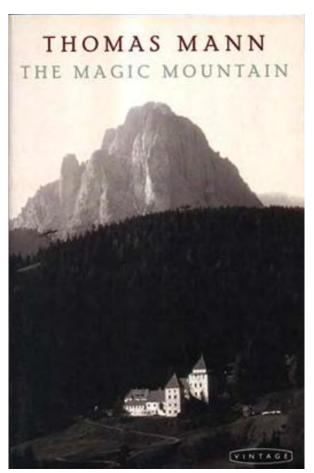
Tuberculosis throughout History: PEOPLE

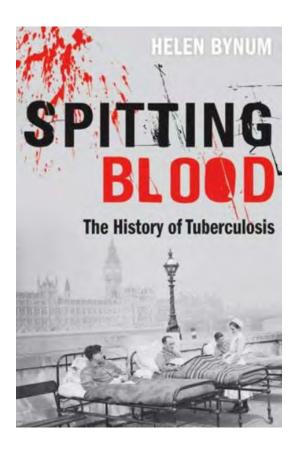


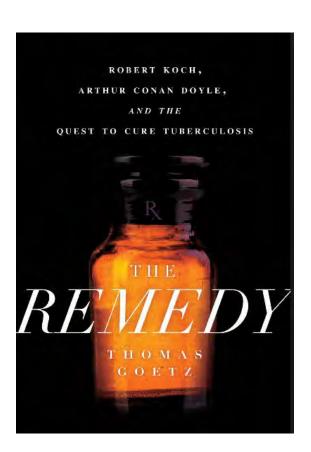
Nelson Mandela John Keats Bronte sisters Jane Austen Franz Kafka Anton Chekhov George Orwell Frederic Chopin DH Lawrence...

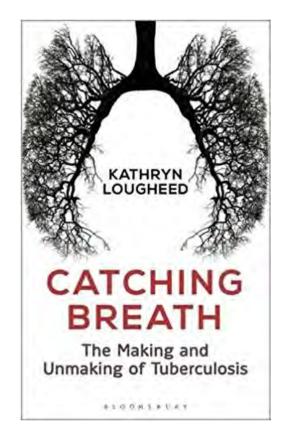






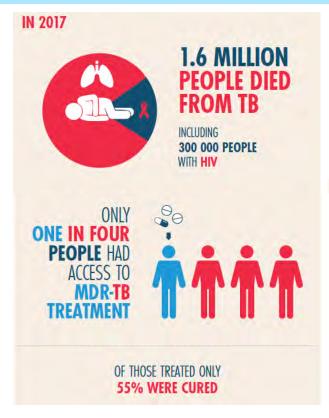








TB is still a huge problem globally!







6.4 MILLION WERE DETECTED AND NOTIFIED

3.6 MILLION
PEOPLE WITH
TB WERE
UNDIAGNOSED
OR DETECTED AND
NOT REPORTED

ONLY 36%
OF PEOPLE NEWLY ENROLLED IN
HIV CARE WERE STARTED ON TB
PREVENTIVE TREATMENT



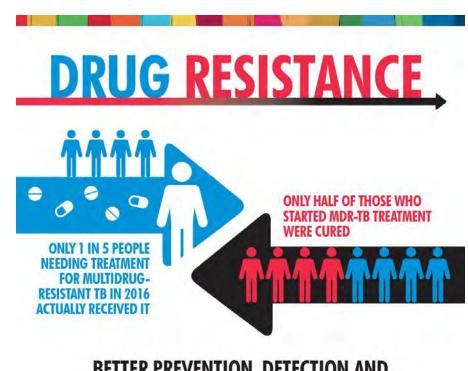
ONLY 23%
OF CHILDREN UNDER 5 YEARS,
ESTIMATED TO BE ELIGIBLE FOR TB
PREVENTIVE TREATMENT WERE
STARTED ON IT.



WHO strongly recommends preventive treatment for people living with HIV, and children under 5 years living in households with TB.

Drug-resistant TB

558000 people developed disease resistant to at least *rifampicin*—the most effective first-line TB drug.



BETTER PREVENTION, DETECTION AND CURE WILL ADDRESS THE MDR-TB CRISIS



What is the strategy for TB control?

In the absence of a good vaccine, "test and treat" is the key strategy for control

Detect TB cases (once patients become sick) and put them on 6 month, short-course, multidrug therapy, and ensure adherence

Thereby reduce transmission to others

Packaged as the "DOTS" strategy

- 70/85 targets:
 - Detect 70% of smear-positive cases
 - Cure 85% of the cases identified

DOTS has saved lives, and cured many....





TARGETS ON TRACK

- ✓ Reduction in TB mortality rate of 45% since 1990
- √ 37 million lives saved since 2000
- √ 86% cure rate and 61 million patients cured, 1995-2013

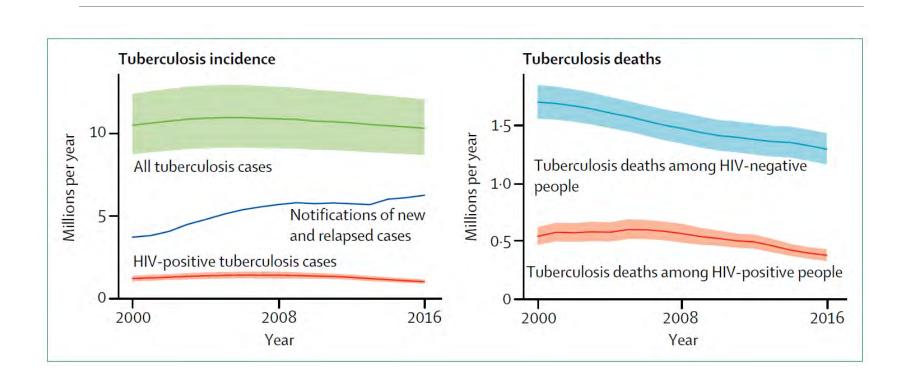
BUT....

