Public-Private Coalition's High-Profile Delinkage Policy For Emerging Vaccines

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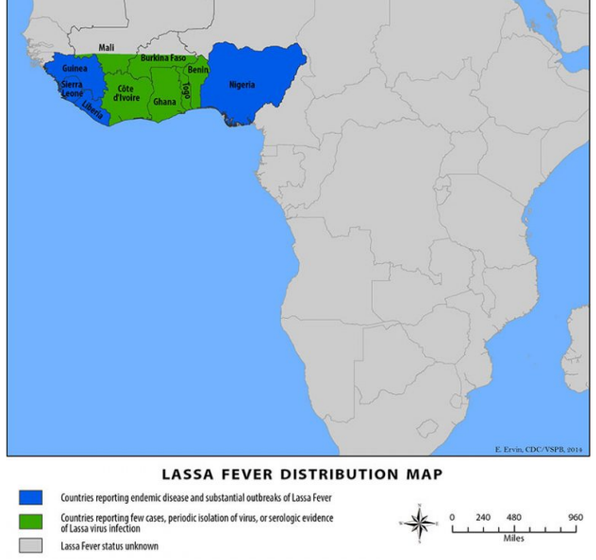
It's early February in Tchaourou district, Borgou in Benin, and a pregnant woman is admitted to hospital. Her premature baby is born by caesarean section but she dies a day later on February 12th. It turns out she had Lassa fever, a deadly viral haemorrhagic disease. But that's only discovered after the baby is discharged from hospital and taken to northern Togo. The newborn also becomes ill and is taken to hospital for treatment.

Desperate to track down anyone who had come into contact with mother or baby, the authorities need to make sure this disease doesn't spread. Already there have been several cases of Lassa fever throughout Benin, Togo, Burkina Faso and Nigeria this year.

Lassa fever is one of a number of diseases that pose a public health risk because of their epidemic potential and for which

there are no, or insufficient, vaccines or drugs.



Lassa distribution map

It's on a list, put together by the WHO, of pathogens that could cause epidemics, and for which vaccines do not yet exist. Also on the list are, of course, Ebola which killed over 11,000 people in West Africa between 2014 and 2015 and Crimean Congo haemorrhagic fever, Marburg, Middle East respiratory syndrome (MERS) and Severe acute respiratory syndrome (SARS) coronavirus diseases, Nipah and Rift Valley fever. That list is part of a global strategy and preparedness plan against epidemics called the R&D Blueprint.

Actually, there is ongoing vaccine research into many of these diseases, but they are at very early stages, often languishing within government research facilities with little funding to turn them into working vaccines. There are around 14 MERS vaccine research projects at this stage, for instance.

Thankfully, promising candidate Lassa fever vaccines could soon be funded through a public-private partnership of pharmaceutical companies, research organisations and donors. This, the Coalition for Epidemic Preparedness Innovations (CEPI), was launched in January launched to fill the massive gap in vaccine R&D for emerging epidemic diseases.

Currently, CEPI is whittling down a long list of applications from researchers working on candidate Lassa fever vaccines. The final shortlist will be released on 24 May along with several other candidate vaccines against coronavirus (MERS) and Nipah virus. Applicants on the shortlist will be invited to submit more detailed applications so that CEPI can decide which of these promising candidates to fund.

The awards will go to individual organisations, but more likely consortia of non-profit organisations, government research institutes, academics with biotech start-ups and vaccine manufacturers.

Ultimately, it will fund vaccines through various stages in the trials process: late-stage preclinical, clinical phase I and phase II safety and efficacy trials. By 2021, it plans to have pushed between four and six of these candidate vaccines – against two or three priority pathogens ready for phase 3 trials at a cost of between $0.6 – 1 billion (phase 3 testing can only happen during an outbreak, as was attempted during the last Ebola outbreak).

CEPI was launched in direct response to the lack of research into vaccines that led to the largest ever Ebola outbreak, which reached major city centres and threatened to spread further. Because the disease had only ever affected small, rural and poor populations, developing Ebola vaccines had not previously been considered worthwhile.

So CEPI, which includes founder members India and Norway, as well as the

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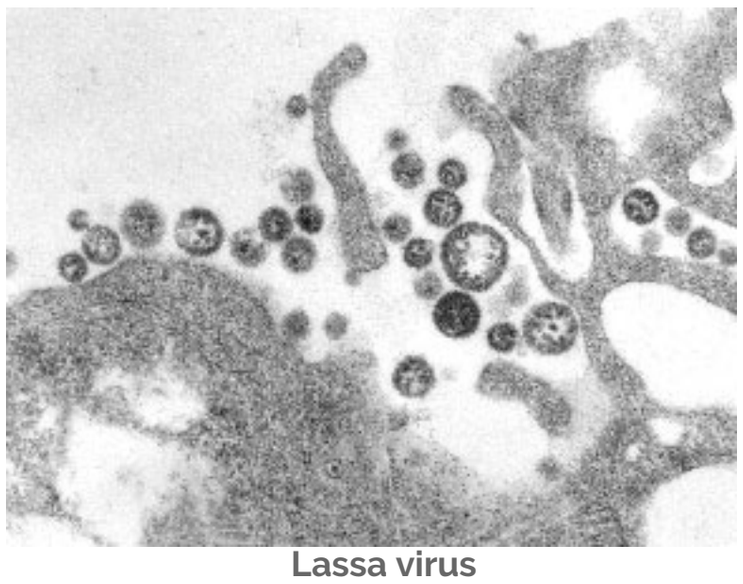

