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Published

2021

Journal Title

Journal of Health Care Law and Policy

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THE EFFECT OF PROPRIETARY AND ATTRIBUTION CLAIMS ON DATA SHARING DURING INFECTIOUS DISEASE EMERGENCIES⁺

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I. INTRODUCTION

Responding to infectious disease emergencies is critically dependent upon the collection, analysis, and sharing of relevant data.¹ These data include clinical, epidemiological, laboratory, surveillance, emergency response, geospatial, health facility data, knowledge, attitude and practices surveys, and pathogen genetic sequences.² In contexts where the pathogen is unknown, or where there

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⁺ This article is based in significant part on reports authored by the authors through funding and support provided by the Wellcome Trust and the GloPID-R (GLOBAL RESEARCH COLLABORATION FOR INFECTIOUS DISEASE PREPAREDNESS) consortium for global infectious disease preparedness. The authors acknowledge and thank the anonymous interviewees who gave their time freely to participate in these case studies. Full versions of the reports are available through the Center for Global Health Science and Security at Georgetown University.

CTR. FOR GLOB. HEALTH SCI. AND SEC., MERS-CoV DATA SHARING CASE STUDY REPORT, GEO. UNIV. MED. CTR. (2018), http://www.glopid-r.org/wp-content/uploads/2019/07/Georgetown_MERS-Case-Study-Report-1.pdf. CTR. FOR GLOB. HEALTH SCI. AND SEC., DATA SHARING DURING THE WEST AFRICA EBOLA PUBLIC HEALTH EMERGENCY: CASE STUDY REPORT, GEO. UNIV. MED. CTR. (Nov. 2018), <http://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-during-west-africa-ebola-public-health-emergency-case-study-report-georgetown.pdf>.

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1. Katrina Hedberg & Julie Maher, *Collecting Data*, in THE CDC FIELD EPIDEMIOLOGY MANUAL Ch. 4 (Sonia A. Rasmussen & Richard A. Goodman eds., 2018).

2. See generally Shweta Bansal et al., *Big Data for Infectious Disease Surveillance and Modeling*. 214 J. INFECTIOUS DISEASES S375, S3575-79 (2016) (explaining how the field of infectious disease research is affected by big data).

is no licensed biomedical intervention, relevant data also includes results from research into diagnostics, therapeutics, and vaccines.³ Recent infectious disease emergencies, including and perhaps especially the COVID-19 pandemic, have demonstrated that commercial and scientific proprietary claims have impeded critical data sharing.⁴ These claims are based on an incoherent patchwork of legal and ethical guidelines that often deteriorate in the face of infectious disease emergencies, creating major barriers to data sharing.⁵ These problems are exacerbated by some of the current incentives put in place by governments, funders, and medical journals.⁶ As we are witnessing today, climate change, urbanization and conflict are factors contributing to the emergence of novel pathogens that are likely to threaten human health security, it is crucial to identify the legal, social, and ethical barriers to data sharing and construct solutions to them now, before responders are in the midst of an infectious disease emergency.⁷

Supported by the Wellcome Trust and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), in 2018 we undertook comprehensive literature reviews and anonymized interviews with aid workers, anthropologists, clinicians, data scientists, funders, epidemiologists, journalists, and researchers at for-profit and non-profit biomedical research organizations to assess data sharing barriers experienced during the 2012 Middle East respiratory syndrome coronavirus (MERS-CoV) outbreak in Saudi Arabia⁸ and the 2014-16 West Africa Ebola public health emergency.⁹ The project aimed to assess the legal, regulatory, administrative, ethical, technological, and cultural variables that facilitated or obstructed data sharing during the outbreak and research response in order to identify opportunities to enhance data sharing in future

3. *See generally id.*

4. *See generally* Paul David, *The Economic Logic of "Open Science" and the Balance Between Private Property Rights and the Public Domain in Scientific Data and Information: A Primer*, THE ROLE OF SCI. AND TECH. DATA AND INFO. IN THE PUB. DOMAIN: PROC. OF A SYMP. (2003) (describing the conflict between incentives for cooperative vs. non-cooperative behavior in scientific and technological fields); *see also* Michelle Rourke et al., *Policy Opportunities to Enhance Sharing for Pandemic Research*, 368 SCIENCE 716 (2020).

5. *Id.*

6. *Id.*

7. INST. OF MED., THE INFLUENCE OF GLOBAL ENVIRONMENTAL CHANGE ON INFECTIOUS DISEASE DYNAMICS 10-11, 39, 42-44, 53-63 (2014).

8. CTR. FOR GLOB. HEALTH SCI. AND SEC., MERS-CoV DATA SHARING CASE STUDY REPORT, GEO. UNIV. MED. CTR. (2018), http://www.glopid-r.org/wp-content/uploads/2019/07/Georgetown_MERS-Case-Study-Report-1.pdf [hereinafter MERS-CoV Case Study].

9. CTR. FOR GLOB. HEALTH SCI. AND SEC., DATA SHARING DURING THE WEST AFRICA EBOLA PUBLIC HEALTH EMERGENCY: CASE STUDY REPORT, GEO. UNIV. MED. CTR. (Nov.2018), <http://www.glopid-r.org/wp-content/uploads/2019/07/data-sharing-during-west-africa-ebola-public-health-emergency-case-study-report-georgetown.pdf> [hereinafter West Africa Ebola Case Study].

outbreaks. The full project reports outlining the case study methodology can be found on the GloPID-R website.¹⁰

Our case studies revealed that while some data sharing barriers were unique to geopolitical context (Guinea, Liberia, and Sierra Leone had among the world's weakest health infrastructures)¹¹ or political environment (Saudi Arabia used press controls to limit awareness of its MERS-CoV outbreak),¹² the most significant barriers to data sharing were common to both situations, embedded in legal conceptions (and misconceptions) of ownership and attribution and ethical ambiguities surrounding emergency research ethics (e.g., to whom ethical duties were owed, when those duties were eased by a humanitarian emergency, and how grievances for breaches of ethics might be brought and resolved).¹³ In both the MERS-CoV and Ebola case studies, researchers feared that sharing data early and informally would jeopardize the attribution required for professional advancement, the novelty for publication in high-impact journals or patent applications, or the contracts with their funders.¹⁴ For-profit firms worried that sharing data, especially inconclusive or adverse results, might threaten investments for medical countermeasures that, while ineffective against Ebola or MERS-CoV, might have promise against other pathogens.¹⁵

This article provides an overview of our case studies that identified critical gaps in the law and ethics of data sharing during public health emergencies.¹⁶ Using the 2012 outbreak of MERS-CoV in Saudi Arabia and the 2014-16 West Africa Ebola public health emergency, our case studies revealed that proprietary and attribution-oriented claims represent critical barriers to sharing data relevant to effective response, and we recommend ways to lower those barriers.¹⁷ Part II of this article provides an overview of our analysis of the 2012 outbreak of MERS-CoV in Saudi Arabia.¹⁸ Part III analyzes the 2014-16 West Africa Ebola public health emergency.¹⁹ Part IV recommends solutions to data sharing barriers identified in Parts II and III.²⁰ Part V provides a conclusion and brief reflections on these issues in relation to the ongoing COVID-19 pandemic.²¹

10. MERS-CoV Case Study, *supra* note 8; West Africa Ebola Case Study, *supra* note 9.

11. *See generally Health Systems Situation in Guinea, Liberia, and Sierra Leone*, WHO (Dec. 10-11, 2014) <https://www.who.int/csr/disease/ebola/health-systems/health-systems-ppt1.pdf?ua=1> (asserting that Guinea, Liberia, and Sierra Leone have poor health infrastructure).

12. *See infra* Part II.e.

13. Jean-Paul Chretien et al., *Make Data Sharing Routine to Prepare for Public Health Emergencies*, PLOS MED. 1, 1-4 (2016).

14. MERS-CoV Case Study, *supra* note 8; West Africa Ebola Case Study, *supra* note 9.

15. West Africa Ebola Case Study, *supra* note 9, at 11, 13, 25.

16. MERS-CoV Case Study, *supra* note 8; West Africa Ebola Case Study, *supra* note 9.

17. MERS-CoV Case Study, *supra* note 8; West Africa Ebola Case Study, *supra* note 9.

18. *See infra* Part II.

19. *See infra* Part III.

20. *See infra* Part IV.

21. *See infra* Part V.