Ref: Global TB Control Report 2014





TB cases and deaths in slow decline, 1990-2016

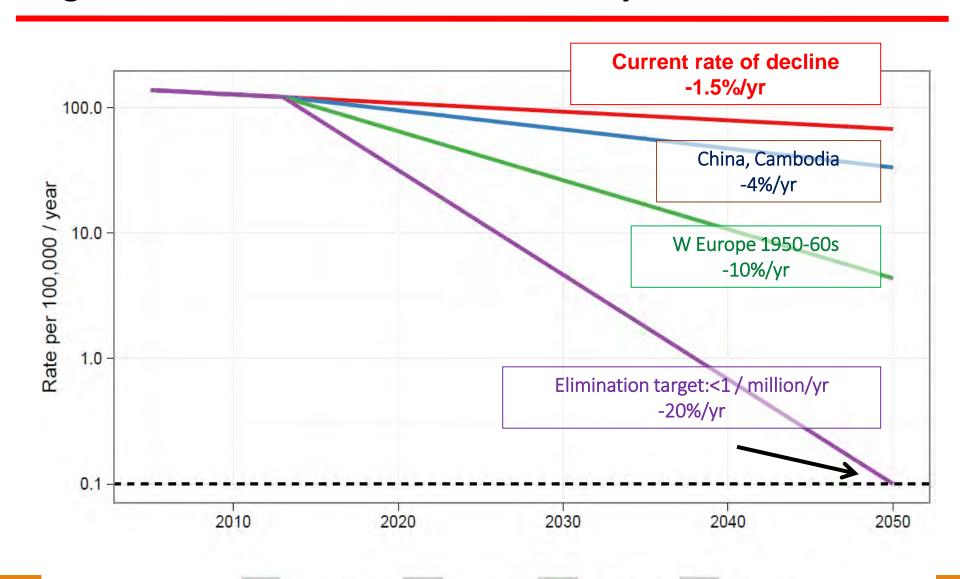




Full implementation of Global Plan: 2015 MDG target reached but TB not eliminated by 2050

Current decline

PROGRAMME



Recent best

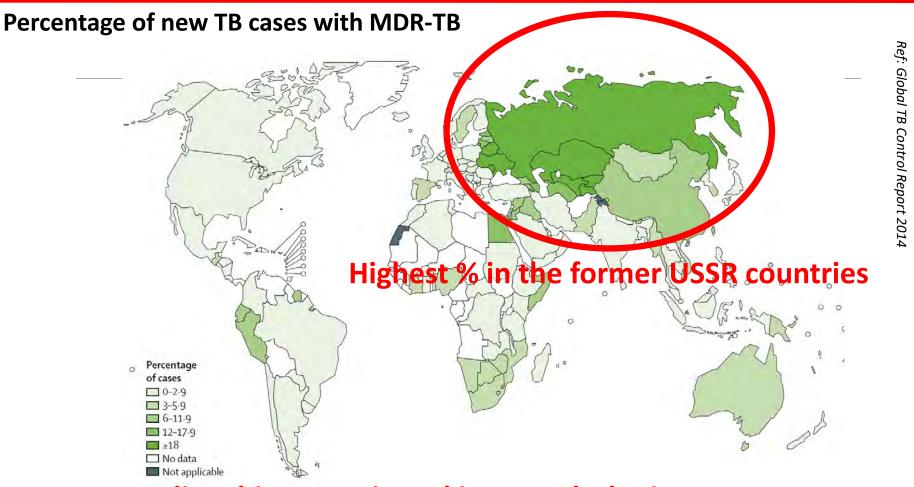
All-time best

Elimination

World Health Organization

MDR-TB is a crisis in some areas





India, China, Russia, Pakistan and Ukraine have 60% of all MDR-TB cases

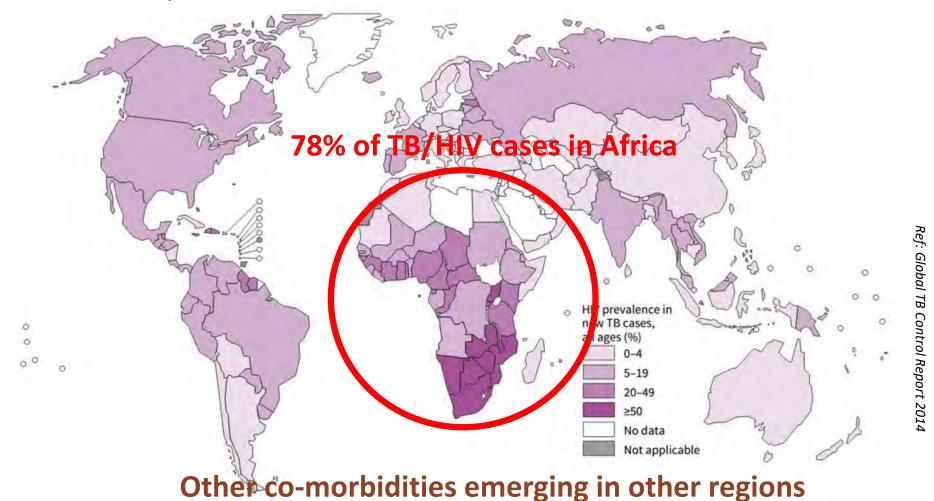




TB/HIV is a huge problem in Africa



Estimated HIV prevalence in new TB cases, 2013







FUNDING GAPS IMPEDE EFFORTS TO END TB

FUNDING GAP

TB CARE AND PREVENTION:



