



# From Research To Action (Why Advocacy Matters)

Madhukar Pai, MD, PhD  
Canada Research Chair in Epidemiology & Global Health  
McGill University, Montreal

# The Sunday Magazine with Piya Chattopadhyay



Will Omicron finally spur wealthy nations to back vaccine equity?

▶ Play Segment 21:24 [Share Segment](#)

As the Omicron COVID-19 variant overwhelms people and health care systems in Canada, Dr. Madhukar Pai is pleading with elected officials to look beyond borders and boosters to focus on true global health equity as the key to ending the pandemic. The Canada Research Chair in Epidemiology and Global Health at McGill University in Montreal joins Piya Chattopadhyay to discuss what must be done to share vaccines, treatments and other tools that are vital in the fight against COVID-19.

Aired: Jan. 9, 2022



HEALTH

## The Pandemic Is Following a Very Predictable and Depressing Pattern

As with diseases such as malaria and HIV, rich countries are "moving on" from COVID while poor ones continue to get ravaged.

By Nadia A. Sam Agudu, Boghuma Kabisen Titanji, Fredros Okumu, and Madhukar Pai



## Opinion: India's covid-19 crisis is a dire warning for all countries



A relative of a person who died of covid-19 is consoled by another during cremation in Jammu, India, on April 26. (Channi Anand/AP)

Opinion by **Madhukar Pai** and **Manu Prakash**

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April 30, 2021 at 2:50 p.m. EDT

# CASE STUDY 1: HOW INDIA BANNED BAD TESTS AND MADE GOOD TESTS MORE ACCESSIBLE?



# Serological (antibody-detection) tests for TB... (2007-2009)

...have been around for a long time

...are attractive, especially if made into point of care tests

- But serological tests have variable accuracies and a limited clinical role (based on 3 systematic reviews in 2007-2009)

OPEN ACCESS Freely available online

PLOS MEDICINE

## Commercial Serological Antibody Detection Tests for the Diagnosis of Pulmonary Tuberculosis: A Systematic Review

Karen R. Steingart<sup>1,2</sup>, Megan Henry<sup>3</sup>, Suman Laal<sup>4,5,6</sup>, Philip C. Hopewell<sup>1,2</sup>, Andrew Ramsay<sup>7</sup>, Dick Menzies<sup>8,9</sup>, Jane Cunningham<sup>7</sup>, Karin Welding<sup>10</sup>, Madhukar Pai<sup>8,9\*</sup>

CLINICAL AND VACCINE IMMUNOLOGY, Feb. 2009, p. 260–276  
1556-6811/09/\$08.00+0 doi:10.1128/CVI.00355-08

Vol. 16, No. 2

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## Performance of Purified Antigens for Serodiagnosis of Pulmonary Tuberculosis: a Meta-Analysis<sup>‡</sup>

Karen R. Steingart,<sup>1\*</sup> Nandini Dendukuri,<sup>2</sup> Megan Henry,<sup>3,‡</sup> Ian Schiller,<sup>2</sup> Payam Nahid,<sup>4</sup> Philip C. Hopewell,<sup>1,4</sup> Andrew Ramsay,<sup>5</sup> Madhukar Pai,<sup>2</sup> and Suman Laal<sup>6,7,8</sup>

A systematic review of commercial serological antibody detection tests for the diagnosis of extrapulmonary tuberculosis

Karen R Steingart, Megan Henry, Suman Laal, Philip C Hopewell, Andrew Ramsay, Dick Menzies, Jane Cunningham, Karin Welding, Madhukar Pai

.....  
*Thorax* 2007;62:911–918. doi: 10.1136/thx.2006.075754

# How big was the problem anyways?

Widespread use of serological tests for tuberculosis:  
data from 22 high-burden countries

**17 of 22 used these tests!**

In India alone, we estimated > 1.5 million tests @ over 15 million USD per year!

# The market flooded with tests with unproven claims of high accuracy

<b>SEROCHECK-MTB</b>	<b>Rapid Test for Antibodies to <i>Mycobacterium tuberculosis</i> in serum/ plasma/whole blood</b>
<b>Application</b>	<ul style="list-style-type: none"> <li>As a additional diagnostic tool in tuberculosis smear negative, culture positive suspects and tuberculosis smear negative, culture negative suspects</li> <li>Extrapulmonary TB suspects</li> <li>Pediatric cases</li> <li>Diagnosis of suspect TB cases in HIV uninfected individuals</li> </ul>
<b>Principle</b>	Self performing, rapid , semi-quantitative two-site sandwich immunoassay , lateral flow device
<b>Sensitivity</b>	100%
<b>Specificity</b>	100%

Sensitivity = 100%  
Specificity = 100%



## 2) Comparison SD Rapid TB vs. a commercial anti-TB ELISA

The SD Rapid TB have tested with positive and negative clinical samples tested by a leading commercial ELISA test. The result shows that the SD Rapid TB is very accurate to other commercial ELISA test.

		A Commercial PHA		Total Results
		Positive	Negative	
A commercial anti- M.tuberculosis ELISA kit	Positive	112	2	114
	Negative	1	350	351
Total Results		113	352	465

In a comparison of the SD Rapid TB versus a leading commercial ELISA test, results gave sensitivity of 98.2% (112/114), a specificity of 99.7 % (350/351), and a total agreement of 99.35% (462/465).

Sensitivity = 98%  
Specificity = 100%



## PERFORMANCE CHARACTERISTICS:

Sensitivity : Sera were collected from patients under anti TB treatment. Results of sputum examination were not available. Among 75 sera collected, samples were positive by the TB onsite Rapid screening Test Thus, the test sensitivity is 93%.

Sensitivity = 93%  
Specificity = 100%

Specificity : In 53 sera derived from Northern America, all the samples were negative.

# So, we did a lot of advocacy to raise awareness about this issue



THE NEW YORKER | REPORTING & ESSAYS |

## LETTER FROM INDIA

### A DEADLY MISDIAGNOSIS

*Is it possible to save the millions of people who die from TB?*

by Michael Specter

NOVEMBER 15, 2010



Hospital Road in Darbhanga is home to dozens of unregulated doctors and drug wholesalers. Photograph by Lynsey Addario.



23 March 2011 Last updated at 20:16 ET

## Misdiagnosis behind Bihar's deadly TB epidemic



Mohd Noor Alam is among millions of TB patients in India

On World Tuberculosis Day, health officials in the northern Indian state of Bihar are warning of an epidemic of a virulent form of multi drug-resistant TB unless cases are detected more quickly and accurately. The BBC's Geeta Pandey reports from the town of Hajipur, in Bihar, on a disease that kills two Indians every three minutes.

