MEDECINS SANS FRONTIERES

STIJN DEBORGGRAEVE

MSF ACCESS CAMPAIGN

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TB ADVOCACY

Swiss TPH Hybrid Symposium
The Tuberculosis Pandemic – a Call to Action
Science, Application, Politics
21-22 March 2023, Basel, Switzerland

15,400

PEOPLE STARTED ON TB TREATMENT IN MSF PROGRAMMES IN 2021

1,840

PEOPLE STARTED ON DRUG-RESISTANT TB TREATMENT IN MSF PROGRAMMES IN 2021


Photo: MSF/Igor Barbero

ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

DR-TB DRUGS UNDER THE MICROSCOPE 2022

8TH EDITION

Pricing and patent landscape of medicines for adults and children

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EXECUTIVE SUMMARY

In 2021 and 2022, tuberculosis (TB) research delivered promising results about medicines and treatment regimens with the capacity to treat people affected by drug-resistant (DR)-TB more quickly and effectively, and with much-improved tolerability for patients.

As a result, BPaLM and BPaL, two new all-oral regimens, both of six months' duration, are recommended for multidrug-resistant/rifampicin-resistant (MDR/RR)-TB and pre-extensively drug-resistant (pre-XDR)-TB. These are alternatives to longer or more toxic regimens. More evidence is being generated by ongoing clinical trials assessing short all-oral regimens for fluoroquinolone (FQ)-susceptible MDR-TB and FQ-resistant MDR-TB.

Children affected by DR-TB can now be treated with regimens fully made of medicines available in child-friendly formulations. Previously, children had to be treated with adult formulations that had to be crushed or split, which carried the risk of not achieving correct therapeutic levels.

While the availability of patient-friendly medicines and regimens is a positive development, they continue to remain inaccessible to many people, in part due to their high prices and licensing arrangements by pharmaceutical corporations and other drug developers.

Bedaquiline, a component of all short and most long regimens to treat DR-TB in adults, currently accounts for 35-40% and 35-70% respectively of the overall cost of regimens. The compound patent on bedaquiline is set to expire in July 2023, but the restrictive terms of a voluntary license between pharmaceutical corporation Johnson & Johnson (J&J) and not-for-profit organisation TB Alliance (TBA) may act as a barrier to the entry on the market of generic versions of the drug. This will in turn delay the scale-up of more affordable bedaquiline-containing regimens.

Vaishnavi, 7 years old and living with DR-TB, held by her mother Vahida, interacts with MSF nurse Preethi.

Pretomanid is a component of the two new all-oral regimens recommended by World Health Organization (WHO). The medicine is currently priced at US$56/month at the Global Drug Facility (GDF). However, given the significant public and philanthropic resources that funded the development of the medicine this price is unjustified. Researchers estimate that pretomanid can be produced and sold at a profit for less than $35/month.

Delamanid is one of the most expensive medicines used to treat DR-TB. Its high prices – it is 13-18 times more expensive than what is estimated it could be profitably sold for – represent a major challenge to procurement of sufficient quantities of the medicine by national TB programmes and other TB care providers. Generic competition is needed to contribute to making a more affordable version of delamanid available.

Due to the impact of the COVID pandemic on health systems, the number of people diagnosed with and on treatment for TB, including DR-TB, has declined dramatically in the last two years. Now more than ever there is a need to scale up access to these shorter and more effective treatments. But to do so, pharmaceutical corporations' evergreening practices and their opaque and restrictive licensing arrangements need to be scrutinised and contested.

Given the limited number of children being diagnosed with and treated for DR-TB, manufacturers may not consider the paediatric TB market viable. It is imperative that pooling procurement across national TB programmes is considered to ensure sustainable supply, alongside stepping up efforts to diagnose and treat more children with DR-TB.