FUNDING GAP OF US\$ 2.3 BILLION IN 2017

RESEARCH & DEVELOPMENT:



FUNDING GAP OF US\$ 1.2 BILLION PER YEAR REQUIRED FOR THE DEVELOPMENT OF NEW TOOLS



67th World Health Assembly, Geneva, May 2014







Global strategy and targets for tuberculosis prevention, care and control after 2015



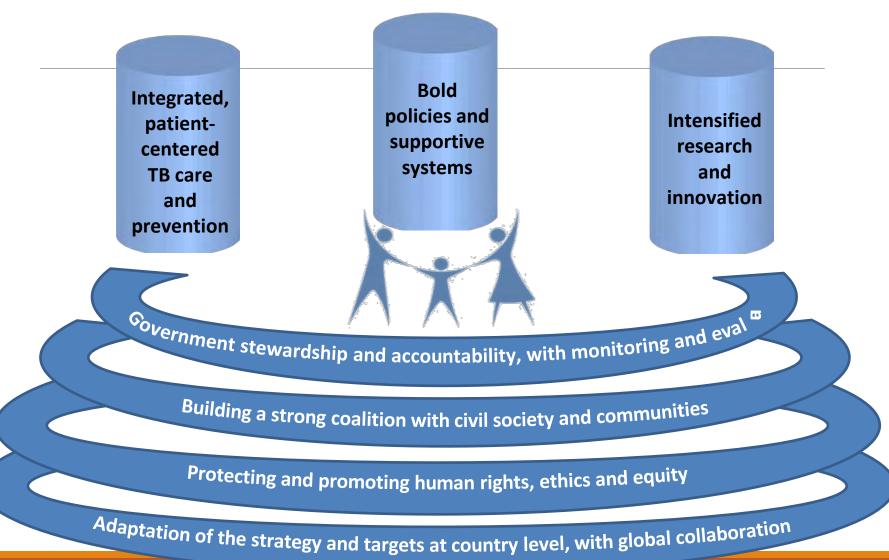
VISION	A world free of tuberculosis — zero deaths, disease and suffering due to tuberculosis	
GOAL	End the global tuberculosis epidemic	
MILESTONES FOR 2025	- 75% reduction in tuberculosis deaths (compared with 2015); - 50% reduction in tuberculosis incidence rate (compared with 2015) (less than 55 tuberculosis cases per 100 000 population) - No affected families facing catastrophic costs due to tuberculosis	
TARGETS FOR 2035	- 95% reduction in tuberculosis deaths (compared with 2015) - 90% reduction in tuberculosis incidence rate (compared with 2015) (less than 10 tuberculosis cases per 100 000 population) - No affected families facing catastrophic costs due to tuberculosis	

PRINCIPLES

- 1. Government stewardship and accountability, with monitoring and evaluation
- 2. Strong coalition with civil society organizations and communities
- 3. Protection and promotion of human rights, ethics and equity
- 4. Adaptation of the strategy and targets at country level, with global collaboration



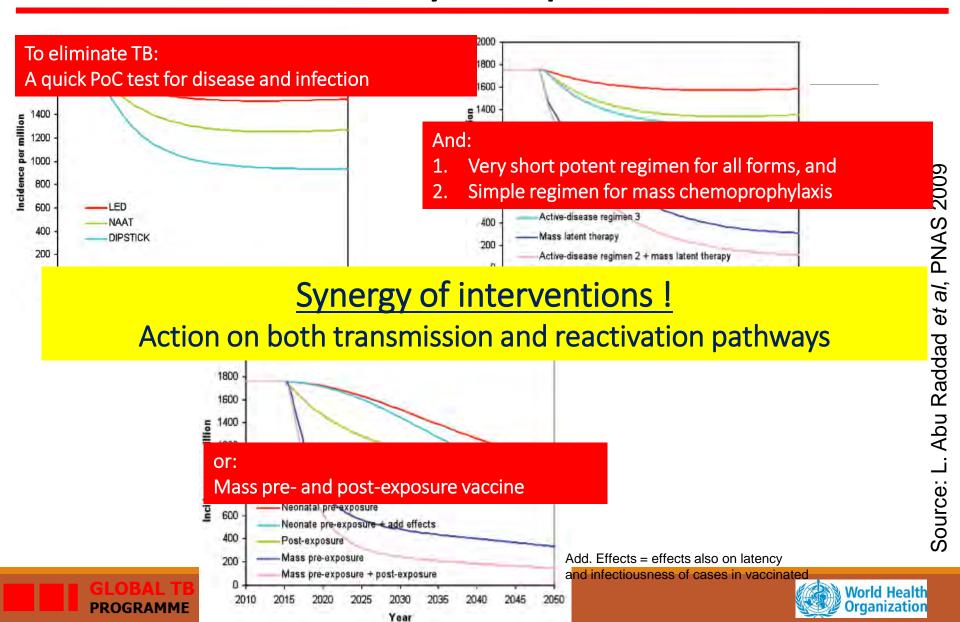
The End TB Strategy: 3 pillars and 4 Principles







Mathematical modeling suggests that multiple interventions are necessary for impact



TB in Canada



EDITORIAL

Tuberculosis in Nunavut: a century of failure

Noni MacDonald MD MSc, Paul C. Hébert MD MHSc, Matthew B. Stanbrook MD PhD



Stephen Lewis calls on Ottawa to step up as Nunavut grapples with TB 'crisis'

