

Improving access to essential medicines: lessons learnt



World Health
Organization

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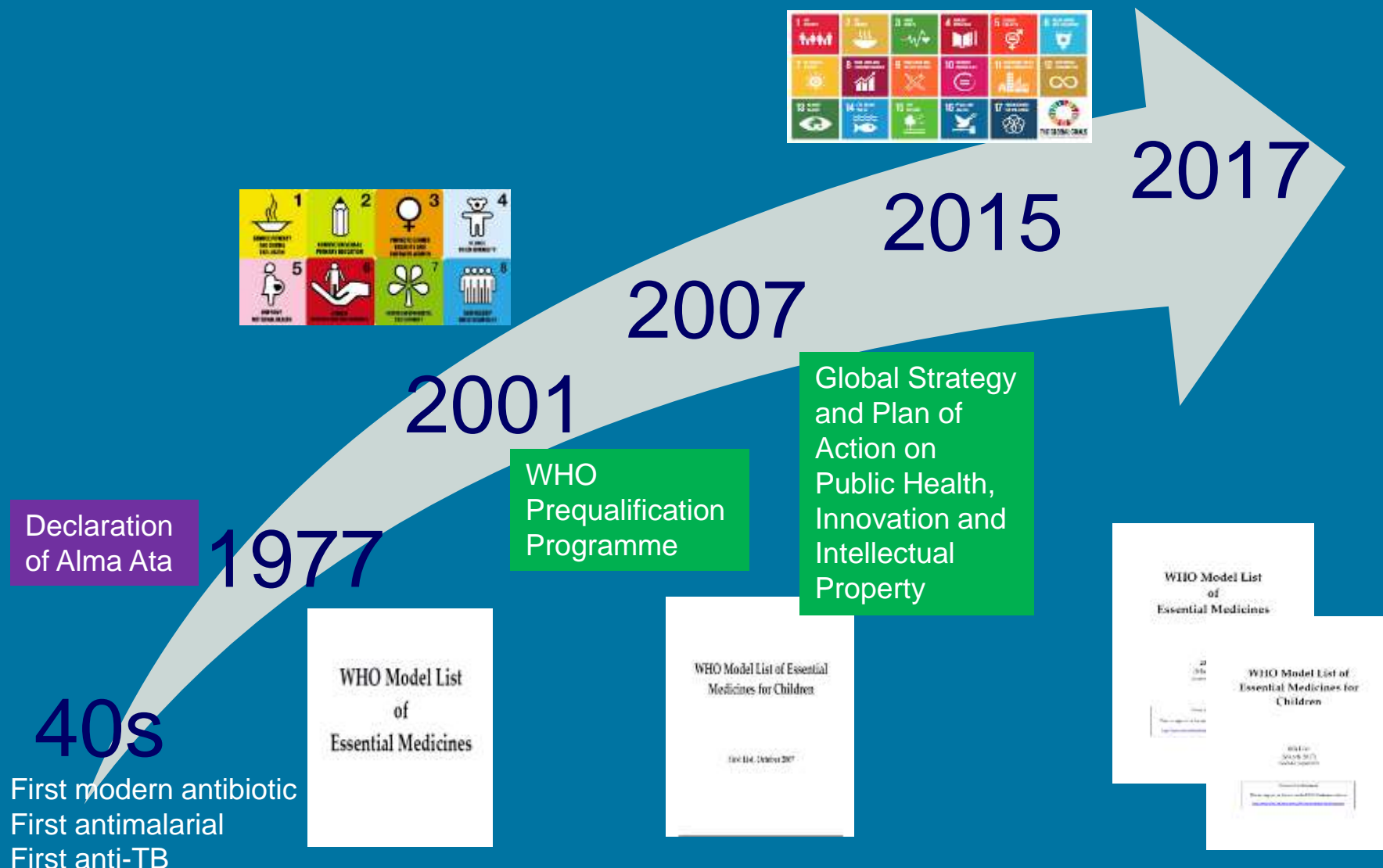
Rome, 5 April 2018

WHO Vision

A world where every child, man and woman has access to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life



The evolution of WHO programs to improve access to essential medicines



The problem

- **2 billion people with no access to essential medicines**
- **Substantial economic impact of pharmaceuticals**
- **Specificities related to different pathologies**
- **Variability of price**
- **Irrational use of drugs and poor drug quality**



