Access to Global Health Technologies

PROF. MADHUKAR PAI, MD, PHD

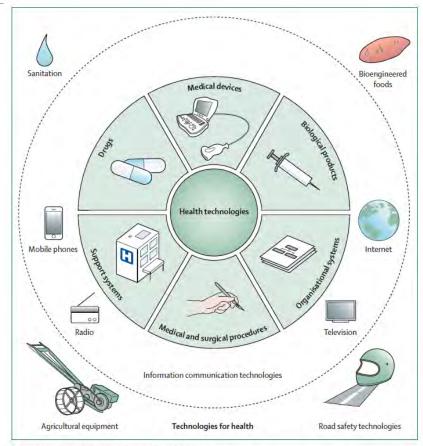
DIRECTOR, MCGILL GLOBAL HEALTH PROGRAMS

DIRECTOR, MCGILL INTERNATIONAL TB CENTRE



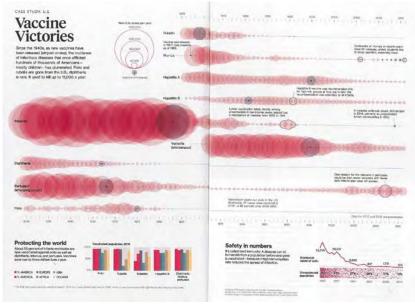


Technologies: big part of the global health landscape today











WHO: Trials show new Ebola vaccine is 'highly effective'







In global health, this is what we really care about

Good products get developed

They undergo adequate evaluation

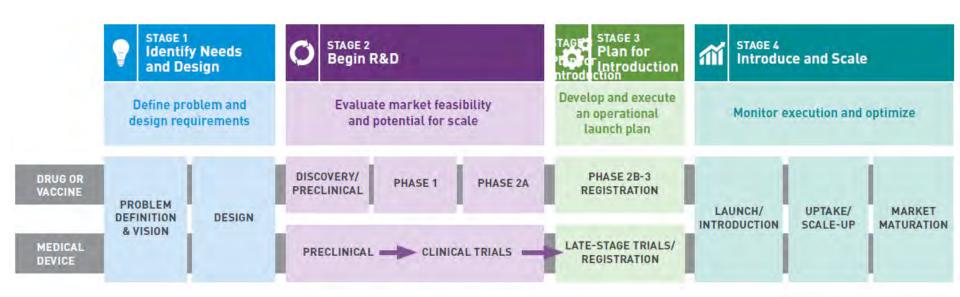
Evidence-based policies get formulated

Products and policies get implemented in countries

Impact is seen on disease burden

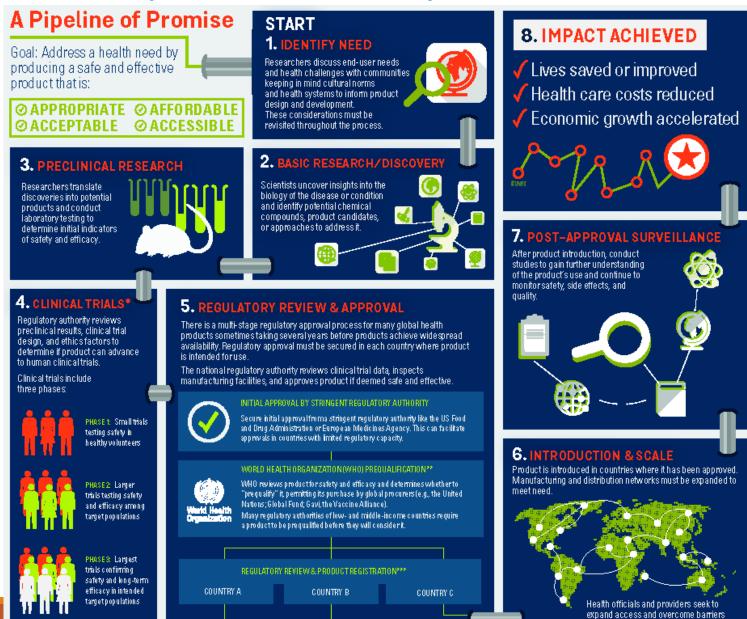
This could be a single long value chain...