Founder of AIDS-Free World wrapped up trip to Nunavut to meet with people affected by disease

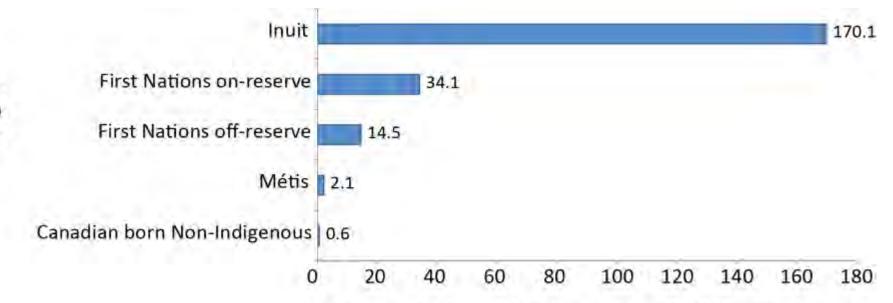
Nunavut, (Codie McLachlan/The Canadian Press)



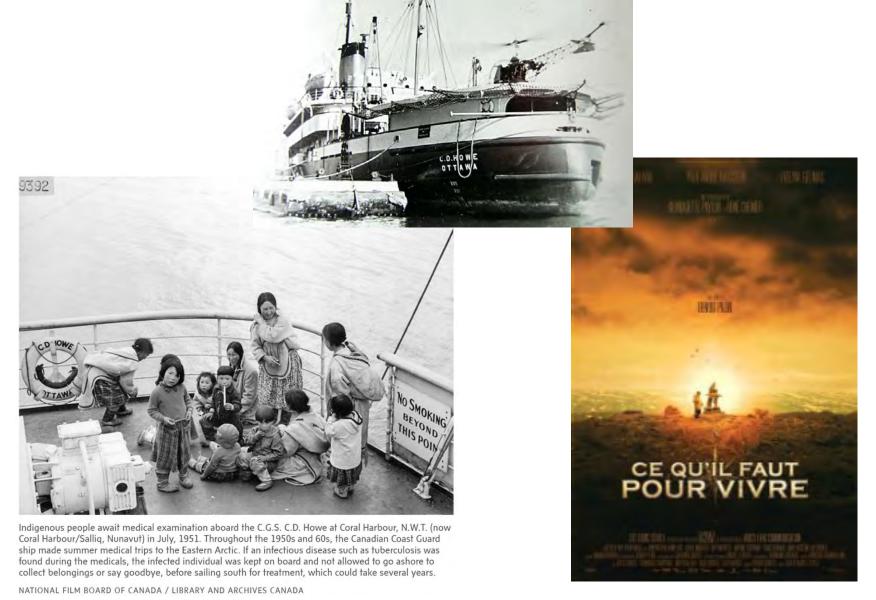
Stay Connected with CBC News

Lewis said he had five points to make about the issue.

- The rate of tuberculosis in the territory is unacceptably high.
- There is a shortage of nursing staff who speak Inuktitut and specialize in treating TB.
- The lasting effects of colonialism are continuing and making the problem worse.
- Food insecurity and a lack of housing negatively affects health.
- The effects of the C.D. Howe medical ship, which took Inuit patients south for TB treatment in the 1950s and '60s, is still being felt.



Tubercuclosis incidence rate per 100,000 population



https://www.theglobeandmail.com/opinion/article-out-in-the-cold-what-the-tb-crisis-in-

nunavut-reveals-about-canada/

https://en.wikipedia.org/wiki/The_Necessities_of_Life

SOCIAL & ECONOMIC INEQUITY IN INUIT NUNANGAT

Many Inuit face social and economic inequities that impact our health and wellbeing

INUIT NUNANGAT

\$23,485 The median individual income for Inuit in Inuit Nunangat¹

52% of Inuit in Nunangat live in crowded homes*1

34% of Inuit aged 25 to 64 in Inuit Nunangat have earned a high school diploma¹

70% of Inuit households in Nunavut do not have enough to eat²

The number of physicians per 100,000 population in Nunavut⁴

47.5% of Inuit in Inuit Nunangat are employed¹

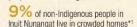
72.4 years
The average life expectancy
for residents in Inuit Nunangat¹⁵

12.3 The infant mortality rate per 1000 for Inuit infants in Canada.⁶

ALL CANADIANS

\$92,011 The median individual income for non-Indigenous

people in Inuit Nunangat1





8% of all Canadian households do not have enough to eat³

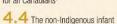


119 The mean number of physicians per 100,000 population in Urban Health Authorities⁴

60.2% of all Canadians are employed



82.9 years
The average life expectancy
for all Canadians⁵



4.4 The non-Indigenous infant mortality rate per 1000 for Canada.6

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Shirin Rodrendstrar and Emma Hawkins, Health at a Glarice. Food Insecurity in Canada (Ottawa, ON: Statistics Canada, March 25, 2015). Canadain Institute for Health Information, Supply, Distribution and Mignation of Physicisms in Canada, 2014 (Ottawi, ON: Canadain Institute for Health Information, September 2015).

*Costom but urbased on Statistics Canada's Projections of the Aberiginal Population and Households in Canada's 2011 to 201



Journal of Epidemiology and Global Health In Press, Corrected Proof DOI: https://doi.org/10.2991/jegh.k.190314.002; ISSN 2210-6006 https://www.atlantis-press.com/journals/jegh



The Enduring Plague: How Tuberculosis in Canadian Indigenous Communities is Emblematic of a Greater Failure in Healthcare Equality

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Health equality Indigenous health care tuberculosis

ABSTRACT

Despite global strides made in prevention and treatment, tuberculosis (TB) remains an acute problem for Indigenous people in Canada. TB affects Indigenous communities at significantly higher rates than the general Canadian population, for whom it is a disease of the past. This paper suggests how colonialism and its history of violence have shot the face of TB in Canada, and thus how TB is a telling point of analysis for considering the lack of equity and equality in healthcare delivery in Canada.

