



Module 202 Slides

William Fisher

WilmerHale Professor of Intellectual Property Law

Harvard Law School

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The following images appear in the background of the lecture on “Improving Pharmaceutical Markets” in the PatentX lecture series. A recording of the lecture itself is available at <https://ipxcourses.org/lectures-2/>. Removed from their original context, the images will not make much sense. The function of this collection of images is to enable persons who have already watched the lecture to review the material it contains.

The terms on which these materials may be used or modified are available at <http://ipxcourses.org>.



Fig 3. Registration Application Submissions and Approval in SSA for an anonymized antiretroviral drug, demonstrating 1) the variance in approval timelines across SSA countries and 2) the spread in manufacturer submissions. Red triangles represent the moment of dossier submission to the SRA or NRA, green triangles the market authorization approval by the NRA, and the grey arrows the review process.

Source: Vincent Ahonkhai et al., "Speeding Access to Vaccines and Medicines in Low- and Middle-Income Countries: A Case for Change and a Framework for Optimized Product Market Authorization," *PLoS ONE* 11, no. 11 (2016)



Collaborating Institutions

- Global Access in Action (Harvard University)
- Mission for Essential Drugs & Supplies (MEDS)
- Ministries of Health in Participating Countries
- Innospectra
- London School of Hygiene and Tropical Medicine
- Infectious Diseases Data Observatory
- World Health Organization



Components:

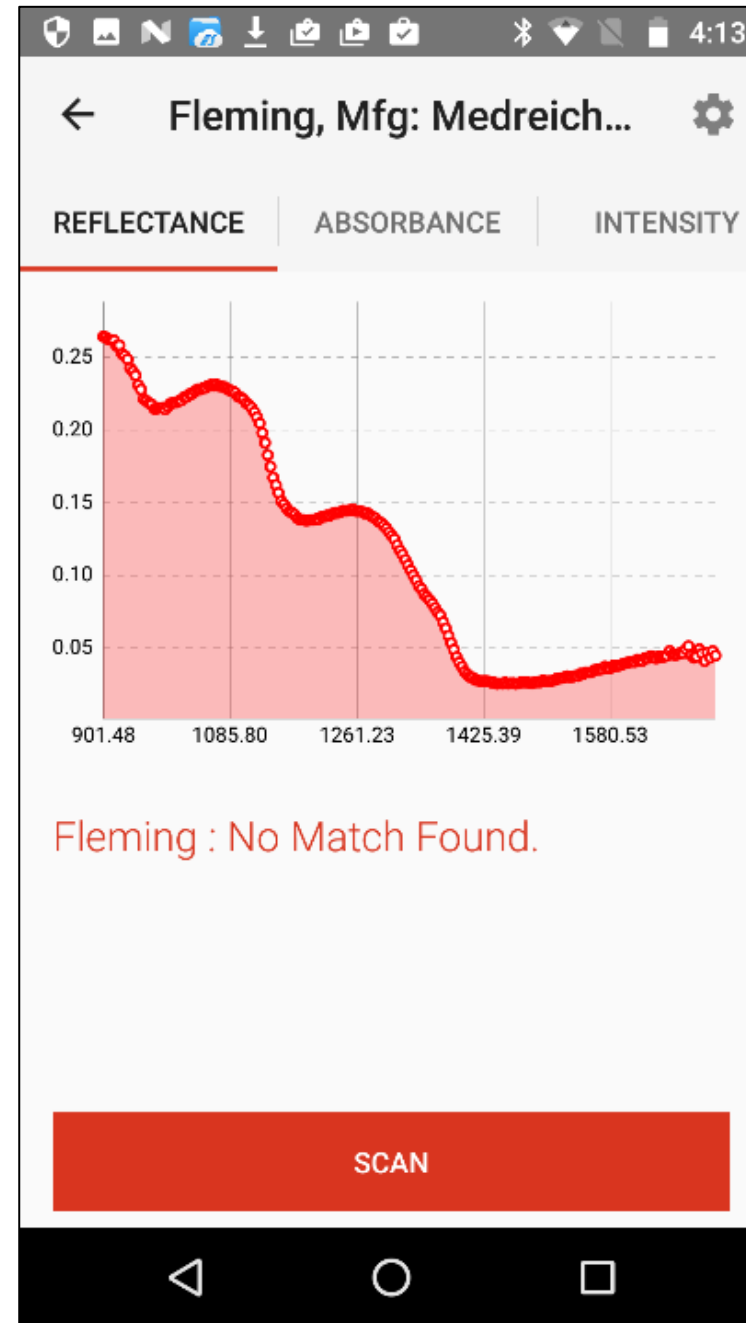
- NIR Scanner
- Motorola smartphone
- Custom software (developed by Global Good)
- Database (library of profiles of authentic medicines)





