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Ebola vaccines, evidentiary charisma and the rise of global health emergency research

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Abstract

The 2013–2016 West African Ebola outbreak was both a catastrophic public health disaster and a rare research opportunity. This paper analyses how the tensions between the humanitarian imperatives of disease control and the epistemic conventions of bioscientific inquiry played out in the accelerated development, testing and licensure of Ebola vaccines. Beginning with the epidemiological projections of the disease’s spread, the paper develops the notion of evidentiary charisma to capture the power of experimental designs and data packages to marshal public health salience, recruit moral legitimacy and short-circuit scientific contestation. Attention to the charismatic dimensions of Ebola vaccine R&D helps to unpick the simultaneous appeals to exception and convention in the unfolding of a global health crisis, and to trace the normative and technical contours of the emerging paradigm of emergency research.

Keywords: Ebola; global health emergency; vaccines; clinical trials; epidemiological models; charisma.

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Introduction

Accounts of the 2013–2016 West African Ebola outbreak tend to share a lead: the epidemic, we are told, was unprecedented. Formerly only known to afflict rural populations within the Congo and Nile basins, through a ‘perfect storm’ of socio-political, environmental and epidemiological factors the outbreak became a *bona fide* global health emergency (Fauci, 2015; Piot, 2014; see also Boozary *et al.*, 2014). From Guinea’s Forest Region, the disease spilled across borders and boarded planes, cropping up in urban areas without identifiable transmission chains. The failure to trace and contain infection devastated local health systems, strained humanitarian capacity and exposed the limits of global health governance. An ‘epidemic of fear’, the outbreak’s political reverberations spoke to the evocative power of Ebola as meme – a virality disproportionate to the contagious potential of the virus (see Hofman & Au, 2017). ‘This Ebola event is different’, Margaret Chan, the then Director-General of the World Health Organization (WHO), conceded at the epidemic’s peak. ‘Very different. This is likely the greatest peacetime challenge that the United Nations and its agencies have ever faced’ (Chan, 2014).

The extraordinary nature of the West African Ebola outbreak and the interventions that exceptionality set in motion have been focal points of social scientific critique (e.g. Benton & Dionne, 2015; Evans, 2016; Lakoff, 2015a; Nguyen, 2014; De Waal, 2014). In particular, this scholarship has spotlighted the geopolitical stakes involved in the epidemic’s transit from public health crisis to international emergency. The high case mortality rate associated with Ebola suggests that regardless of size, any outbreak will be considered a serious disease event. Over the past 20 years, the public health challenges these events pose have been met by Médecins Sans Frontières (MSF; Doctors without Borders). MSF’s blend of medical expertise and logistical efficiency has made the organization the *de facto* responders to deadly outbreaks of this kind (Redfield, 2013). But when the West African epidemic spread beyond the technical means of non-governmental medical humanitarianism, MSF broke with its core commitment to political autonomy and called upon the international community to deploy their respective armed forces.¹ The UN Security Council responded to this appeal with an equally unparalleled resolution urging member states to provide expertise, resources and supplies to the region. Unanimously supported by the General Assembly – a historic 131-country consensus – the resolution also encouraged the WHO, national and multilateral organizations to facilitate the accelerated development of experimental therapies, diagnostics and vaccines. In the days that followed, the UN established its first-ever emergency health mission, UNMEER (UN Mission for Emergency Ebola Response), to implement and coordinate those efforts under the leadership of the WHO (United Nations, 2014).

The diversity of actors, agencies and resources brought into alignment to contain the West African outbreak clearly constituted a departure from the business of global health as usual. However, despite its scale and operational complexity, the Ebola Response was guided by the bureaucratic mechanisms and political priorities that have come to characterize contemporary global
health governance (see Caremel et al., 2017; Lakoff, 2010). The militarized roll-out of containment measures, the ratcheting up of data surveillance systems and point-of-transit screening protocols, the emphases on risk communication and pharmaceutical solutions are the classic strategies of sovereign nation-states, preventing cross-border contagion while minimizing disruptions to global traffic and trade (e.g. Leach, 2015; Roemer-Mahler & Elbe, 2016; De Waal, 2014; see also Fassin & Pandolfi, 2010). While epidemiologically unprecedented, a large-scale Ebola outbreak had been anticipated by International Health Regulations under the terms of reference for a ‘Public Health Emergency of International Concern’ (PHEIC):

a situation that is serious, unusual or unexpected; carries implications for public health beyond the affected State’s national border; and may require immediate international action. (WHO, 2008 [2005], p. 9)

The declaration of a PHEIC is an inflection point in global health practice, marking the transformation of a public health issue into a security threat (see Collier & Lakoff, 2008; Cooper, 2006; Fidler & Gostin, 2006; Lakoff, 2017). But it also signals an epistemic shift: by definition both serious and unusual, the anomalous occurrence of the PHEIC complicates global health intervention by calling into question the forms of expert knowledge upon which conventional disease control measures rely. Epidemiological trends and incidences, the historical mortality and morbidity of an infection, risk-based calculations and cost–benefit analyses are ill-suited to managing a catastrophic epidemic singularity. ‘Black Swan events’ demand speculative and creative modes of global health attention, such as simulation exercises and viral forecasting techniques – what prominent infectious disease control expert Michael Osterholm describes as ‘a forward thinking, which is ultimately aimed at securing our collective future’ (Osterholm et al., 2015; see also, Caduff, 2015; Lachenal, 2014).

The incongruities between these styles of reasoning are critical to understanding why this Ebola event was, in Chan’s words, so very different. The West African outbreak was classified as a PHEIC on 8 August 2014 – nearly five months after the first laboratory-confirmed case. Widely condemned, that lag time has prompted considerable self-reflection by the global health community. A series of expert-led reviews of the outbreak response have pointed to the WHO’s dependence on the financial support and political will of member states as one of the key stumbling blocks to the rapid decision-making and coordination needed to avert the disaster (WHO, 2016a; see also Piot et al., 2017). But while the efficacy of the Ebola response was undoubtedly hamstrung by what MSF described as a ‘vacuum of leadership’ (MSF, 2015, p. 6), the WHO’s early failure to recognize the situation unfolding in West Africa as extraordinary speaks of a more conceptual set of constraints. Just days after cases were first identified, the WHO deployed a team that assessed the situation as challenging in its scope, but imminently controllable through conventional public health methods, such as surveillance, contact tracing and
community engagement. That confidence – or, according to some, complacency – obscured the outbreak’s pandemic potential, mistaking what was truly different about its spread for what was merely difficult. The WHO’s inaction was, thus, as much a failure of leadership as of imagination: an inability to envision crisis before its consequences became all too real (see Lakoff, 2016).

