Will We Be Ready for the Next War?

TO THE EDITOR—The title of Dr Schooley’s editorial, “All’s (Almost) Quiet on the Western Front: Will We Be Ready for the Next War?” [1] raises a key question: What is the role of the US Department of Defense (DoD) in the Ebola outbreak response?

Because Ebola is a biological warfare threat, the DoD has been developing medical countermeasures through its biological defense program for more than a decade. Six DoD-sponsored candidates, intended for biological defense under field conditions, were accelerated in collaboration with civilian partners to support outbreak response.

The US Food and Drug Administration (FDA) granted Emergency Use Authorizations to 2 DoD-sponsored polymerase chain reaction–based diagnostic assays, EZ-1 and BT-E. DoD provides test kits to support African and US treatment centers; >20 000 kits are pre-positioned
in DoD facilities and the Centers for Disease Control and Prevention’s Laboratory Response Network.

The DoD and its partners accelerated a vaccine candidate [2] from a long-standing project to produce a trivalent vaccine against Ebola, Marburg, and Sudan viruses, provided 50,000 doses for clinical trials, and accelerated treatment candidates that offer a spectrum of therapeutic strategies: viral neutralization via monoclonal antibodies (ZMapp), small molecule antagonism of a viral enzyme (favipiravir), and RNA interference (TKM-100802) [3–6].

The DoD conducted preclinical and clinical research at the US Army Medical Research Institute of Infectious Diseases and the Walter Reed Army Institute of Research, respectively. Dr Schooley emphasizes the need to standardize reagents, assays, and controls for animal models; DoD, interagency, academic, and international partners coordinate these efforts through the Filovirus Animal Model Non-clinical Group [6]. Dr Schooley notes that decreasing incidence rates may preclude evaluation of efficacy in clinical trials [7–9] during this outbreak; we agree that developing local capacities and coordinating product developers, host-nation ministries of health, and institutional review boards are essential to proactively establish clinical trial sites and pre-position study protocols to expedite evaluation and fielding of medical countermeasures, in addition to continued research in accordance with the FDA’s Animal Rule.

The DoD supports the US Whole-of-Government response in coordination with the National Institutes of Health and other organizations within the Department of Health and Human Services, and in partnership with industry and academia [6]. The fact that no countermeasures had attained regulatory approval before the start of this outbreak is an obvious disappointment in the face of a public health disaster. However, years of prior research built the foundation for the acceleration of 6 candidates from preclinical or early clinical development to Emergency Use Authorizations and clinical trials within months of the epidemic’s discovery, unprecedented in outbreaks of other emerging pathogens including highly pathogenic avian influenza, novel zoonotic coronaviruses, and Nipah virus. By accelerating candidates toward regulatory approval, the DoD is positioned to offer diagnostics, vaccines, and treatments generated by its biological defense program. Coordination of biological defense and public health response is vital to optimize outcomes and maximize efficient utilization of resources, and because the challenges posed by both biological weapons and emerging diseases are open-ended [10].

Notes

Acknowledgments. Medical Countermeasure Systems (MCS), a component of the Joint Program Executive Office for Chemical and Biological Defense in the US Department of Defense (DoD), provides US military forces and the nation with safe, effective, and innovative medical solutions to counter chemical, biological, radiological, and nuclear threats.

Disclaimer. The opinions expressed herein are those of the authors, and do not reflect the official opinions or positions of the US Army, the Joint Program Manager–MCS, the US DoD, or the US government.

Potential conflict of interest. Both authors: No reported conflicts.
Both authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

George W. Christopher1 and Mark G. Kortepeter2
1Joint Program Manager–Medical Countermeasure Systems, Fort Belvoir, Virginia; and 2Uniformed Services University for the Health Sciences, Bethesda, Maryland

References


Correspondence: George W. Christopher, MD, Joint Program Manager–Medical Countermeasure Systems, 10109 Gridley Rd, Bldg 314, 2nd Flr, Fort Belvoir, VA 22060-5865 (george.w.christopher.civ@mail.mil).

Clinical Infectious Diseases® 2015;61(9):1488–9
Published by Oxford University Press on behalf of the Infectious Diseases Society of America 2015. This work is written by (a) US Government employee(s) and is in the public domain in the US. DOI: 10.1093/cid/civ564