Procedure:

- 1) Turn on the devices
- 2) Select a pill to be scanned
- 3) Select the type of drug that the pill purports to be
- 4) Use camera to photograph the packaging
(automatically dated and geo-tagged)
- 5) Place pill on scan head
- 6) Press "Scan"
- 7) Report of the scan appears on the smartphone





The records of the scans performed by each device are regularly downloaded and aggregated.

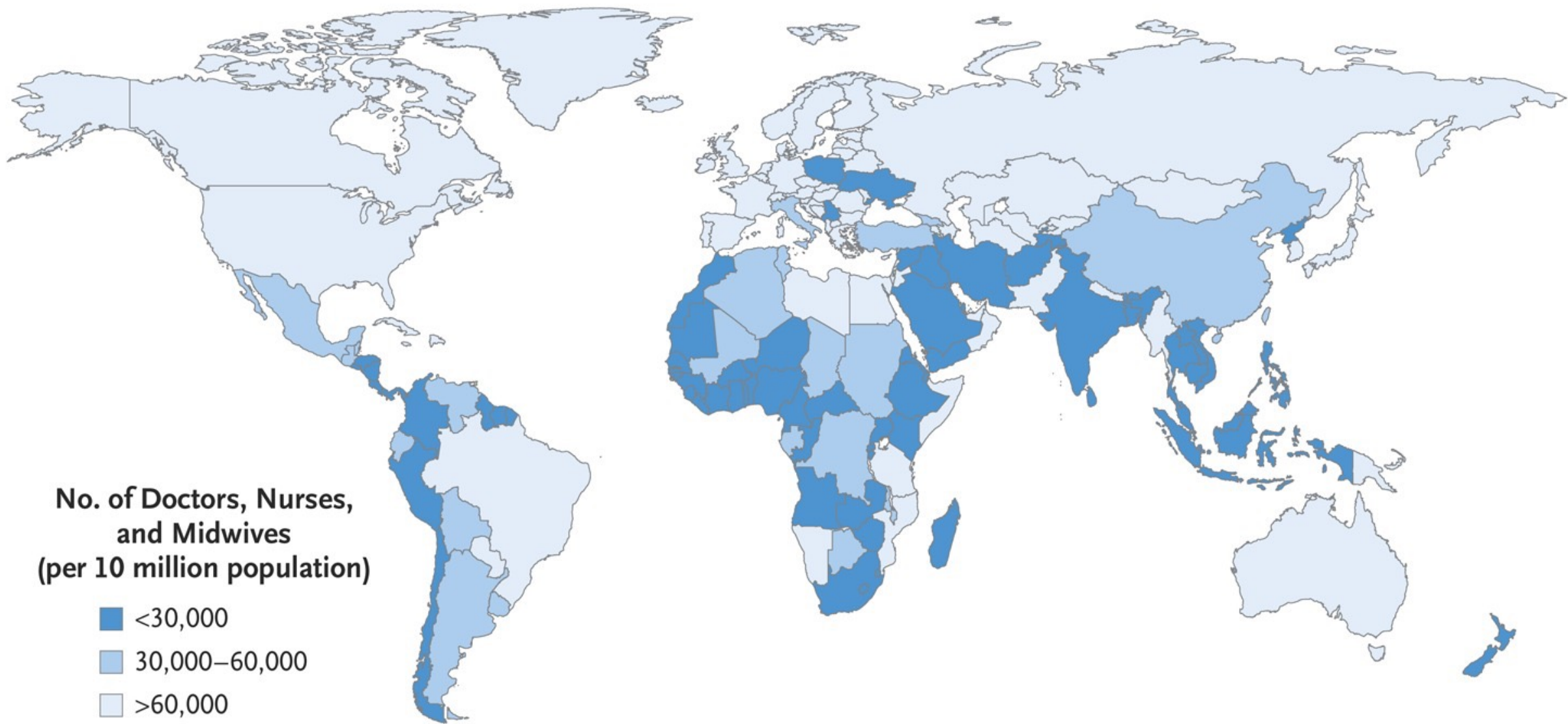
- The data will then be used to generate a map of current “hotspots,” which will guide further testing;
- In addition, the data gathered in each participating country will be shared (in a secure environment) with Health Ministries in other participating countries