This paper begins at the point when the imaginary of an unprecedented event took hold. Once declared a PHEIC, the West African Ebola outbreak ushered in a new set of investigative priorities and protocols, guided by ‘a moral obligation to learn as much as possible as quickly as possible’ (WHO, 2016b, p. 30). My primary interest lies with the forms of fact-making that emerged under these conditions of acceleration. Reworking the Ebola outbreak into an object of knowledge and a platform for innovation involved developing new norms and standards of research practice that could effectively square the demands of investigative integrity with those of emergency humanitarian action. These styles of evidence form the basis of the WHO’s (2016c) R&D blueprint for action to prevent epidemics and constitute one of the most significant global health legacies of the West African crisis.

The paper proceeds in five parts. The first section explores the epidemiological models through which the emergency took shape. Drawing from Andrew Lakoff’s (2016) analysis of the actuarial and sentinel logics that underwrite disease threat management, I explore how the ‘hockey-stick graph’ – an iconic figure of exponential growth – brought together the calculative and the speculative dimensions of pandemic preparedness and, in so doing, precipitated an exceptional international response. While these projections quickly proved to be wildly inaccurate, the sense of urgency the hockey-stick conveyed transformed Ebola’s value as an object of, and resource for, global health investment.

In the section that follows, I elaborate the hockey-stick’s evocative power in terms of its evidentiary charisma. Charisma has provided a useful heuristic to unpick the logics of global health prioritization, helping to explain, for instance, the failure of some diseases to generate concern (Herrick, 2017) or the prophetic power of scientists to bring others into focus (Caduff, 2014, 2015). These elaborations of global health charisma clarify the vicissitudes of attention and neglect at work in the Ebola outbreak. The temporal structures of charismatic authority provide the necessary conceptual groundwork for the subsequent section, which lays out the moral and affective architecture of experimental vaccine research under the auspices of the response.

Sections four and five consider how those collective concerns were brought to bear on the accelerated development, testing and licensure of Ebola vaccines. Experimental vaccination, promising to both alleviate present suffering and pre-empt future disaster, provides an acute insight into the evidentiary practices of global health R&D. The WHO’s involvement in the fast-track development and testing of an Ebola vaccine candidate in Guinea was one of the organization’s greatest achievements during the response. Ebola vaccine trials have now become a reference point for the evidentiary needs, data sharing protocols and regulatory adjustments necessary for research in the context of global health emergencies.
My analysis is informed by experiences of working within various research contexts during the outbreak. Serving on the scientific advisory boards for different experimental Ebola therapeutics provided an overview of the challenges designing emergency research posed, and allowed me to observe through what moral, technical and political means those challenges were met. Conducting anthropological research in Guinea and Sierra Leone into the impact of the response on local health infrastructures clarified some of the tensions between these ‘higher-level’ decision-making processes and the priorities of local researchers in these countries. These sets of insights are anchored by my work as a member of the WHO’s Strategic Advisory Group of Experts (SAGE) on Ebola Vaccines and Vaccinations. In my capacity as a member of SAGE, I was involved in reviewing available data on the safety and efficacy of different vaccine candidates and in drafting recommendations for future immunization. Much of this work revolved around discussions over what kind of evidence would be sufficient to counter the uncertainties attendant to investigations undertaken in a crisis situation. This paper argues that these emerging styles of evidentiary persuasion are key to understanding the shifting trajectories of the global health project.4

The hockey-stick

At the end of September 2014, on the heels of the UN’s Ebola Emergency Response directive, the WHO convened a two-day meeting to hasten the testing and licensure of Ebola vaccines. Near the end of the second day, Margaret Chan made an unexpected appearance. She began by commenting on the diversity of the assembled expertise: ‘this is one of the very few times’, Chan noted, ‘I go into a room that I know fewer than 10 people’. While encouraged by the presence of fresh faces, she lamented the continuing lack of robust international engagement – an indication that the urgency of the situation had not been fully grasped:

In a humane world nobody should accept what has happened in West Africa. This is history in the making, with the number of cases, yes – but the shape of the curve is what matters, not the number. The hockey-stick curve is really very worrying … this must be a moment for the international community to come together. We must work at breakneck pace.5

Sometime in early August, the extraordinary nature of the Ebola outbreak had taken shape, and that shape was a hockey-stick (Figure 1). The hockey-stick curve describes a transition from incremental to exponential growth – a figure that to this audience was shorthand for an epidemic out of control.6 At the time of the meeting, 6,553 cases of Ebola had been reported and the situation looked bleak. Epidemiological analyses showed that the outbreak was doubling roughly every two to three weeks – a trend which, if continued, would devastate the region and threaten populations across the globe. The WHO’s Response
Team estimated case numbers could exceed 20,000 by the end of November (WHO Response Team, 2014; see also Chowell et al., 2007). Extrapolating infection rates further ahead, the United States’ Centers of Disease Control (CDC) projected numbers in West Africa to reach upwards of 1.4 million by mid-January (Meltzer et al., 2014).