Single, linear value chain





In reality, it is messy



to acceptance and use,

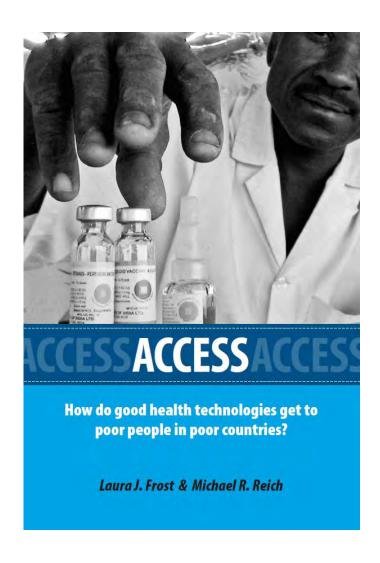
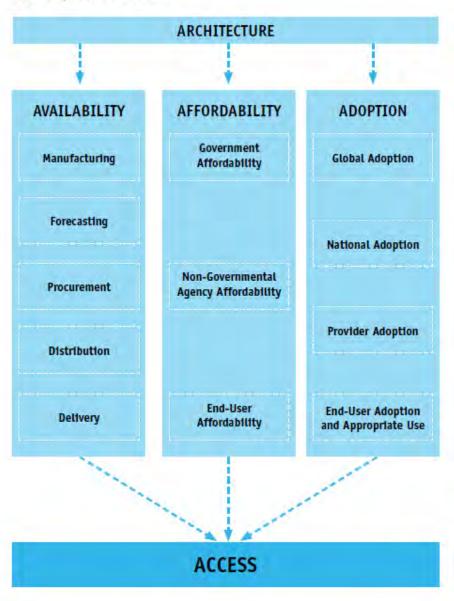


Figure 2.1 | The access framework



AVAILABILITY

TB Care Today



















Why are we still using old tools in TB?

Broken pharma R&D model

Insufficient investment (money, time)

Academics and funders are risk-averse

Inadequate industry-academia partnerships

Market forces and decisions

Regulatory hurdles

Even when new tools are developed, access is a big issue



FEATURE ARTICLE





POINT OF VIEW

Tuberculosis innovations mean little if they cannot save lives

Abstract The past decade has seen the emergence of new diagnostics and drugs for tuberculosis, a disease that kills over 1.8 million people each year. However, these new tools are yet to reach scale, and access remains a major challenge for patients in low and middle income countries. Urgent action is needed if we are committed to ending the TB epidemic. This means raising the level of ambition, embracing innovation, increasing financial investments, addressing implementation gaps, and ensuring that new technologies reach those who need them to survive. Otherwise, the promise of innovative technologies will never be realized.

DOI: 10.7554/eLife.25956.001

MADHUKAR PAI* AND JENNIFER FURIN



CANADA LIVING

Featuring fresh takes and real-time analysis from HuffPost's signature lineup of contributors



Dr. Madhukar Pai Become a tan
Professor & Director of Global Health, McGill Universit



Jennifer Furin, MD., PhD Become a tan Infectious diseases specialist and medical anthropologist currently a lecturer at Harvard Medical School

Bridging The Gap Between Tuberculosis Innovation And Access

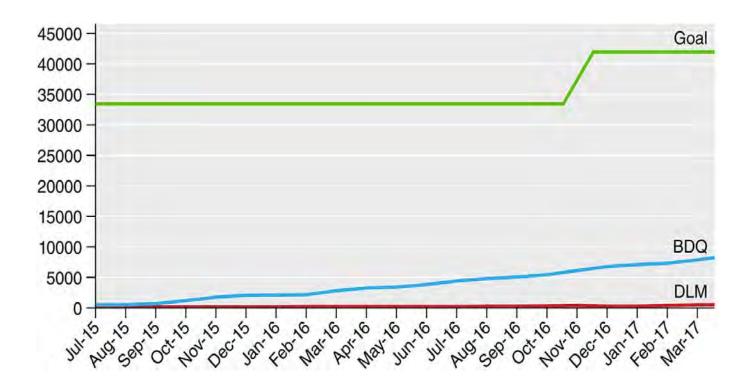
Posted: 05/02/2017 9:54 am EDT | Updated: 05/02/2017 10:01 am EDT

Never bring a knife to a gunfight. And yet, the global tuberculosis (TB) community has been doing precisely that for decades — fighting a protracted battle with antiquated, inefficient tools, including an insensitive diagnostic (i.e. sputum microscopy), a low-efficacy vaccine (i.e. BCG), and drug regimens that have hardly changed for decades.