Advantages

- 1) Fast
- 2) Inexpensive
- 3) Training of Inspectors requires only a few hours
- 4) Enables quick, random tests of pharmacies and distributors
- 5) Each participating country benefits from data gathered in other participating countries
- 6) Data can be used both to purge the health-care system of falsified drugs and to inform selection of (and negotiations with) suppliers
- 7) Facilitates local production of medicines and vaccines

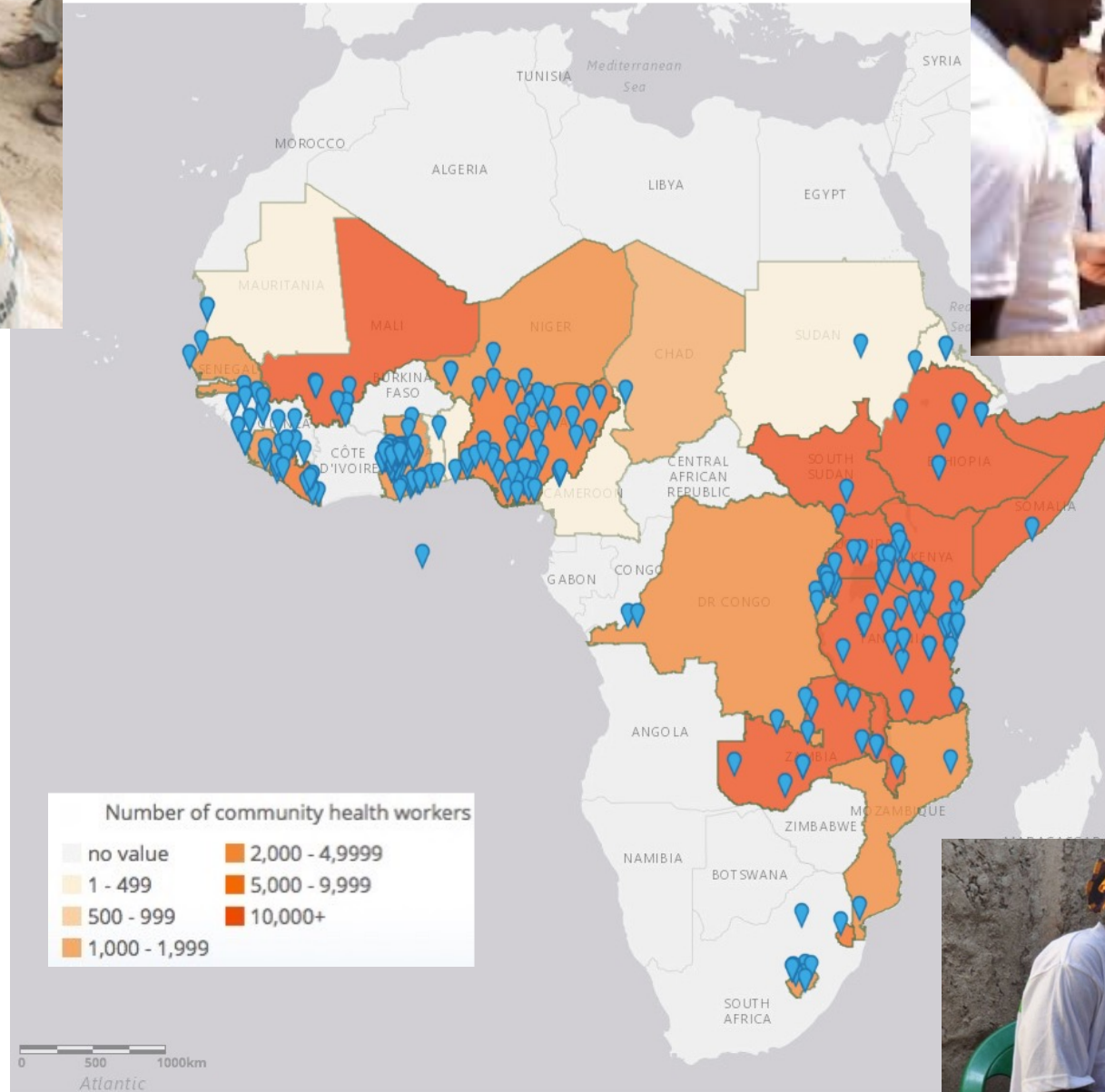




Community Health Workers, defined

Lay health workers who:

- Live in the area they serve
- Are primarily based in the community (as opposed to a health facility)
- Belong to the formal health system (i.e., are managed by the government or an implementing NGO)
- Perform tasks related to health care delivery, and
- Have received organized training but may not have received formal or paraprofessional certification or tertiary education degree