The exponential growth in case numbers was, needless to say, alarming. But it was the curve’s inflection point that granted these epidemiological projections their truly terrifying proportions. Throughout the spring, the epidemic had developed along the lines of previous Ebola outbreaks, spiking at around 100 cases, then gradually decreasing as control measures were implemented. What happened during the summer months is unclear. Situation reports of the outbreak only began to appear on the WHO website in late August. Compiled from national databases at irregular intervals, this information was difficult to work with both from an analytical and, owing to its PDF format, practical perspective (see Althaus, 2016). It was only after Caitlin Rivers, then a graduate student at Virginia Tech University, hand-digitized the WHO’s counts of cumulative case numbers that the epidemic’s transmission dynamics became amenable to analysis (Rivers et al., 2014). The initial analyses diverged considerably, all projecting exponential growth, but within a wide range. The reason for this discrepancy had to do with a lack of confidence in the collected epidemiological figures. Models of future mortality rates were recalibrated to account for ‘underreporting’ – a euphemism for the combined challenges of a weak public health system and a hostile population (e.g. Chretien et al., 2015). The heuristic significance of unreported cases is addressed in the

Figure 1 Combined epidemiological curves of West African Ebola virus disease cases (WHO Response Team, 2014, p. 1486)
opening paragraph of the WHO Ebola Response Team’s first detailed analysis of the outbreak:

The true numbers of cases and deaths are certainly higher. There are numerous reports of symptomatic persons evading diagnosis and treatment, of laboratory diagnoses that have not been included in national databases, and of persons with suspected EVD [Ebola Virus Disease] who were buried without a diagnosis having been made. (WHO Response Team, 2014, p. 1481)

In other words, the presumed inadequacies of data were integrated into epidemiological analyses in a way that amplified assumptions about the scale of the outbreak. The CDC’s forecasts, to take one example, compared the difference between reported cases and expert estimates of the numbers of beds in use to derive a ‘correction factor’ of 2.5 which, when multiplied by initial estimates, produced the predicted figure of 21,000 cases by the end of September.

Considering how the incompleteness of epidemiological data was handled at the start of the epidemic, these models of the epidemic’s hidden magnitude are striking. At the WHO’s first Ebola press conference in April 2014, Doctor Stéphane Hugonnet emphasized the importance of looking beyond the case counts in understanding the epidemic’s trajectory:

We should not focus too much on the figures and the numbers because this changes every day – a patient arrives, is suspect, then he’s investigated and then he might be discarded or confirmed and so the number changes every day. I think most important is the trends and the geographical spread of the infection. (WHO, 2014a)

At this point in the epidemic, those trends suggested an international outbreak and a serious one, but not a global health emergency. Rising case numbers were contextualized by previous Ebola outbreaks – what Lakoff terms an ‘actuarial logic’ built upon the assumption that ‘possible threats to collective life can be known through careful demographic and epidemiological research’ (Lakoff, 2015b, p. 45). The outbreak’s inflection point – its shift from ‘blade’ to ‘stick’ – attenuated the explanatory power of historical statistics and foregrounded instead the hypothetical outbreak projections. Analyses of Ebola’s basic reproductive number (R0) are indicative. Reports suggested that, despite the alarming increase in numbers, the strain wreaking havoc in West Africa was infecting people at the known rate – an R0 that in the grand scheme of infectious disease is relatively low. That a mutation in the Ebola virus was not behind the outbreak’s magnitude did little to assuage fears of its catastrophic potential. In a press release titled ‘Why the Ebola outbreak has been underestimated’, the WHO described the existence of ‘numerous shadow-zones’ where Ebola cases ‘cannot be investigated because of community resistance’ (WHO, 2014c). Underreporting or misdiagnoses were just the tip of the iceberg: populations were hiding bodies,
looting treatment units and attacking surveillance teams. Social life was emerging in a way that was almost as threatening as its viral counterpart. What was needed, the report suggested, was ‘to produce more realistic estimates and thus communicate the true magnitude of needs’.9

The hockey-stick curve produced that sense of realism. Like other ‘sentinel devices’ that Lakoff associates with the contemporary biosecurity concern with ‘the sudden and unpredictable’, adjustments for ‘underreporting’ captured the apocalyptic potential of what had previously been regarded as a controllable virus. The hockey-stick graph provided the necessary proof that this outbreak was, in fact, an extraordinary event and was thus able ‘to stimulate action when decision is imperative but knowledge is incomplete’ (Lakoff, 2015b, p. 45). While rather late in the day for West African populations, ‘the models’, according to Caitlin Rivers, ‘helped to inspire and inform the strong international response’ (Rivers, 2014, p. 492).

As spurs for global health attention, the models were effective; as guides for public health action, however, they were less so. Empty beds in newly built treatment units testified to the gross disparity between the modellers’ predictions and the situation on the ground (see Owada et al., 2016). From October into Christmas, case numbers declined across the region, and precipitously in Liberia. The WHO initially warned against false optimism – ‘it’s like saying your pet tiger is under control’, commented Bruce Aylward, WHO Assistant Director-General in charge of operational response.10 But while a ‘shadow epidemic’ remained within the realm of possibility, as case numbers continued to plateau across the region, dire admonitions began to seem more precautionary than prognostic. Up to this point, the unreliability of epidemiological data had been regarded as a key handicap to containment. Now, questions were raised about the accuracy of mathematical modelling and, more broadly, the value of such predictions in guiding public health interventions (Butler, 2014; cf. McGoey, 2012).

Modellers defended their calculations as representing a worst-case scenario. Neil Ferguson, epidemiologist at the WHO Ebola Response, emphasized the model’s pragmatic potential, as an instrument ‘to wake up the world and say that this could be really bad if we don’t do anything’ (The Economist, 2015). Martin Meltzer, senior CDC epidemiologist, made a similar point: ‘We were telling policy makers that if we don’t do something, this is what will happen … we needed them to know that we could see millions of people infected with Ebola’ (Yasmin, 2014). By refocusing international attention, the hockey-stick curve conveyed that vision and arguably had ensured that the Ebola doomsday did not come to pass.