Availability of essential medicines

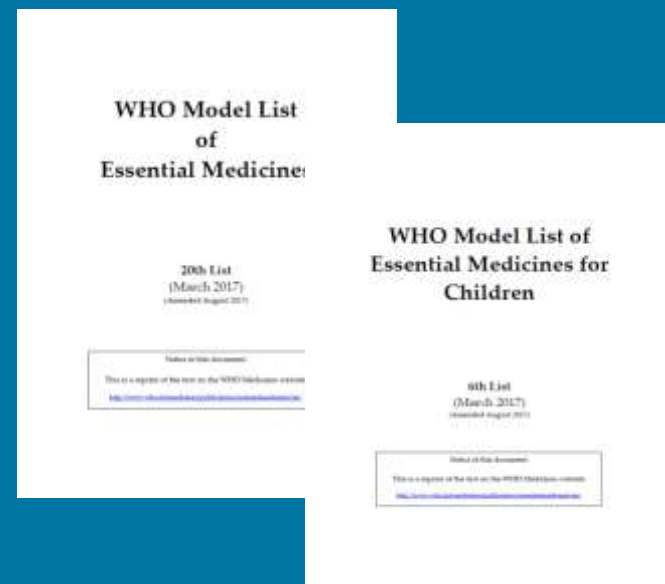
Median availability of selected generic medicines in public and private health facilities, 2007-2013



Source: Surveys using WHO/HAI standard methodology conducted between 2001 and 2012 (available at: <http://www.haiweb.org/medicineprices/>). Countries are classified into income groups using World Bank list of economies (July 2012).

Model Essential Medicines Lists: Prioritising medicines for health systems

- The Model List – a guide for developing national essential medicines lists
- Concept of essential medicines to promote health equity
- The 20th WHO EML and 6th WHO EMLc, March 2017





The new EML 2017

40 **Years** of the Model List
of **Essential Medicines**
1977 - 2017



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11:00 am ET
May 8, 2015 CANCER

WHO Adds Gilead Hepatitis C Drugs to its List of Essential Medicines

ARTICLE COMMENTS (0)

ABBVIE | CANCER | GILEAD SCIENCES | GLEEVED | GLIVEC | HARVONI | HEPATITIS C

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By ED SILVERMAN

As the debate over the cost of prescription drugs accelerates, the World Health Organization has added several treatments for cancer and hepatitis C to its list of so-called essential medicines, which the agency believes should be made available at affordable prices.

The move comes amid growing friction between payers – both public and private – and the pharmaceutical industry over drug pricing. The addition by the WHO follows requests by consumer groups for the agency to widen its list to include some of the latest treatments carrying high price tags.

Among the drugs added to the list are three hepatitis C treatments – Sovaldi and Harvoni, which are sold by Gilead Sciences, and the Viekira Pak medication sold by AbbVie.



PREVIOUS
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'Cancer treatment ain't just for the rich'

WHO added 16 new anti-cancer medicines to the model list of essential medicines (WHO EML) o

Written by Anuradha Mascarenhas

Updated: May 16, 2015, 9:34

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ABOUT AUTHOR



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Tobacco use – smoking and chewing – is the single most important factor which causes cancer.

WHO adds Hepatitis C drugs in the list of essential medicines

By Karla Petrow - May 8, 2015



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Pricy new hepatitis C and cancer drugs make Essential Medicines List

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By Jim Cooney | 11 May 2015 12:31pm | 10 Comments

Several expensive new drugs that treat hepatitis C and some common cancers appear on the latest Essential Medicines List (EML) published by the World Health Organization (WHO). An expert committee every 2 years selects medicines for the list based on scientific evidence that the drugs work and are safe and cost effective. This year's list, released 8 May,

WHO adds hepatitis C drugs to essential list, urges lower prices

LONDON
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The World Health Organization (WHO) logo is pictured at the entrance of headquarters in Geneva, January 25, 2015.

The World Health Organization has added new curative treatments for hepatitis C to its essential medicines list, but the U.N. agency said prices needed to fall to make them accessible to patients in poorer countries.

The treatment of hepatitis C, which affects about 150 million people globally and kills around half a million each year, has been transformed by the arrival of new drugs, such as Gilead's Sovaldi.

These products can cure hepatitis C but are out of reach at Western prices to patients in

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NEVER Do This

WHO – The world health organization added an updated list of essential medicines that should be included in new treatment options. For the first time, it added hepatitis C drug in this list.