**hindustantimes** west india

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### mumbai

## Antibody blood tests not reliable enough: WHO

Sonal Shrivastava, Hindustan Times  
Mumbai, March 24, 2011

0 Comments | Like | Tweet | Share | More

A recent report by the World Health Organisation (WHO) has advised against using serodiagnostic test, which is used commonly in India to diagnose tuberculosis (TB). WHO's Strategic and Technical Advisory Group for TB (STAG TB) in September 2010 recommended that the serodiagnostic test should not be used to diagnose active TB because of its poor performance and adverse impact of misdiagnosis in patients.

The study, reported in the January issue of The Lancet, a UK-based medical journal, stated that though no international guidelines recommend its use, scores of commercial serological tests for TB are being sold in India and this could worsen the TB epidemic in the country.

Most city doctors agree with the WHO report.

"Serological test, or antibody blood tests, are not sufficiently reliable to diagnose TB or rule it out with any accuracy," said Dr Zahir Udwadia, consultant chest medicine, Hinduja Hospital.

Dr Camilia Rodrigues, consultant microbiologist, Hinduja Hospital, said that there is compelling evidence that these tests perform poorly in our setting and often give false positive results.

"Patients are then unnecessarily put on anti-TB treatment for months when it is sometimes not required," she said.

Dr Madhukar Pai, a professor at McGill University, Montreal, and co-chair of the Stop TB Partnership's New Diagnostics Working Group, said in an e-mail that in India 1.5 million TB serological tests are done every year. "The market size of this independent test is at least Rs 70 crore per year," said Pai.

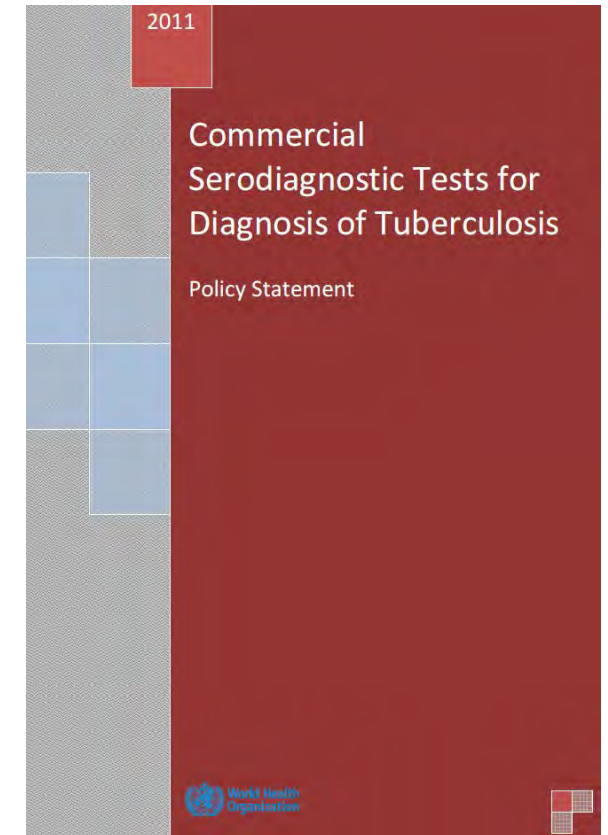
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must read

# Finally, in 2011, WHO issues negative policy

- WHO agreed to consider a policy recommendation in 2010!
  - Updated meta-analysis was commissioned (Steingart et al. PLoS Med 2011)
  - Cost-effectiveness model was also conducted (Dowdy et al. PLoS Med 2011)
  - WHO EG meeting was held
- Final WHO policy was published on 20 July 2011



# June 2012: India bans TB serologics!



## Let Us Stop Malpractices in TB Diagnosis



### Inaccurate Serological Blood Tests for Diagnosis of TB banned by the Government of India in Public Interest



MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health and Family Welfare)  
**NOTIFICATION**  
New Delhi, the 7th June, 2012

**G.S.R. 432(E).**- Whereas the Central Government is satisfied that the use of the serodiagnostic test kits for diagnosis of tuberculosis are giving inconsistent and imprecise results leading to wrong diagnosis and their use is likely to involve risk to human beings and whereas safer alternatives are available:

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the manufacture, sale, distribution and use of the said test kits in public interest;

Now, therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibit the manufacture for sale, distribution and use of the following test kits with immediate effect.

**"Serodiagnostic test kits for diagnosis of tuberculosis"**

#### Frequently asked questions on the notification

##### Q. What is the reason behind the ban?

ANS: There is proven scientific evidence that serodiagnostic tests for TB provide inconsistent and imprecise results despite high claims of its accuracy

**No More Deaths From TB  
Together We Can Make India TB Free**

Free Diagnosis and Treatment for TB is Available  
For More Details Please Contact Concerned District TB Officer

##### Q. What is the consequence of inconsistent and imprecise results?

ANS: The dependence on such unreliable tests can be harmful as many patients will end up undergoing TB treatment without any need for it as they are wrongly diagnosed as TB. At the same time, the test also misses many TB patients thus denying treatment at the right time. Such patients will continue to suffer and even spread the infection to other healthy individuals.

##### Q: What is meant by "serodiagnostic test kits" for tuberculosis?

ANS: Serodiagnostic tests for tuberculosis are tests that detect the antibody response to tuberculosis causing bacteria in blood samples of suspected tuberculosis patients.

##### Q. Is the ban applicable to Indian as well as imported TB serodiagnostic kits?

ANS: Yes, the ban is applicable to all kits manufactured in India as well as all types of imported kits.

##### Q. How can TB be detected if all blood tests have been banned? Are there any alternative tests available?

ANS: Government of India has approved the following tests for diagnosis of TB:

- Sputum examination under microscope
- Culture tests
- Newer molecular tests.

##### Q. What are Interferon-gamma release assays (IGRAs)?

ANS: IGRAs are laboratory blood test that measure the cell-mediated immune response of TB in infected individuals.

##### Q. In which situation should IGRAs not be used?

ANS: IGRAs blood tests have limited use as they cannot differentiate between active pulmonary TB disease and latent TB infection. Hence IGRAs should not be used as stand alone tests to detect active TB disease.

**REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAM**  
Ministry of Health and Family Welfare, Government of India

But WHO-endorsed tests were very expensive in the private sector:  
private sector excluded from pricing agreements

GeneXpert



\$10 for public sector in India

\$40 for private sector in India

Line probe assay





€ 7.50 for public sector in India

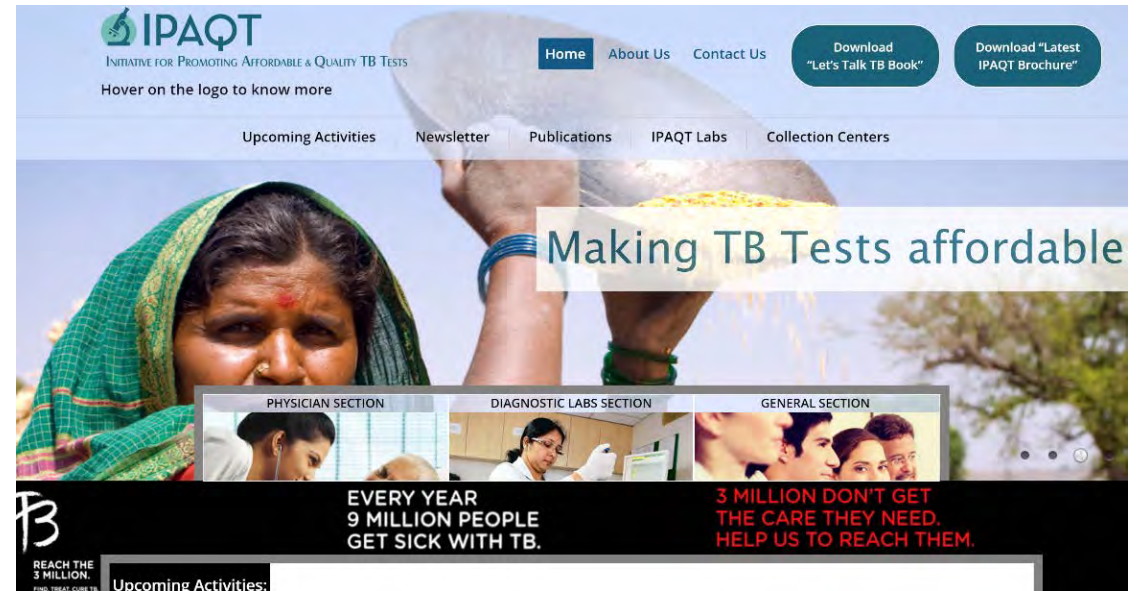
€ 15 for private sector in India

Practice

BMJ Global Health

## Initiative for Promoting Affordable and Quality Tuberculosis Tests (IPAQT): a market-shaping intervention in India

Harkesh Dabas,<sup>1</sup> Sarang Deo ,<sup>2</sup> Manisha Sabharwal,<sup>1</sup> Arnab Pal,<sup>1</sup> Sachin Salim,<sup>1</sup> Lakshmi Nair,<sup>1</sup> Kaartikeya Chauhan,<sup>1</sup> Prateek Maheshwari,<sup>1</sup> Aparna Parulkar,<sup>1</sup> Ritu Singh,<sup>1</sup> Manasi Chitalia,<sup>1</sup> Rigveda Kadam,<sup>1</sup> Manjot Kaur,<sup>1</sup> Collins Oghor,<sup>3</sup> Nirros Ponnudurai,<sup>3</sup> Sameer Kumta,<sup>4</sup> Peter Small,<sup>4</sup> Puneet Dewan,<sup>4</sup> Madhukar Pai <sup>3</sup>



IPAQT  
INITIATIVE FOR PROMOTING AFFORDABLE & QUALITY TB TESTS

Home About Us Contact Us Download "Let's Talk TB Book" Download "Latest IPAQT Brochure"

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Upcoming Activities Newsletter Publications IPAQT Labs Collection Centers

Making TB Tests affordable

PHYSICIAN SECTION DIAGNOSTIC LABS SECTION GENERAL SECTION

EVERY YEAR 9 MILLION PEOPLE GET SICK WITH TB. 3 MILLION DON'T GET THE CARE THEY NEED. HELP US TO REACH THEM.

REACH THE 3 MILLION. FIND TREAT. CURE TB. Upcoming Activities:

<http://www.ipaqt.org/>

**THE STORY  
CONTINUES**

...

*Down  
the  
Rabbit  
HOLE*

# IPAQT now in Pakistan & Philippines & also includes HIV and HCV tests



'IPAQT is now seen as a novel market-shaping business model to increase access to quality diagnostics'

## Diagnostic lab group in India to offer HCV and HIV tests at almost half the price

India, experts said, has the third largest HIV (human immunodeficiency virus) epidemic in the world with an estimated burden of over two million.

### IPAQT: subsidised Xpert TB test in private labs gets popular

The test will cost Rs.2,000 from January 15

R. PRASAD

The number of labs/private hospitals in the country offering the WHO-approved tests like GeneXpert, Line Probe Assay (LPA) for diagnosing TB disease at a subsidised price has reached 54. There are over 10,000 collection centres spread across the country.

In eight months since the novel initiative — Improving Access to Affordable & Quality TB Tests (IPAQT) — was launched, the number people accessing these labs for the



**THE PROOF:** Over 15,000 people in India have availed the GeneXpert test in eight months after IPAQT came into being. — PHOTO: K. PICHUMANI

## 70 labs in India cut TB test bill by half

Malathy Iyer | TN

**Mumbai:** Awareness about drug-resistant tuberculosis across India increased in the last two years after Hinduja Hospital's doctors highlighted the plight of patients who were resistant to all 12 known TB drugs. This is borne out by the fact that the number of sophisticated TB tests—called GeneXpert and Hain line probe assays—done from April to December 2013 stood

at 10,000, compared to 5,000 in 2012. The volume of tests would increase to a great extent if the prices were kept low," said Dr Pai.

Dr Madhukar Pai, an epidemiologist from Canada's McGill University, who has been instrumental in putting the initiative together, said that while the government has upgraded diagnostic facilities, most Indians still prefer the private sector. "The only way to reach out to them was by offering affordable tests. We convinced the labs that the volume of tests would increase to a great extent if the prices were kept low," said Dr Pai. Considering that 70% of Indians seek healthcare in the private sector by paying from their own pocket, the IPAQT logic clicked. Around 380 diagnostic outlets from Maharashtra are a part of IPAQT; 170 are from Mumbai and Navi Mumbai.

Dr B R Das from SRL Diagnostics, one of the largest diagnostic chains in India, said, "We now offer GeneXpert at Rs 2,000 from the initial cost of Rs 3,500. We conduct approximately 900 GeneXpert tests a month, compared to 50 tests a month two years ago."

Dr Shamma Shetye from Metropolis Healthcare Ltd said, "Since the price is fixed across partner IPAQT labs, it ensures standardization of prices for the patient."

Public health experts believe that low awareness of drug-resistant TB, coupled with high costs of diagnostic tests had worsened the TB epidemic in the country; two people died every three minutes in

**TESTS WITH REDUCED COSTS**

**Xpert MTB/RIF | ₹2,000**  
Detects multidrug resistant TB in two hours. Considered a game-changer in the battle against TB

**Hain Genotype LPA | ₹1,600**  
Specialized gene-based test to detect resistance to two drugs. Recommended by the World Health Organisation

**MGIT Liquid Culture & BacT/Alert Liquid Culture | ₹900 each**  
Popular tests used by doctors across the world to detect multidrug resistant strains

BMJ

BMJ 2013;346:f2161 doi: 10.1136/bmj.f2161 (Published 5 April 2013)

Page 1 of 1

NEWS

Private firms form initiative to offer accurate and affordable TB tests

# **CASE STUDY 2: HOW WHO RELEASED THE FIRST ESSENTIAL DIAGNOSTICS LIST**

# A great idea emerges in June 2016

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## Time for a Model List of Essential Diagnostics

Lee F. Schroeder, M.D., Ph.D., Jeannette Guarner, M.D., Ali Elbireer, Ph.D., M.B.A., Philip E. Castle, Ph.D., M.P.H., and Timothy K. Amukele, M.D., Ph.D.