A critically ill patient, with possible drug-resistant TB being examined by his physician. Unfortunately, this patient did not have access to novel diagnostic testing or treatment and died of his disease. (Photo: Dr Jennifer Furin, with permission from the physician and the patient)

Access to new TB drugs



As of March 1, 2017 there were <u>8,195 persons who have ever taken bedaquiline and 496 who have ever taken delamanid under program conditions</u>. How does that compare to the need? The most conservative estimate would be that these medications are needed in approximately 42,000 patients per year, or one-third of the number of persons initiated on MDR-TB treatment annually.

Why?

- Lack of adequate funding to national TB programs
- Regulatory hurdles
- 3. High cost of tools
- 4. Restrictive policies
- 5. Bureaucratic apathy & implementation failures
- 6. In the case of new drugs, a desire to protect the drug (as opposed to protecting patients) coupled with excessive concern about potential side effects

AFFORDABILITY

American caravan arrives in Canadian 'birthplace of insulin' for cheaper medicine











U.S. residents come to Canada to purchase life-saving type 1 diabetes medication

Thomson Reuters · Posted: Jun 29, 2019 2:58 PM ET | Last Updated: June 29



Quinn Nystrom holds insulin she purchased in Canada after travelling over the border for more affordable medication. (Lorenda Reddekopp/CBC)

THE AMERICAN PROSPECT

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The Insulin Racket

NATALIE SHURE JUNE 24, 2019

Insulin is a 100-year-old drug whose wholesale price has tripled in ten years. The reasons why explain everything wrong with America's broken prescription drug market.



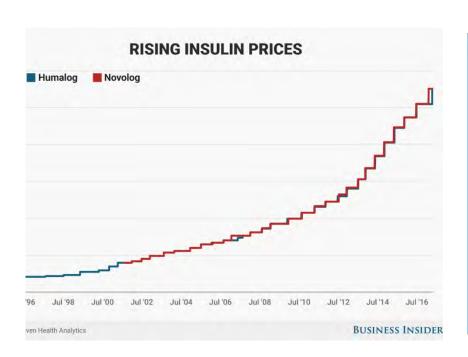


About the Author

Natalie Shure is a writer and researcher whose work focuses on health, history, and politics.

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Neoliberalism: Political Success,
Economic Failure



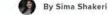
Key Facts & Statistics:

- 50% of people around the world in need of insulin cannot reliably access it because it is unavailable, unaffordable, or both**
- Monthly out-of-pocket costs for diabetes supplies the USA are anywhere from \$0 to \$1700 USD*
- In Syria, up to 77% of income can be spent on diabetes supplies, if any are available*
- Monthly costs for diabetes supplies in Brazil can be as much as \$700 USD, or 82% of a person's income*
- Full diabetes management in Kenya could cost about \$120 USD per month, but the average monthly salary in Kenya is \$216 USD*
- Discontinuation of insulin use was the leading cause of diabetic ketoacidosis in 68% of people in a USA inner city^v

 $\underline{\text{https://www.t1international.com/media/assets/file/Advocacy Toolkit - WEB SPREADS.pdf}}$











With Americans increasingly crossing the border to buy insulin in Canada, prompting worries of a shortage, in a situation that Vermont Senator Bernie



The simple reason is Canada, like many other industrialized countries, has price controls on the cost of pharmaceuticals. The <u>Patented Medicine Prices Review</u> <u>Board</u> ensures the price of patented medicine sold in Canada is "not excessive" and remains "comparable with prices in other countries."