EML 2017 – major changes/updates

- **Antibiotic comprehensive review**
 - 3 tiered categorisation: ACCESS, WATCH and RESERVE
 - 23 syndromes reviewed: first and second choice
- **Cancer: 8 medicines, 2 approvals**
- **HIV: dolutegravir, PreP**
- **HepC: sofosbuvir + velpatasivir (pangenotypic)**
- **Contraception: ulipristal and MPA**

EML AWaRe categorization



ACCESS GROUP (29 antibiotics)

First and second choice antibiotics for the empiric treatment of most common/relevant infectious syndromes (21 syndromes).

First choices are usually narrow spectrum agents with positive benefit-to-risk ratios, and low resistance potential, whereas second choices are generally broader spectrum antibiotics with higher resistance potential, or less favorable benefit-to-risk ratios.

WATCH GROUP (7 antibiotic classes)

Antibiotics with higher resistance potential whose use as first and second choice treatment should be limited to a small number of syndromes or patient groups.

These medicines should be prioritized as key targets of stewardship programs and monitoring.

RESERVE GROUP (8 antibiotics or classes)

Antibiotics to be used mainly as 'last resort' treatment options that could be protected and prioritized as key targets of high-intensity stewardship programs.

ACCESS GROUP

Amikacin	Cefalexin	Clarithromycin*	Nitrofurantoin
Amoxicillin	Cefazolin	Clindamycin	Phenoxymethylpenicillin
Amoxicillin + clavulanic acid	Cefixime*	Cloxacillin	Piperacillin + tazobactam*
Ampicillin	Cefotaxime*	Doxycycline	Procaine benzylpenicillin
Azithromycin*	Ceftriaxone*	Gentamicin	Spectinomycin
Benzathine benzylpenicillin	Chloramphenicol	Meropenem*	Sulfamethoxazole + trimethoprim
Benzylpenicillin	Ciprofloxacin*	Metronidazole	Vancomycin*

WATCH GROUP

Quinolones and fluoroquinolones (e.g. ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin)

3rd-generation cephalosporins (with or without beta-lactamase inhibitor, e.g. cefixime, ceftriaxone, cefotaxime, ceftazidime)

Macrolides (e.g. azithromycin, clarithromycin, erythromycin)

Glycopeptides (e.g. teicoplanin, vancomycin)

Anti-pseudomonal penicillins with beta-lactamase inhibitor (e.g. piperacillin + tazobactam)

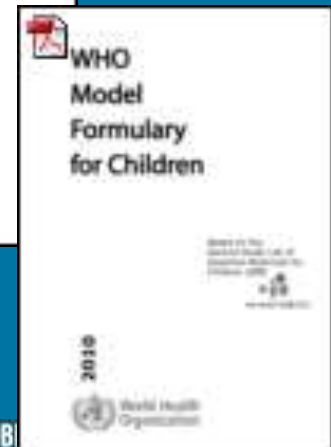
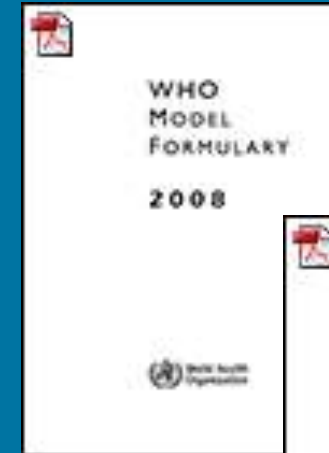
Carbapenems (e.g. meropenem, imipenem + cilastatin) and Penems (e.g. faropenem)

RESERVE GROUP

Aztreonam	Daptomycin
4th generation cephalosporins (e.g. cefepime)	5th generation cephalosporins (e.g. ceftaroline)
Fosfomycin (IV)	Oxazolidinones (e.g. linezolid)
Polymyxins (e.g. polymyxin B, colistin)	Tigecycline