The Model List of Essential Medicines (EML) maintained by the World Health Organization (WHO) plays a central role in global health policy. We believe that it's time to establish a similarly influential Model List of Essential Diagnostics (EDL). According to the WHO, the items included in the EML are “drugs that satisfy the health care needs of the population [and] . . . are

intended to be available at all times . . . at a price the individual and community can afford.” Inclusion in the EML is often necessary before large funders (ministries of health, nongovernmental organizations, and insurers) will invest in and orchestrate negotiated, large-scale procurement of a given medication.

Diagnostic tests are also required for fulfilling the health

care needs of populations. They are critical to the management of communicable and noncommunicable diseases, surveillance of emerging infectious threats such as the Ebola and Zika viruses, and the safe and rational use of EML medicines, including stewardship of antiinfective agents to reduce the likelihood of the development of microbial resistance. Improved access to diagnostics

# Why do we need an EDL?



## Why The World Needs An Essential Diagnostics List

Without diagnostics, medicine is blind. And yet, diagnostics receive much less attention than vaccines and drugs.

[forbes.com](https://www.forbes.com)

Lee Schroeder, Tim Amukele, Madhukar Pai

1. Improve patient care and clinical outcomes
2. Help detect emerging infectious threats
3. Increase affordability
4. Reduce antimicrobial resistance
5. Improve regulation and quality of diagnostics
6. Facilitate laboratory accreditation and training
7. Improve supply chain and laboratory infrastructure
8. Facilitate change in healthcare provider behavior
9. Inform new technology development
10. Facilitate epi surveys, program evaluation and disease elimination

August 2016

**Forbes**



Africa has an essential medicines list. Now it needs one for diagnostics

October 25, 2018 12:01pm EDT

Essential medicines require essential diagnostics

06/12/2017 03:14 EDT | Updated 06/12/2017 03:14 EDT



Dr. Madhukar Pai  
Professor & Director of Global Health, McGill University



PAMELA MOORE VIA GETTY IMAGES

TRENDING

**GHTC** global health technologies coalition advancing innovation to save lives

Marie-Paule Kieny  
Assistant Director-General, Health Systems and Innovation  
World Health Organization  
20 Avenue Appia  
1211 Geneva  
Switzerland

November 16, 2016

**Letter on behalf of the Global Health Technologies Coalition: Critical need for an Essential Diagnostics List**

Dear Dr. Kieny,

The Global Health Technologies Coalition (GHTC)—a group of more than 25 nonprofit organizations—advancing policies to accelerate the creation of new technologies to bring healthy lives within reach for all people—applauds the vital work of the Essential Medicines and Health Products Department within your World Health Organization (WHO) cluster in establishing the Model Lists of Essential Medicines (EMLs). By providing science-based guidance to countries on which drugs, biologics, and diagnostic agents to include in national standards, EMLs have had a dramatic impact on global public health. As argued in a recent *New England Journal of Medicine* article,<sup>1</sup> as well as in multiple other op-eds,<sup>2,3</sup> a similar model list for diagnostic tests would have an equally transformative impact. GHTC therefore fully endorses these calls for a Model List of Essential Diagnostics (EDL) and respectfully requests your and the WHO's leadership in establishing it.

An EDL would provide a vital tool to help increase access to the diagnostic tests necessary to maximize the use of limited health resources and improve health outcomes. Improved diagnostic capacity, such as point-of-care tests, could enable earlier identification of disease outbreaks, saving the lives and costs associated with epidemics. In the fight against antimicrobial resistance (AMR), rapid diagnostics to specify treatment and improved antibiotic susceptibility testing enable treatment to be better targeted to the patient's specific infection, as well as to ensure appropriate regimen use. Both help to conserve the efficacy of current antibiotics. Where these diagnostics exist but are not in routine use, the EDL provides a forceful policy argument for governments to invest in making them available.

Furthermore, by detailing which diagnostics are necessary to support health interventions, an EDL could readily expose where there are gaps in existing appropriate diagnostic tools. In this way, the list could

<sup>1</sup> Schroeder LF, Guarnet J, Elbreer A, Castle PE, Amukele TK. Time for a Model List of Essential Diagnostics. *New England Journal of Medicine*. June 30;374(26):2511-4  
<sup>2</sup> Schroeder LF, Amukele TK. Africa has an essential medicines list. Now it needs one for diagnostics [op-ed]. *The Conversation*. October 25, 2016. <http://theconversation.com/africa-has-an-essential-medicines-list-now-it-needs-one-for-diagnostics-80771>  
<sup>3</sup> Schroeder LF, Amukele TK, Pai M. Why the world needs an essential diagnostics list [op-ed]. *Forbes*. August 6, 2016. <http://www.forbes.com/sites/forbes/2016/08/06/why-the-world-needs-an-essential-diagnostics-list/#5a275248729a>

**GHTC** global health technologies coalition advancing innovation to save lives

signal to product developers, industry, and donors where funding and attention is needed to facilitate research and development (R&D).

Given WHO's experience in hosting the EML, its ongoing work developing technical guidance on diagnostics, its work in laboratory accreditation, and its widely-respected role in setting global norms, GHTC believes WHO is uniquely positioned to lead the development and implementation of an EDL. We respectfully urge you to support the establishment of an EDL and stand ready to advocate with member states on behalf of an EDL that would save money overall, encourage R&D for needed diagnostics, and increase access.

We thank you for your consideration of this request and would appreciate the opportunity to discuss the issue with you further. We eagerly await your response, and ask that you kindly direct it to Matthew Robinson at [MRobinson@ghtrcoalition.org](mailto:MRobinson@ghtrcoalition.org) by November 30.