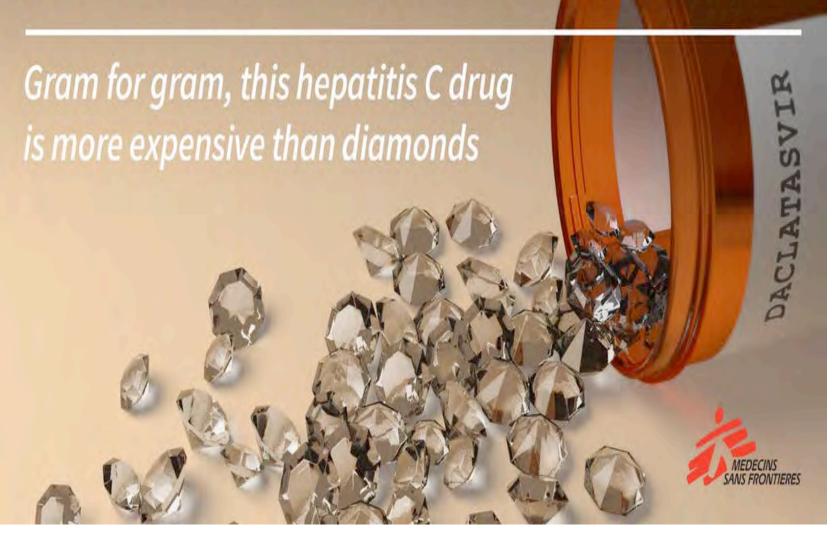
ACCESS TO HEPATITIS C TREATMENT 2016

Of 80 million people infected - over 1 million had access to Hep C treatment



We have a long way to go

MEDICINES SHOULDN'T BE A LUXURY





Of the 275,000 women in the world who die of cervical cancer every year, more than 85% are in low-income countries, where the incidence of HPV infection is higher and few women have access to screening and treatment - GAVI



HPV vaccines are among the most expensive adult vaccines, often costing close to \$400 in the US private sector for a full threedose course of therapy

ADOPTION & SCALE

Even when products are developed, availability does not necessarily mean they get scaled-up

Global coverage (%) (date) = launch year DRUG 100% Avg. HICI Hepatitis B DIAGNOSTIC Vaccine (Avg. HIC) 75% ORS (1977)50% Hib Vaccine (1987) ARVs **ACTs** (1987 LMIC) [1999] 25% Rotavirus Vaccine Years from launch 0% 5 20 10 15 25 30 ACT: artemisinin-based combination therapy ARV: antiretroviral Hib: Haemophilus influenza type b HIC: high-income countries LMIC: lower- and middle-income countries ORS: oral rehydration solution

Figure 1. Years to scale-up

While drugs, diagnostics, and vaccines typically scale within the first two years of launch in developed countries, they often take decades to scale in lower- and middle-income countries.

Better Therapies For TB Are Here, But They Will Not Deliver Themselves



Madhukar Pai Contributor ①
Healthcare
I write about global health, infectious diseases, and equity



- -Planning, alignment and engagement of stakeholders
- -Strong policies
- -Pathfinder countries
- -Go beyond donation programs
- -Active regulators
- -Donor support
- -United TB community & advocacy

Several interesting case studies & models to improve access to tools

Anti-retrovirals

Hepatitis B vaccines

HPV vaccination

Rota virus vaccine

Hepatitis C drugs

New TB diagnostic and drugs

Canada's Ebola vaccine

GAVI

DNDi

Global Drug

Facility

Affordable

Medicine for

Malaria (AMfM)

CEPI



http://fireintheblood.com/

Most models try to address demand and supply side issues

	Description or examples	
Supply side		
Preventing delay in generic entry	Expedited or abbreviated application processes, early working (Bolar) provisions, and biowaivers	
Incentivising market authorisation	Incentives for manufacturers to file an application for market authorisation of a generic medicine	
Assuring quality of generic medicines	Requirements for bioequivalence testing and the publication of lists of interchangeable medicines; transparency of reviews of such evidence; reliance on decisions taken by stringent regulators or prequalification	
Using TRIPS flexibility Policies that enable the use of TRIPS flexibilities, including undisclosed data protection that does not prohibit the registration of a generic		
Increasing competition between manufacturers	Patent pools, improving transparency of patent information, and publishing information on the prices of medicines	
Pricing for affordability	ility Internal reference pricing, external reference pricing, pricing controls, the regulation of distribution chain mark-ups, and charges; pooled procureme and tenders	
Demand side		
Promoting generic prescribing	Prescribing medicines by the international non-proprietary (generic) name	
Enabling substitutions	Mandate or enable the dispensing of generic equivalents instead of branded products by pharmacists and other dispensers	
Adapting medicines reimbursement policies	Promoting generic medicines via waiver of copayments or the application of internal reference pricing	
Promoting independent medicines information		
Monitoring consumption	Monitor and report the consumption pattern of generic medicines	
RIPS=Trade-Related Aspects of	Intellectual Property Rights. to increase competition and reduce prices ¹⁶²	

The Lancet Commissions
Essential medicines for universal health coverage
2016

Summary table of different countries and results of their price reduction intervention for Hep C drugs