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Government aims to eliminate tuberculosis in Canada's North by 2030



The Mycobacterium tuberculosis (TB) bacteria is shown in a 2006 high magnification scanning electron micrograph (SEM) image. (CDC / Janice Carr)

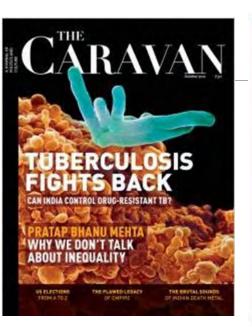
Federal government aims to eliminate tuberculosis in Canada's North by 2030

By The Canadian Press

Indigenous Services Minister Jane Philipott (left) and Health Minister Ginette Petitpas Taylor (centre) look on as Inuit Tapiriit Kanatami (ITK) President Natan Obed addresses media in the Foyer outside the House of Commons in Ottawa on Thursday, Oct.5, 2017.

THE CANADIAN PRESS/Sean Kilipatrick

Case study of India





THE WALL STREET JOURNAL.

India in Race to Contain Untreatable Tuberculosis

BY GERTA ANAND

MUMBAI—India's slow response to years of medical warnings now threatens to turn the country into an incubator for a mutant strain of tuberculosis that is proving resistant to all known treatments, raising alarms of a new global health hazard.

"We finally have ended up with a virtually untreatable strain" of tuberculosis in India, said Dr. Zarir Udwadia, one of the country's leading TB authorities.

In December, Dr. Udwadia reported in a medical journal that he had four tuberculosis patients resistant to all treatment. By January, he had a dozen cases, then 15.

A government backlash began immediately. Anonymous health-ministry officials denied the reports through media outlets. They accused Dr. Udwadia and his colleagues of starting a panic. A Mumbai city health official seized patient samples for verification in government labs.

In April, the government quietly confirmed the strain, according to internal Indian health-ministry documents reviewed by The Wall Street Journal.

Spread of the strain could return tuberculosis

to the fatal plague that killed two-thirds of people afflicted, before modern treatments were developed in the 1940s, said Mario Raviglione, director of the Stop TB Department of the World Health Organization. The WHO is now assisting India to combat the strain.

The number of known cases in India is small but geographically dispersed. Dr. Udwadia's patients are in Mumbai, at the P.D. Hinduja National Hospital & Medical Research Center. In the high-tech hub of Bangalore, St. John's National Academy of Health Sciences has seen six cases. And in New Delhi, the All India Institute of Medical Sciences has confirmed another two, said officials at the institutions.

"While this handful of cases is worrying, it's just the tip of the iceberg," said Dr. Soumya Swaminathan, of India's National Institute for Research in Tuberculosis. For treatments, Dr. Udwadia said, "We've got nothing."

Ashok Kumar, head of India's tuberculosis-con-Please turn to page A12

COVERSTORY



How Fight to Tame TB Made It Stronger

The World Health Organization's longstanding strategy for fighting tuberculosis is showing deadly unintended consequences: By focusing for years on the easiest-to-cure patients, it helped allow TB strains to spread that are now all but untreatable by modern medicine.

> By Geeta Anand in Mumbai and Betsy McKay in Atlanta

The WHO and a growing chorus of global health experts are now calling for a significant overhaul in the way nations with widespread drug-resistant TB combat the disease. It amounts to a de facto acknowledgment that the WHO's TB strategy, and the countries that use it, failed to adapt quickly enough as the disease formed more powerful, resistant strains.

"The TB community has been too conservative" on a global scale, said Puneet Dewan, until recently a senior officer in the WHO's India tuberculosis program. "We should have pushed sooner for a more aggressive, comprehensive approach" toward drug resistance, he said this month in an interview. "There was a cost in failing to do that. We're paying that cost today."

The WHO played a particularly sizable role in designing the tuberculosis program in India, which has seen a steep decline in regular TB. But India and other poor countries are now in the midst of an epidemic of drugresistant strains—deadlier and harder-to-treat varieties of one of the world's top infectious-disease killers.

G.R. Khatri, who headed India's TB program more than a decade ago, called the epidemic of resistant TB in Mumbai "a recipe

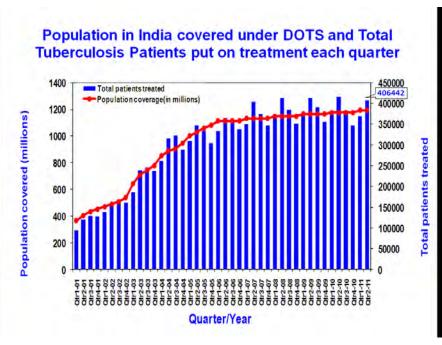
for disaster." The WHO should have known it was so bad and bears responsibility, he said. "What has the WHO been doing?"

In pilot testing across India this year of a new diagnostic method, some 6.6% of untreated TB patients were drug-resistant—suggesting far higher rates than the 2% to 3% levels India and the WHO have cited for years. The test was a collaboration of international aid groups and India's government.