The next section elaborates the hockey-stick graph’s revelatory capacities and persuasive power. A notion of evidentiary charisma helps to unpick the truth this visual analogue of exponential growth disclosed about the unfolding Ebola outbreak. The moral outrage and collective responsibility unleashed by this charismatic reworking of the outbreak sets the stage for the significance of experimental Ebola vaccines to the response.
The power of epidemiological signs

Reflecting on recent experiences in Botswana researching alcohol consumption, Clare Herrick (2017) describes the frenzied response to the Ebola outbreak occurring over 3,000 miles away. It was a degree of public concern and political mobilization that alcohol abuse has yet to receive despite its profound public health consequences. Herrick attributes that disjuncture between perceptions of public health risk and evidence of disease burden to a ‘charismatic gap’ (Herrick, 2017, p. 105). Extending Max Weber’s ideas about styles of political authority to the processes of global health prioritization, she argues that non-communicable diseases (NCDs), like alcoholism, lack the exceptionality that ‘incites affective responses such as fear, anxiety, awe or disgust’ (Herrick, 2017, p. 112). NCDs, she argues, are a rational abstraction; the term ambiguously designates a diversity of conditions that require complex and long-term interventions. Without expressive lexicon or vivid iconography, NCDs exist almost exclusively in metrics. Global health attention, Herrick argues, is not a measure of the breadth of scientific evidence but rather of the intensity of ‘collective distress’ (Herrick, 2017, p. 113). Only diseases that convey an acute sense of threat or empathy can garner public concern and precipitate political action. Circumscribed to the tedium of incidence and prevalence, NCDs fail to engage popular imagination and persist as so-called ‘neglected epidemics’.

Herrick’s use of charisma to elucidate the tensions between medical actuality and global health salience is instructive. The kinds of attention the Ebola outbreak did – and, crucially, did not – receive had more to do with the virus’ mythic countenance than with the epidemic’s epidemiological realities. Characterized by bleeding from the pores and eyes, Ebola’s sheer virulence is, to quote Herrick, ‘devastatingly charismatic’ (Herrick, 2017, p. 100). Its obscure origins in African ecologies are archetypical of the ‘outbreak narrative’ that drive biosecurity agendas and marry pathogenic ‘emergence’ to catastrophic terrorism (Wald, 2007; see also Bonwitt et al., 2018; Brown & Kelly, 2014; Cooper, 2006; Lynteris, 2016). Ebola possesses what Jamie Lorimer (2007) helpfully terms a ‘negative aesthetic charisma’ – a monstrous alterity that triggers a collective sense of aversion rather than one of distress (Lorimer, 2007, p. 919). Further torqued by racism and antiquated notions of cultural difference, West Africans were largely blamed for their role in spreading the infection. Even at the height of media attention, their suffering remained occluded by the sensationalism of backward practices and ‘shadow-zones’ of resistance (see Honigsbaum, 2017; Kelly & Mari-Saez, in press; Nuñes, 2016). Set squarely within the conventions of horror, Ebola’s discursive foundations foreclosed genuine empathy with the infected.

These affective dynamics of fear, disgust, hysteria and shame found their statistical legitimation in the hockey-stick. As a ‘worst-case scenario’, the hockey-stick belongs to the register of ‘pandemic prophesy’, a designation Carlo Caduff (2015) gives to scientific claims made in the name of public health preparedness. Less data-driven than ‘scientifically inspired’, the
authority of a catastrophic forecast, Caduff argues, rests not in the accuracy of its model, but in the resonance of its prognosis (Caduff, 2015, p. 5). Proclamations of the coming plague capture the eschatological structures of feeling that predominate in times of radical uncertainty (see also Stewart & Harding, 1999). The hockey-stick’s dramatic and seemingly irreversible sweep keyed into popular notions of Ebola as the world-ending ‘Andromeda strain’. The data alone were possibly misleading. Statistical adjustments were required to capture the catastrophic reality of the situation (Figure 2).

But there is more to the persuasive power of epidemiological forecasts than their latent millenarianism. For the public health professionals and infectious disease microbiologists that Caduff describes, uncertainty is the epistemic baseline. People travel, viruses mutate, experiments fail. An emphasis on preparedness thus reflects ‘a natural evolution that is always ahead of the curve and a scientific understanding that is always behind’ (Caduff, 2014, p. 302). It is this ‘temporal disjuncture’ between incomplete knowledge and unintelligible object, Caduff argues, that gives scientific prophesies of the coming pandemic their political purchase. In a post-Rumsfeld policy climate, invoking ‘unknown unknowns’ creates a framework of justification for pre-emptive interventions. The imminence and inscrutability of risk, in other words, creates the space for political action. It ‘enables actors to commit a leap of faith’, Caduff writes. ‘It allows them to have trust in a particular kind of future, even if there is no evidence that this future is likely to materialise’ (Caduff, 2014, p. 302).

There are few figures that communicate temporal disjuncture more powerfully than those depicting exponential growth. In the context of an outbreak, the exponential curve inscribes an alarming acceleration – with every new

![Ebola outbreak expected to accelerate in October](source: HealthMap.org/Boston Children’s Hospital, 30th September 2014, with permission.)

**Figure 2** Projected outbreak acceleration, M.S. Majumder for HealthMap/Boston Children’s Hospital, 30th September 2014, with permission.
case, the outbreak becomes harder to control, its pace a feature of its own scale (Kelly, 2015). Once the rate of Ebola infections was described as advancing exponentially, experts began to question the adequacy of conventional outbreak control techniques to slow transmission. The hockey-stick played out that game of catch-up to its logical conclusion, projecting a future haunted by the spectre of hesitation and delay.

But the belatedness the hockey-stick communicates also has a specific antecedent, a history of catastrophic projection that complicates the degree of faith it commands. The hockey-stick graph is a statistical artefact of climatology. The term was coined to describe a model produced by Michael Mann, Raymond Bradley and Malcolm Hughes in their 1998 paper on global temperature fluctuations over the past millennium. Their graph, reproduced in the Third Assessment Report of the United Nation’s Intergovernmental Panel on Climate Change (IPCC), synthesized highly diverse archival, meteorological and palaeoclimatological data sets. Their analysis showed the dramatic impact of industrial activity on the climate (Figure 3).

Arguably one of the most contentious graphs in the history of science, the hockey-stick precipitated bitter debates in academic and popular media, leading to professional misconduct hearings and, ultimately, citizen science projects devoted to auditing the validity of climate models (Edwards, 2010). In particular, the dissonance between the spatial and temporal complexity of the data and the certainty conveyed by the long blue ‘blade’ and vertical red ‘stick’

![Figure 3](image.png)
invited scepticism and inspired mistrust (Walsh, 2015). Rather than a smoking gun for anthropogenic climate change, the graph became to some a symbol for politically motivated data manipulation and an obstacle for policy deliberation. Refocusing debate on the technical nuances of how to account for environmental changes, the hockey-stick effectively forestalled a more pragmatic discussion over how best to mitigate them (Demeritt, 2006).