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ACCESS CAMPAIGN

TB ADVOCACY

Innovation

Policies

Use

Access

Political will

Innovation

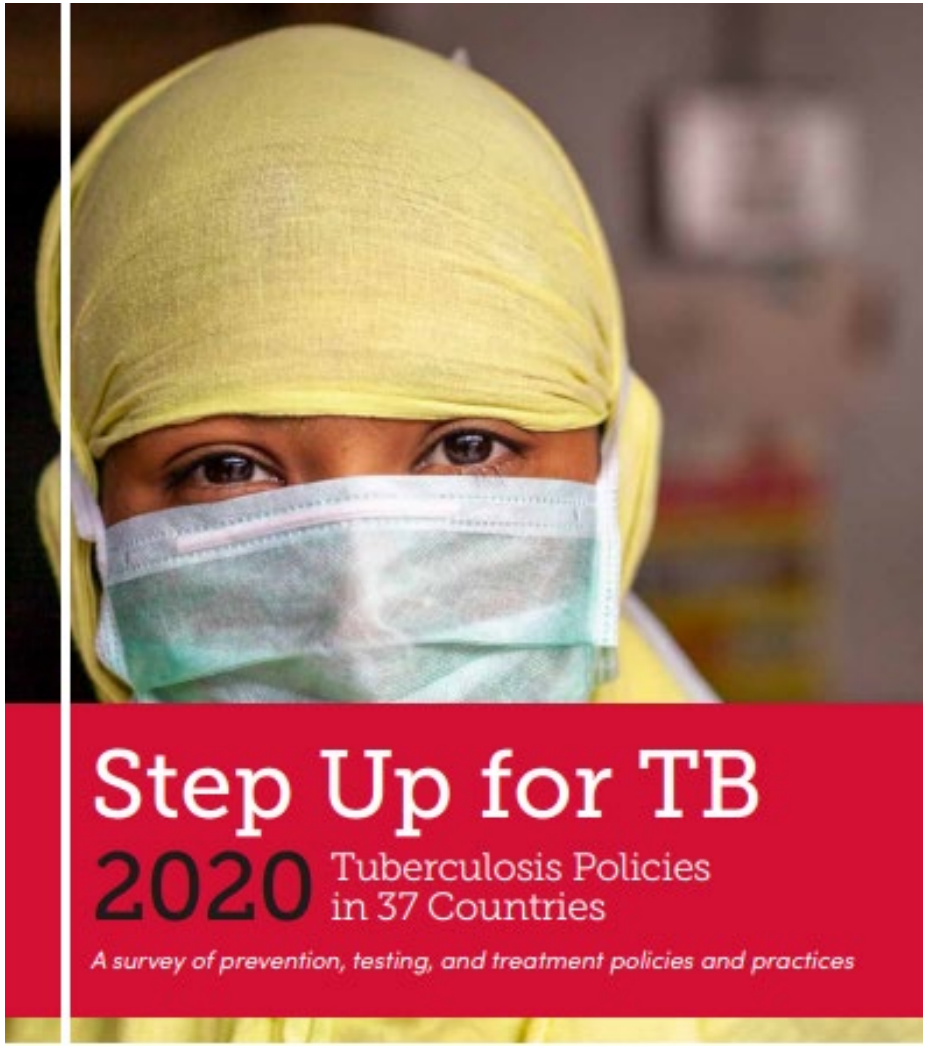
https://msf-access.medium.com/the-deadly-gap-in-diagnosing-children-with-tuberculosis-2f0673117940

> *"In our clinic, every day we see children with symptoms that could be TB. We are an experienced team and have the laboratory TB tests available but for most children who come to us, we just cannot confirm the diagnosis of TB."*
> - Dr Lazro Fidelle, Malakal, South Sudan

> *"Our biggest challenge is collecting a sputum sample from the child to test for TB. While sputum is the standard specimen that we use to detect TB, small children are often not able to produce sufficient sputum to test."*
> - Dr Lazro Fidelle, Malakal, South Sudan

> *"Most of the time we go ahead and treat the child without any positive lab test results. However, this decision to treat must always balance the need for timely and lifesaving treatment with the need to avoid unnecessary treatment of children who may not have TB but another respiratory infection. So we welcome the updated WHO guidelines which now provide clear evidence-based clinical algorithms to diagnose TB, even when test results are not available."*
> - Dr Lazro Fidelle, Malakal, South Sudan

Policies



https://msfaccess.org/step-tb-tb-policies-37-countries-4th-ed

Key findings

RAPID MOLECULAR DIAGNOSTICS

28/34 (82%) COUNTRIES' policies indicate that a rapid molecular diagnostic is the initial test for all people with signs and symptoms of TB.[v]

17/24 (71%) COUNTRIES' policies do not limit the use of rapid molecular diagnostics to certain facilities, among countries with rapid molecular diagnostics as the initial test for all people with signs and symptoms of TB.

TB LAM

13/37 (35%) COUNTRIES' policies do not require a CD4 count to routinely test people living with HIV who are severely sick or have advanced HIV disease using TB LAM, in line with WHO recommendations; **1/37 (3%)** country policy does require a CD4 count; and **23/37 (62%)** countries do not indicate TB LAM in their policies for routine use.

10/14 (71%) COUNTRIES with policies to routinely test people living with HIV who are severely sick or have advanced HIV disease using TB LAM have implemented this policy and use it in practice.