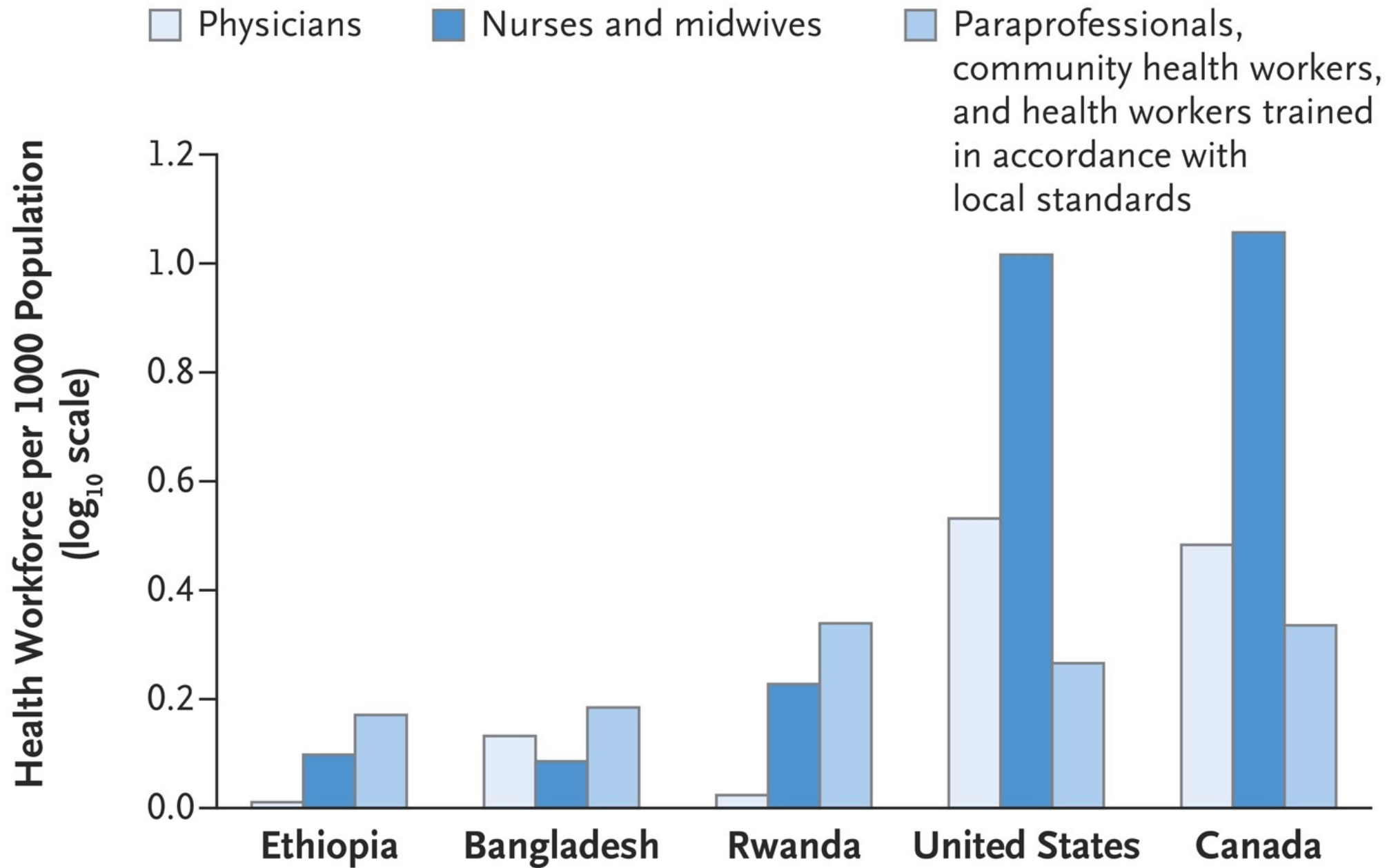


Source: https://www.globalhealthdelivery.org/files/ghd/files/ghd-c11_chw_concept



Courtesy of Jonathan Torgovnik/Getty Images Reportage







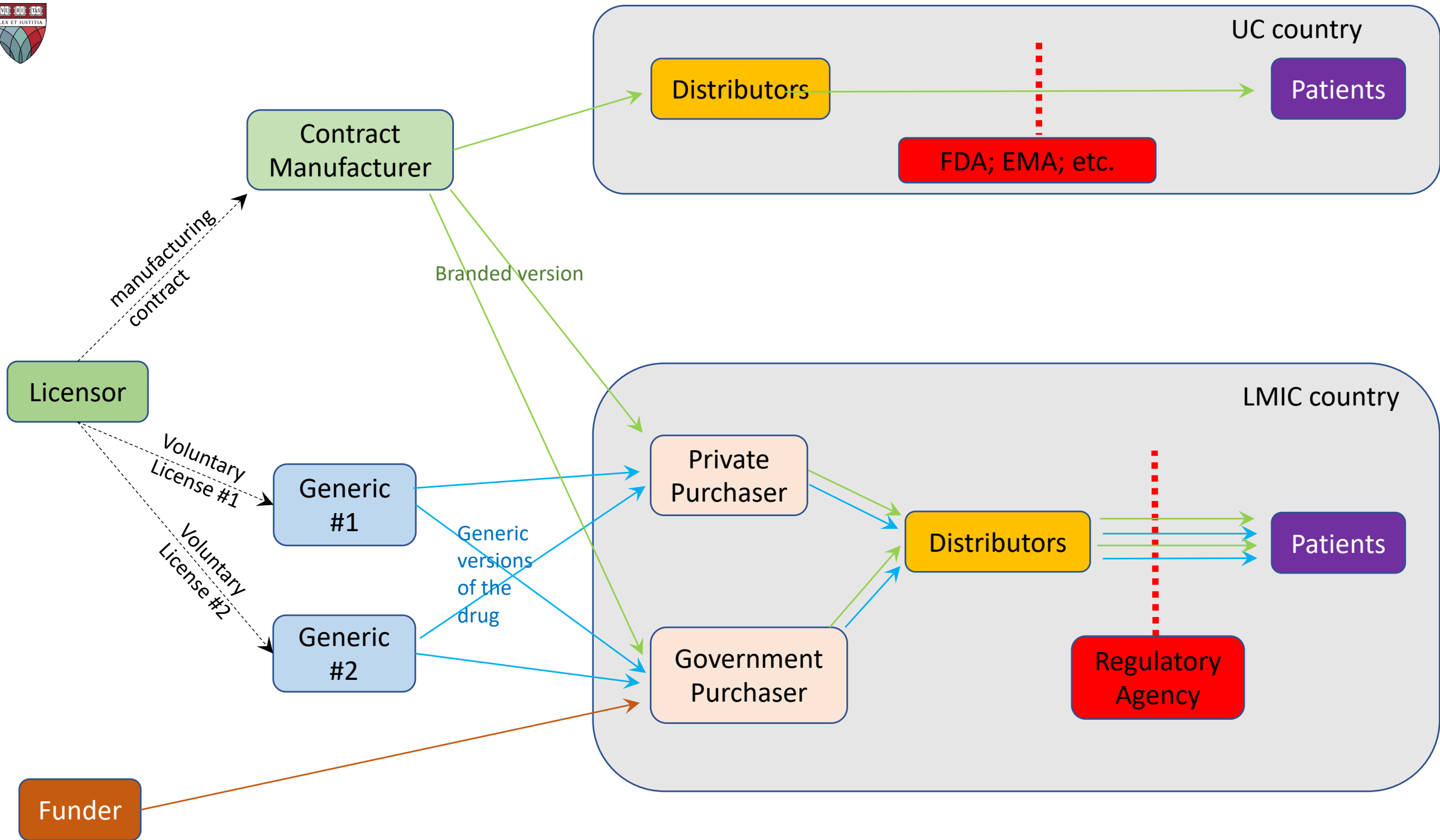
Effectiveness

- “Systematic reviews have concluded that CHWs can safely and effectively deliver health services as diverse as birth control injections; perinatal and neonatal care; case management and prevention of malaria, diarrhea, and acute respiratory infections; and HIV care management.
- “Meta-analysis of moderate-quality evidence indicates that CHWs can, in comparison to usual care, increase the number of children whose immunizations are up-to-date; promote the initiation of exclusive breastfeeding; increase care seeking for pregnancy-related complications; and improve pulmonary TB cure rates.
- “Modeling of health system investments in CHWs found that the return was as high as 10:1 when accounting for increased productivity from a healthier population, the avoidance of the high costs of health crises, and the economic impact of increased employment.”