The epidemiological afterlife of the hockey-stick controversy resonates in the Ebola outbreak response. Following the rapid decline of the epidemic, accusations of statistical overestimation echoed perennial climate change controversies over the hypothetical assumptions built into models (see Lahsen, 2005). But when Margaret Chan drew attention to the hockey-stick curve, her concern was not scientific accuracy but rather international engagement. At this moment, the hockey-stick articulated both the exceptional nature of the outbreak – ‘history in the making’ – and the dangers of binding political action to the accuracy of scientific claims. A more measured approach could lead the global health community to sleepwalk into a public health catastrophe. The hockey-stick demanded a suspension of disbelief, an imaginative leap into the pandemic future. That leap, moreover, had a moral propulsion. The role international inaction played in the scale of the outbreak – to say nothing of the decades of entrenched regional impoverishment and systematic geopolitical neglect – suggested that the situation in West Africa was not only dire but, to quote Chan, ‘inhumane’. The hockey-stick played into this sense of the disaster as something ‘manmade’ – as much an unexpected crisis as a reckoning for the global health status quo (see Martin-Moreno et al., 2014).

For Herrick and Caduff, the arc of global health attention follows the transition of systematic epidemiological investigation ‘into the universe of the unverifiable’ (Caduff, 2014, p. 313). The salience of certain diseases or the eminence of scientific ‘prophets’ operates through the production of uncertainty, mystery and enchantment – an unknowability that bestows power through collective faith. Charisma is therefore a highly relational quality, hinging upon popular deference and unconditional support. ‘It is a recognition’, writes Weber,

> on the part of those subject to authority which is decisive for the validity of charisma. This is freely given and guaranteed by what is held to be a ‘sign’ or proof, originally always a miracle, and consists in devotion to the corresponding revelation, hero worship or absolute trust in the leader. (Weber, 1968, p. 48)

This proof, Weber goes on to argue, is not the sum–total of the charismatic leader’s power – genuine charisma, indicative of a gift of grace, cannot be subject to any test. The validation of charismatic authority is better understood as an iterative process – a perennial interplay and feedback between the actions of the leader and the expectations of his followers. Demonstrations of charisma are transformative events, bringing about ‘a completely new orientation of all attitudes towards all forms of life and to the “world” in general’ (Weber, 1968,
While that reorientation suggests a radical break from social convention, charisma ultimately appeals to pre-existing beliefs and convictions: it is, to quote Clifford Geertz, ‘an abiding, if combustible, aspect of social life that occasionally bursts into open flame’ (Geertz, 1977, p. 151). Thus the proof, whether a heroic deed or miracle, does not merely validate an individual’s capacities to lead but rather links his or her mission to gathering social momentum (see Turner, 1996). Interpreted through enthusiasm, despair and hope, the proof provides a framework through which to interpret crisis, a transcendent truth that gives meaning to the dread of everyday life (Weber, 1968, p. 49).

Extending charisma from the qualities of an individual leader to the forms of authority that arise from an extraordinary situation, the hockey-stick’s power as an instrument of revelation becomes apparent (see Hansen & Verkaaik, 2009). The hockey-stick validates and amplifies an understanding of the Ebola outbreak’s existential significance as both a global health and a moral crisis, creating a symbolic anchor for the response. Its curve, the syntax for apocalyptic anxieties, provided a centre of gravity around which solidarity could form—a sense of purpose and collective duty to a moral cause.

The promise of vaccines

That collective sentiment was buoyed by hope: an apocalyptic forecast found its redemption in the promise of an Ebola vaccine. There were practical reasons why vaccines were regarded as a research priority. The discomfort and dangers of wearing biosafety equipment, the virulence of the disease and the difficulty of conducting research on mortally ill patients suggested that a vaccine could make public health headway where a therapeutic treatment could not (Kanapathipillai et al., 2014). Moreover, with such high transmission in the communities, many experts believed that a vaccine was the only clinical intervention that would not be overrun by the number of new infections (e.g. Flynn & Bartunek, 2014; Whitty et al., 2014). An effective Ebola vaccine also appealed to a profound faith in the powers of public health. The paradigmatic example of biomedical triumphalism, a vaccine offered a way to make up for lost time, a ‘magic bullet’ to halt the current outbreak and provide a permanent solution for those yet to come (cf. Ehrenstein & Neyland, 2018; Nature, 2014).

By the time experts gathered in Geneva to discuss options for expediting vaccine R&D in late September 2014, two candidates were at advanced stages of preclinical development. As part of their expanded research portfolio in bio-defence, the US National Institute of Allergy and Infectious Diseases (NIAID) had engineered chAd3-EBOV, a vaccine derived from a non-replicating chimpanzee adenovirus currently under development by GlaxoSmithKlein (GSK). The second vaccine under discussion was the rVSV-ZEBOV. Based on a weakened version of the vesicular stomatitis virus, this candidate had been created by scientists working under the auspices of the Public Health Agency of Canada and was licensed by Merck. Single doses of both vaccines had shown 100 per
cent protection in non-human primates at four to five weeks and a strong immune response in humans (Lambe et al., 2017). A number of other similarly promising candidates, including those from Johnson & Johnson, the Chinese company, CanSino, and Russia’s Gamaleya Center for Epidemiology and Microbiology were in the pipeline. In the months to follow, a dozen candidate vaccines would undergo rapid clinical development.