Lassa virus

Getting candidate vaccines to the end of phase 2 is crucial, because this is the point that proves the concept of the vaccine with human and toxicology data. Investors are more likely to come up with cash for expensive phase 3 testing in large-scale populations once this proof-of-concept has been established, according to Dr Lee C. Smith, principal consultant & managing director at GreyRigge Associates, a biotech consultancy that has worked on a number of vaccines from chikungunya to dengue and MERS.

"There's a huge cost to these things and a fair risk," he said. "When you have something like CEPI, that de-risks the programme for the investors, they are then investing in something with the risk of it falling over before licensure reduced."

Crucially, CEPI will try to streamline any processes that can be put in place in advance of an outbreak.

CEPI is just starting to consider ideas on how to optimise individual steps of the research process to enable rapid vaccine development. It's also looking to fund so-called platform technologies, clever ways of enabling different vaccines to be created from the same basic scaffolding. The hope is that platform technologies will be a faster and cheaper way of creating vaccines, rather than building individual vaccines against each pathogen from scratch, as is the case today.

But CEPI intends phase 3 clinical trial planning for outbreaks, funding manufacturers to maintain pilot stockpiles of vaccines, ensuring regulatory requirements are understood well in advance so manufacturers know exactly what data is required in individual jurisdictions.

But it's unlikely these vaccines will be profitable. Working vaccines may never be used, and if they are, demand will be erratic and won't benefit from economies of scale.

"The challenge of these kinds of vaccines is that because the volume of production will be much lower than the volume of production in large-scale vaccination programs, the cost vaccine dose will be higher than for regular vaccines," said John-Arne Røttingen, CEPI's interim CEO.

But at the same time, prices must be low enough for low and middle income countries to afford.

In fact, India articulated the quandary at the 140th Session of the Meeting of the Executive Board of the WHO on 24 January 2017. In a discussion on research and development for potentially epidemic diseases, Dr Sumit Seth, first secretary of the Permanent Mission of India, announced that it had joined CEPI to accelerate the development of vaccines for emerging infectious diseases. But there were important considerations.

"We believe that there is a need to closely align CEPI with WHO Emergency R&D Blueprint and suitably address issues related to de-linkage, access and intellectual property," he said.

That's why CEPI will be developing global access arrangements with these vaccine developers to ensure that they are reimbursed for their direct and direct costs – as well as ensuring that low and middle income countries can afford to buy the vaccines.

A month later, on 27 February, the interim CEPI board met in Oslo approved an equitable access policy, shared risks and shared benefits policy and the management of intellectual property.

Interestingly, CEPI does not want to own IP on vaccine candidates. That applies to background IP – patents on candidates that exist before it funds them – and foreground IP, which are patentable developments that may have come to light during the R&D process it funds.

"It's really important to differentiate between holding the IP and being able to either control the IP or have the conditions on the use of the IP," Røttingen said. "I think from a public investor point of view you can achieve a lot through control or through conditions."

Importantly, Røttingen believes CEPI can manage to delink prices of vaccines from the cost. That will be the case if CEPI is the sole investor or is investing together with public funders that also favour de-linkage models.

"We can't set the price but we will be able to make sure that vaccines are produced in a way that minimises costs," he said. "That can be either through a competitive model where more than one manufacturer produces, or through contracting one facility which agrees to a cost of goods level price."

That's why the organisation is in talks with manufacturers in low and middle income countries. The plan is to help ensure that there are alternative manufacturers able to produce vaccines more cheaply in a relatively short amount of time, if costs of production cannot be kept down elsewhere or if production needs to be scaled up quickly.

The advantage of that strategy is that CEPI will be helping increase regional capacity for manufacturing too, said Røttingen. In the long run, those manufacturers may also ramp up their R&D programmes and ultimately apply for their own R&D grants from CEPI, he added.

Things are a bit more complicated if CEPI is just one of many funders. In such circumstances, however, the plan is to issue licences with very specific conditions to ensure that lower prices apply to specific low-income groups.

"We will have hard requirements on equitable access through pricing arrangements," he said. "Those requirements will apply to all populations in low and lower-middle income countries and in marginalized or vulnerable populations where prices should be as low as possible."

What's clear is that CEPI believes there are significant downsides to taking ownership of IP. It has costs related to keeping it running, is complex and expensive.

"We don't want to take that sort of responsibility and we don't want to set up an organisation with these kinds of capacities," he said. "We believe the implementing organisations will be better equipped to do so."

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Tatum Anderson may be reached at info@ip-watch.ch.

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