Sincerely,

AERAS

American Society of Tropical Medicine and Hygiene

Elizabeth Glaser Pediatric AIDS Foundation

fhi360

Diagnose. Diagnose matters. FIND

Global Alliance to Prevent Prematurity and Stillbirth

Global Health Council

Infectious Diseases Society of America

Medicines for Malaria Venture

PATH

TB Alliance

CC: Suzanne Hill

# WHO announced EDL development in June 2017



## WHO to develop Essential Diagnostics List

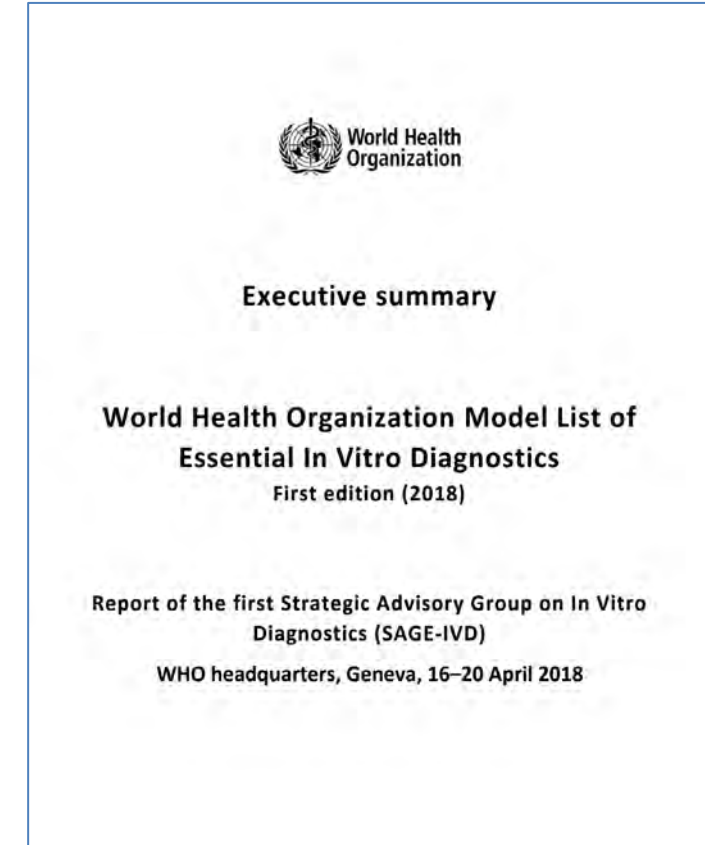
15 JUNE 2017 - The 20<sup>th</sup> WHO Model List of Essential Medicines was published on 6 June this year, with a number of important new additions, including a recommendation by the Expert Committee on the Selection of Essential Medicines that WHO develop an Essential Diagnostics List (EDL). Based on that recommendation, WHO has begun to lay the ground for the preparation of the list, which will become an important contribution to Universal Health Coverage (UHC).

Like the established Essential Medicines List, the EDL is intended to provide evidence-based guidance to countries to create their own national lists of essential diagnostic tests and tools. National essential medicines lists have been successful in facilitating access to treatment and promoting affordable prices, particularly in low-resourced countries, by prioritizing the most important medicines all countries need to make available to their populations. It is expected that national essential diagnostics lists will provide the same benefits for diagnostic tests.

- EDL list initially focus on in vitro diagnostics (IVDs) for priority areas such as TB, malaria, HIV and Hepatitis B & C, but that it should be expanded as soon as possible to other important conditions, including other antimicrobials and NCDs.
- As a first step, WHO is creating a Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD), which will advise WHO on global policies and the development of the EDL.

First SAGE IVD Meeting in April 2018

WHO published First EDL in May 2018





Health care is an essential human right – and so is a proper diagnosis

May 16, 2018 6:31am EDT

GLOBAL HEALTH

## For First Time, W.H.O. Names Some Lab Tests ‘Essential’

### It begins with diagnosis



MADHUKAR PAI & KAMINI WALIA

How often have you popped antibiotics without quite knowing what infection you had? Whether it is fever, diarrhoea, or cough, medicines are heavily over-prescribed, while diagnostic tests are rarely used. Nearly one in two Indians with diabetes is unaware that he has the disease. Cervical and breast cancer are usually detected when they are advanced, resulting in poor survival rates.

In India, patient studies show that primary-care providers (urban and rural) make a correct diagnosis in less than a quarter of patients who present themselves with typical symptoms of angina, tuberculosis (TB), asthma, and pneumonia. These studies also show an excessive use of medicines and little testing. Not surprisingly, India is one of the world’s biggest consumer of antibiotics, and antibiotic resistance is a looming threat.



Taking blood for an H.I.V. test at a mobile clinic in KwaZulu Natal, South Africa. The World Health Organization has recommended 113 diagnostic tests it considers essential to every health care system in the world. Stephane De Sakutin/Agence France-Presse — Getty Images



## Essential diagnostics: a lever for health systems reform?



For more on the Essential Diagnostics List see [http://www.who.int/medical\\_devices/diagnostics/Selection\\_in-vitro\\_diagnostics/en/](http://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/)

For more on the Essential Medicines List see <http://www.who.int/medicines/publications/essentialmedicines/en/>

For The Lancet Series on Pathology and Laboratory Medicine see <https://www.thelancet.com/series/pathology-laboratory-medicine>

Last week, WHO released its first Essential Diagnostics List. Designed to complement the Essential Medicines list first released over 40 years ago, the list defines an essential package of diagnostic tests for use in primary care and laboratory settings. 58 of these tests are aimed at supporting the diagnosis and monitoring of common conditions such as cardiovascular diseases, diabetes, and anaemia, and 55 tests are targeted at high priority diseases including HIV, hepatitis B and C, and malaria.

Timely and accurate diagnosis is fundamental to achieving quality patient-centred care and has myriad benefits beyond individuals including enabling rapid detection of disease outbreaks and reducing the inappropriate use of antibiotics. WHO will update the list annually, with plans to broaden its remit to include tests for addressing neglected tropical diseases, antimicrobial resistance, and the specific requirements of disease outbreak and emergency settings, among other areas.

Although an obvious step in the right direction, the true test of the Essential Diagnostics List will be in its implementation. As *The Lancet*’s recent Series on

pathology and laboratory medicine highlighted, achieving equitable access to cost-effective and accurate diagnostic services, particularly in low-income and middle-income countries, requires addressing gaps in health financing, workforces, and infrastructure. By setting explicit priorities for the delivery of diagnostic services, the list provides an opportunity to enhance health system performance more broadly. And through making people aware of an internationally recognised basic standard, this list could also empower patients to hold providers accountable for delivering the essential package of tests.

Whether the Essential Diagnostics List will contribute to the health systems capacity building required for universal health coverage and other health-related Sustainable Development Goals will depend, crucially, on integrating its application and adaptation to local contexts with rigorous evaluation efforts. Without investment in health systems research alongside attempts to achieve delivery of this essential package, the opportunity to make comprehensive progress in improving diagnostic services around the world may well be squandered. ■ *The Lancet*



The desperate global need for medical diagnostics

June 6, 2018 5:24am EDT

**THE STORY  
CONTINUES**

...