Introducing unproven interventions in the context of a public health emergency is hugely problematic. In the early days of the outbreak, despite offers from pharmaceutical representatives, vaccine trials were not considered appropriate. The uproar that followed the use of experimental therapies on US volunteers while infected African health care professionals were denied access put the possibility of conducting clinical trials during the outbreak back on the table (see O’Dempsey, 2017). An expert panel convened by the WHO to provide guidance on the use of experimental Ebola treatments, diagnostics and vaccines argued that Ebola’s high mortality rate and transmission intensity compelled a departure from conventional systems of medical regulation and governance. Under these extraordinary circumstances, the committee deemed it acceptable on both ethical and evidential grounds to use as potential treatments or for prevention unregistered interventions that have shown promising results in the laboratory and in animal models. Provided that certain conditions are met. (WHO, 2014b, p. 1)

Those conditions reflected the ethical, scientific and operational considerations of the potential risks of an investigational intervention and the specific demands of the context of care (Rid & Emanuel, 2014). Because no treatment or vaccine had undergone tests in humans, it was argued that their use could not be compassionate. Evidence first had to be generated before any moral claims could be made for the right to access.

However, the processes involved in bringing a vaccine from preclinical testing to development were ill-suited to meet the urgent demands of the crisis. Systems of financing, ethical review and standards of evidence had to be redesigned to bridge the exigencies of humanitarian disaster with the regulatory demands of a future vaccine stockpile. Clinical trials offered a point of convergence for these demands. ‘Researchers have a moral duty’, the WHO’s report concluded, ‘to evaluate these interventions in clinical trials that are of the best possible design in the current exceptional circumstances of the West African Ebola outbreak’ (WHO, 2014b, p. 7).

**Urgent, historic designs**

What constituted ‘the best possible’ design was the subject of fierce debate. Individually randomized placebo-controlled, clinical trials (RCTs) are widely regarded as the gold standard for medical evidence and a *sine qua non* for...
regulatory approval (e.g. Kelly & Geissler, 2011; Wahlberg & McGoey, 2007). While there was a consensus that first-in-human trials on healthy volunteers should be evaluated using an RCT design, the prospect of randomizing mortally ill patients or, in the case of vaccines, highly vulnerable populations to a placebo raised hackles. Holding firmly to the standard of the RCT some proponents argued that experiments deviating from a rigorously blinded and randomized design would risk producing inscrutable results and thus, ‘waste scarce intervention–related resources, making them profoundly unethical’ (Lanini et al., 2015, p. 738). A random schedule was the only way to control for the confounding factors introduced by the complexity of the investigative context, and the lack of knowledge about either the therapeutic products or Ebola’s clinical pathogenesis. In light of the scarcity of the experimental interventions, moreover, random allocation would ensure distributive justice (e.g. Goodman, 2014).12

MSF, who did not take the decision to engage in clinical trials lightly, rejected the use of the RCT designs as an inappropriate measure to evaluate Ebola interventions in the midst of an outbreak.13 The demand on front-line providers to withhold potentially effective treatment or prophylaxis from patients and populations were felt to be too much to bear (Rid & Antierens, 2017). Academics and practitioners echoed these concerns. Community relations were already precariously fragile; an investigation that would be perceived as condemning some individuals to death would risk fuelling resistance (see Adebamowo et al., 2014; Sissoko et al., 2016). ‘Adaptive designs’ which emphasize real-time flexibility provided a methodological alternative (Montgomery, 2017). The ‘stepped wedge’ design, for instance, involves the vaccination of participants or groups of participants in a sequence over an extended period of time. This staggered schedule solved the problem of leaving vulnerable populations unprotected, as all trial participants would be vaccinated, but just some before others. Analysing data at multiple different ‘steps’ also gave investigators the opportunity to stop the trial if the intervention proved to be ineffective (e.g. Piszczek & Paltrow, 2015).

The design does, however, have some drawbacks. For one, it tends to take longer to implement than an RCT, where comparisons are conducted in parallel. The lag time between intervention and control groups – or the lack of ‘concurrent controls’ – can also introduce confounding factors. In the case of the Ebola vaccine trials, investigators had to assume that the risk of infection was the same for all groups across the period of the trial. There were ways to adjust for that time effect, but they had implications for the statistical power of the trials and, thus, on its sample size (Barker et al., 2016).

Like those catalysed by the hockey-stick, debates over trial design revolved around the axis of time. The pace at which vaccine candidates had moved from laboratory experiments on animals to large-scale studies in the human population was breath-taking. But in the context of research on humans, however, the value of research speed is articulated both in terms of timely results and rapid access – priorities that can be difficult to align. The first late-stage efficacy (Phase 2/3) vaccine trials showcased the stark differences
in opinion on the degree to which methodological rigour could be sacrificed for product availability. In Liberia, the US NIAID collaborated with the Liberian Ministry of Health (MOH) to implement a three-arm, double-blind placebo-controlled randomized trial. The trial’s sample size was set at 27,000 healthy individuals, who would be randomized to one of the two vaccine candidates or a placebo. Their health status would be followed over the course of a year. In Sierra Leone, the CDC, the Ministry of Health and Sanitation (MOHS) and the University of Sierra Leone implemented a trial aimed at 6,000 health and frontline workers. Using a stepped-wedge design, participants were assigned randomly to one of two time frames for vaccination with rVSV-ZEBOV, either immediately or after six months.14

As soon as these trials began enrolment a different sense of urgency took hold. The news that the epidemic had begun to plateau indicated to contributors to a second high-level meeting for Ebola vaccines and financing in January 2015 that the ‘window of opportunity to prove efficacy may be closing’ (WHO, 2015b, p. 4). Relief that the outbreak was slowing was duly expressed. However, the implications of this positive public health turn for scientific research were profound. Pointed questions were raised about the likelihood of either trial being able to generate any robust conclusions, and these concerns were soon borne out. Ultimately both the Liberian and Sierra Leonean experiments were unable to recruit the necessary numbers to evaluate vaccine efficacy and had to be modified to focus on safety and immune response. While the terror of a hypothetical tipping point may have provided its justification, research could only be sustained by epidemiological actualities. Without the cases, vaccines could not be tested nor their promise vindicated.