II. MERS-CoV

This Part will describe the discovery of the virus that causes MERS-CoV, the outbreak that ensued, and barriers to sharing data relevant to researching the new pathogen and responding to the infectious disease emergency. These barriers included proprietary claims over the virus and related genetic material, demands for authorship and attribution by governmental officials, and press controls imposed by the Saudi government. The MERS-CoV episode identifies factors that are inherent within the scientific process as it now prevails as well as the responsibilities of governments in the context of sharing data during infectious disease emergencies.

a. Background

In September 2012, Dr. Ali Mohamed Zaki, an Egyptian physician working in Saudi Arabia, reported the isolation of a new betacoronavirus he suspected had caused the severe respiratory symptoms, renal failure, and death of a patient.²² Later dubbed the “Middle East respiratory syndrome coronavirus” (MERS-CoV), this emerging infectious disease has now been responsible for more than 2,200 laboratory-confirmed infections in people from 27 countries, and close to 800 deaths.²³ The vast majority of these cases have been recorded in Saudi Arabia; however, MERS-CoV is considered a severe emerging disease with the potential to cause a major global health emergency.²⁴ With a case fatality rate of around 35%, and no specific treatments or vaccines, MERS-CoV remains a global research and development priority.²⁵

Epidemiological investigations have revealed that primary human infections with MERS-CoV are often, but not always, associated with contact

22. MERS-CoV Case Study, *supra* note 8, at 1 (citing to Email from Dr. Ali Mohamed Zaki, Professor of Microbiology, Virology Lab of Dr. Soliman Fakeeh Hosp. Jeddah Sudai Arabia, to ProMed (Sept. 15, 2012, 15:51:26), <http://www.promedmail.org/direct.php?id=1302733>; Ali M. Zaki et al., *Isolation of a Novel Coronavirus From a Man With Pneumonia in Saudi Arabia*, PUBMED.GOV (Nov. 8, 2012), [HTTPS://PUBMED.NCBI.NLM.NIH.GOV/23075143/](https://pubmed.ncbi.nlm.nih.gov/23075143/)).

23. MERS-CoV Case Study, *supra* note 8, at 1 (citing to Raoul J. de Groot et al., *Middle East Respiratory Synfrom Coronavirus (MERS-CoV): Announcement of the Coronavirus Study Group*, 87 J. VIROL. 7790 (2013); *MERS Situation Update, June 2018*, WHO. REG'L OFFICE E. MEDITERRANEAN, <http://www.emro.who.int/pandemic-epidemic-diseases/mers-cov/mers-situation-update-june-2018.html> (last updated June 2018).

24. MERS-CoV Case Study, *supra* note 8, at 1 (citing to *2018 Annual Review of Diseases Prioritized Under the Research and Development Blueprint*, WHO 2 (Feb. 6-7, 2018), <http://www.who.int/emergencies/diseases/2018prioritization-report.pdf?ua=1>).

25. MERS-CoV Case Study, *supra* note 8, at 1 (citing to *MERS Situation Update, June 2018*, WHO. REG'L OFFICE E. MEDITERRANEAN, <http://www.emro.who.int/pandemic-epidemic-diseases/mers-cov/mers-situation-update-june-2018.html> (last updated June 2018); *2018 Annual Review of Diseases Prioritized Under the Research and Development Blueprint*, WHO 2 (Feb. 6-7, 2018), <http://www.who.int/emergencies/diseases/2018prioritization-report.pdf?ua=1>).

with dromedary camels around the Arabian Peninsula.²⁶ Human-to-human transmission of MERS-CoV has been responsible for case clusters in family groups and healthcare facilities.²⁷ The incidence of hospital-acquired infections has been reduced with the employment of strict infection control measures, and the international public health community remains on high alert for new introductions.²⁸

Investigations into the initial MERS outbreak in Saudi Arabia were said to be “marked by bitter disagreements between public health authorities and scientists about the virus’s discovery and the ensuing publications, processes, and patenting of products.”²⁹ In their statement regarding the tenth meeting of the International Health Regulations (IHR) Emergency Committee regarding MERS in September 2015, three years after the first case was reported, the World Health Organization (WHO) stated that “[t]imely sharing of detailed information of public health importance, including from research studies conducted in the affected countries, and virological surveillance, remains limited and has fallen short of expectations.”³⁰

As an emerging pathogen first discovered less than a decade ago, the outbreak of MERS-CoV is an insightful case study for contemporaneous data sharing practices during public health emergencies.³¹ The research response in the early days of the outbreak involved the isolation and identification of the novel coronavirus, epidemiological investigations, and the development of diagnostics.³² Later stages of the research response are ongoing and involve investigations into viral pathogenesis, the animal reservoir species, transmission dynamics, the efficacy of known antiviral drugs against MERS-CoV, and the development and testing of vaccines.³³

The early data sharing practices associated with the MERS-CoV research response were plagued by many of the same problems encountered during other public health emergencies.³⁴ There were problems associated with: (a) ill-defined

26. MERS-CoV Case Study, *supra* note 8, at 1 (citing to Manal Al-Gethamy et al., *A Case of Long-Term Excretion and Subclinical Infection with Middle East Respiratory Syndrome Coronavirus in a Healthcare Worker*, 60 *CLINICAL INFECTIOUS DISEASES* 973 (2015)).

27. MERS-CoV Case Study, *supra* note 8, at 1.

28. MERS-CoV Case Study, *supra* note 8, at 1 (citing to *WHO MERS-CoV Global Summary and Assessment of Risk*, WHO 1 (July 21, 2017), <http://www.who.int/emergencies/mers-cov/risk-assessment-july-2017.pdf?ua=1>).

29. MERS-CoV Case Study, *supra* note 8, at 1 (citing to Scott J. N. McNabb et al., *Triumphs, Trials, and Tribulations of the Global Response to MERS Coronavirus*, 2 *LANCET* 436 (2014)).

30. MERS-CoV Case Study, *supra* note 8, at 1 (citing to *WHO Statement on the Tenth Meeting of the IHR Emergency Committee Regarding MERS*, WHO (Sept. 3, 2015), <https://www.who.int/mediacentre/news/statements/2015/ihr-emergency-committee-mers/en/>).

31. MERS-CoV Case Study, *supra* note 8, at 2.

32. MERS-CoV Case Study, *supra* note 8, at 2.

33. MERS-CoV Case Study, *supra* note 8, at 2.

34. MERS-CoV Case Study, *supra* note 8, at 2.

norms around data sharing, (b) uncertainty about which parties were responsible for sharing certain data and who should bear the associated costs of data curation and maintenance, (c) intellectual property considerations, (d) pressure to publish in scientific journals before data was released to the public, (e) technical barriers associated with appropriately disseminating and securing the data, and (f) concerns about data reliability and suitability.³⁵ There were also data and information sharing issues that were specific to the MERS outbreak and research response precisely because it is a newly emerging pathogen.³⁶ For instance, there were disputes between parties trying to exercise competing legal rights over the MERS virus and controlling access to virus samples, and there were cultural factors that impacted how data were collected and disseminated.³⁷

b. Proprietary Claims by Scientists and Governments

Biological samples play an essential role in the development of public health data.³⁸ Virus isolates are required to identify the pathogen, develop diagnostics and vaccines, and generate genetic sequence data.³⁹ That genetic sequence data can be used to monitor pathogen evolution, identify genetic determinants of virulence, pathogenicity and transmissibility, and to find potential targets for drugs.⁴⁰ Phylogenetic analyses on these data can help to elucidate transmission patterns.⁴¹ There is an ongoing requirement for novel virus samples as the outbreak progresses (this is particularly important for RNA viruses like coronaviruses) to monitor pathogen evolution and detect the development of drug resistance.⁴² Human serum samples are required to measure neutralizing antibody titers, develop serological assays and to estimate what proportion of the population may have been exposed to the pathogen.⁴³ For any emerging pathogens with a likely zoonotic reservoir, samples will also be required from animals to determine the host species, exposure rates, and the chain of transmission.⁴⁴ Biological samples are the essential progenitor of so much data that access to samples is of critical importance in the discussion on data sharing.⁴⁵

Investigations into the initial MERS-CoV outbreak in Saudi Arabia were said to be “marked by bitter disagreements between public health authorities and