5/8 (63%) COUNTRIES that have implemented TB LAM for routine use have done so in both inpatient and outpatient settings, while **3/8 (38%)** countries limit routine use of TB LAM to inpatient settings, although the test is also recommended by WHO for outpatients.[vi]

9/13 (69%) COUNTRIES' policies indicate that TB treatment can be initiated based on TB LAM results without a confirmatory test. In the remaining 4 countries, either bacteriological confirmation using another test is required or the policies were not clear.[vii]

DRUG SUSCEPTIBILITY TESTING

31/36 (86%) COUNTRIES' policies indicate rifampicin resistance testing for all people with bacteriologically confirmed TB.

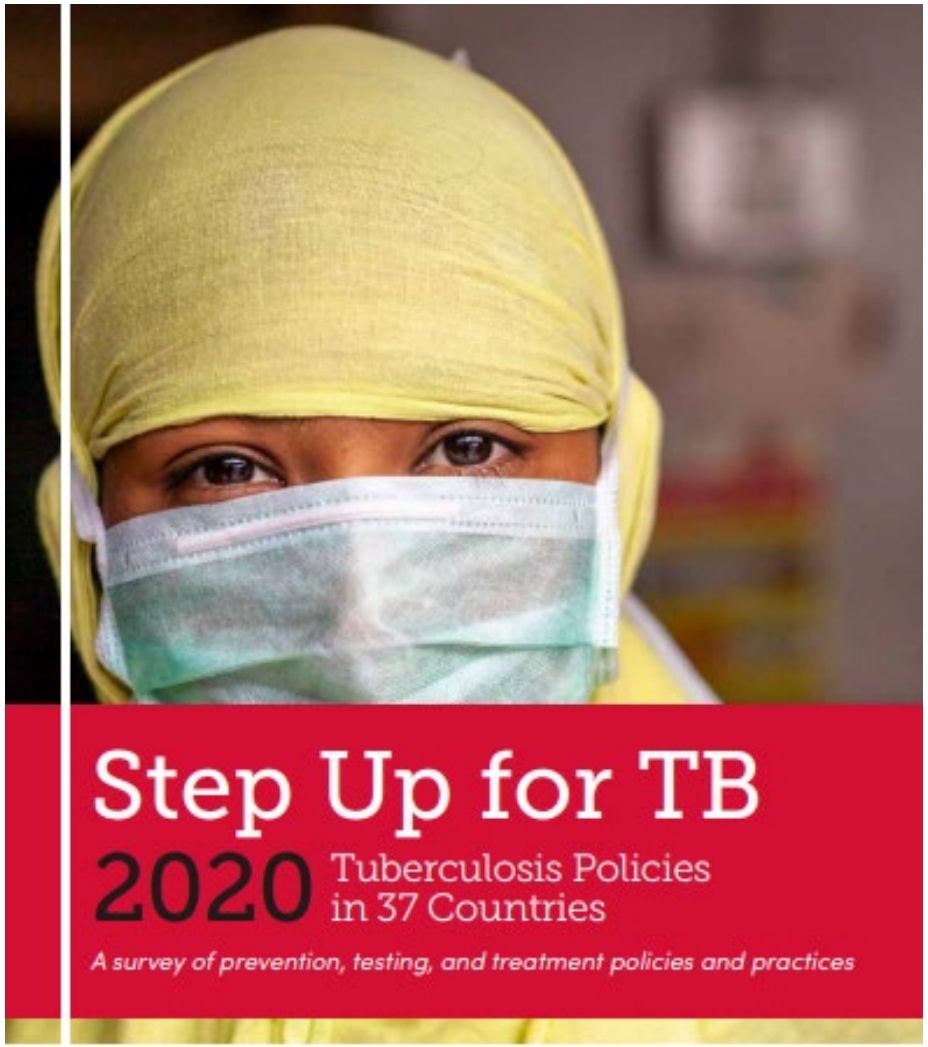
11/36 (31%) COUNTRIES' policies indicate isoniazid resistance testing for all people starting on drug-susceptible TB treatment.

37/37 (100%) COUNTRIES' policies indicate that people with rifampicin-resistant TB are further tested for resistance to at least fluoroquinolones.

10/35 (29%) COUNTRIES have drug susceptibility testing routinely available for the drug-resistant medicines bedaquiline, delamanid, linezolid and/or clofazimine, when these medicines are used in country, according to national TB programmes.

6/33 (18%) COUNTRIES' policies indicate rifampicin and isoniazid resistance for all people starting on treatment; at least fluoroquinolone resistance testing for all people with rifampicin-resistant TB; and drug susceptibility testing methods available in country for rifampicin, isoniazid, fluoroquinolones, bedaquiline, delamanid, linezolid and/or clofazimine, when these drugs are used for routine treatment.

