Ebola and the need for restructuring pharmaceutical incentives

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The Ebola outbreak in West Africa has claimed the lives of over 9000 people largely due to a combination of poor health care infrastructure in affected countries, traditional beliefs and cultural practices, including the consumption of bushmeat and certain burial rituals that have amplified transmission, and the lack of therapeutic interventions such as medications and vaccinations [1,2]. Ebola virus was discovered in 1976, and since then there have been over 30 outbreaks, the majority occurring in Sub-Saharan Africa, yet development of medications has been negligible [3]. Moreover, while the current epidemic has spurred a new race to develop Ebola vaccines and treatment regimens, the current patent system makes it unlikely that people in the most afflicted nations will have access to such vaccines or medications when they are brought to market without the assistance of development aid initiatives from the United Nations (UN), World Health Organization, the GAVI Alliance and other multinational global entities.

While there have been just a handful of deaths outside of Africa, the vast majority of fatalities from Ebola virus have been in low-income African countries. This is largely because wealthy nations have been able to mount strong public health responses through providing effective medical care to stabilize patients, enforcing strict isolation protocols to prevent further transmission, and accessing experimental therapies for use in their populations, including ZMapp and TKM-Ebola [4]. Several other drugs and vaccines are also under rapid development, most notably ChAd3, which was recently highlighted in the New England Journal of Medicine as having immunogenicity in humans [5]. According to a February 2015 press release from the UN and WHO, large-scale research trials have now begun in Liberia, with Sierra Leone and Guinea to follow soon [6]. But when these drugs are fully approved for international distribution, will they be affordable for all? Given the current global drug-patenting paradigm with its 20-year delay on generic competition, patent holders can set drug prices as high as they please, effectively making their drugs inaccessible to poor populations.

Moreover, with a limited supply of Ebola medications even in the near future, wealthy nations will likely stockpile the drugs and vaccines as was done with Tamiflu in 2009, preventing poorer nations from accessing therapy to treat those who are currently infected [7]. There is no financial or political mechanism to ensure that drugs and vaccines are

The West African Ebola epidemic has created market demand for the rapid development of vaccines and therapeutics, but the current global patent system does not ensure that the poor will have access to these products.
available and affordable for the people of Guinea, Liberia, Sierra Leone and other poor nations at high risk of Ebola epidemics. As of December 2014, the GAVI Alliance has made a commitment of US$ 300 million to purchase Ebola vaccines for those in affected countries, but this is only an ad hoc solution as opposed to a fundamental restructuring of the system [8].

The affordable provision of treatment for people in West Africa is not only an ethical imperative, but also the best strategy to keep Ebola from spreading to other continents on a larger scale. Ultimately, the international community must intervene to ensure that future Ebola medications are sold at a tiered price to developing countries that are most heavily afflicted. But it remains unclear if this can or will happen.

While making Ebola medications accessible to all will be the challenge going forward, we should also ask why no therapy for this high-fatality virus was brought to market since its discovery 40 years ago. The reason lies in the way our pharmaceutical innovation system is structured. Four years ago, scientists at the National Institute of Allergy and Infectious Disease developed an Ebola vaccine that was able to prevent animal transmission, but no pharmaceutical company was interested in taking it to trial in human subjects [9]. While there are programmes, such as the USAID Emerging Pandemic Threats programme, to detect potential pandemic illness, there is little financial promise for major pharmaceutical companies to invest in vaccines or drugs for these potential threats until they are a threat to countries that have consumers who can afford them [10].

Had there been significant Ebola outbreaks in affluent nations rather than in Sub-Saharan Africa in the past few decades, we would likely have an arsenal of medications in stock today. While pharmaceutical companies continue to profit from sales of non-essential medicines, and neglect investments in medicines that are needed mainly by the poor, the global community ends up paying as result. Current estimates by the World Bank put the cost of the Ebola outbreak at upwards of US$ 32.6 billion by the end of 2015 – vastly more than what it would have cost to develop effective therapies to stop the epidemic in its tracks [11].

Ultimately, the approach to controlling developing pandemic diseases is multifold. Strengthening health systems, as discussed by Boozary et al., will be important for controlling the spread of disease [12]. However, without access to medications, strong health systems can only do so much to prevent transmission and provide effective care. To cure patients and suppress further transmission, an effective complement to the current pharmaceutical drug development system is urgently needed (Table 1).
As described in detail in *The Lancet* by Banerjee et al., the Health Impact Fund (HIF) can play this role and help overcome the current inefficiencies and inequities of the patent system [13]. The HIF would give pharmaceutical innovators the option of registering any new medicine, thereby agreeing to provide it at cost anywhere it is needed. In exchange, the firm is rewarded based on the drug’s actual health impact, in essence its success in reducing morbidity and mortality. The HIF would pay out a fixed amount of money each year, divided among the registered medicines according to their respective health impact. The HIF would be most attractive for products that are expected to have a large global health impact but relatively low profitability under conventional monopoly pricing. If most countries agreed to contribute around 0.01% of their GNI, the HIF could get started with annual reward pools of US$ 6 billion.

Ebola is no isolated case. Several hundred new infectious diseases have emerged in the last century, mostly in low-income regions, and under present rules global market forces have proven insufficient to promote innovation. By rewarding health impact regardless of the patient’s socioeconomic status, the HIF would provide strong incentives to study such diseases, to develop remedies against them and to promote optimal use of treatments even in the poorest regions [14]. The HIF would answer a moral imperative—to respect and protect the health and lives of the poor—as well as a prudential one—to be smart and proactive in our perennial battle against disease.
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