

# Postprint

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## **Impure politics and pure science: efficacious Ebola medications are only a palliation and not a cure for structural disadvantage**

**Degeling C<sup>1</sup>, Johnson J, Mayes C. (2015)**

Caplan and colleagues (2015) present a strong argument for using alternative trial designs for experimental treatments for Ebola virus disease (EVD). This argument is, of course, not new. There is a significant body of work in the philosophy of medicine which highlights the moral authority given to RCTs and the fact that RCTs are often chosen not because they are needed but because people simply do not recognise that they can get evidence that is just as useful from other trial designs (Kerridge 2010).

The popularity of RCTs as a research methodology is supported by positivist assumptions that well-conducted RCTs permit experimenters to make strong causal claims and conclusions because this trial design uniquely controls for confounding factors. RCTs do generally provide robust evidence, yet as the philosopher of science John Worrall (2007) demonstrates, randomisation, as a methodological principle, is not a sufficient condition to guarantee that the trial outcome will not be adversely influenced by uncontrolled or unknown factors. What this means is that RCTs are not necessarily epistemically secure or even always epistemically superior. But, like other trial designs, the data generated by RCTs needs to be interpreted in light of other sources and forms of evidence. This raises concerns that the epistemic and moral authority accorded to RCTs can mandate inappropriate and ineffective interventions, and divert attention and resources away from other ways of addressing problems.

RCTs are designed to establish the efficacy of interventions, not their effectiveness. Efficacy captures what happens in ideal circumstances – RCTs tell us what will happen in a population of patients given a treatment under specific sets of controlled conditions. RCTs do not necessarily provide a solid base for extrapolating or generalising what might happen when different types of individuals are given a treatment under different conditions (Cartwright 2011). For policy and practice – and especially at a time of pressing need – we do not need to know that one therapy works better than others (the standard of care (SOC) and /or other experimental agents) under specific sets of controlled conditions. What we really need to know is that the intervention will be effective where it is needed most (Cartwright 2011). RCTs are not necessarily the “gold standard” but merely a standard trial design in

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which important considerations such as affordability, sustainability and public acceptability remain unaddressed. This is undoubtedly relevant to arguments regarding the conduct of RCTs in West Africa as it suggests not only that randomisation of participants in drug trials in this setting is morally suspect because of the vulnerability of participants, the nature of the disease and the lack of capacity and resource scarcity of the setting – but also because assumptions about the epistemic and ethical benefits of RCTs are questionable; especially if the goal of the research is to choose the most effective therapy – the one that is most appropriate to the socio-cultural, economic and political conditions in which it is likely to be used.

Caplan and colleagues (2015) are right to point out that, epistemologically speaking, RCTs are not needed and that sufficient evidence about the efficacy of new Ebola therapies can and should be obtained from other sources. However it is our contention that current debates about the scientific purity of different trial designs are a distraction from the goal of developing effective interventions for EVD. This is because the purpose of this research [or the 'job' as described in the target article's title] is not unproblematic and should be subjected to ethical scrutiny. It is significant that arguments about different trial designs for potential Ebola therapies point to the importance of accommodating local conditions and resource settings. Caplan and colleagues (2015) are careful to limit the frame of their inquiry to research ethics. But if the social instability and resource scarcity of the setting where the drug trial is to be conducted are significant epistemic and ethical concerns, it is arguable that the underlying structural conditions should not be treated as a 'natural state' that policymakers and researchers must navigate. Rather, these structural conditions themselves warrant deeper consideration (Hooker et al. 2014).

Infectious diseases such as Ebola, have, historically, been understood and approached in two ways: as matters of contamination and as matters of configuration (Rosenberg 1992). From the perspective of contamination – disease is the transfer and progress of infection between and within individuals. In the case of the current Ebola outbreak, it seems that the index case was a two year-old boy infected from eating bush-meat (flying fox) sourced from a market in Guéckédou, in south-eastern Guinea. Yet even as contact exposure, host-pathogen interactions and clinical interventions determine the disease state of individuals, these interactions take place in a social and material environment that can be configured in ways that enhance or inhibit the risk of infection and disease pathogenicity. Of this the field epidemiologists Daniel Bausch and Lara Schwarz (2014, e3056) note:

*Ebola virus outbreaks typically constitute yet another health and economic burden to Africa's most disadvantaged populations. ... The effect of a stalled economy and government is 3-fold. First, poverty drives people to expand their range of activities to stay alive, plunging deeper into the forest to expand the geographic as well as species range of hunted game and to find wood to make charcoal and deeper into mines to extract minerals, enhancing their risk of exposure to Ebola virus and other zoonotic pathogens in these remote corners. Then, the situation is compounded when the unlucky infected person presents to an impoverished and neglected healthcare facility where a supply of gloves, clean needles, and disinfectants is not a given, leaving patients and healthcare workers alike vulnerable to nosocomial transmission.*

The cross-species transmissibility and spread of emerging infectious diseases such as EVD arises from changes in land use, and the intensification of trade, travel and/or animal husbandry practices (Wallace et al. 2014). The way that society is configured then exposes

specific populations to a higher or lower risk of infection and enables greater or lesser access to effective healthcare.

Over the past 40 years many West Africa nations have undergone a process of 'de-development'. The implementation of structural-adjustment programs (SAPs) in exchange for World Bank and International Monetary Fund loans re-configured the conditions of infection (Jones 2011). While SAPs promised economic growth via global trade, they also led to the erosion of much of the local public infrastructure needed to prevent and control an infectious disease outbreak. Analyses of the unprecedented nature of the current outbreak EVD tend to focus on cultural burial practices or lack of drugs. Yet SAPs, civil war, political instability, corruption, neglect, mass refugee migrations and deforestation have undoubtedly played a decisive role in creating the conditions and amplifying the risks of infection (Bausch and Schwarz 2014).

Despite significant re-configuration of the social and material environment, the contamination view of infectious disease dominates ethical thinking about responses to EVD - valorising individualised technological solutions and diverting attention away from the upstream socio-ecological causes and structural drivers of incidence. Drug trials for EVD that are not integrated with local measures which seek to address differences in people's capacities, preferences, cultural commitments and socio-economic and environmental circumstances are ultimately more likely to produce ineffective interventions while also entrenching global health inequities.

If the proposed solutions become ever more technological, isolationist and consumerist in orientation, then existing structures, systems and settings are increasingly likely to be seen as natural states, and, thereby, not amenable to reform. The development of an effective therapy for EVD is only part of 'the job' that needs to be completed. Prioritising studies that aim to test pharmaceutical efficacy rather than develop effective interventions that can be sourced and managed locally amounts to a program of research that further embeds then medicalizes the consequences of environmental degradation, poverty and structural disadvantage. Interventions being tested for outbreaks of infectious disease in the developing world need to be affordable, readily accessible by those who need them and appropriate to local conditions. If Western interests continue to trump local interests we should ask: whose *health* is being prioritized; which *public* and which *good* are we seeking to protect? (Scoones and Forster 2009)

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