

CONSIDERATIONS ON THE RIGHT TO SCIENCE FOR DEVELOPING SIMPLER, POINT-OF-CARE DIAGNOSTICS

By Annette Gaudino and Bryn Gay

Interview with:

Amy Yorston, BLINK Diagnostics¹

Stijn Deborggraeve, Jessica Burry, Yuanqiong Hu, and Greg Elder, Médecins Sans Frontières (MSF) Access Campaign²

To understand different perspectives on the right to science and how it can be applied to diagnostics, we interviewed a unique, open access diagnostics company, BLINK, and the international humanitarian medical non-governmental organization, MSF. Open Science and an open access business model can democratize people's access to the benefits of scientific technologies.

Do you think the right to science framework is useful for making the case for investing in new medical technologies?

BLINK: The right to science addresses issues of cooperation and the sharing of ideas and technology. It speaks to the accretive power of knowledge, education, and research. Not only is it useful, but it's fundamental for developing a clear and logical case for investment.

MSF: The way science is currently financed, owned, and disseminated often neglects vulnerable populations in developing countries, which could contribute to violations of human rights.

How do you see diagnostics as falling within the scope of the right to science?

BLINK: Diagnostics have not always received the attention they should, whether that is for R&D investment, regulatory frameworks, or development of algorithms [or pathways for making medical decisions within clinical settings]. The right to science exists to ensure the benefit of scientific developments is experienced by all individuals; diagnostic tests most definitely fall within the category of scientific development.

MSF: Diagnosis is the starting point of medical care, and good quality and affordable diagnostics are particularly important for developing countries with fragile health care systems.

Profit-making diagnostic companies often receive extensive public funding for R&D of new diagnostic tests, but once in the market, tests are not affordable for most people. In addition, new diagnostic tests for infectious diseases are extensively evaluated using important contributions by developing countries, whereby the patients participating in such trials may never see the test once it's in the market because it's simply too expensive.

The cost of R&D at companies should be delinked from end-product prices and sales volumes. - MSF

How do you see the current field of diagnostics—particularly for infectious diseases, such as hepatitis C—as meeting or failing people's needs and rights to science?

BLINK: For many diagnostic companies, infectious diseases just don't make a good business case because they exist within flawed and fragmented ecosystems, and so the necessary products don't get developed.

MSF: In addition to failing universal rights to scientific innovation in diagnostics, the most vulnerable populations are often neglected, such as children, pregnant women, people living with HIV, and people who use drugs.

How do you see intellectual property (IP) and privatization of scientific research as advancing or impeding scientific progress and people's enjoyment of the right to science?

BLINK: The knowledge created by publicly funded research must be widely known and must be accessible to everyone, without limitations. We believe that IP does not impede the right to science, as whenever a healthy market is present,

The knowledge created by publicly funded research must be widely known and must be accessible to everyone, without limitations. – BLINK Diagnostics

companies with different approaches will compete to deliver the best solution. However, in other markets—like in low- and middle-income countries, neglected diseases, etcetera—this may not be the case, and public funders have to step in.

In the course of our technology development work, we have generated IP that we want and need to protect, but we're trying to balance this by placing it within an open access business model. The proof will be in trying to implement this in a real-world setting—but if we don't try then it definitely won't work, will it?

Expanding access to original research by having more available for free—out from behind paywalls—would serve the right to science well. Original research needs to be available to anyone, anywhere for free.

MSF: There are recognized incoherencies among human rights and IP systems in the context of access to medicines.³ Although IP has been used as one of the means of stimulating innovations, it has not delivered innovation according to health needs, especially for vulnerable populations.

For more than 20 years, the MSF Access Campaign has been challenging the unjust situation of how IP—particularly patents and exclusivity rights on test data—has been manipulated by companies and hindered access to medical tools by vulnerable populations.

Are there any enabling policies or practices that would facilitate and help advance scientific progress in the area of simpler, accessible diagnostics, particularly for hepatitis B and C?

BLINK: Commitments to fully funded elimination campaigns would make a big difference! Broadly speaking, R&D funding needs to be more sustainable, consistent, and less dependent on time-bound grants. In particular reference to hepatitis B and C, the funding scope needs to be broadened to include implementation. Any product, whether that is a diagnostic or a drug, is meaningless if there's no money to buy it and implement it in a program.

This can be achieved with a model that guarantees upfront purchase if certain product characteristics are met. Scale up is another issue that new products face. Scale is necessary to reach certain cost goals, which leads to purchase commitments and potentially to capital expenditure funding of manufacturing lines.

MSF: The cost of R&D at companies should be delinked from end-product prices and sales volumes. Pooled procurement has been successful in negotiating fairer prices. Support to small- and medium-sized companies to comply with quality and regulatory standards may help improve competition and in breaking monopolies. Expensive [separate service contracts, instrument and consumable procurement] are a barrier for uptake and should be replaced by affordable all-inclusive pricing models.

How can we, as advocates, convince funders or investors to invest in diagnostics using the right to science framework?

BLINK: Anyone who is investing wants to see outcomes. We must transition away from using the right to science as a purely academic exercise to demonstrating its impact. Health economic analyses and their derived conclusions regarding funding needs and mechanisms are useful here.

MSF: The right to science is universal, including the innovations stemming thereof, and should support decisions to fund R&D and making diagnostics tests available to all people. Companies, funders, and governments should bear clear obligations to ensure access to diagnostics, medicines, and vaccines as integral parts of the right to health and the right to science. At the end, theoretical frameworks are only useful when they translate into practical implementations in improving health.

Endnotes

The views and opinions expressed in this article are those of the authors and do not reflect the official policy or position of the company or organization. The interviews have been edited for clarity and brevity, and square brackets were added to define or elaborate a concept.

1. BLINK Diagnostics, based in Germany, was started in 2015 by a team of experienced in vitro diagnostics developers. The company is developing an open-access point-of-care product platform, the BLINK One, a cross-analytical digital multiplexing technology that enables development of ultra-sensitive assays with multiplex and quantitative capabilities. <https://www.blink-dx.com/>.
2. Médecins Sans Frontières (MSF) is an international humanitarian medical NGO. The MSF Access Campaign, launched in 1999, has played a leading role in the access to medicines movement, helping secure low-cost generic medicines and rapid diagnostics. <https://msfaccess.org/>.
3. United Nations Secretary-General's High-Level Panel on Access to Medicines. Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies. 2016. <http://www.unsgaccessmeds.org/final-report/>.