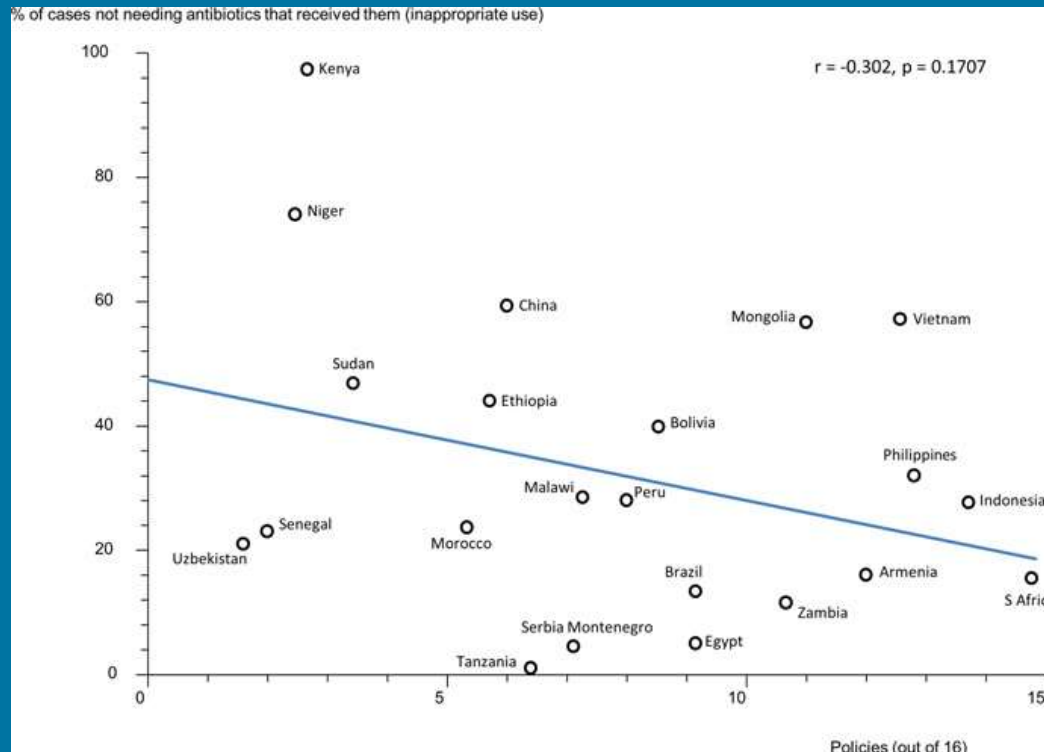
Proper use of essential medicines

- Improves patient safety
- Limits unnecessary medical spending
- Reduces antimicrobial resistance
- WHO Model Formulary
- WHO Model Formulary for Children



WHO Essential Medicines policy implementation reduces inappropriate antibiotics use

Correlation between the number of implemented policies (out of 16) and the percentage of patients not needing antibiotics who received them. Correlation coefficient (r) = -0.302, p = 0.1707. Each data point (circle) represents a country.



Source: The impact of WHO Essential Medicines Policies on inappropriate Use of Antibiotics. K A Holloway et al. PLOS ONE | DOI:10.1371/journal.pone.0152020 March 22, 2016

WHO Prequalification of medicines

- A service provided by WHO to assess quality, safety and efficacy
- 2001 Focus on medicines for HIV/AIDS, tuberculosis and malaria
- 2006 Reproductive health medicines and products
- 2012 WHO List of Prequalified Medicinal Products: 316 medicines for priority diseases
- Highly successful to increase access to medicines and build capacity in countries



Keeping substandard and falsified products out of the supply chain



- Products that enjoy lucrative commercial markets or are in short supply are particularly susceptible to falsification
- They cause harm
- WHO Global Surveillance and Monitoring System for Substandard and Falsified Medicines launched in Africa in 2013
- Global Medical Product Alert