35. MERS-CoV Case Study, *supra* note 8, at 2.

36. MERS-CoV Case Study, *supra* note 8, at 2.

37. MERS-CoV Case Study, *supra* note 8, at 2.

38. MERS-CoV Case Study, *supra* note 8, at 8.

39. MERS-CoV Case Study, *supra* note 8, at 8.

40. MERS-CoV Case Study, *supra* note 8, at 8.

41. MERS-CoV Case Study, *supra* note 8 at 8.

42. MERS-CoV Case Study, *supra* note 8, at 8-9.

43. MERS-CoV Case Study, *supra* note 8, at 9.

44. MERS-CoV Case Study, *supra* note 8, at 9.

45. MERS-CoV Case Study, *supra* note 8, at 9.

scientists about the virus' discovery and the ensuing publications, processes, and patenting of products."⁴⁶ After encountering difficulties identifying the causative agent for his patient's illness, Dr Zaki sent a clinical specimen to Erasmus Medical Centre in the Netherlands in June 2012.⁴⁷ The Erasmus team isolated and sequenced the novel coronavirus and Dr Zaki reported the details of this discovery to ProMED-mail on September 15, 2012.⁴⁸ The report was publicly posted to ProMED-mail on September 20th.⁴⁹ On September 23rd, the team at Erasmus, along with Dr. Zaki, applied for a patent claiming "the nucleic acid and/or amino acid sequences of the MERS-CoV genome" as well as "diagnostic means and methods, prophylactic means and methods and therapeutic means and methods."⁵⁰ The Saudi government contested the claims and asserted their country's rights to the virus, as well as attributive rights derivative of the virus, including to publications.⁵¹ Scientists reported halting research on MERS-CoV altogether after the legal terrain became fraught from competing ownership claims.⁵² These competing claims – the patent application claiming the genetic sequence of MERS-CoV by Erasmus Medical Center and the sovereignty-like claim over MERS-CoV samples by Saudi Arabia – created a climate of confusion and fear of legal action if research and development (R&D) activities impinged on such rights.⁵³

Our case study revealed that the action of applying for a patent on the genetic sequence of the virus presented both perceived and real barriers to data sharing.⁵⁴ Although patenting the genetic sequence of a virus is not the same as *owning* the virus, the perception was that valuable derivatives were at stake.⁵⁵ In a press release from May 2013, Erasmus Medical Center stated "[i]t is clearly a misunderstanding that Erasmus [Medical Center] owns the virus. Only specific

46. MERS-CoV Case Study, *supra* note 8, at 1 (citing to Scott J. N. McNabb et al., *Triumphs, Trials, and Tribulations of the Global Response to MERS Coronavirus*, 2 LANCET 436, 436 (2014)).

47. MERS-CoV Case Study, *supra* note 8, at 9 (citing to Kai Kupferschmidt, *As Outbreak Continues, Confusions Reigns Over Virus Patents*, SCIENCE MAGAZINE (May 28, 2013) <https://www.sciencemag.org/news/2013/05/outbreak-continues-confusion-reigns-over-virus-patents>).

48. MERS-CoV Case Study, *supra* note 8, at 9 (citing to Email from Dr. Ali Mohamed Zaki, Professor of Microbiology, Virology Lab of Dr. Soliman Fakeeh Hosp. Jeddah Sudai Arabia, to ProMed (Sept. 15, 2012, 15:51:26), <http://www.promedmail.org/direct.php?id=1302733>).

49. MERS-CoV Case Study, *supra* note 8, at 9 (citing to Email from Dr. Ali Mohamed Zaki, Professor of Microbiology, Virology Lab of Dr. Soliman Fakeeh Hosp. Jeddah Sudai Arabia, to ProMed (Sept. 15, 2012, 15:51:26), <http://www.promedmail.org/direct.php?id=1302733>).

50. MERS-CoV Case Study, *supra* note 8, at 9 (citing to U.S. Patent No. 2015/0275183 A1 (filed Sept. 23, 2012)).

51. MERS-CoV Case Study, *supra* note 8, at 10.

52. MERS-CoV Case Study, *supra* note 8, at 11.

53. MERS-CoV Case Study, *supra* note 8, at 9 (citing to U.S. Patent No. 2015/0275183 A1 (filed Sept. 23, 2012)).

54. MERS-CoV Case Study, *supra* note 8, at 9.

55. MERS-CoV Case Study, *supra* note 8, at 9.

applications related to it, like vaccines and medicines can be patented.”⁵⁶ However, confusion is understandable as the patent application (WO 2014/045254 A2), sought just days after MERS was first reported, claims “the nucleic acid and/or amino acid sequences of the MERS-CoV genome and sequences specifically encoding (parts of) viral proteins and antigenic polypeptides” as well as “diagnostic means and methods, prophylactic means and methods and therapeutic means and methods.”⁵⁷ Even before the recent court challenges to gene patent eligibility around the world (e.g., the U.S. Supreme Court in 2013 and the High Court of Australia in 2015; noting that isolated gene sequences are still patentable in Europe), the suite of protections afforded patent holders of isolated gene sequences was unclear.⁵⁸ The extension of intellectual property rights over the MERS virus introduced an unsettling level of uncertainty for scientists who wanted to conduct research on MERS-CoV, and especially for those parties with a view to commercializing diagnostics, vaccines and medications.⁵⁹

The practice of patenting virus sequence data was not unprecedented, or uncommon, even during health emergencies. The SARS virus, for example, was the subject of multiple patent applications from scientists in Canada, the U.S., and Hong Kong during the outbreak in 2003.⁶⁰ Ultimately, the resulting patent pool was managed by the WHO.⁶¹ But, the global context had changed somewhat since the SARS outbreak in 2003, and the sovereign rights of nation states over their genetic resources (which included pathogens as highlighted by Indonesia in 2006-2007) was top of mind for many countries.⁶² The Saudis voiced strong disapproval and during the World Health Assembly in May 2013, Dr Margaret Chan, then Director-General of the WHO, said of the Erasmus patent application

56. MERS-CoV Case Study, *supra* note 8, at 9 (citing to Press Release, Erasmus Med. Ctr., Erasmus MC: No Restrictions for Public Health Research into MERS Coronavirus (May 23, 2013) (<https://www6.erasmusmc.nl/perskamer/archief/2013/4164294/>)).

57. MERS-CoV Case Study, *supra* note 8, at 9 (citing to U.S. Patent No. 2015/0275183 A1 (filed Sept. 23, 2012)).

58. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *D’Arcy v. Myriad Genetics, Inc. & ANOR* [2015 HCA 35]; MERS-CoV Case Study, *supra* note 8, at 9; see generally ANDREW STEWART ET AL., *INTELLECTUAL PROPERTY IN AUSTRALIA* (6th ed. 2018).

59. MERS-CoV Case Study, *supra* note 8, at 9.

60. MERS-CoV Case Study, *supra* note 8, at 10 (citing to Press Release, Erasmus Med. Ctr., Erasmus MC: No Restrictions for Public Health Research into MERS Coronavirus (May 23, 2013) (<https://www6.erasmusmc.nl/perskamer/archief/2013/4164294/>)).

61. MERS-CoV Case Study, *supra* note 8, at 10; see also Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and ACCESS to Essential Medicines*, 5 MELB. J. OF INT’L L. 335-74 (2004).

62. MERS-CoV Case Study, *supra* note 8, at 10; see Sam F. Halabi, *Viral Sovereignty, Intellectual Property, and the Changing Global System for Sharing Pathogens for Infectious Disease Research*, 28 ANNALS OF HEALTH L. 101, 104, 114-15 (2019); see also Michelle F. Rourke, *Viruses for Sale: All Viruses Are Subject to Access and Benefit-Sharing Obligations Under the Convention on Biological Diversity*, 39 EUR. INTELL. PROP. REV. 1, 6, 20, 25-26 (2017).

that she would “follow it up,” adding, “I will look at the legal implications together with the Kingdom of Saudi Arabia. No [intellectual property] should stand in the way of you, the countries of the world, to protect your people.”⁶³

The views expressed by the interviewees on the issue of virus access and ownership ranged the spectrum.⁶⁴ Some were indifferent as to the practice of patenting virus sequences and others sympathized with the Saudi government.⁶⁵ Both sets of legal rights are still rather nebulous, and this undoubtedly led to confusion about what research was permissible during the response to MERS-CoV.⁶⁶ During a health crisis, there is little time to negotiate access agreements or challenge property rights in a court of law.⁶⁷ Scientific researchers are hesitant to conduct R&D if they sense it could result in legal action and/or reputational damage.⁶⁸ This is especially so for researchers looking to develop diagnostics, vaccines and medications for the market as competing legal interests could jeopardize their R&D investment.⁶⁹ The bottom line is that this confusion stifled the research response and these legal ambiguities must be clarified to reduce barriers generating and accessing data and information during public health emergencies.⁷⁰

c. The Publishing Imperative

Related to proprietary claims is the role of academic attribution and ownership. The pressure to publish in academic journals is an important barrier to data sharing during public health emergencies.⁷¹ The desire to be the first to publish, fear of being scooped, and the requirement to have an impressive publication record for career progression create incentives for scientists to withhold research data until they can be guaranteed attribution.⁷² These fears and desires are magnified in public health emergencies because the outbreak of a novel pathogen provides a unique opportunity to conduct truly groundbreaking research.⁷³

63. MERS-CoV Case Study, *supra* note 8, at 9 (citing to *WHO Urges Information Sharing Over Novel Coronavirus*, BBC HEALTH NEWS (May 24, 2013), <https://www.bbc.com/news/health-22649922>).