Country Description of Intervention		Cost of SOF per treatment of 12 weeks (per pill) pre-intervention	Cost of SOF per treatment of 12 weeks (per pill) post-intervention	Number of people who have accessed lower price medication	
Australia (High-income)	Volume-based pricing deal	84,000\$ AUS (1,000\$)	Free to patients after normal co-payment scheme	25,890 people initiated treatment in 2016	
Canada (High- income)	Leveraging collective buying power	55,000\$ USD (655\$)	Prices not disclosed due to confidentiality	Newer prices not yet implemented	
Malaysia (Upper middle-income)	Compulsory licenses	12,000\$ USD (143\$)	Price is lower than 300\$ USD, but SOF alone not disclosed	Newer prices not yet implements. RCTs needed for regulatory purposes	
India (Lower middle-income)	Voluntary licenses generic competition	900\$ USD (10.71\$)	22\$ USD (0.26\$)	42,000 people had received treatment by the end of 2015	
Egypt (Lower middle-income)	Challenging patents generic competition	900\$ USD (10.71\$)	Gilead's SOF 250\$ USD (2.98\$) Generic SOF 51\$ USD (0.61\$)	More than 1 million people had accessed treatment by the end of 2016	

PPHS511 Case Study, Fall 2017

Criminal Cost: The High Price of the Hepatitis C Medication Sofosbuvir

Authors: Adam Palayew B.Sc.(honors)¹, Elitsa Papazova², Mauli Patel³, Nevena Veljanovic³, Marie Ezran⁴, Claudia Woronko B.Sc.(honors)¹

Case study: Xpert MTB/RIF test for TB and rifampicin resistance







Smear microscopy

Rapid molecular test



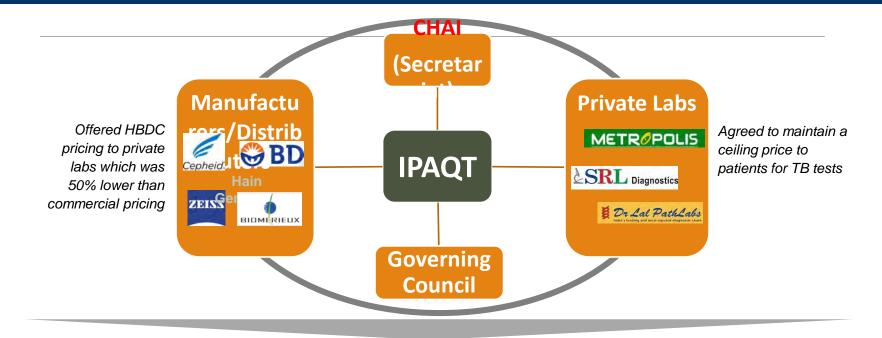


CASE STUDY

Catalyzing the market for accurate tuberculosis testing in India's extensive private sector through IPAQT

INCREASING ACCESS TO ACCURATE, VALIDATED DIAGNOSTICS IN THE PRIVATE SECTOR IS KEY TO REDUCING INDIA'S HIGH TUBERCULOSIS BURDEN. CHAI FACILITATED A PARTNERSHIP BETWEEN PRIVATE SECTOR LABORATORIES AND MANUFACTURERS TO SUPPORT ADOPTION OF A LOW-PRICE, HIGH-VOLUME MODEL THAT IMPROVES ACCESS TO QUALITY DIAGNOSTICS AND STRENGTHENS LINKAGES IN INDIA'S HEALTHCARE SYSTEM.

What is IPAQT?



Lower input price to labs

GeneXpert	Pre-IPAQT (\$/Unit)	•
Capital	30,00,000	15,00,00
Investment	30,00,000	0
Cartridges	2300	1150

Resulting in lower price to patient



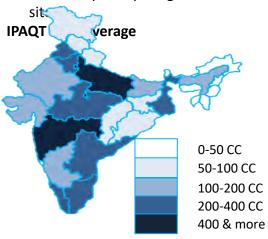
GX Hain LPA

MGIT

What has IPAQT achieved?

Ensured pan India availability of quality TB tests

- IPAQT network is truly nationwide
- 210 labs, & >6,000 collection centers (cc); all major chain labs.
- >80% Indian districts with at least one participating collection

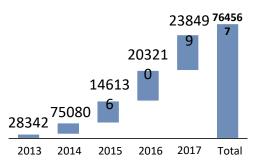


10x increase in test volumes

Steady YoY increase in test orders. ~85% of the GX volumes through IPAQT labs

YoY IPAQT Test Volumes

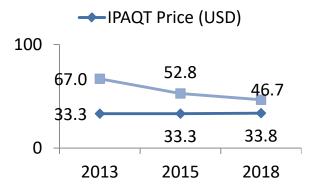
Σ(GeneXpert, Hain LPA, BacT/Alert



Commercial prices of GX reduced over a period of time¹

YoY GX pricing trends in the private sector suggest that IPAQT has been successful in driving down the commercial GX price