Use



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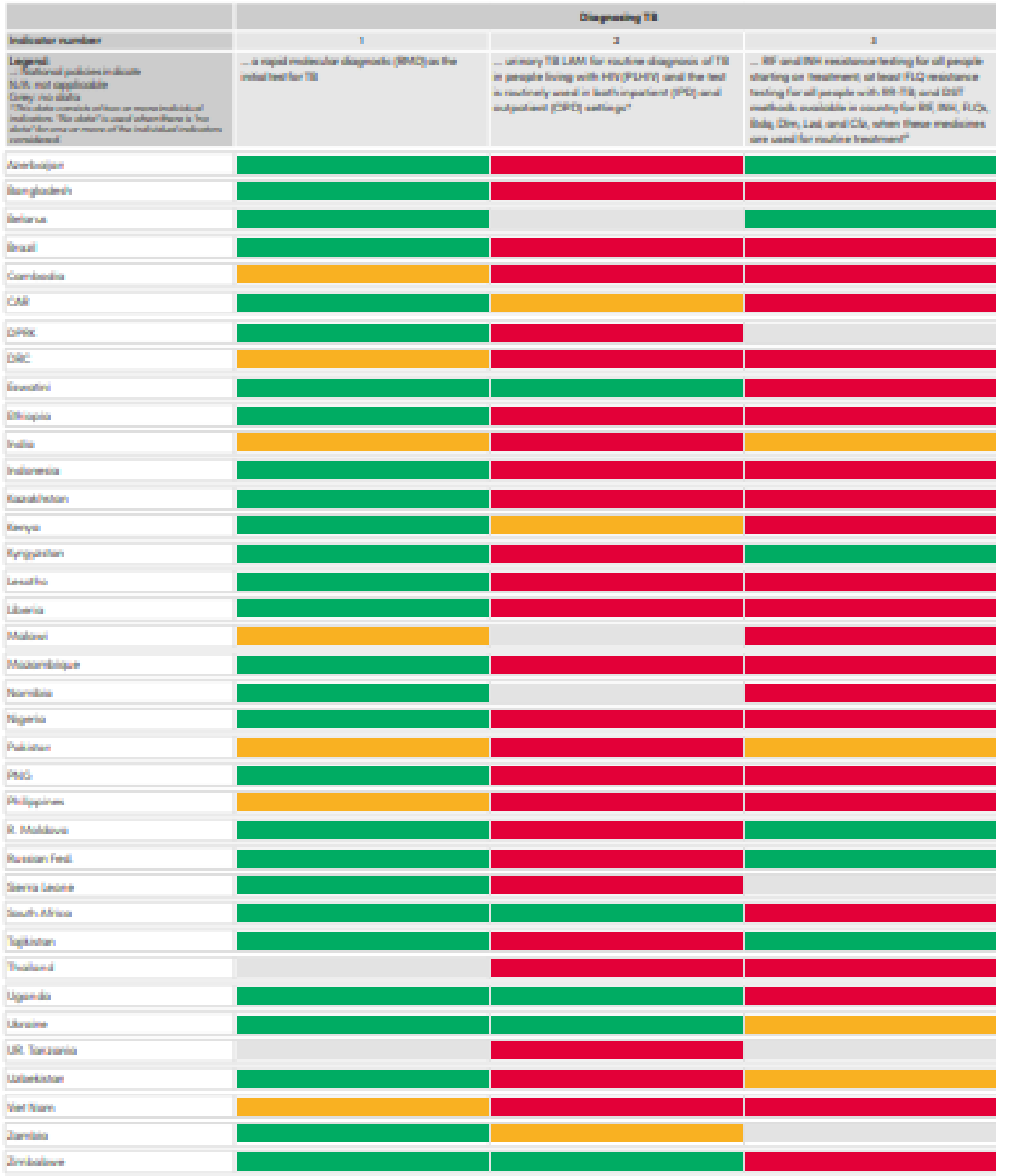
Stop TB Partnership