*Down  
the  
Rabbit  
HOLE*

# How will the WHO EDL have an impact?

- Countries will need to adopt/adapt the EDL and develop National EDLs, just as they have done with National EMLs
- Countries will then need to invest in laboratory strengthening, regulation, price control mechanisms, procurement, supply chain, training, etc., to make sure EDL tests are available, affordable and accessible at various tiers of the health system

## ICMR releases India's first National Essential Diagnostics List

By EDx News Bureau On Aug 30, 2019

LAB DIAGNOSTICS



## *National Essential Diagnostics List*



*Indian Council of Medical Research  
Ansari Nagar, New Delhi-110029, India  
2019*

## Availability of essential diagnostics in primary care in India

Mikashmi Kohli · Kamini Walia · Sumit Mazumdar · Catharina C Boehme · Zachary Katz · Madhukar Pai ✉

Published: October, 2018 · DOI: [https://doi.org/10.1016/S1473-3099\(18\)30539-5](https://doi.org/10.1016/S1473-3099(18)30539-5)



Microbes and Infection

Available online 28 September 2020

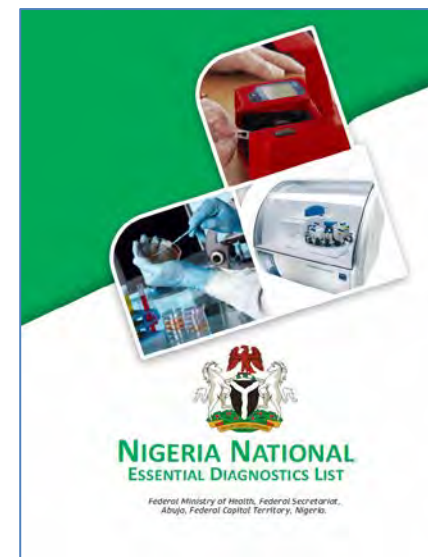
In Press, Corrected Proof



Letter to the editor

## Availability of essential diagnostics at primary care public clinics in Peru

Jean Sánchez-Sánchez, Janis Alarcón-Loayza, Luz Villa-Castillo, Mikashmi Kohli, Catharina C. Boehme, Sergio Carmona, Patricia J. García, Madhukar Pai, Cesar Ugarte-Gil ✉



**NIGERIA NATIONAL  
ESSENTIAL DIAGNOSTICS LIST**

Federal Ministry of Health, Federal Secretariat,  
Abuja, Federal Capital Territory, Nigeria.

Practice

BMJ Global Health

## The inclusion of diagnostics in national health insurance schemes in Cambodia, India, Indonesia, Nepal, Pakistan, Philippines and Viet Nam

Jacob Bigio,<sup>1,2</sup> Emma Hannay,<sup>3</sup> Madhukar Pai,<sup>4</sup> Bacht Alisjahbana,<sup>5</sup> Rishav Das,<sup>1,2</sup> Huy Ba Huynh,<sup>8</sup> Uzma Khan,<sup>7</sup> Lalaine Mortera,<sup>8</sup> Thu Anh Nguyen,<sup>9,10</sup> Muhammad Aamir Safdar,<sup>11</sup> Suvesh Shrestha,<sup>12</sup> A Venkat Raman,<sup>13</sup> Sharat Chandra Verma,<sup>14</sup> Vijayashree Yellappa,<sup>15</sup> Divya Srivastava,<sup>16</sup>

Forbes

# Let's Worry About Diagnostic Capacity, Not Just During Outbreaks



Madhukar Pai Contributor

Healthcare

*I write about global health, infectious diseases, and equity*



Forbes

# To Improve Access To Diagnostics, Countries Must Adapt The WHO Essential Diagnostics List



Madhukar Pai Contributor

Healthcare

*I write about global health, infectious diseases, and equity*

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What I have learnt

# Advocacy is necessary, because things rarely happen on their own



# Key lessons

- Research rarely gets translated into policy without diving into rabbit holes
- Policy change required prolonged, persistent work with stakeholders
  - LOT of ups and downs!
  - Human touch and relationships matter (diplomacy!)
- Data, analytics and papers are often helpful, but not sufficient
  - Evidence needs to be simplified & communicated well
  - Engagement of stakeholders is key to socialize ideas & get buy-in
  - Local ownership of data & local leadership is key
- Advocacy & diplomacy is often critical
  - People, Patients, civil society, celebs, media, MPs – can be powerful allies
- A champion is often necessary: if internal, that is ideal

# AIDS Activism, A Playbook For Global Health Advocacy



Madhukar Pai Contributor @  
Healthcare

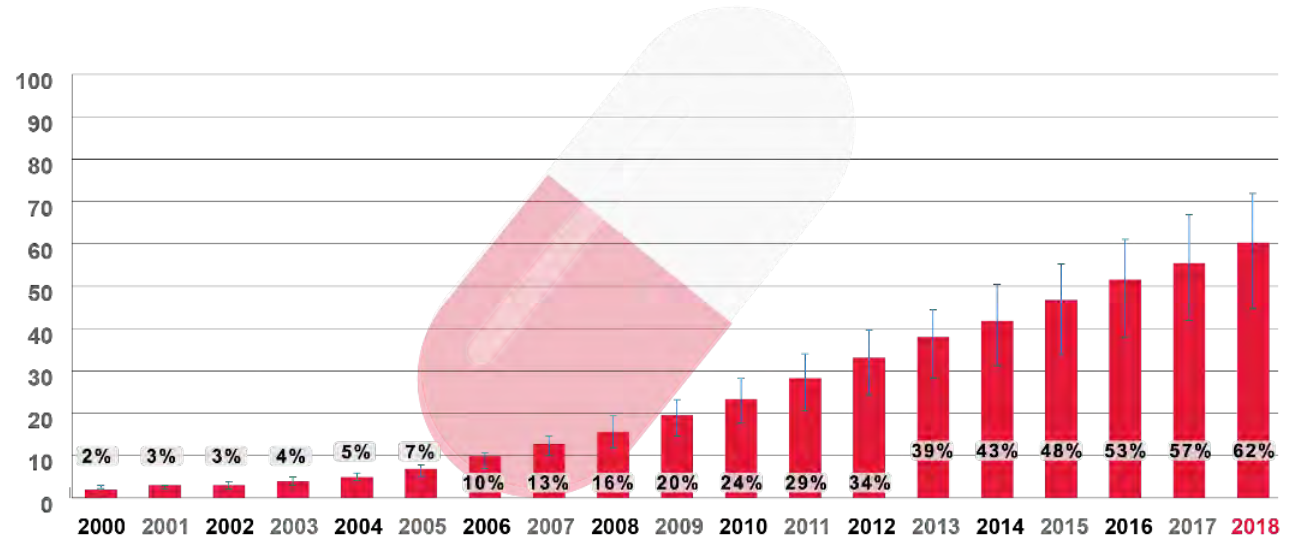
I write about global health, infectious diseases, and equity

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NEW YORK CITY AIDS MEMORIAL, NEW YORK, UNITED STATES - 2017/03/30: Hundreds gathered on a rally at ...