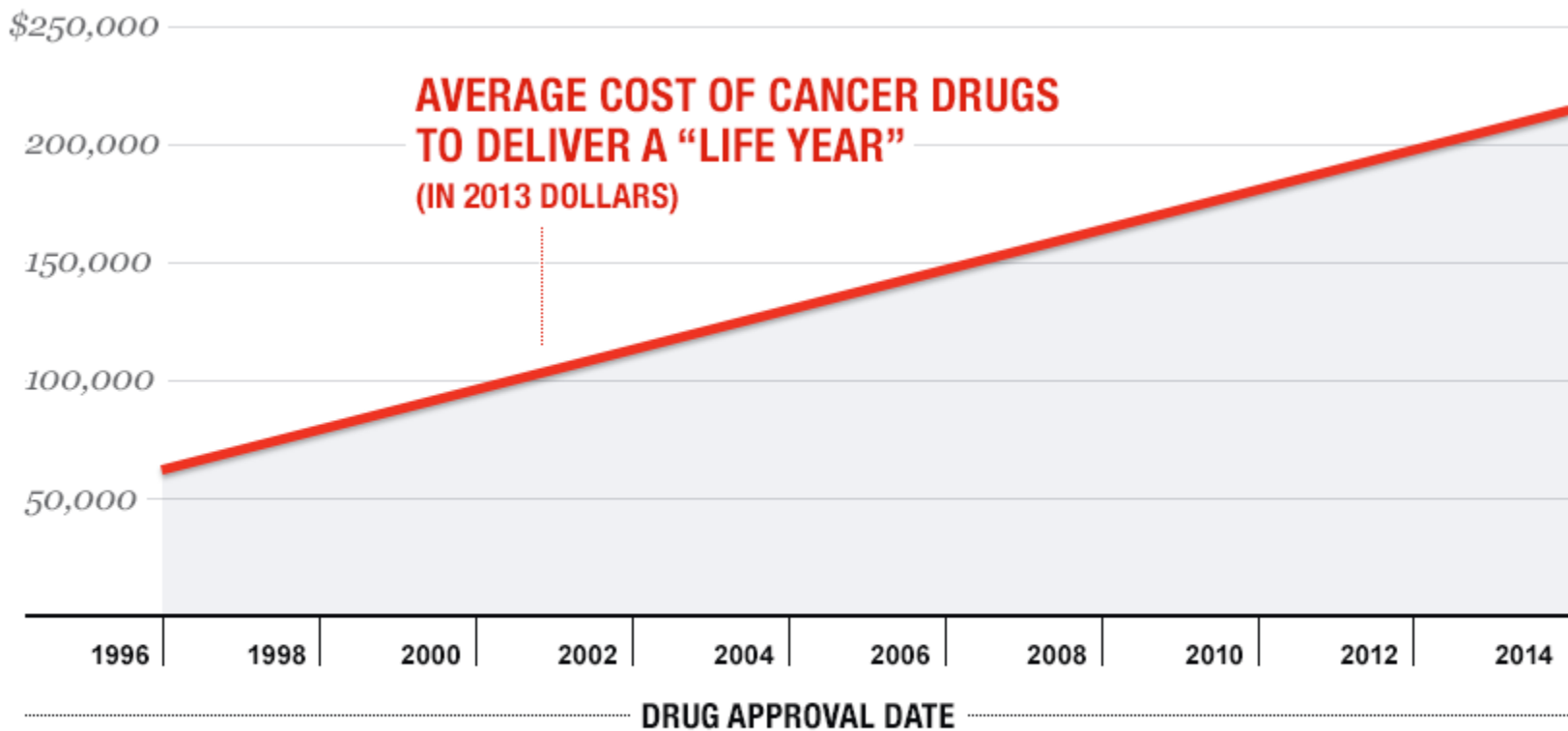
The power of partnership

- To promote R&D for diseases that affect the poor
- Meningitis Vaccine Project, coordinated by WHO and PATH
- Coalition for Epidemic Preparedness Innovations
- Global Antibiotic Research and Development Partnership

Improving industry behaviours

- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 2008
- Access to Medicine Index, 2008
- Medicines Patent Pool, 2010





SOURCE: DAVID H. HOWARD, PETER B. BACH, ERNST R. BERNDT, AND RENA M. CONTI, "PRICING IN THE MARKET FOR ANTICANCER DRUGS,"
JOURNAL OF ECONOMIC PERSPECTIVES, 2015

Bach, Fortune Sept. 2015

A model for fair pricing

- Prices so high they are unaffordable
- Prices so low they drive high-quality manufacturers out of the market, leading to drug shortages
- To reach UHC a model for fair pricing is needed to make essential medicines available in sustainable quantities at affordable prices



Conclusions

- **Access to essential medicines depends on complexities related to cost of medicines, specificities related to pathologies and variability in price dynamics**
- **Policies aiming at UHC increase access to essential medicines and have the potential of eliminating deadly diseases**
- **WHO is committed to help Member States to achieve universal access to safe and quality assured medicines by promoting appropriate use of essential medicines, strengthening regulations, and building partnership for responsible industry and fair pricing**

Thank you



World Health
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"No one should have to choose between death and financial hardship. No one should have to choose between buying medicine and buying food."

**Tedros Adhanom
Ghebreyesus**