https://msfaccess.org/step-tb-tb-policies-37-countries-4th-ed

EXECUTIVE SUMMARY DASHBOARD



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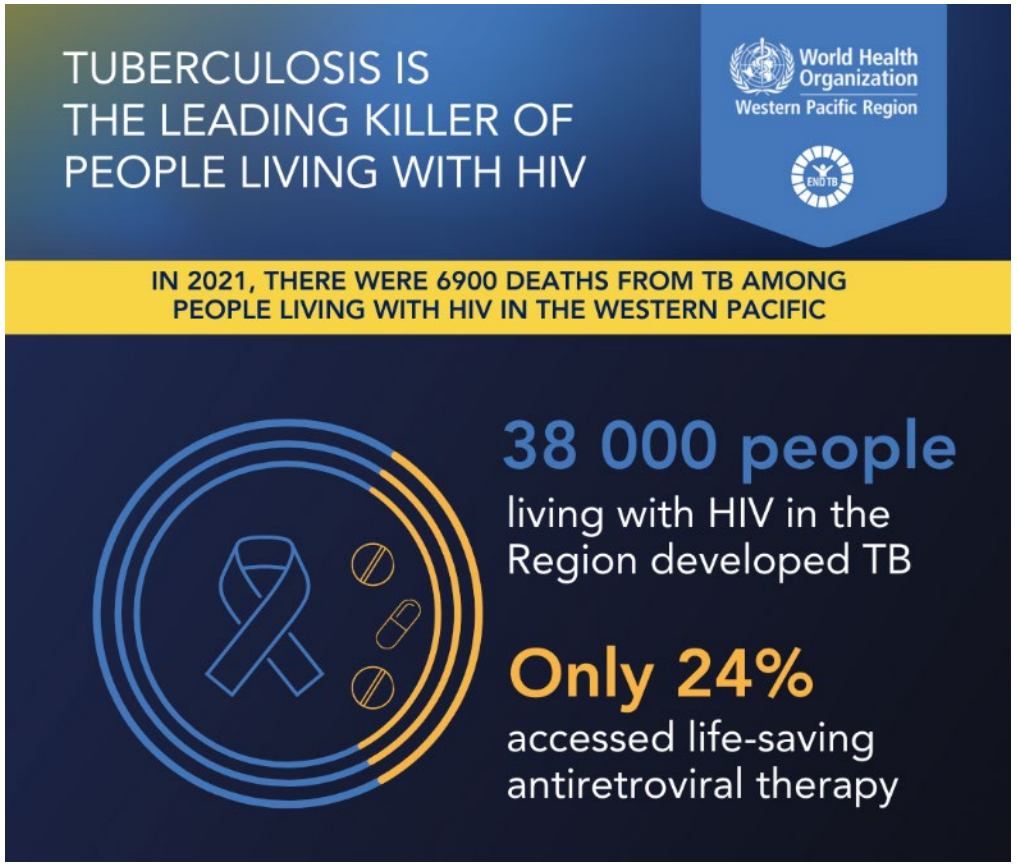
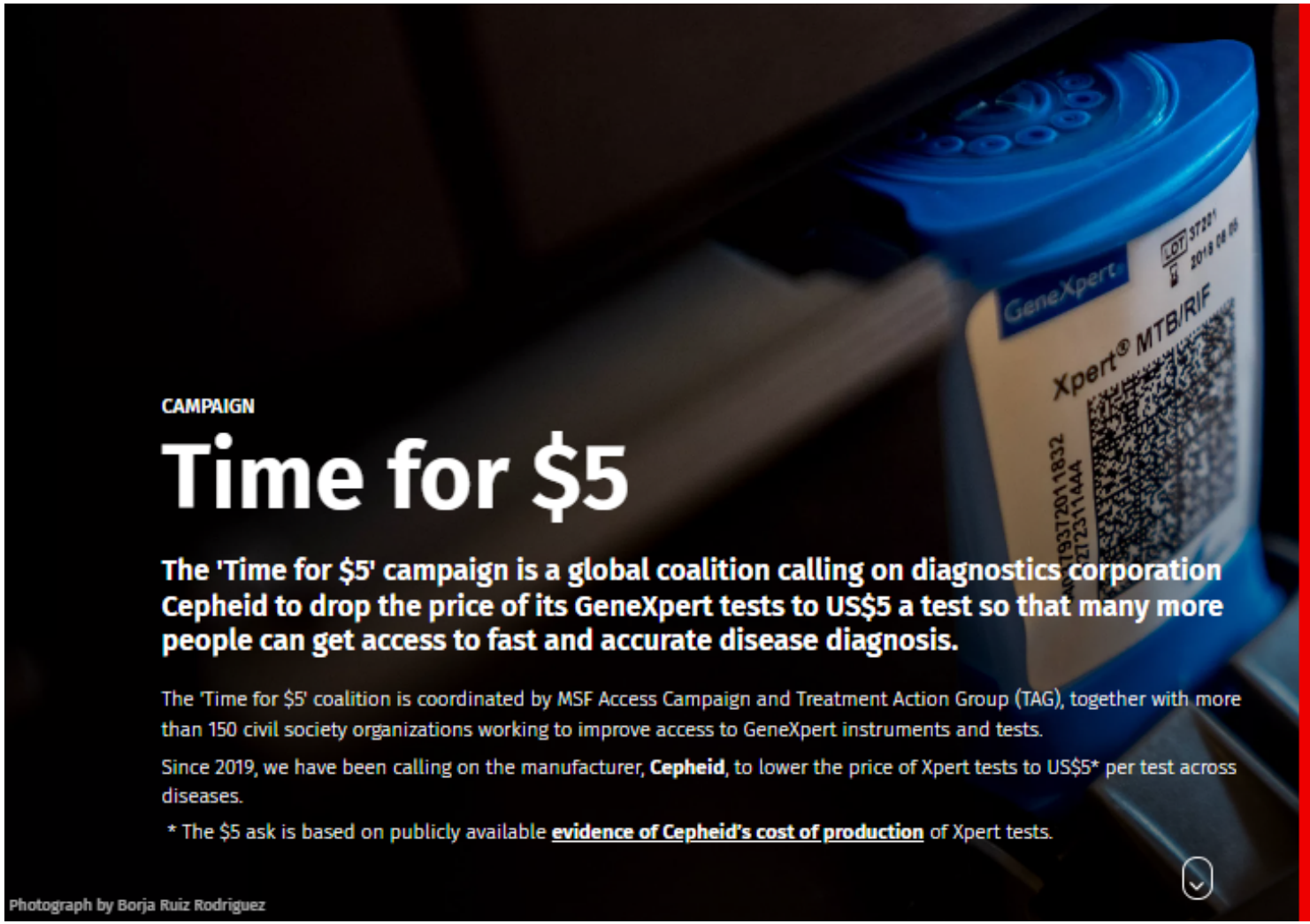