[+] LIGHTROCKET VIA GETTY IMAGES



<https://www.forbes.com/sites/madhukarpai/2019/11/30/aids-activism-a-playbook-for-global-health-advocacy/#289c014840a1>

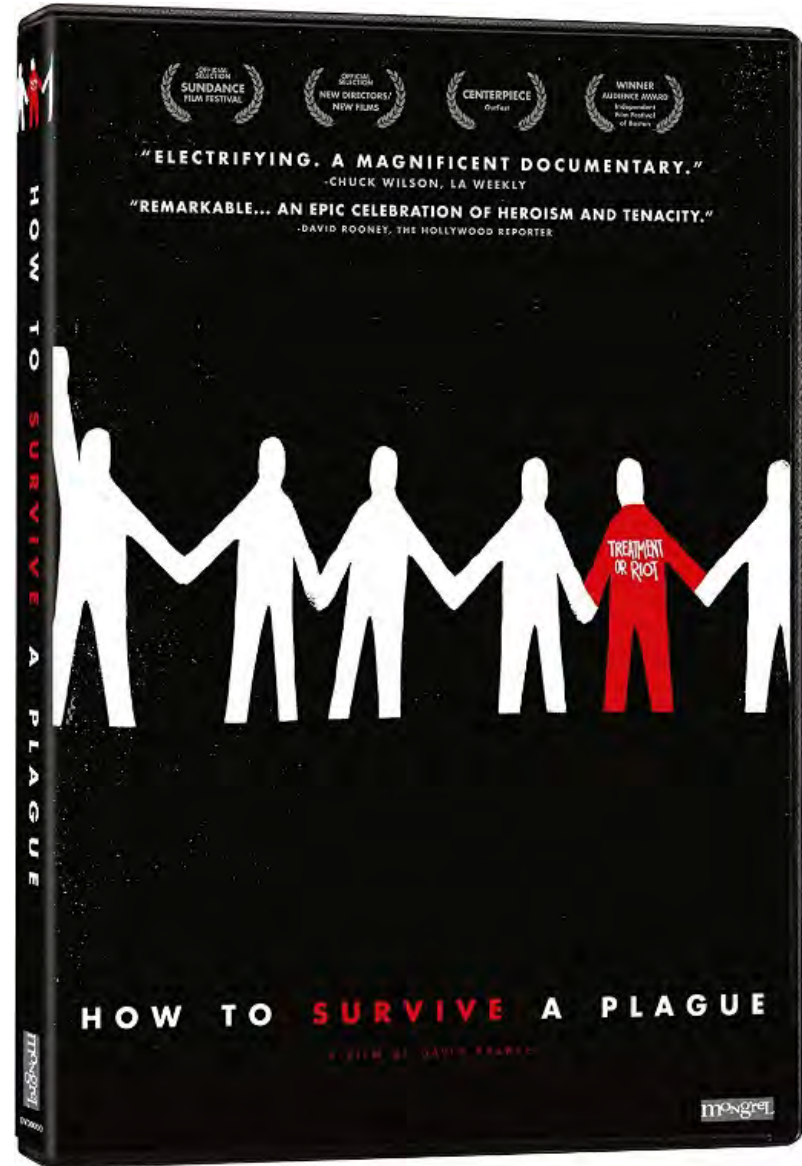
"Breathtakingly important. . . . David France managed to simultaneously break my heart and rekindle my anger." —Steven Palrow, *The Washington Post*

# HOW TO SURVIVE A PLAGUE

THE STORY OF HOW ACTIVISTS AND SCIENTISTS TAMED AIDS



DAVID FRANCE

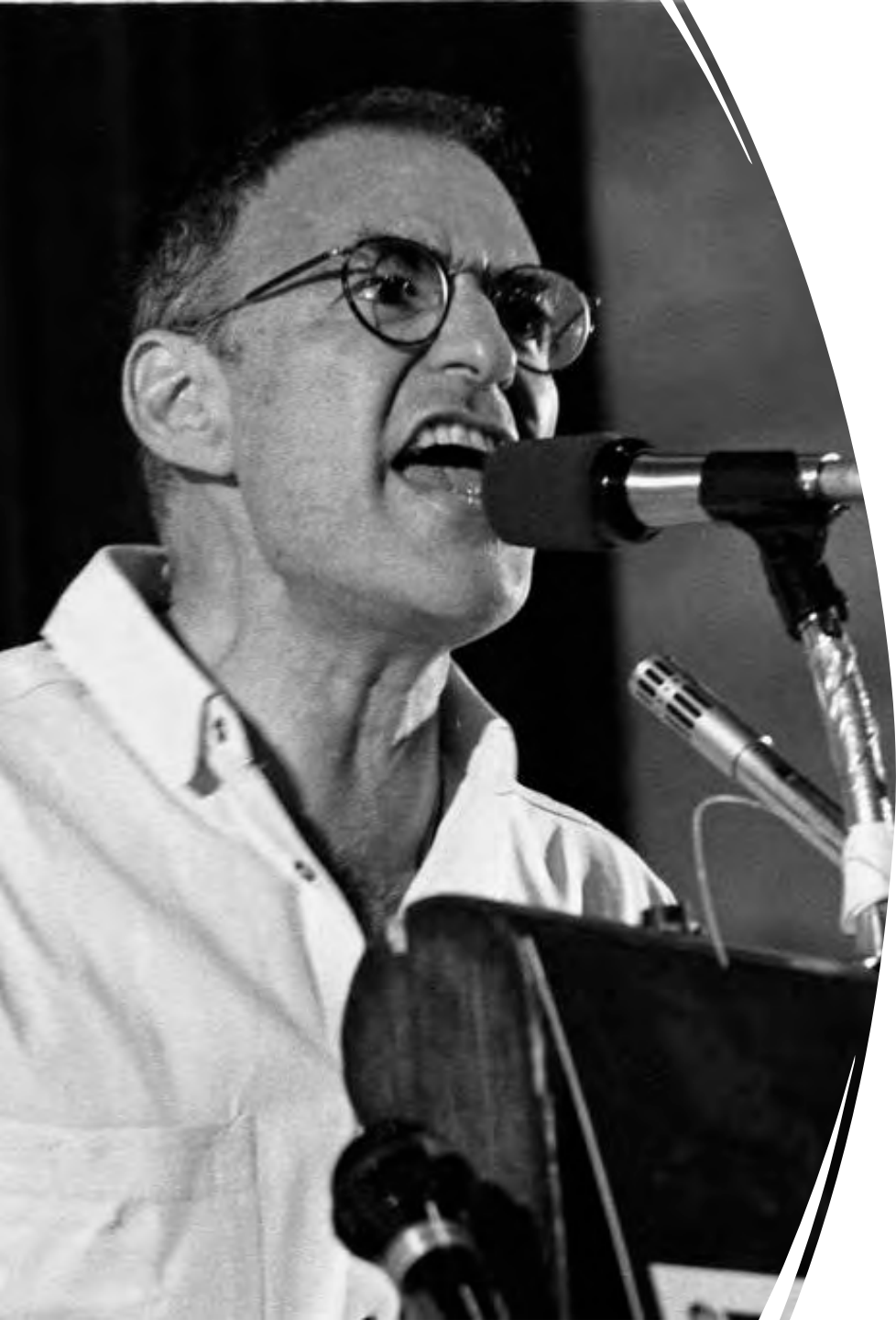


# They built on other movements

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- Gay rights
- Civil rights
- Anti-apartheid...