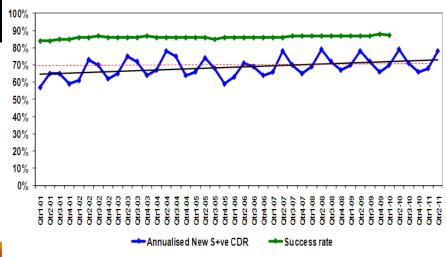
At one clinic in Mumbai, research showed more than one quarter of 566 TB patients tested in recent months were resistant to the most powerful treatment, according to data obtained by The Wall Street Journal through India's Right to Information Act. The results are preliminary, but in the absence of any nationwide survey they offer a sense of what India's drug-resistance rates might be.

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Indian TB Programme: DOTS coverage is high (quantity is good!)



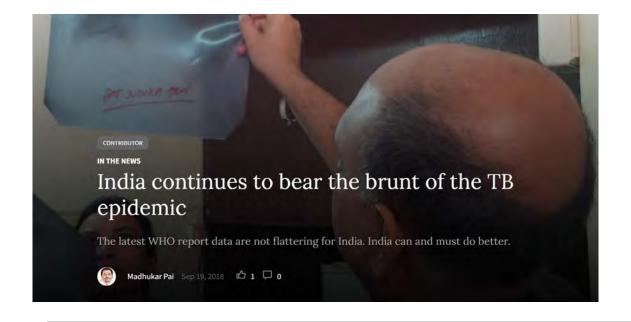




[•]Population projected from 2001 census

[•]Estimated no. of NSP cases - 75/100,000 population per year (based on recent ARTI report)

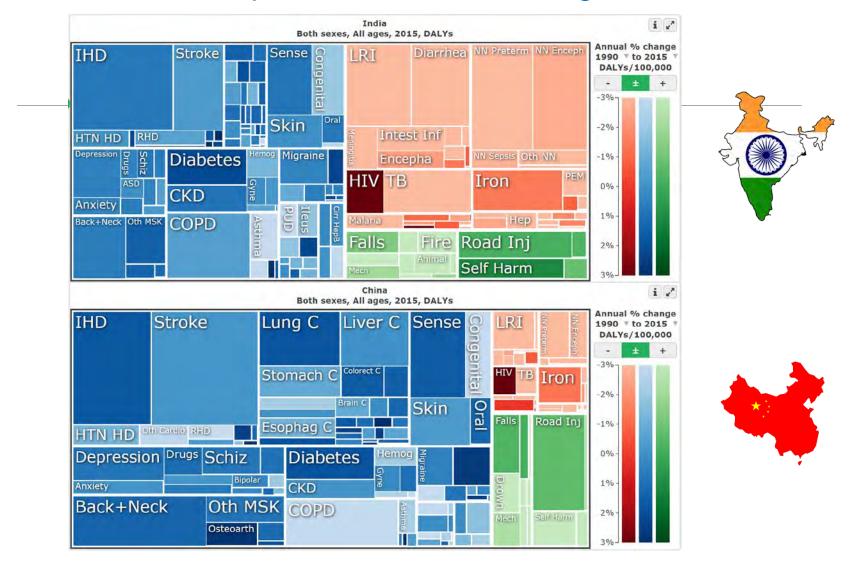
And yet...



In 2017, an estimated 2.7 million people developed TB disease, and over 400000 people died. So, India accounts for 27% of the global estimated cases, and 25% of the estimated deaths.

https://naturemicrobiologycommunity.nature.com/channels/315-in-the-news/posts/38992-india-continues-to-bear-the-brunt-of-the-tb-epidemic

TB is one of the top 5 causes of death at ages 30-69 in India



TB is one of the top 5 causes of death at ages 30-69 in India, whereas in China, TB is no longer one of the top 10 causes

Reducing global tuberculosis deaths—time for India to step up

As another World Tuberculosis Day passes by the outlook for tuberculosis control is far from optimistic, especially for India, the ground zero for the global epidemic. Last year, WHO declared that the tuberculosis epidemic was worse than previously thought, with an estimated 10-4 million new tuberculosis cases worldwide in 2015.¹ WHO estimated that globally 1-8 million people died from tuberculosis in 2015, of whom 0-4 million were also infected with HIV.¹ Although global tuberculosis deaths declined by 22% between 2000 and 2015, it is remarkable that tuberculosis today is responsible for more deaths than HIV and malaria combined, and continues to rank among the top ten causes of deaths worldwide.¹



WHO estimates that India accounts for 2-8 million (27%) of the 10-4 million new cases, and 29% of the 1-8 million deaths. According to the Registrar General of India's Million Death Study, which documented causes of death in 1-4 million households, tuberculosis remained one of the top five causes of death among people aged 30–69 years. By contrast, in China tuberculosis is no longer one of the top ten reasons for dying. Importantly, the declines in the age-standardised tuberculosis death rates in India mostly occurred between 2001 and 2007, with a slowing of the decline from 2008 to 2013. Most tuberculosis deaths in India continue to be among young adults in the economically productive age group, with high economic and social costs.

Why are so many Indians dying of a curable infectious disease in 2017? There are several factors that contribute to India's enormous tuberculosis death toll. First, India has not adequately tackled key determinants of tuberculosis, especially malnutrition and tobacco smoking, which have been clearly linked with excess tuberculosis mortality. Second, India continues to underinvest in health, with governmental expenditure on health being one of the lowest in the world at 1.4% of the gross domestic product. This underinvestment is reflected in India's Revised National Tuberculosis Control Program (RNTCP) that has struggled to receive budgets commensurate with the scale of India's epidemic.