https://msfaccess.org/20-tool-checklist-diagnosing-treating-and-preventing-aids

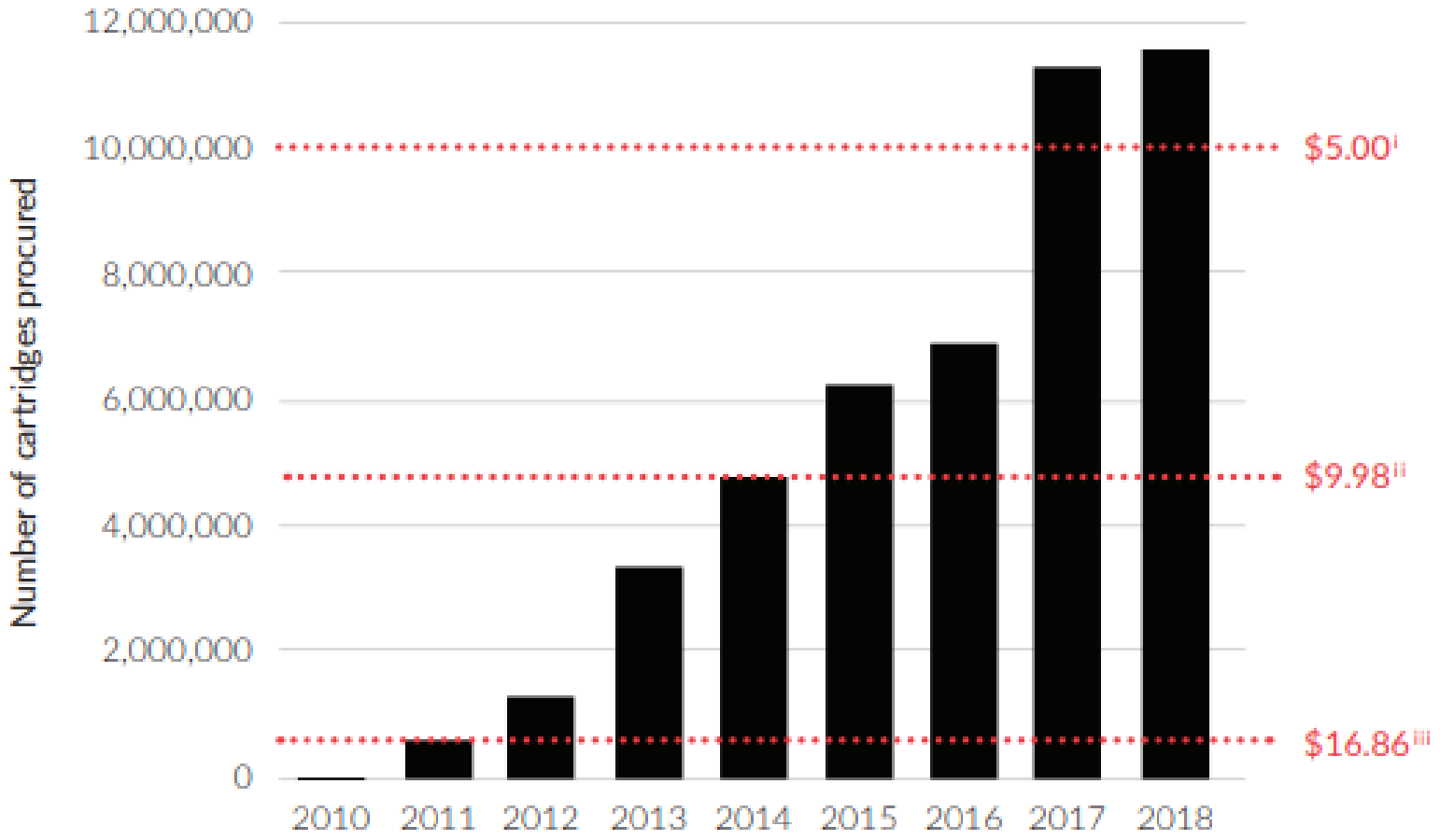
Access



But Cepheid refuses to reduce the price and still prioritizes making profit over saving lives.

https://msfaccess.org/time-for-5

Figure 1: Annual volumes and estimated volume-based prices of Xpert TB test cartridges procured by high-burden countries, 2010–2018[28, 29, 30]