# They used the fear and outrage

---

- “What makes activism work is [patients’] anger and fear...somehow you have to be able to capture that, put it in a bottle and bottle it and use it.”
- Larry Kramer

**They  
mobilized  
and  
organized**

---



They played  
good cop/bad  
cop



# A NATIONAL AIDS TREATMENT RESEARCH AGENDA

V International Conference on AIDS  
Montreal, June 1989

REVISED: SEPTEMBER, 1989

**ACT UP**

**AIDS Coalition to Unleash Power / New York**

ACT UP is a diverse, non-partisan group of individuals united in anger and committed to direct action to end the AIDS crisis.



# They knew their stuff

---

# They got into the weeds

---

- R&D
- Funding
- Drug trials
- Regulation
- Pricing
- Access
- Guidelines



AACCT  
CLINICAL TRIALS



HPTN  
HIV Prevention  
Trials Network

OPINION

# Single-issue advocacy in global health: Possibilities and perils

**Katri Bertram**<sup>1</sup>, **Madhukar Pai** <sup>2\*</sup>

**1** Partners of Impact, Berlin, Germany, **2** McGill School of Population and Global Health, McGill University, Montreal, Quebec, Canada



*“There is no thing as  
a single-issue struggle  
because we do not  
live single-issue lives”*

*—Audre Lorde*

# Single issue advocacy is popular because

- It is often easier to rally people around a clear, simple call to action.
- Donors often push for it
- Everyone needs to see quick wins and success stories to keep motivated.

# Perils of single-issue advocacy

- When we advocate for single issues, we sometimes lose sight of the broader context that erodes progress in our area
- When we are laser-beam focused on a single issue, we can end up competing instead of collaborating
- Single issue advocacy ignores people's realities, intersectionality, and multi-morbidity
- Single-issue advocacy imposes a tunnel vision, and that comes with the inability to expand the scope for solutions
- No silver bullets!

# How do we deal these perils of single-issue advocacy?

- We can advocate for universal health coverage (UHC), stronger health systems, and greater investments in issues that affect health outcomes overall, in addition to advocating for whatever we are most passionate about
- UHC is the one thing that grows the pie and unites us all, regardless of which area or population group we care about.
- There is no area in global health that will not benefit from UHC and a stronger, more equitable health system



# Building larger movements



Forbes

# People Power, Not Powerful People, Can Help End Inequality



Madhukar Pai Contributor @  
Healthcare

I write about global health, infectious diseases, and equity



Listen to this article now

16:33



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'This powerful book makes clear why we cannot rely on elites to fix inequality and why it is up to us, together. Ben Phillips introduces us to the frontline heroes of the fight against inequality, and shows how we have won previous struggles and can win now.'

**Winnie Byanyima, Executive Director of UNAIDS and former executive director of Oxfam International**

'Inequality would not be a major issue around the world without the work of Ben Phillips. He has helped mobilize people power to transform the imbalances that destabilize our economies and scar our communities. This practical book empowers readers with the data, information, arguments and advice they need to be able to help bring an end to this crisis.'

**Ann Pettifor, Co-founder of Jubilee 2000 and author of The Case for the Green New Deal**

INEQUALITY IS THE CRISIS OF OUR TIME. The gap between a few at the top and the rest of society damages us all. No longer able to deny the crisis, every government in the world has pledged to fix it – and yet it keeps on getting worse.

In this book, anti-inequality campaigner Ben Phillips shows why we have to win this fight, and how to do so. Drawing on his insider experience and personal exchanges with the real-life heroes of successful movements, he reveals how the battle against inequality has been won before, and shares a practical plan for defeating inequality again. He maps a route for us to overcome deference, build our collective power and create a new story.

Most books on inequality are about what other people ought to do about it – this book is about why winning the fight needs you. Tired of feeling helpless and want to know what you can do about spiralling inequality? This is the book for you.

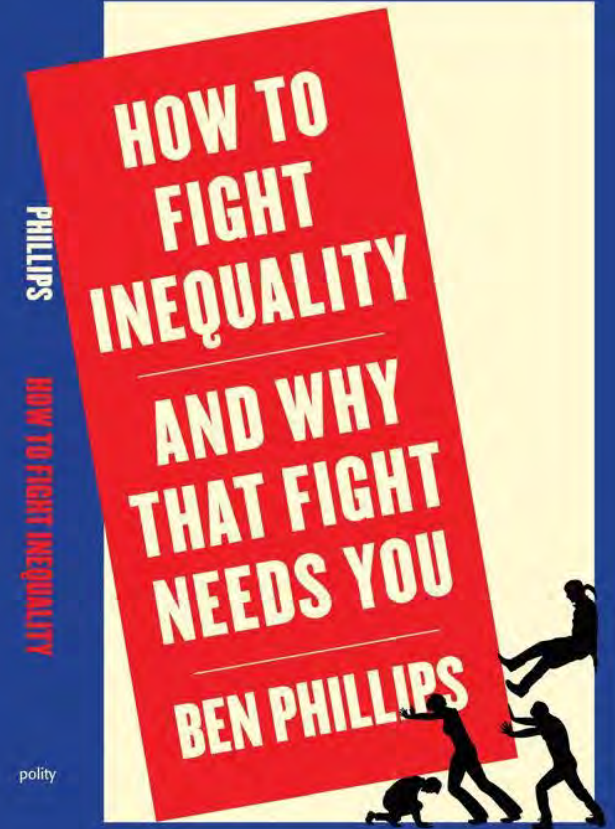
BEN PHILLIPS is an international civil society activist and writer. He led campaigns for Oxfam and ActionAid, co-founded the Fight Inequality Alliance, and addressed the United Nations on inequality.

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Cover design by David A. Gee

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# Key messages from the book

- The fight against inequality will not be won by powerful people, philanthropists or those in leadership roles.
- It requires *people power*.
- Regular people (like you and me) need to wake up to the inequities that surround us, use our voices, organize, build coalitions and actively work to bring about the changes we want to see.
- This approach has worked in the past and can work again.
- But the fight will have to be won; it won't be conceded by those who benefit from inequality.