How to stay one step ahead of an outbreak

INTELLECTUAL PROPERTY

BUILDING AN INNOVATION CULTURE CAN HELP COUNTRIES PREPARE FOR THE OUTBREAK OF DISEASES SUCH AS EBOLA, WRITE **RACHEL CHU** AND **MEIR PUGATCH** OF PUGATCH CONSILIUM

Illustration by John Holcroft

One year on from the first signs of the current Ebola outbreak, and the first vaccine candidates for the disease are just now finishing the initial phase of clinical trials. Though these products represent hope for containing the epidemic and preventing further loss of life, this hope nonetheless comes too late for the 21,000 people that have already contracted Ebola and the more than 8000 of these that have died.

What west Africa and the world needed earlier rather than later was the availability of treatments and vaccines that would cure affected patients and cut off the chain of transmission. Instead, even though the compounds themselves had already been developed and tested in the laboratory prior to the outbreak of the pandemic, they had not yet been taken to the key phase of human testing when the first cases of Ebola were reported in December 2012.

Lessons to learn

Thanks in no small part to unprecedented co-operation within the international health community, the first deployable Ebola vaccines are expected to be ready in mid-2015. Yet, what lessons can be learned regarding how to be better equipped next time a pandemic hits?

Among many other takeaways from the past year, one is that as much as is possible, enabling clinical trials on potential treatments and vaccines to occur in advance of a serious outbreak is critical. Governments – developed and developing alike – may ask themselves what they can do to facilitate clinical trials in relation to diseases at risk for widespread outbreaks. Which policies should be in place and where should efforts be focused in order to provide an environment that stimulates this type of investment?

Although increasing resources directed towards the health system is among the most obvious steps policymakers can take, one element often overlooked is the level of support toward innovation. In fact, the investment in R&D and, even more importantly, intellectual property (IP) protection is as important as building a health system capacity for attracting needed clinical trials – whether to prepare for future pandemics or to enable access to cutting-edge cancer or diabetes treatments. Why is this, and what kind of growth in clinical trial activity can countries expect to achieve through strengthening support for innovation?

Why IP matters

Conducting clinical trials is part of an extensive process for determining which compounds out of hundreds under investigation may be further developed and eventually brought to market. The clinical trials portion of the biopharmaceutical R&D process represents an undertaking of six to seven years (or 55% to 75% of the total R&D process) at estimated costs of $85m to $1.2bn, according to a report called The R&D Cost of a New Medicine by the UK's Office of

Health Economics. Given the scale of investment, clinical trials are typically sponsored by biopharmaceutical companies.

Within this model, IP rights do two major things. First, they provide a guarantee of temporary market exclusivity that facilitates a return on investment and further re-investment in R&D. Second, they act as a platform for transferring technologies among R&D entities. Licensing proprietary technologies is a key channel for providing access to needed components, not least in Ebola-related R&D. For instance, GSK's Ebola vaccine candidate was created by Swiss/Italian biotech firm Okairos and the US National Institutes of Health's Vaccine Research Center, and then acquired by GSK for clinical development.

Hence, a strong legal basis for IP protection, as well as its enforcement in a given market, assures biopharmaceutical companies and other investors that their IP assets will be protected from infringement as they develop, test and launch products in that market. Put differently, given the huge amount of investment in drug development, including clinical trials, markets with holes in IP protection are less likely to be selected as clinical trial hosts.

Technology transfer

Applying this model to fund the R&D of communicable diseases is a well-established challenge. Even still, in the R&D models currently used to develop drugs aimed at low-income countries, IP rights play a role. Hence, a strong IP environment is not any less important, both for technology transfer as well as for allowing companies to enter the market without major risks of appropriation of proprietary technologies and know-how.

On these bases, it is in countries' interest to strengthen and maintain IP protection if they are to experience adequate clinical trial activity – including in relation to products aimed at potential pandemics. But how important are robust IP rights, especially for cash-strapped governments that must select policy priorities carefully? Which policies represent the most strategic investments if countries are to be prepared for future pandemics?

A wide array of policies impact the level of clinical trial activity taking place in a given country. These include the capacity of the health system, such as the number of clinicians, hospitals, technologies and instruments. They may also think of well-functioning regulations as well as cost-effectiveness.

What might not necessarily be on policymakers' radars when it comes to policies determining clinical trial activity is the presence of overall conditions and a mindset supporting innovation. Such an innovation 'culture' includes, among many things: a country's emphasis on R&D; the level of funding geared specifically towards R&D; the extent to which inventors may own their inventions and are enabled to invest in the R&D process; and how effectively countries assure research-based companies that by investing more deeply in the market they will not risk the unauthorised use of their proprietary technologies and know-how.

A recent study by Pugatch Consilium suggests that a dedicated environment for innovation is actually just as, if not more, important as the health system capacity to clinical trial activity. Using a regression analysis of data on 23 developed and developing countries, the study finds that clinical trial activity is better explained by the strength of IP protection (as well as the level of R&D expenditure) than by the number of hospital beds or investment in health.

Just about 30% of clinical trial intensity can be explained by factors related to health system capacity and level of health spending, while more than 40% can be explained by factors related to a pro-innovation culture – IP protection and R&D spending.

For example, the relationship between clinical trial intensity and IP protection is considerably stronger than between clinical trial intensity and health spending. Countries scoring highly in current standards for measuring biopharmaceutical IP protection (such as the US Chamber's GIPC International IP Index) host 10 to 20 clinical trials per 1 million people in the population. In contrast, countries with low scores (below 60% of the total possible score for life sciences-related indicators in the GIPC Index) have four trials per 1 million people or fewer.

> SUCH A PROACTIVE APPROACH ENABLES ACCESS TO CUTTING-EDGE TREATMENTS AT THE TIME THEY ARE NEEDED MOST

Policy insights

What does this knowledge about clinical trial activity reveal concerning policies that would allow countries to secure the investment in clinical trials needed to minimise the impact of a future pandemic?

Certainly countries should ensure the availability of adequate technology and facilities as well as physicians. However, at the same time policymakers should not neglect nurturing an innovation culture in their country, both generally and specifically for the biopharmaceutical sector. A strong legal and regulatory framework and overall support for R&D should benefit from the same level of focus if countries would like to attract and/or maintain investment in clinical research.

Such a proactive approach not only helps enable access to cutting-edge treatments at the time they are needed most, it also leads to local capacity building that allows countries to be better prepared overall for pandemics. This capacity building includes both the availability of skilled professionals equipped to deliver treatments as well as more generally in terms of the economic benefits for the local biopharmaceutical industry that comes with hosting clinical trials.

If the world wants to stay ahead of future pandemics, instead of playing catch-up at the expense of thousands of lives, investment in drug testing and scale-up must take place in advance of major outbreaks. Countries can facilitate clinical trial activity aimed at potential epidemics by shoring up IP protection, on top of providing the necessary resources, financing and regulatory frameworks that support biopharmaceutical R&D. ■

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