All, however, was not lost. Aware of what an effective vaccine might mean to its population, the Guinean government approached the WHO to help coordinate a third trial in the country. With the support of a number of academic and charity partners – including the Wellcome Trust, the UK Department for International Development and the Norwegian Ministry of Foreign Affairs – the WHO initiated a vaccine trial called Ebola ça Suffit (Ebola, this is enough). The trial used a ‘ring vaccination’ strategy, a new experimental design built around infected individuals. After an Ebola case was diagnosed, the research team made a list of all the people with whom the sick individual may have come into contact – and the close contacts of those contacts – over the previous three weeks (the maximum time it takes to contract the disease after exposure). This high-risk group constituted a single ‘ring’. Each ring was then randomized to receive the vaccine either immediately or after three weeks. In a fashion similar to the stepped-wedge design, all those enrolled would eventually receive the vaccine, but in this case after a much shorter period of time.

What was most striking about this design was how, by recruiting those at highest risk of infection, it succeeded in maximizing the opportunities to enrol participants, while essentially functioning as a targeted public health measure. The experiment also carried with it a powerful legacy. The ‘ring vaccination’ design was adapted from a key infection control tool used in the
eradication of smallpox, arguably the WHO’s greatest triumph: in just over a
decade, the mortality rate for the disease went from 2–3 million a year to zero. The strategy of vaccinating populations at greatest risk – building herd
immunity through communal rings – provided a solution to the intractable
problem of vaccine shortage (Heymann, 2004), making the smallpox eradication
programme, according to the then Director-General of the WHO, Halfdan
Mahler, ‘a triumph of management not medicine’ (see Kamradt-Scott, 2015).

The WHO’s Ebola ça Suffit vaccine team was acutely aware of this history. Presentations on the trial design, and later of its highly encouraging outcomes,
begin with a slide displaying the symbol of the smallpox eradication campaign
beside the terrifying image of a child, face covered with pustules, afflicted by
the disease. Conjuring those memories led to some criticism. According to
Annette Rid and Franklin Miller (2016), ‘the prevailing ethical confusion
about the trial design raises concern that its broad acceptance rests on false
beliefs and expectations’ (Rid & Miller, 2016, p. 432). Remarkably, however,
those expectations seem to have been met in this case. Among the 5,837
people who were vaccinated, none became infected with Ebola. For those in
the control group who did not receive vaccination, 23 cases were detected: a
reported efficacy of 100 per cent (Henao-Restrepo et al., 2017).

While stunning, these results demand some qualification, which the following
section will explore. Yet the fact that the roundly criticized WHO would be
responsible for producing a highly effective vaccine is a narrative that is difficult
to resist. ‘A lot of the lessons learnt and memories of the eradication of smallpox
played a role in designing how this was assessed’, Jeremy Farrar, the Director of
the Wellcome Trust, explained in an interview. There were reasons to be cau-
tious about the vaccine, but the investigative process – the coordination of part-
ners, the ingenious balance of robust science and humanitarian demands – was,Farrar believed, a testament to the WHO’s import for global health. ‘History
rhymes’, he mused; ‘it does not always repeat itself, but it often rhymes’.15 In
a time of crisis and alleged institutional failure, Ebola ça Suffit galvanized
hope through a charismatic expression of a greater truth.

A preponderance of evidence

In initiating an accelerated programme of vaccine R&D, the WHO put forward
the principle of ‘pursuing all vaccines until they fail’ (WHO, 2014b). This com-
mitment was intended to serve as a bulwark against dramatic changes in the epi-
demic that might discourage pharmaceutical companies to continue investment.
Research, it was argued, must continue so that ‘fully licensed and approved vac-
cines [can be] stockpiled in readiness for the next Ebola outbreak’.16

The stockpile is currently being assembled. GAVI, the vaccine alliance, has
agreed to pay Merck $5 million towards the further development of rVSV-
ZEBOV, provided it secures regulatory approval.17 In addition to the 300,000
doses of the vaccine the company has made available for emergency use,
Merck has submitted applications to the European Medicines Agency and the US Food and Drug Administration and has received priority status ensuring expedited review. Considering the 100 per cent efficacy shown in the Guinea trial, the process towards licensure should be swift and straightforward.

Some questions about the significance of these results remain, however. Despite the statistical power attributed to the focus on a high-risk population, the trial enrolled relatively small numbers of participants. It was also conducted at a late stage in the outbreak, so other forms of protection, associated with increased public awareness, might have played some role in reducing infections. Indeed, it is unclear to what extent those vaccinated had actually been exposed to Ebola. Moreover, on average, more individuals were enrolled in clusters that received the vaccine after three weeks, increasing the chances for Ebola infections to occur (Krause, 2015). Finally and crucially, in order to make the trial acceptable to communities, the investigators did not take blood or other samples. While antibody responses were explored in Phase 1 trials, there is a lack of clarity on the immunological mechanisms conferring protection or how long it might last (Lambe et al., 2017; Rechtien et al., 2017).

These gaps in the data could ultimately be filled by further clinical studies in an emergency context, which licensure from the WHO’s Emergency Use Assessment and Listing Procedure (EUAL) could provide. Following the decision to allow for the testing of unproven interventions in the outbreak, the WHO set up the EUAL to determine the ‘minimal level of information’ necessary to allow populations to gain access to a therapy in times of crisis. This pathway involves synthesizing different forms of evidence: ‘If large scale study results are not available, WHO will consider whether the preponderance of evidence from the pre-clinical and early human studies and any other information of which it is aware’ (WHO, 2015a, p. 4). The pathway resembles the FDA’s Animal Efficacy Rule, which was introduced in the wake of the 9/11 attacks to approve biologics that could potentially prevent deadly conditions for which human efficacy trials are neither feasible nor ethical. The Rule allows for data from preclinical studies to be bridged with a robust safety and toxicity profile and information on immune correlates.

The regulatory status of these evidentiary assemblages is set to become increasingly relevant in light of the number of Ebola vaccines which have advanced through clinical development but for which large-scale studies are likely to be impossible. One of the consequences of the compelling results of the ring vaccine trial is that experimenting with other vaccines in an outbreak would be considered unethical. Designs that compare new interventions to this vaccine may be proposed, but to generate conclusive results would require an outbreak of a size that is unlikely to occur again. While in all likelihood highly effective, the rVSV-ZEBOV is arguably inferior in many respects to the other 12 candidates in development. The vaccine has stringent cold-chain requirements – it must be kept at minus 80 degrees Celsius, while other candidates are stable at higher temperatures. It is also only effective against the Zaire strain of Ebola, whereas others are multivalent, providing protection against a
range of relevant filoviruses. Finally, it has produced a significant number of serious, if not severe, adverse reactions in the form of arthritis (Krause, 2015).