64. See MERS-CoV Case Study, *supra* note 8, at 11 (discussing viewpoints of interviewees).

65. MERS-CoV Case Study, *supra* note 8, at 11.

66. MERS-CoV Case Study, *supra* note 8, at 11.

67. MERS-CoV Case Study, *supra* note 8, at 11.

68. MERS-CoV Case Study, *supra* note 8, at 11.

69. MERS-CoV Case Study, *supra* note 8, at 11.

70. MERS-CoV Case Study, *supra* note 8, at 11.

71. See MERS-CoV Case Study, *supra* note 8, at 13 (highlighting interviewees' perception of the incentive to publish, particularly during public health crises).

72. MERS-CoV Case Study, *supra* note 8, at 13.

73. MERS-CoV Case Study, *supra* note 8, at 13.

One key delay to publishing in journals during the MERS-CoV response were authorship disputes by both researchers and the Saudi government.⁷⁴

In off-the-record conversations [...] a number of scientists complained the Saudi deputy health minister in the early days of MERS [...] was keen to maintain control over data, specimens and access, and to be named a prominent author of any scientific papers that emerged. In the first couple of years of MERS research, the publications section of [his] CV mushroomed.⁷⁵

Indeed, the outbreak highlighted the variance in academic cultures with respect to ethical criteria to be applied for authorship. In order to be named an author under principles set forth by the International Committee of Medical Journal Editors, a researcher would have to have made: (a) “substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work”; (b) have “draft[ed] the work or revis[ed] it critically for important intellectual content”; (c) have authority to approve the final version to be published; and (d) agree to be accountable for all aspects of the work.⁷⁶ But, in many countries, especially those where laboratories are scarce and access to technology is limited, playing roles in data collection, analysis, or administrative assistance is often sufficient for authorship recognition.⁷⁷ During the initial outbreak and research response to MERS-CoV, some scientists resisted authorship and attribution demands, and, when they did so, faced limitations on access to data and biological samples.⁷⁸

d. Incongruities in Patient Data Collection

Attitudes to illness and medical care vary across countries and this can play a role in the approach of clinicians taking patients’ medical histories and the sorts of information the patients themselves divulge.⁷⁹ Patients may not realize the sorts of information that are useful to clinicians and investigators taking medical histories.⁸⁰ Particularly with a novel pathogen, it can be difficult to determine

74. MERS-CoV Case Study, *supra* note 8, at 13.

75. MERS-CoV Case Study, *supra* note 8, at 13 (citing to Helen Branswell, *MERS’s Best Friend is Ignorance, So It’s Time to Wise Up*, THE NEW HUMANITARIAN (June 16, 2015), <http://www.thenewhumanitarian.org/analysis/2015/06/16/mers-s-best-friend-ignorance-so-it-s-time-wise>).

76. *Defining the Role of Authors and Contributors*, INT’L COMMITTEE OF MED. J. EDITORS, <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> (last visited Feb 29, 2020).

77. MERS-CoV Case Study, *supra* note 8, at 13-14.

78. MERS-CoV Case Study, *supra* note 8, at 13-14.

79. MERS-CoV Case Study, *supra* note 8, at 7 (citing to Jyh-Gang Hsieh et al., *An Anthropological Approach to Teach and Evaluate Cultural Competence in Medical Students – The Application of Mini-Ethnography in Medical History Taking*, 21 MED EDUC. ONLINE 1,4-5 (2016)).

80. MERS-CoV Case Study, *supra* note 8, at 8.

what line of questioning will produce relevant answers.⁸¹ If a patient is not aware of the significance of their personal circumstances, they are very unlikely to freely offer any uncomfortable or embarrassing personal information.⁸² This highlights the importance of taking an open-minded approach to collecting medical histories and information in the early days of a novel infectious disease outbreak.⁸³ If possible, it is always better to collect more data than is thought necessary.⁸⁴ This also underscores the importance of maintaining patient confidentiality and anonymizing data so that individuals and communities are not stigmatized because of their health status or circumstances.⁸⁵ Not least of all because this increases peoples' reluctance to divulge private information, impeding future data collection.⁸⁶

The professional culture of clinicians can determine the types of data that are collected, particularly when that data might be considered subjective.⁸⁷ In Saudi Arabia, there were certain hospital practices that were identified as problematic by physicians and public health specialists from other countries, but some Saudi physicians did not see these as unusual or worthy of questioning.⁸⁸ This situation highlights the importance of having outsiders actively participating in the outbreak response: some information will only be identifiable and therefore deemed worthy of collection by people not already accustomed to the affected country's professional and clinical norms.⁸⁹

e. Press Controls

The news media is the primary means of informing the public about an unfolding health situation and, when at its best, can be a formidable education tool. While social media networks are now providing direct avenues of communication between public health authorities and the general population, these outlets still do not have the reach and impact of the mass media.⁹⁰ Scientific and clinical advances are often reported through the popular news media and more specialized scientific and medical news outlets.⁹¹ Media reports also act as a source of essential data for public health authorities, including the WHO and the United States' Centers for Disease Control and Prevention (CDC).⁹² Big data

81. MERS-CoV Case Study, *supra* note 8, at 8.

82. MERS-CoV Case Study, *supra* note 8, at 8.

83. MERS-CoV Case Study, *supra* note 8, at 8.

84. MERS-CoV Case Study, *supra* note 8, at 8.

85. MERS-CoV Case Study, *supra* note 8, at 8.

86. MERS-CoV Case Study, *supra* note 8, at 8.

87. MERS-CoV Case Study, *supra* note 8, at 8.

88. MERS-CoV Case Study, *supra* note 8, at 8.

89. MERS-CoV Case Study, *supra* note 8, at 8.

90. MERS-CoV Case Study, *supra* note 8, at 6.

91. MERS-CoV Case Study, *supra* note 8, at 6-7.

92. MERS-CoV Case Study, *supra* note 8, at 7.

aggregating tools such as the Global Public Health Intelligence Network (GPHIN), maintained by the Public Health Agency of Canada, analyzes around 20,000 online news reports daily.⁹³ Media reports are also collated by ProMED-mail with email alerts sent to subscribers.⁹⁴ Media reports can therefore be seen as both a vital source of data for public health stakeholders around the world (including clinicians, epidemiologists, data scientists and policy experts) and as an outlet for data and information generated by researchers, clinicians and public health authorities.⁹⁵

The lack of a free press in Saudi Arabia was a major barrier to data sharing during the MERS-CoV outbreak and research response.⁹⁶ In their 2012 Freedom of the Press report, the independent media watchdog organization, Freedom House reported:

The media environment in Saudi Arabia remained among the most repressive in the Arab world, and in 2011, the government moved to tighten the reins on the already heavily censored and state-dominated press.⁹⁷

Additionally, in 2011, a royal decree amending press freedoms in Saudi Arabia criminalized any criticism of Saudi senior religious figures and government officials.⁹⁸ Furthermore, in 2012, all daily newspapers in Saudi Arabia were “controlled by individuals affiliated with the royal family” and broadcast media stations were under government control.⁹⁹ While the internet and satellite television provided access to some international media outlets, “the Saudi government has been known to directly censor both local and international media.”¹⁰⁰

Our case study revealed that the absence of trustworthy information from official sources and the lack of a free press in Saudi Arabia created an increased

93. MERS-CoV Case Study, *supra* note 8, at 7 (citing to Marie Dion et al., *Big Data and the Global Public Health Intelligence Network (GPHIN)*, 41 CANADA COMMUNICABLE DISEASE REP 209 (2015)).

94. MERS-CoV Case Study, *supra* note 8, at 7.

95. MERS-CoV Case Study, *supra* note 8, at 7.

96. MERS-CoV Case Study, *supra* note 8, at 7.

97. MERS-CoV Case Study, *supra* note 8, at 7 (citing to *Saudi Arabia, Freedom of the Press 2012*, FREEDOM HOUSE (2012), https://www.justice.gov/sites/default/files/eoir/legacy/2013/11/07/Saudi%20Arabia_2.pdf).