Third, implementation failures and a weak health system have led to suboptimal cascade of care in the public system. About half a million patients with tuberculosis in

www.thelancet.com Vol 389 March 25, 2017

1174

*Madhukar Pai, Natasha Correa, Nerges Mistry, Prabhat Jha

McGill International TB Centre and McGill Global Health Programs, McGill University, Montreal QC H3A 1A2, Canada (MP); Manipal McGill Centre for Infectious Diseases, Manipal University, Manipal, India (MP); Centre for Global Health Research, St Michael's Hospital and Dalla Lana School of Public Health, University of Toronto, Toronto, Canada (NC, PJ); and Foundation for Medical Research, Mumbai, India (NM)

Social determinants: poverty, malnutrition and TB in India

e4

THE NATIONAL MEDICAL JOURNAL OF INDIA

VOL. 27, NO. 3, 2014

Original Article

Undernutrition and the incidence of tuberculosis in India: National and subnational estimates of the populationattributable fraction related to undernutrition

ANURAG BHARGAVA, ANDREA BENEDETTI, OLIVIA OXLADE, MADHUKAR PAI, DICK MENZIES

"The overall prevalence of undernutrition in the age group of 15–49 years was 36% among women and 34% among men. About half of all cases of active TB ... were attributable to undernutrition."

OPEN & ACCESS Freely available online



Tuberculosis and Poverty: Why Are the Poor at Greater Risk in India?

Olivia Oxlade1, Megan Murray1,2,3*

1 Department of Epidemiology, Harvard School of Public Health, Boston, Massachusetts, United States of America, 2 Division of Global Health Equity, Brigham and Women's Hospital, Boston, Massachusetts, United States of America, 3 Infectious Disease Unit, Massachusetts General Hospital, Boston, Massachusetts, United States of America

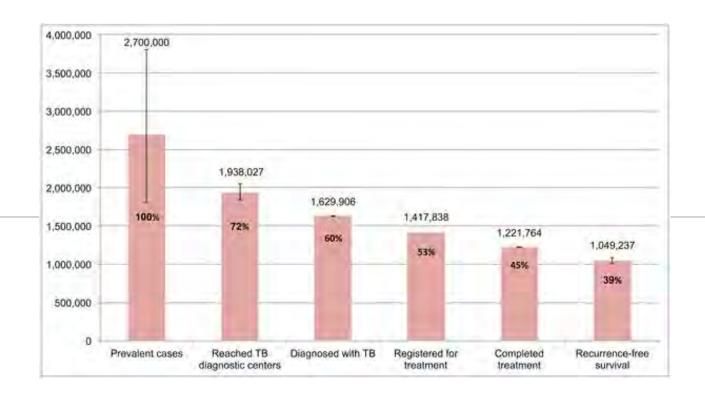
"TB control strategies should be targeted to the poorest populations that are most at risk, and should address the most important determinants of disease—specifically low BMI and indoor air pollution."



RESEARCH ARTICLE

The Tuberculosis Cascade of Care in India's Public Sector: A Systematic Review and Metaanalysis

Ramnath Subbaraman^{1,2}*, Ruvandhi R. Nathavitharana^{3,4}, Srinath Satyanarayana^{5,6}, Madhukar Pai⁵, Beena E. Thomas⁷, Vineet K. Chadha⁸, Kiran Rade⁹, Soumya Swaminathan¹⁰, Kenneth H. Mayer^{3,11}



Diagnostic delays & long pathways

INT J TUBERC LUNG DIS 18(3):255–266 © 2014 The Union http://dx.doi.org/10.5588/ijtld.13.0585 E-published ahead of print 9 January 2014

Delays in diagnosis and treatment of pulmonary tuberculosis in India: a systematic review

C. T. Sreeramareddy, * Z. Z. Qin, † S. Satyanarayana, † R. Subbaraman, † M. Pai†

*Department of Population Medicine, Faculty of Medicine and Health Science, University Tunku Abdul Rahman, Selangor, Malaysia; *Department of Epidemiology and Biostatistics, McGill International TB Centre, McGill University, Montreal, Quebec, Canada; *Division of Infectious Diseases, Brigham and Women's Hospital, Boston, Massachusetts, USA

An average TB patient in India is diagnosed with TB after a delay of 2 months, and is seen by 3 healthcare providers before diagnosis

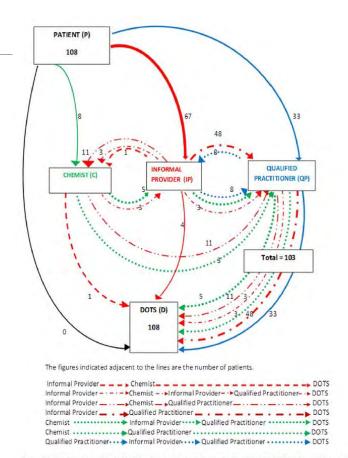


Figure 1. Pathways undertaken by the patients to reach the RNTCP (DOTS) Facilities, Delhi, India. doi:10.1371/journal.pone.0042458.q001

Kapoor et al. PLoS ONE 2012

Simulated patient studies in India show that most primary care providers do not manage TB well





Use of standardised patients to assess quality of tuberculosis $\gg @ \updownarrow \bigcirc$ care: a pilot, cross-sectional study



Jishnu Das, Ada Kwan, Benjamin Daniels, Srinath Satyanarayana, Ramnath Subbaraman, Sofi Bergkvist, Ranendra K Das, Veena Das, Madhukar Pai

Use of standardised patients to assess antibiotic dispensing for tuberculosis by pharmacies in urban India: a cross-sectional study



Srinath Satyanarayana, Ada Kwan, Benjamin Doniels, Ramnath Subbaraman, Andrew McDowell, Sofi Bergkvist, Ranendra K Das, Veena Das, Jishnu Das*, Madhukar Pai*





RESEARCH ARTICLE

Variations in the quality of tuberculosis care in urban India: A cross-sectional, standardized patient study in two cities