GX Price to Patient



^{1 –} Ponnudurai et al, J Epi Global Health 2018

IPAQT labs offer the lowest price for Xpert MTB/Rif Test in the private sector

Country	Mean price for Xpert MTB/RIF 2015	Mean price for Xpert MTB/RIF 2017-18	Range 2015	Range 2017-18	Labs contacted in 2015 with Xpert testing	Labs contacted in 2017-18 with Xpert testing
Kenya	\$80.60	\$85.36	\$51-\$171	\$58.20- \$149.38	5	5
IPAQT* member laboratories	\$30.26	\$33.80	Fixed Price	Fixed Price		
Rest of Private Sector	\$52.82	\$46.70	\$27.84-\$86.55	\$24.67- \$80.19	13	22
Pakistan	\$37.26	\$47.67	\$25.96-\$58.65	\$25.63- \$66.45	4	7
Philippines	\$155.44	\$152.49	\$128-\$183	\$106.4-\$170	9	8
Bangladesh	\$74.75	\$64.20	\$45.50-\$130	\$42-\$90	4	6
Afghanistan	\$50.00	No Xpert			1	
Uganda	No Xpert	No Xpert			••	••
Vietnam	No Xpert	No Xpert				
Indonesia	No Xpert	No Xpert				
Myanmar	No Xpert	\$71.03				1
Nigeria	No Xpert	\$175.00		\$115.00- \$235.00		2
Cambodia	No Xpert	No Xpert			••	••

- The average price to the patient of US \$68.73 in 2015 v/s US \$84.53 (range \$46.70-\$175.00) that patients pay now, translates to a 23% increase.
- The 2015 and 2017-18 data show a similar trend, with IPAQT laboratories still offering the lowest price (US \$33.80) among all 12 countries.
- The gap between IPAQT and market prices in India has narrowed between 2015 and 2018, suggesting that IPAQT might have played a role in increasing affordability in the private sector at large.

Source: Ponnudurai et al. J Epi Global Health 2018



BMJ

BMJ 2013;346:12161 doi: 10.1136/bmj./2161 (Published 5 April 2013)

NE

Private firms form initiative to offer accurate and affordable TB tests

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 IPAOT came into being, - PHOTO: K, PICHUMANI

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

70 labs in India cut TB test bill by half

Malathy Iyer TNN

Mumbai: Awareness about drugresistant 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 sophistizated TB tests—called GeneXpert and Hain line probe assays—done from April to December 2013 stood

TESTS WITH REDUCED COSTS

Xpert MTB/RIF | ₹2,000
Detects multidray 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



nostic laboratory chains in India to offer drug-sensitivity tests for TBat half the price.

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 Pal.

Considering that 70% of Indians seek healthcare in the private sector by paying from their own pocket, the IPAQT logic clicked. Around 390 diagnostic outlets from Maharashtra are a part of IPAQT; 170 are from Mumbai and Navi Mumbai.

Dr B R Das from SRL Diagnostic tics, one of the largest diagnostic chains in India, said, "We now offer GeneExpertat Rs 2,000 from the initial cost of Rs 3,500. We conduct approximately 900 GeneXperi 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

Plan to Fight De

BY GEETA ANAND

NEW DELHI-An international health initiative has brokered a landmark accord that aims to



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June 14, 2013

Dr. Madhukar Pai Associate Director McGill International TB Centre Department of Epidemiology & Biostatistics 1020 Pine Avenue West Montreal QC H3A 1A2 Canada

Dear Dr. Pai:

Thank you for meeting with me during my visit to Mumbai. It was a great discussion, and I enjoyed learning more about India's private diagnostics industry and its role in improving tuberculosis control.

I was very impressed with your comprehensive understanding of the diagnostics landscape in India and your work to ban unreliable serological tests and replace them with more suitable WHO endorsed tests. In particular, I appreciate your heroic efforts to reduce cost and increase access through the IPAQ coalition. I look forward to hearing of future progress.

It was a pleasure meeting you, and I appreciate your sharing your time and expertise with me.

Sincerely,

Plan 1

An int

View

Bill Hates

Bill Gates



Gavi's business model in six steps

Getting vaccines on the

agenda

Securing predictable financing



Immunisation is a commitment for life that requires guaranteed, longterm funding.