Treatment Action Group

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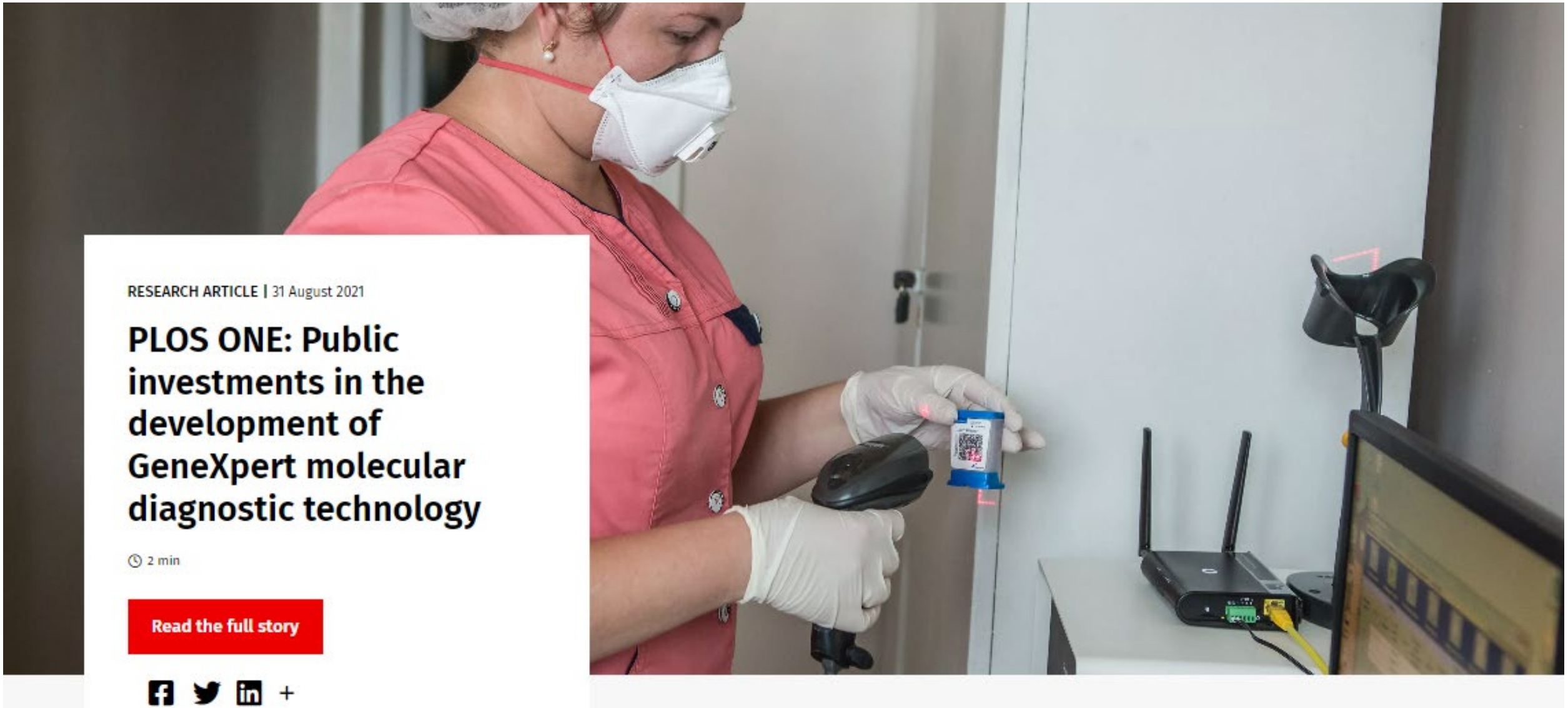
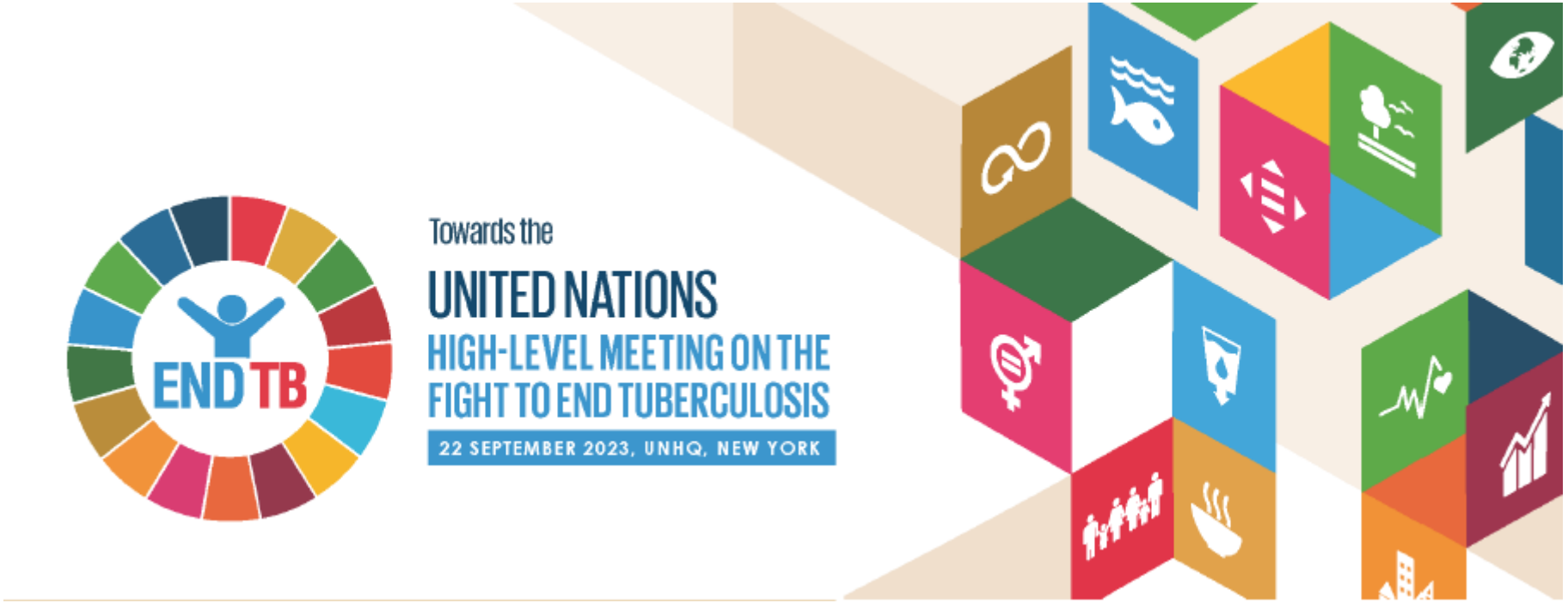
https://www.treatmentactiongroup.org/publication/realizing-returns-on-u-s-government-investments-in-genexpert-diagnostic-technologies/



https://msfaccess.org/plos-one-public-investments-development-genexpert-molecular-diagnostic-technology

Political will



STATEMENT | 01 FEBRUARY 2023

MSF Statement on EB152/5 - Strengthening diagnostics capacity

1 min

DIAGNOSTICS

MSF @ the 152nd WHO Executive Board

The resolution recognises that affordable prices of diagnostics are a key enabler for strengthening diagnostics capacity. However, it fails to take into account the need to improve transparency in public investments, cost of production and pricing structure of diagnostics.

https://msfaccess.org/msf-statement-eb1525-strengthening-diagnostics-capacity