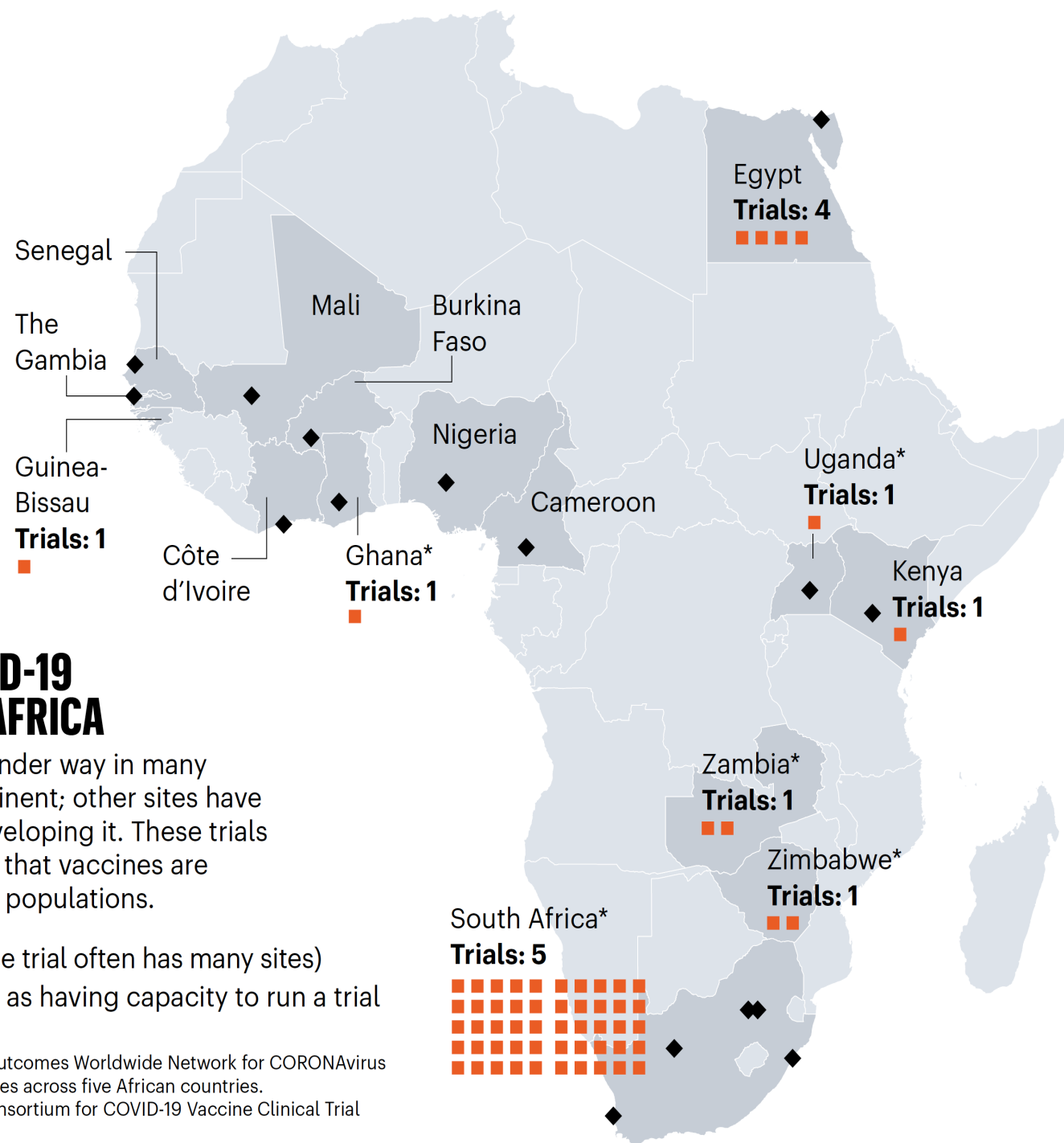
Funding

- One of the principal limits on the scale of these systems is the shortage of funds from governments and foundations
- This hampers recruitment and retention
- Roughly half of the cost of most of the systems is devoted to purchasing the drugs they distribute to patients
- Lowering the cost of the drugs would enable expansion of the systems and/or better recruitment and training





Source: John N. Nkengasong et al., "Covid-19 Vaccines: How to Ensure Africa Has Access," *Nature* (2020), <https://www.nature.com/articles/d41586-020-02774-8>.



TESTING COVID-19 VACCINES IN AFRICA

Clinical trials are under way in many places on the continent; other sites have capacity or are developing it. These trials can help to ensure that vaccines are effective in African populations.

- Sites for trials (one trial often has many sites)
- ◆ Institution† listed as having capacity to run a trial

*The COVID-19 Research Outcomes Worldwide Network for CORONAVirus prevenTION trial has ten sites across five African countries.

†Member of Africa CDC Consortium for COVID-19 Vaccine Clinical Trial (CONCVACT).