Ada Kwan^{1,2}, Benjamin Daniels¹, Vaibhav Saria³, Srinath Satyanarayana⁴, Ramnath Subbaraman⁵, Andrew McDowell⁶, Sofi Bergkvist⁷, Ranendra K. Das³, Veena Das8, Jishnu Das1,9‡, Madhukar Pai10,11‡*

BMJ Global Health

Tuberculosis: treatment failure, or failure to treat? Lessons from India and South Africa

Nesri Padayatchi, ⁹ 1.2 Amrita Daftary, ³ Naressa Naidu, ^{1,2} Kogieleum Naidoo, ^{1,2} Madhukar Pai³

To cite: Padayatchi N, Daftary A, Naidu N, et al. Tuberculosis: treatment failure, or failure to treat? Lessons from India and South Africa. BMJ Glob Health 2019;4:e001097. doi:10.1136/bmjgh-2018-001097

Handling editor Alberto L Garcia-Basteiro

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/ bmjgh-2018-001097).

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ABSTRACT

Tuberculosis (TB) remains an enormous public health concern globally. India and South Africa rank among the top 10 high TB burden countries with the highest absolute burden of TB, and the second highest rate of TB incidence, respectively. Although the primary drivers of TB transmission vary considerably between these two countries, they do indeed share common themes. In 2017, only 64% of the global estimated incident cases of TB were reported, the remaining 36% of 'missing' cases were either undiagnosed, untreated or unreported. These 'missing TB cases' have generated much hype for the challenges they present in achieving the End TB Strategy. Although India and South Africa have indeed made significant strides in TB control, analysis of the patient cascade of care clearly suggests that these 'missed' patients are not really missing-most are actively engaging the health system—the system, however, is failing to appropriately manage them. In short, quality of TB care is suboptimal and must urgently be addressed, merely focusing on coverage of TB services is no longer sufficient. While the world awaits revolutionary vaccines, drugs and diagnostics, programmatic data indicate that much can be done to accelerate the

Summary box

- In 2017, only 64% of the global estimated incident cases of tuberculosis (TB) were reported worldwide, the remaining 36% of 'missing' cases were either undiagnosed, untreated or unreported.
- Analysis of the patient cascade of care in India and South Africa suggests that these 'missed' patients are not really missing; most are actively engaging the health system (public and private) but not adequately managed.
- ▶ National TB control programmes need to identify gaps and weaknesses along the entire patient care cascade, addressing barriers to appropriate diagnosis, linkages to treatment postdiagnosis while strengthening both public and private healthcare sectors, and bridging the gap between provider knowledge and practice.
- Integration of TB services within universal health coverage is critical for identifying and managing missing patients with TB.

On 1 Feb 2017, India announced TB elimination by 2025!



But Indian government is not spending enough on TB!



https://theconversation.com/indias-ambitious-new-plan-to-conquer-tb-needs-cash-and-commitment-84821

Health itself is not a priority for India





India ranks 127 out of 188 countries in progress towards health related SDG goals!

India spends <1.5% GDP on health, less than all other BRICS countries!

https://thewire.in/179865/punching-well-weight-india-progress-towards-health-related-sdg-goals/

This is where advocacy is critical

TB - The Ticking Time Bomb





http://www.satyamevjayate.in/tb-the-ticking-time-bomb/episode-4watchvideo.aspx?uid=s3e4-ev-v1&lang=hindi

https://www.youtube.com/watch?v=znyXf 4hQC
0

Can TB patients demand better services?





They Survived TB. Here Are Their Stories - Everylifecounts.NDTV.com
The patients of tuberculosis need more than just medicines. They need acceptance and care. With this common understanding in mind, TB surviv... everylifecounts.ndtv.com

http://www.survivorsagainsttb.com/



BMJ 2017;356:i6344 doi: 10.1136/bmj.i6344 (Published 2017 February 08)

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PRACTICE

WHAT YOUR PATIENT IS THINKING

Fighting TB requires empowered patients

In this article from India, Deepti Chavan describes the differences in health outcomes when patients are able to access the information they need

Deepti Chavan

INDIA REAL TIME

Indian Woman Wins Right to Use Last-Resort Tuberculosis Drug

Family of 18-year-old suffering from drug-resistant TB had petitioned court



A security woman stands guard outside the Group of TB Hospitals in Mumbai, in a September 2015 photo, PHOTO: DANISH SIDDIQUI/REUTERS



Experts Speak On Patna Teen Girl's Fight For TB Drug

Written By: Snigdha Basu January 17, 2017





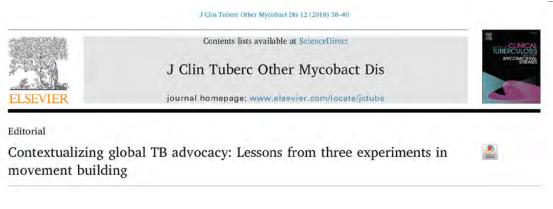




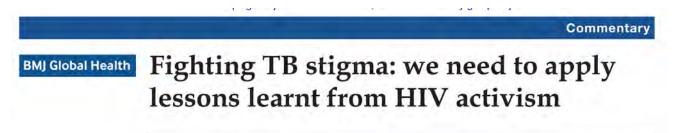


The teenager who is battling tuberculosis is 18 years old and weighs 24 Kgs.

TB has a lot to learn from the HIV movement...



https://www.sciencedirect.com/science/article/pii/S2405579418300342



Amrita Daftary, 1.2 Mike Frick, 3 Nandita Venkatesan, 4 Madhukar Pai 1.5

https://gh.bmj.com/content/2/4/e000515