Developing countries decide for themselves how best to use Gavi support for immunisation.

Strengthening health delivery systems

Donor and developing countries

need to see proof of the value of

new vaccines before investing.



It's not enough to buy new vaccines. They have to safely reach every child.

Working together for healthy vaccine markets



Gavi's market shaping efforts aim to make life-saving vaccines and other immunisation products more accessible and affordable for lower-income countries.

Country commitment to cofinancing



National immunisation programes must survive long after Gavi support stops.

The vaccine goal

The sustainability goal

immunisation programmes.

Improve sustainability of national

Accelerate equitable uptake and coverage

The systems goal

Increase effectiveness and efficiency of immunisation delivery as an integrated part of strengthened health systems.

The market shaping goal

Shape markets for vaccines and other immunisation products.

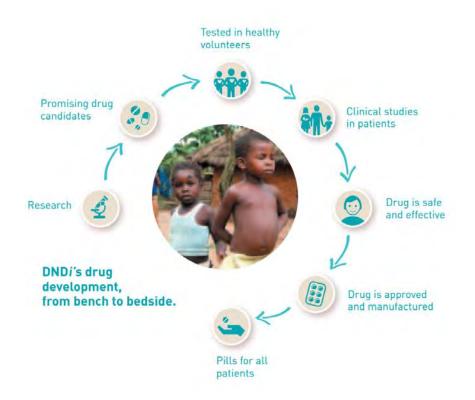


Drugs for Neglected Diseases *initiative* (DND*i*) is a collaborative, patients' needs-driven, non-profit drug research and development (R&D) organization that is developing new treatments for neglected diseases.

and underway in other East African countrie

25.000

treated in East Africa



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Easy-to-use, affordable, field-adapted, non-patented



Only child-adapted

dosage form

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recommended

in revised Indian VL elimination roadmap

DNDi co-developed fexinidazole, the first all-oral treatment for sleeping sickness



#Fexinidazole



What about universities? How can we help?







Project Summary

"Canadian Universities play a critical role in addressing global chailenges such as HIV/AIDS. Tuberculosis, and other neglected diseases. It is importative that we continue to give priority to the lives of millions through licensing practices that allow our world-class research to reach those that need it most. This Report Card helps us measure the impact our universities have on global health. It clearly shows Canadian Universities are falling short students, feeulty and related communities must late the Indiventities into santin.

-Stephen Lewis, Co-Director of AIDS-Free World, Canada's Former Ambassador to the United Nations

"The UAEM Canadian Global Equity in Biomedical Research Report highlights a worning lack of transparency on publicly funded borneatical research carried out by Canadian Universities. With only a third of clinical trials data disclosed and only one university adopting global access licensing, this Report card proves once again that universities have a long way to go. It is time for universities to fulfill their responsibility to ensure that publicly funded biomedical research is available for the public good."

Rachel Kiddell-Monroe, ISID Professor of Practice McGill

UAEM's Canadian Report Card project evaluates 15 of Canada's research-intensive universities on their contributions to biomedical research on neglected health needs, access to medicines, and education concerning access and innovation issues. The Report Card uses both cubicity available and self-reported information to evaluate academic institutions on three key questions.

- To what extent are universities investing in innovative biomedical research that addresses the neglected health needs of resourcelimited populations?
- 2. When universities license their medical breakthroughs for commercial development, are they doing so in ways that ensures equilibite access for all manipulated and valuerable populations in high, middle and low-income countries? What steps are they taking to ensure innovative treatments are made available at affordable noises?
- What efforts are universities making to educate the next generation of global health leaders about the crucial impact that academic institutions can have on global health through their biomodical research and licensing activities?

GLOBAL HEALTH COMMENTARY

The Global Access Initiative at The University of British Columbia (UBC): Availability of UBC Discoveries and Technologies to the Developing World

KISHOR M. WASAN, 14 SHEILA J. THORNTON, 1 IAN BELL, 2 REBECCA E. GOULDING, 3 MICHAEL GRETES, 3 ANDREW P. GRAY, 3 ROBERT E.W. HANCOCK, 4 BARBARA CAMPBELL 5

Received 5 June 2008; revised 6 June 2008; accepted 9 June 2008

Published online 7 August 2008 in Wiley InterScience (www.interscience.wiley.com), DOI 10.1002/jps.21495