Ultimately the decision will lie with African regulatory agencies – a point which was driven home during the most recent outbreak of Ebola in the Democratic Republic of the Congo (DRC). When cases were confirmed, the WHO and GAVI quickly began taking the necessary steps to offer the vaccine under experimental conditions. However, despite that engagement the DRC government did not submit a request for deployment. Three weeks into the outbreak, the government finally issued an authorization to conduct a ring vaccination trial. Because no new cases emerged, however, the vaccine was never shipped to the country. The delay received some criticism, but considering the logistics of deploying the vaccine in the forested conditions of the Likati health zone, the reasons were understandable (see Cohen, 2017). Moreover, unlike West Africa, the DRC was familiar with the management of Ebola outbreaks through measures that would not subject their populations to the risk of an unproven vaccine or the anxieties brought on by an experimental trial. The charismatic public health promise of the rVSV, so powerfully evidenced by the ring vaccine trial, in this case, was simply not compelling enough.

Routine emergency

This paper has examined the cadence of evidence under emergency conditions. It began by scrutinizing the role epidemiological uncertainties play in reframing a familiar epidemic into an extraordinary event. Drawing from Weberian analyses of global health attention, I explored the integration of uncertainty and collective sentiment into a mode of evidentiary charisma. Weber’s conceptualization of charisma as a ‘revolutionary force’ that can compel individuals into collective action helps illuminate the blending of rational, normative and affective commitments that qualified traditional epidemiological models and made the international community move. That movement, I suggest, was oriented by the promise and expectation of an Ebola vaccine. The controversies and conflicts around clinical trial design reflected the tensions between the force of that orientation and the complex moral architecture of the outbreak response. Ultimately, producing evidence of vaccine efficacy exposed the deep structures of fear and desire that underline global health authority and the limitations of that authority in the face of public health realities.

In his introduction to the 1968 edition of On charisma and institution building, S.N. Eisenstadt argued that Weber’s analysis of the routinization of charisma suggests that continuity and not disruption is key to its political power and social relevance:

The true test of any great charismatic leader lies not in his ability to create a single event or great movement, but also in his ability to leave a continuous impact on an institutional structure – to transform any given institutional
setting by infusing into it some of his charismatic vision, by investing the regular, orderly offices, or some aspects of social organization, with some of its charismatic qualities and aura. (Eisenstadt, 1968, p. xxi)

Following the West African Ebola outbreak, a number of strong claims have been made about the transformative impact of the response on global health. Margaret Chan characterized vaccine research in particular as a ‘generational opportunity’, which, regardless of the success of any single preventative or therapeutic product, has succeeded in garnering the necessary political will to reconfigure the mechanisms that govern global health R&D (WHO, 2015b). A number of new initiatives have now been put in place to incentivize the discovery of vaccines for pathogens that fail to gain the attention of the pharmaceutical industry, and the WHO has used the example of ring vaccination trials to develop new norms and standards for research conducted during health emergencies (Kieny, 2018). It remains to be seen, however, how these norms and standards will be legitimized, and what forms of institutional and collective action will materialize out of research conducted in times of emergency. As the global health enterprise becomes increasingly oriented towards anticipating uncertain futures, it is critical that we confront the mechanisms through which charismatic evidence emerges in contexts of crisis, and the processes by which it infuses with seemingly irresistible authority the designs and interventions of powerful actors and institutions.

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Notes

1 In the past, MSF’s unequivocalness on the incompatibility between military interventions and humanitarian aid has been sacrosanct. The organization was therefore emphatic that the role of military assets in Ebola-affected regions should be circumscribed to medical expertise, logistical support and supply and exclude strategies of crowd control, quarantine and containment (see http://af.reuters.com/article/topNews/idAFKBN0GX1QP20140902; see also Benton, 2017).
2 Those limitations are written into the organizational structure of the WHO, whose technical and scientific experts tend to be located at headquarters in Geneva while authority to respond to outbreaks remains in the hands of regional offices (see Sprecher, 2017).
3 ‘We know very well how this virus is transmitted’, WHO Assistant Director-General for Health Security, Keiji Fukuda, assured the audience at a press conference in Geneva on 8 April 2014. ‘This is an infection for which … the risk of getting infected is low with the right precautions’ (http://www.who.int/mediacentre/multimedia/Ebola_outbreak_Guinea_transcript_08APR2014.pdf).
4 The data discussed in this paper is only that which is publicly available.
6 The ‘hockey-stick’ is not a technical epidemiological term, but rather popular shorthand for a system that has gone past a ‘tipping point’ and is thus beyond control (see Hinchliffe et al., 2013).
7 The Centre for Mathematical Modeling at the London School of Hygiene launched a similar initiative (see: http://cmmid.lshtm.ac.uk/research/ebola/).
8 Because Ebola only spreads through close physical contact with very sick people or corpses, its R0 tends to hover between 1.3 and 1.8. In contrast, for every one person sick with measles, 30 can become infected.
9 The anxiety of African ‘traditions’ formed the baseline of a number of more refined modelling efforts emphasizing funerals as superspreading events that could alone be enough to sustain the epidemic (see Pandey et al., 2014).
11 GSK representative, personal communication, 29 September 2015.
12 For more on the methodological faith and fervour the RCT inspires see Bothwell et al. (2016).
13 While MSF was involved in the latter stages of a vaccine research in Guinea, the organization initially privileged their patient-focus and only engaged with research into therapeutics (Rid & Antierens, 2017).
14 https://www.cdc.gov/media/releases/2015/t0414-strive.html
17 Initially this agreement was contingent upon Merck securing regulatory approval by the end of 2017, a deadline the company has not met. GAVI, however, has indicated that the filing delay will not substantially affect their arrangement (see Sagonowsky, 2017).

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References


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