98. MERS-CoV Case Study, *supra* note 8, at 7 (citing to *Saudi Arabia, Freedom of the Press 2012*, FREEDOM HOUSE (2012), https://www.justice.gov/sites/default/files/eoir/legacy/2013/11/07/Saudi%20Arabia_2.pdf).

99. MERS-CoV Case Study, *supra* note 8, at 7 (citing to *Saudi Arabia, Freedom of the Press 2012*, FREEDOM HOUSE (2012), https://www.justice.gov/sites/default/files/eoir/legacy/2013/11/07/Saudi%20Arabia_2.pdf).

100. MERS-CoV Case Study, *supra* note 8, at 7 (citing to *Saudi Arabia, Freedom of the Press 2012*, FREEDOM HOUSE (2012), https://www.justice.gov/sites/default/files/eoir/legacy/2013/11/07/Saudi%20Arabia_2.pdf).

dependence on informal channels of information, including through personal and professional contacts and social media.¹⁰¹ It also highlighted contextual differences which may impede the flow of information.¹⁰² For instance, in Saudi Arabia there is not a robust norm of critically examining the official statements of government departments.¹⁰³ News stories from Saudi media outlets in the early days of the outbreak were often verbatim reproductions of official government press releases.¹⁰⁴ During public health emergencies news reporting is an important communications tool and a vital data input to disease detection programs and digital epidemiological research.¹⁰⁵ It also influences how much attention a particular issue will receive by the public and politicians.¹⁰⁶ Therefore, freedom of the press is vitally important for effective data sharing in public health emergencies.¹⁰⁷

III. EBOLA

This Part will describe the origin of the 2014-16 Ebola outbreak in West Africa, the early gaps in data collection and sharing that followed its detection, and the ensuing barriers to sharing data relevant to researching the new pathogen and responding to the infectious disease emergency. These barriers included proprietary claims over the virus and related genetic material, disparities in approaches to patient privacy and informed consent, and a lack of legal infrastructure for data sharing. The West Africa Ebola episode identifies factors that were specific to the biomedical innovation process as well as the responsibilities of governments in the context of sharing data during infectious disease emergencies.

a. Background

On December 6, 2013, Emile Ouamouno, a 2-year-old from Meliandou, a small village in the Guinea *forestière*, died after four days of suffering from vomiting, fever, and black stool.¹⁰⁸ The cause of his infection is unknown, although he is now widely considered to be the index case for the outbreak of Ebola hemorrhagic fever now, “Ebola Virus Disease” (EVD).¹⁰⁹ Within a

101. MERS-CoV Case Study, *supra* note 8, at 7.

102. MERS-CoV Case Study, *supra* note 8, at 7.

103. MERS-CoV Case Study, *supra* note 8, at 7.

104. MERS-CoV Case Study, *supra* note 8, at 7.

105. MERS-CoV Case Study, *supra* note 8, at 7.

106. MERS-CoV Case Study, *supra* note 8, at 7.

107. MERS-CoV Case Study, *supra* note 8, at 7.

108. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to Michelle Roberts, *First Ebola Boy Likely Infected by Playing in Bat Tree*, BBC NEWS (Dec. 30, 2014), <https://www.bbc.com/news/health-30632453>).

109. West Africa Ebola Case Study, *supra* note 9, at 1.

month, the child's sister, mother, and grandmother died after experiencing similar symptoms.¹¹⁰ The funeral for the latter was attended by a midwife who passed the disease to relatives in another village, and to a health care worker treating her.¹¹¹ That health care worker was treated at a hospital in Macenta, about 80 kilometers (50 miles) east. Additionally, a doctor who treated her also contracted Ebola.¹¹² The doctor then passed it to his brothers in Kissidougou, 133 kilometers (83 miles) away.¹¹³

Although the outbreak of EVD originated in Guinea, between December 2013 and March 2014, it spread more rapidly in the eastern regions of Sierra Leone and then in North Central Liberia, followed by Nzérékoré in Guinea.¹¹⁴ Between December 2013 and April 2016, a total of 28,616 suspected, probable, and confirmed cases of EVD were reported.¹¹⁵ A total of 11,310 deaths were attributed to the outbreak.¹¹⁶ The largest numbers of cases and deaths occurred in Guinea, Liberia, and Sierra Leone, but 36 cases were reported from Italy, Mali, Nigeria, Senegal, Spain, the United Kingdom, and the United States.¹¹⁷ After reaching a peak of 950 confirmed cases per week in September 2014, the incidence dropped precipitously toward the end of that year.¹¹⁸

Epidemiological investigations have revealed that primary human infections with the Ebola virus are associated with the handling of infected chimpanzees, gorillas, fruit bats, monkeys, forest antelope, and porcupines.¹¹⁹ Human-to-human transmission of Ebola occurs through close and direct physical contact with infected bodily fluids, the most infectious being blood, feces and vomit.¹²⁰ Funeral practices in the region that involved touching and washing dead

110. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to Mohamed F. Jalloh et al., *Assessments of Ebola knowledge, Attitudes and Practices in Forécariah, Guinea and Kambia, Sierra Leone, July–August 2015*, 372 PHIL. TRANS. R. SOC. B. (2017)).

111. West Africa Ebola Case Study, *supra* note 9, at 1; *see also* Holly Yan & Esprit Smith, *Ebola: Who Was Patient Zero? Disease Traced Back to 2-year-old in Guinea*, CNN (Jan. 21, 2015, 6:40 PM), <https://www.cnn.com/2014/10/28/health/ebola-patient-zero/index.html>.

112. West Africa Ebola Case Study, *supra* note 9, at 1.

113. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to Holly Yan & Esprit Smith, *Ebola: Who Was Patient Zero? Disease Traced Back to 2-year-old in Guinea*, CNN (Jan. 21, 2015, 6:40 PM), <https://www.cnn.com/2014/10/28/health/ebola-patient-zero/index.html>).

114. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to WHO Ebola Response Team, *After Ebola in West Africa - Unpredictable Risks, Preventable Epidemics*, 375 NEW ENG. J. MED., 587 (2016)).

115. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to WHO Ebola Response Team, *After Ebola in West Africa - Unpredictable Risks, Preventable Epidemics*, 375 NEW ENG. J. MED., 587 (2016)).

116. West Africa Ebola Case Study, *supra* note 9, at 1.

117. West Africa Ebola Case Study, *supra* note 9, at 1.

118. West Africa Ebola Case Study, *supra* note 9, at 1.

119. West Africa Ebola Case Study, *supra* note 9, at 1; *see also* *Ebola Virus Disease*, WORLD HEALTH ORGANIZATION, (May 30, 2019), <http://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease>.

120. West Africa Ebola Case Study, *supra* note 9, at 1.

bodies as well as the unsanitary conditions in many healthcare facilities magnified the risks of human-to-human transmission in the infection, treatment, and death cycles.¹²¹ The 2014-16 outbreak was the 24th known outbreak of Ebola and by far the most severe.¹²² A new outbreak occurred in the Democratic Republic of Congo (DRC) in May, 2017 and then the following year on April 4, 2018.¹²³ On August 1, 2018, a new outbreak occurred in North Kivu province, DRC, on the other side of the country from the April outbreak.¹²⁴ With a case fatality rate of around 55%, and with only two vaccines licensed by stringent regulatory authorities Ebola remains a biomedical research priority.¹²⁵

Much remains unknown about Ebola.¹²⁶ Even after nearly 30 outbreaks, scientists still do not know what explains the pathogenicity of the virus, or the exact route of zoonotic transmission.¹²⁷ Fruit bats appear to be the “most likely source of animal-to-human transmission,” although their exact role in the transmission cycle is still unclear.¹²⁸

b. Proprietary and Attribution

As with MERS-CoV, contentions surrounded the accessing and sharing of EVD virus samples in 2014-16. Thousands of Ebola samples were transferred out of the three most affected countries, largely without the consent of patients, and categorically without the consent of their governments, between April and November 2014.¹²⁹ While two teams of researchers made 102 Ebola genome sequences public between April and June of that year, there was a three-month span in which no new virus sequences were made available, even though some

121. West Africa Ebola Case Study, *supra* note 9, at 1; *see also* MEDECINS SANS FRONTIERES, PUSHED TO THE LIMIT AND BEYOND: A YEAR INTO THE LARGEST EVER EBOLA OUTBREAK, (Mar. 23, 2015), <https://www.doctorswithoutborders.org/sites/usa/files/msf143061.pdf>.