ABSTRACT: The University of British Columbia (UBC) became the first university in Canada to develop a strategy for enhancing global access to its technologies. UBC's University-Industry Liaison Office, in collaboration with the UBC chapter of Universities Allied for Essential Medicines (UAEM), established a mandate and developed principles that provide the developing world with access to UBC technologies. This commentary will discuss these principles and provide examples of where they have been applied to several UBC technologies. © 2008 Wiley-Liss, Inc. and the American Pharmacists Association J Pharm Sci 98/791-794, 2009

Keywords: absorption potential; formulation; antiinfectives; vaccine delivery; nanotechnology



that any research and university-developed technologies

development into a drug, vaccine, or medical diagnostic are

created on McGill's campus with potential for further

made affordable to all.

TWITTER

McGill University

¹The University of British Columbia, Faculty of Pharmaceutical Sciences, Division of Pharmaceutics and Biopharmaceutics, 2146 East Mall, Vancouver, B.C., Canada V6T 123

²The University of British Columbia, University Industrial Liaison Office, Vancouver, Canada V6T 123

³The University of British Columbia Universities Allied for Essential Medicines Chapter, Vancouver, Canada V6T 123

⁴The University of British Columbia, Department of Microbiology and Immunology, Vancouver, Canada V6T 123

⁵ Dalhousie University, Halifax, NS, Canada



Visualizing an alternative biomedical R&D system

📋 12th Jan 2018 🧳 Access to medicines 🧳 Research 📮 0 comments



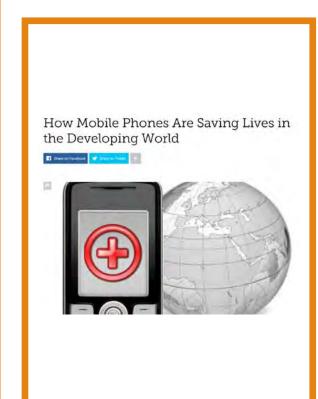


Author: Chloe Hogg

Chloe Hogg is a recent graduate of McGill University with a BA in Economics and International Development. She is a member of the North American Coordinating Committee of Universities Allied for Essential Medicines (UAEM).

http://globalhealth.thelancet.com/2018/01/12/visualizing-alternative-biomedical-rd-system

Can technologies alone save lives?









The Machine That Will Help End TB

Nearly 1.5 million people die from tuberculosis every year, even though most cases can be cured with routine antibiotic treatments. One country's fight to get the ancient scourge under control has an unlikely hero: a simple diagnostic test.

by Jon Cohen December 11, 2012

Tuberculosis is one of the leading causes of death in much of the world; HIV is the only infectious disease that kills more people. Yet many TB cases go undiagnosed.

PROMISE



REALITY

Improved Diagnostics Fail to Halt the Rise of Tuberculosis

TB remains a big killer despite the development of a better test for detecting the disease

By Ewen Callaway, Nature magazine on November 17, 2017





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PROMISE

REALITY

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HEALTH.

Promise unrealized: A birth checklist fails to reduce deaths in rural India

By CASEY ROSS @caseymross / DECEMBER 13, 2017

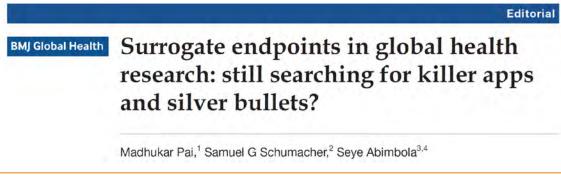


Vinita, 23, holds her baby girl a few hours after her birth at a Community Health Center in Mall, near the capital of Uttar Pradesh.

There are no silver bullets or killer apps in global health...







Open access: http://gh.bmj.com/content/3/2/e000755

Technologies help, but cannot overcome low quality health systems







For real, enduring impact, we need high quality health systems

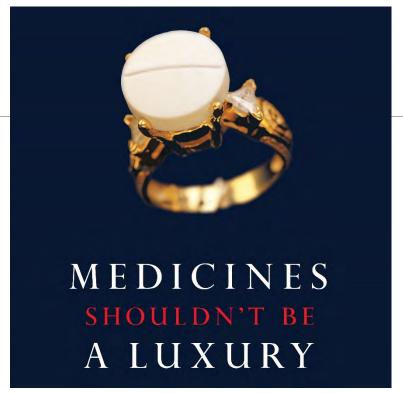


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Commission on
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Thank you! Merci!!



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