122. West Africa Ebola Case Study, *supra* note 9, at 1; *see also* Jonathan Corum, *A History of Ebola in 24 Outbreaks*, N.Y. TIMES (Dec. 29, 2014), <https://www.nytimes.com/interactive/2014/12/30/science/history-of-ebola-in-24-outbreaks.html>.

123. West Africa Ebola Case Study, *supra* note 9, at 1 (citing to WHO HEALTH EMERGENCY PROGRAM, EBOLA VIRUS DISEASE: DEMOCRATIC REPUBLIC OF CONGO EXTERNAL SITUATION REPORT 15 (July 12, 2018), http://apps.who.int/iris/bitstream/handle/10665/273088/SITREP_EVD_DRC_20180712-eng.pdf?ua=1).

124. West Africa Ebola Case Study, *supra* note 9 at 1-2.

125. West Africa Ebola Case Study, *supra* note 9, at 2 (citing to Ana Maria Henao-Restrepo et al., *Efficacy and Effectiveness of an rVSV-Vectored Vaccine Expressing Ebola Surface Glycoprotein: Interim Results from the Guinea Ring Vaccine Cluster-Randomised Trial*, 386 LANCET 857 (2015)).

126. West Africa Ebola Case Study, *supra* note 9, at 2.

127. West Africa Ebola Case Study, *supra* note 9, at 2; *see also* Robert A. Lever & Christopher J. M. Whitty, *Ebola Virus Disease: Emergence, Outbreak and Future Directions*, 117 BRIT. MED. BULL. 95,98-99 (2016).

128. West Africa Ebola Case Study, *supra* note 9, at 2.

129. *See* West Africa Ebola Case Study, *supra* note 9, at 8-9 (highlighting issues related to biological samples).

samples were known to have been sequenced.¹³⁰ In many cases, the whereabouts of the Ebola virus samples that were taken from the countries of origin and resulting research data conducted upon them remains unknown.¹³¹

Our case study revealed that during the 2014-16 Ebola outbreak, data was largely regarded as proprietary even if a large number of stakeholders invoked a “moral imperative” for free and open data sharing due to its importance for the response.¹³² Researchers were reluctant to share data to prevent other researchers from using their work without attribution.¹³³ Indeed, researchers were so mistrustful of sharing data with one another that they largely relied upon a single biologist at the University of Edinburgh to verify their results. Researchers also cited the risk of misuse of data as a reason not to share data.¹³⁴

In August 2014, an advisory panel convened by the Director-General of WHO determined that using Ebola products not yet tested on humans was ethical given the devastating nature of the emergency.¹³⁵ In 2015, trials for the experimental treatments favipiravir and convalescent plasma took place in Guinea, as did trials for brincidofovir in Liberia. The trial for rVSV-EBOV vaccine started in Guinea in March 2015.¹³⁶

Biomedical firms, largely working from research funded by Canadian and U.S. militaries, accelerated the development of therapeutics and vaccines.¹³⁷ Several firms worked in partnership with the ministries of health of the affected countries, including the WHO, the U.S. National Institute for Allergy and Infectious Diseases (NIAID), and the Norwegian Institute of Public Health.¹³⁸ The evidence showing the impact of intellectual property concerns on data sharing was mixed.¹³⁹ A retrospective assessment by WHO authors noted that:

130. See West Africa Ebola Case Study, *supra* note 9.

131. West Africa Ebola Case Study, *supra* note 9, at 8.

132. West Africa Ebola Case Study, *supra* note 9, at 11.

133. West Africa Ebola Case Study, *supra* note 9, at 11 (citing to Declan Butler & David Cyranoski, *Flu Papers Spark Row Over Credit for Data*, NATURE (May 1, 2013), <https://www.nature.com/news/flu-papers-spark-row-over-credit-for-data-1.12901>); see also Ben Goldacre et al., *WHO Consultation on Data and Results Sharing During Public Health Emergencies*, CENTRE FOR EVIDENCE-BASED MED. 8-9 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf.

134. West Africa Ebola Case Study, *supra* note 9, at 12 (citing to *First Diagnostic Test for Ebola Accepted by Who*, WORLD HEALTH ORGANIZATION, https://www.who.int/medicines/news/1st_diagnostic_test_ebola/en/); see also Matthew Brack & Tito Castillo, *Data Sharing for Public Health Emergencies: Key Lessons from Other Sectors*, CHATHAM HOUSE, 6 (Apr. 2015).

135. West Africa Ebola Case Study, *supra* note 9, at 12.

136. West Africa Ebola Case Study, *supra* note 9, at 12.

137. West Africa Ebola Case Study, *supra* note 9, at 12.

138. West Africa Ebola Case Study, *supra* note 9, at 12; see also William W. Fisher III & Katrina Geddes, *Learning from Ebola: How Drug-Development Policy Could Help Stop Outbreaks of Infectious Diseases*, BERKMAN KLEIN CENTER, https://cyber.harvard.edu/people/tfisher/Learning_from_Ebola.pdf.

139. West Africa Ebola Case Study, *supra* note 9, at 12.

[T]rials of two Ebola vaccine candidates (ChAd3-ZEBOV and rVSV-ZEBOV) benefited greatly from an open collaboration between investigators and institutions in Africa, Europe, and North America. These teams, coordinated by the WHO, were able to generate and exchange critical data for the development of urgently needed novel vaccines along faster timelines than have ever before been achieved.¹⁴⁰

However, a story published by *ScienceInsider* argued that at least one company “dragg[ed] its feet” because it was “worried about losing control over the development of the vaccine.”¹⁴¹ Firms asserted that protection of data and trade secrets was necessary for potential future intellectual property and related commercial claims.¹⁴²

The use of trade secrets and other proprietary claims were also applicable to “negative” and inconclusive results.¹⁴³ For example, one promising treatment was tested in Guinea and Sierra Leone, yet, when it did not show efficacy, enrollment in the clinical trial was halted, without further data as to why.¹⁴⁴ Similarly, another firm would not publicly reveal why it withdrew support for a trial of a second treatment in late January after four patients had been treated, despite this information being useful to other parties conducting R&D in the field.¹⁴⁵ Similarly, the experimental drug ZMapp was given to a handful of patients before supplies ran out in August 2014, however, detailed information on patients’ reactions to the drug was not released, owing to fears that this would prevent researchers from publishing on the cases.¹⁴⁶ While data were shared in the context of experimental vaccines, this was largely because firms needed the

140. Kayvon Modjarrad, et al., *Developing Global Norms for Sharing Data and Results During Public Health Emergencies*, 13 PLOS MED. 1, 2 (Jan. 5, 2016), <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1001935&type=printable>; see also West Africa Ebola Case Study, *supra* note 9, at 12.

141. West Africa Ebola Case Study, *supra* note 9, at 12 (citing to William W. Fisher III & Katrina Geddes, *Learning from Ebola: How Drug-Development Policy Could Help Stop Outbreaks of Infectious Diseases*, BERKMAN KLEIN CENTER, https://cyber.harvard.edu/people/tfisher/Learning_from_Ebola.pdf).

142. West Africa Ebola Case Study, *supra* note 9, at 12 (citing to William W. Fisher III & Katrina Geddes, *Learning from Ebola: How Drug-Development Policy Could Help Stop Outbreaks of Infectious Diseases*, BERKMAN KLEIN CENTER, https://cyber.harvard.edu/people/tfisher/Learning_from_Ebola.pdf).

143. West Africa Ebola Case Study, *supra* note 9, at 13.

144. West Africa Ebola Case Study, *supra* note 9, at 13; see also Andrew Pollack, *Clinical Trial of Experimental Ebola Drug is Halted*, N.Y. TIMES (June 19, 2015), <https://www.nytimes.com/2015/06/20/health/clinical-trial-of-experimental-ebola-drug-is-halted.html>.

145. West Africa Ebola Case Study, *supra* note 9, at 13; see also Erika Check Hayden, *Ebola Teaches Tough Lessons about Rapid Research*, NATURE (May 27, 2015), <https://www.nature.com/news/ebola-teaches-tough-lessons-about-rapid-research-1.17623>.

146. West Africa Ebola Case Study, *supra* note 9, at 13 (citing to Erika Check Hayden, *Ebola Teaches Tough Lessons about Rapid Research*, NATURE (May 27, 2015), <https://www.nature.com/news/ebola-teaches-tough-lessons-about-rapid-research-1.17623>).

infrastructure that only governments, funding agencies, and the largest charities could provide.¹⁴⁷ Those stakeholders insisted on sharing as a condition of access.¹⁴⁸

c. The Publishing Imperative

As discussed in Part II (c),¹⁴⁹ one of the fundamental dilemmas for researchers with primarily academic affiliations is in the incentive structure for tenure, promotion, pay, and status. Release of preliminary data might not only subject the researcher to later criticism if the data were erroneous or flawed, but may also jeopardize his or her opportunity to publish the data in peer review journals that satisfy tenure and promotion criteria.¹⁵⁰ Delays and barriers to data sharing of relevant Ebola information included the time taken by authors to prepare, write and submit their papers; desire to first submit results to high profile journals; time taken by journals to review and make decisions about publication; and time taken to complete the publication process.¹⁵¹

These delays applied to all data related to the research response including epidemiological, surveillance, emergency response, health facility data, pathogen genome data, research data including surveys, observational studies, clinical trials of diagnostics, therapeutics and preventives, quality controlled interim results, final research results, and inconclusive results.¹⁵² Measurement of this delay has been far more robust for clinical trial data.¹⁵³ For clinical trials related to Ebola, the median publication lag-time (from the end of the study) was 338 days (range of 157–621 days), the median submission lag-time (from study end to submission to the journal where it was eventually published) was 297 days (116–450 days), and the median review lag-time (from submission to publication) was 178 days (137–193 days).¹⁵⁴

Currently, there are few mainstream efforts to address these barriers during public health emergencies.¹⁵⁵ Publishing research takes time, and the peer review

147. West Africa Ebola Case Study, *supra* note 9, at 13.

148. West Africa Ebola Case Study, *supra* note 9, at 13.

149. *See supra* Part II.c.

150. West Africa Ebola Case Study, *supra* note 9, at 13 (citing to Matthew Brack & Tito Castillo, *Data Sharing For Public Health Emergencies: Key Lessons From Other Sectors*, CHATHAM HOUSE (Apr. 2015), https://www.chathamhouse.org/sites/files/chathamhouse/field/field_document/20150417DataSharingPublicHealthLessonsBrackCastillo.pdf).

151. West Africa Ebola Case Study, *supra* note 9, at 13.

152. West Africa Ebola Case Study, *supra* note 9, at 13.

153. West Africa Ebola Case Study, *supra* note 9, at 13.

154. West Africa Ebola Case Study, *supra* note 9, at 14 (citing to Piero L. Olliaro, *Initiation and Publication Time-Lags of Treatment Trials for Ebola Virus Disease*, 18 THE LANCET: INFECTIOUS DISEASE 28 (Jan. 1, 2018), [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(17\)30698-9/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(17)30698-9/fulltext)).

155. West Africa Ebola Case Study, *supra* note 9, at 14.

process is often not expedited during public health emergencies (although many interviewees in the MERS-CoV context were impressed with the expedited effort many journals made).¹⁵⁶ The earliest published genomic analyses of the Ebola outbreak, crucial for determining where it originated and how it was transmitted, did not appear until August, 2014.¹⁵⁷ This is a long-standing problem. For example, during the 2003 SARS outbreak, an estimated 22% of research studies relating to SARS were submitted to journals, and only 7% were published.¹⁵⁸

The failure to provide or share timely relevant data has been cited as one of the key impediments to mounting an effective response to the Ebola outbreak.¹⁵⁹ Although the outbreak was eventually contained, data sharing and communication breakdowns contributed to a significant delay in acknowledgment about the outbreak's severity and corresponding response.¹⁶⁰

d. Patient Privacy and Informed Consent

Where Ebola treatment centers were established (in both rural areas as well as in and around larger cities) and in the context of formalized healthcare facilities like hospitals, patient confidentiality and informed consent posed challenges for biomedical and clinical researchers.¹⁶¹ In the case of Ebola, these matters became even more relevant given that individual treatment and the public health response were significantly intertwined - sequencing of the Ebola virus strain enabled researchers to trace the outbreak's origin and pattern of transmission.¹⁶² Because people exposed to Ebola showed variability in their

156. West Africa Ebola Case Study, *supra* note 9, at 14.

157. West Africa Ebola Case Study, *supra* note 9, at 14.

158. West Africa Ebola Case Study, *supra* note 9, at 14 (citing to Merson et al., *Trust, Respect, and Reciprocity: Informing Culturally Appropriate Data-Sharing Practice in Vietnam*, J. OF EMPIRICAL RESEARCH ON HUMAN RESEARCH ETHICS (Aug. 21, 2015), <https://journals.sagepub.com/doi/10.1177/1556264615592387>).

159. See Jean-Paul Chretien et al., *Make Data Sharing Routine to Prepare for Public Health Emergencies*, 13 PLOS MED. (Aug. 16, 2016), <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002109> (highlighting obstacles to data sharing during public health emergencies); see also West Africa Ebola Case Study, *supra* note 9, at 2.

160. See West Africa Ebola Case Study, *supra* note 9, at 2 (citing to *Pushed to the Limit and Beyond: a Year Into the Largest Ever Ebola Outbreak*, DOCTORS WITHOUT BORDERS (2015), <https://www.doctorswithoutborders.org/sites/usa/files/msf143061.pdf> (last accessed July 24, 2018)).

161. See West Africa Ebola Case Study, *supra* note 9, at 10.

162. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Stephen K. Gire et al., *Genomic Surveillance Elucidates Ebola Virus Origin and Transmission During The 2014 Outbreak*, 345 AM. ASS'N FOR THE ADVANCEMENT OF SCI. 1369, (Sept. 12, 2014), <https://science.sciencemag.org/content/sci/345/6202/1369.full.pdf>).

susceptibility to infection and disease severity, human genetic variation likely contributed to individual immunity and infectivity.¹⁶³

Much of the research relevant to the development of diagnostics, therapeutics, and vaccines would not be possible without the collection and sharing of human genomic data.¹⁶⁴ In the three most affected countries, genomic data was in some cases collected and labeled with a patient's identifiable information (name, age, sex, etc.).¹⁶⁵ Data could then be theoretically de-identified, but all mechanisms for protecting sensitive health data were rudimentary (e.g., locked file cabinets) or non-existent.¹⁶⁶

The sensitivity of data collected from patients posed a dilemma for researchers: either obtain informed consent and respect confidentiality according to ethical guidelines or facilitate data sharing for purposes of response.¹⁶⁷ Concern over the confidentiality of data about individuals was the single most consistently cited barrier to data sharing.¹⁶⁸ These concerns led many researchers to hesitate or refuse to share data that might compromise patient confidentiality.¹⁶⁹ In the Ebola context, researchers saw firsthand the discrimination faced by both infected persons and survivors, as well as their families.¹⁷⁰ The Liberian Ministry of Health, for example, mandated that no

163. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY IN ETHICS AND EBOLA: PUBLIC HEALTH PLANNING AND RESPONSE (Sept. 30, 2016), <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/5%20Privacy%20-%20Ethics%20and%20Ebola%209.30.16.pdf>).

164. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY IN ETHICS AND EBOLA: PUBLIC HEALTH PLANNING AND RESPONSE (Sept. 30, 2016), <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/5%20Privacy%20-%20Ethics%20and%20Ebola%209.30.16.pdf>).

165. See West Africa Ebola Case Study, *supra* note 9, at 10.

166. See West Africa Ebola Case Study, *supra* note 9, at 10.

167. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Gail Geller et al., *Genomics and Infectious Disease: A Call to Identify the Ethical, Legal and Social Implications for Public Health and Clinical Practice*, 6 GENOME MEDICINE (Nov. 18, 2014), <https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-014-0106-2>).

168. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Ben Goldacre et al., *WHO Consultation on Data and Results Sharing During Public Health Emergencies*. CENTRE FOR EVIDENCE-BASED MED. 9 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf).

169. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Susan Bull et al., *Best Practices for Ethical Sharing of Individual-Level Health Research Data From Low- and Middle-Income Settings*, J. OF EMPIRICAL RES. ON HUM. RES. ETHICS 306 (Aug. 21, 2015), <https://journals.sagepub.com/doi/pdf/10.1177/1556264615594606>).

170. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Gail Geller et al., *Genomics and Infectious Disease: A Call to Identify the Ethical, Legal and Social Implications for Public Health and Clinical Practice*, 6 GENOME MEDICINE (Nov. 18, 2014), <https://genomemedicine.biomedcentral.com/articles/10.1186/s13073-014-0106-2>).

names be released and no bodies photographed.¹⁷¹ Some early genomic analyses admitted that informed consent had not been obtained.¹⁷² There were widespread ambiguities as to whether patients had to consent to downstream uses of their data.¹⁷³ Repeat consent delayed further research and exposed patients to additional risk of stigmatization.¹⁷⁴ Many patients were incapacitated and/or were minors whose parents had died and their guardianship became a complex matter of family, village, or tribal affiliation.¹⁷⁵ All of these unresolved issues contributed to hesitation and refusal to share data during the Ebola outbreak.¹⁷⁶

e. The Lack of Legal Infrastructure for Data Sharing

The structure of data sharing was mediated through entities employed by major funders: the Bill & Melinda Gates Foundation, the CDC, the CDC Foundation, U.K. Department for International Development (DFID), the Paul Allen Foundation, the U.K. Government, and USAID among the most significant.¹⁷⁷ These entities operated under agreements that variously limited or prohibited data sharing, required open data sharing, specified avenues for data sharing, or left the matter of data sharing ambiguous and unpredictable. Entities hired to collect, analyze, or work with some forms of data generally did not share that data outside contractual obligations or financial incentives to do so.¹⁷⁸ “Without agreement about the mutually beneficial roles, responsibilities, and legitimate contributions of clinicians, scientists, and public health authorities, parties end up either encroaching on one another or not communicating.”¹⁷⁹ These practices are reflected in the retrospective reports entities drafted for

171. See West Africa Ebola Case Study, *supra* note 9, at 10.

172. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Sylvian Baize et al., *Emergence of Zaire Ebola Virus Disease in Guinea*, 371 NEW ENG. J. MED. 1419 (Oct. 9, 2014), <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1404505>).

173. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Ben Goldacre et al., *WHO Consultation on Data and Results Sharing During Public Health Emergencies*. CENTRE FOR EVIDENCE-BASED MED. 9 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf).

174. See West Africa Ebola Case Study, *supra* note 9, at 10 (citing to Ben Goldacre et al., *WHO Consultation on Data and Results Sharing During Public Health Emergencies*. CENTRE FOR EVIDENCE-BASED MED. 9 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf).

175. See West Africa Ebola Case Study, *supra* note 9, at 10-11.

176. See West Africa Ebola Case Study, *supra* note 9, at 11 (citing to Kevin J. Emmett et al., *High-resolution Genomic Surveillance of 2014 Ebolavirus Using Shared Subclonal Variants*, PLOS (Feb. 9, 2015), <http://currents.plos.org/outbreaks/index.html%3Fp=52958.html>).

177. See West Africa Ebola Case Study, *supra* note 9, at 14.

178. See West Africa Ebola Case Study, *supra* note 9, at 14.

179. See West Africa Ebola Case Study, *supra* note 9, at 14 (citing to Ben Goldacre et al., *WHO Consultation on Data and Results Sharing During Public Health Emergencies*. CENTRE FOR EVIDENCE-BASED MED. 9 (Sept. 2015), http://www.who.int/medicines/ebola-treatment/background_briefing_on_data_results_sharing_during_phes.pdf).

donors and others, emphasizing a number of geographic locations in which there was a presence, number of volunteers trained, and number of staff hired.¹⁸⁰ One report listed 78 partners and 36 sub-grantees.¹⁸¹

Some funders like the Bill and Melinda Gates Foundation and UK DFID made explicit data sharing and data accessibility requirements, although the commitment is broadly to openness *after* publication.¹⁸² The arrangement between the CDC and one logistics support entity changed depending upon the program officer who had rotated into the field (every four weeks), with each program officer in turn making different decisions on data sharing.¹⁸³ Entities or persons collecting and/or analyzing data would claim that specific agreements under which they worked prohibited data sharing except to specific persons or ministries.¹⁸⁴

With respect to clinical trial data collected following the WHO's August 11, 2014 declaration on emergency uses of products not yet tested in humans, the coordination between the WHO, NIAID, Médecins Sans Frontières (MSF), ministries of health in Guinea, Liberia, and Sierra Leone, the Norwegian Research Council, IRDC Canada, donors, and universities minimized data sharing barriers.¹⁸⁵ This coordination was attributed to agreements that clearly defined roles, transparent and agreed-upon categories of data needed for the trials to show evidence of safety and efficacy, and adequate resources to enroll volunteers, conduct trials, and gather information.¹⁸⁶

IV. SOLUTIONS

Based on our two case studies, we advocate four specific solutions to the legal, social and ethical barriers to data sharing during public health emergencies. First, create a system of contractually-driven incentives that value data, even preliminary data, and financially reward data sharing and/or punish data hoarding. Second, establish a trusted third-party repository where researchers may post data with a meaningful mechanism to address non-attribution, along the lines of the global initiative on sharing avian influenza data GISAID database for influenza researchers.¹⁸⁷ Third, the WHO should lead an effort to

180. See West Africa Ebola Case Study, *supra* note 9, at 14.

181. See West Africa Ebola Case Study, *supra* note 9, at 14 (citing to USAID, *Social Mobilization Lessons Learned: The Ebola Response in Liberia*, JOHNS HOPKINS CTR. FOR COMM'N PROGRAMS 50–52 (2017), <https://healthcommcapacity.org/wp-content/uploads/2017/02/Ebola-Lessons-Learned-ksm.pdf>).

182. See West Africa Ebola Case Study, *supra* note 9, at 14–15.

183. See West Africa Ebola Case Study, *supra* note 9, at 15.

184. See West Africa Ebola Case Study, *supra* note 9, at 15.

185. See West Africa Ebola Case Study, *supra* note 9, at 15.

186. See West Africa Ebola Case Study, *supra* note 9, at 15.

187. See Stefan Elbe & Gemma Buckland-Merrett, *Data, Disease and Diplomacy: GISAID's Innovative Contribution to Global Health*, 1 GLOBAL CHALLENGES 33, (Jan. 10, 2017),

establish guidelines and procedures for protecting patient privacy and confidentiality during public health emergencies. Fourth, expand informal networks of researchers, aid workers, and public health responders, through which much of the (limited) data sharing occurred during both emergencies.

Reform begins with the three sets of stakeholders best positioned to shape the legal, social and ethical environment for data sharing during infectious disease emergencies: (1) governments, (2) funders, and (3) medical journals. Governments should commit through a World Health Assembly Resolution to a statement that rapid sharing of data is critical to preserve global health and to prioritize rapid sharing over other interests. This would help clarify ambiguities in current international law about whether sovereign ownership of relevant data changes during public health emergencies.

This Resolution should also recommend international funding of a comprehensive disease database, where persons, and not organizations, must register and acknowledge use of others' research. Adopting GISAID's requirement that database users be natural persons (as opposed to organizational entities) would facilitate formal and informal networks that have been crucial to breaking down sharing barriers in previous infectious disease emergencies.¹⁸⁸

Establishing an international database would further allow funders to identify researchers, their promised benefits, and develop a taxonomy and system for rewarding the posting of relevant data for other researchers to use. Indeed, funders could expand already existing requirements for recipients to publish in open-access journals.

Finally, medical journals should expand their gatekeeping role, requiring expanded disclosures as to sources of data, attribution, and ethical use of material transfer agreements. Indeed, these journals already have an existing mechanism for doing so; they request Institutional Review Board approval information before publishing data involving human research subjects. Leveraging the influence of journals to protect the integrity of the research process would orient researchers toward better data management practices.

V. CONCLUSION

Legal, social and ethical barriers to data sharing threaten global health and will continue to do so as novel pathogens emerge. Developing incentives, facilitating networks, and creating a centralized data resource are critical steps in responding to, and containing the next infectious disease emergency. Here, we outlined the results of our case studies into data sharing in the 2012 MERS-CoV

<https://onlinelibrary.wiley.com/doi/epdf/10.1002/gch2.1018> (pointing out that GISAID is working on an influenza repository).

188. See *Questionnaire for Databases*, WHO, 7 https://www.who.int/influenza/pip/DBSubmission_GISAID.pdf?ua=1 (last updated Aug. 2018).

outbreak in Saudi Arabia¹⁸⁹ and the 2014-16 West Africa Ebola public health emergency.¹⁹⁰ Our case studies revealed that proprietary claims and concerns about attribution are major barriers to data sharing. Unfortunately, the ongoing COVID-19 pandemic has demonstrated that proprietary and attribution claims continue to create barriers to data sharing during infectious disease emergencies. There is evidence that the sharing requirements related to both information and biological samples created barriers to accessing novel coronavirus samples from China in the early days of the pandemic.¹⁹¹ There are ongoing discussions at the World Trade Organization as to whether poorer countries should be able to obtain exemptions from vaccine licensing fees applicable under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and early online publishing of preprints, while generally providing a net positive for the scientific and policy community, have also contributed to the spread of misinformation (and perhaps even disinformation) when very little was known about the virus. The sorts of analyses conducted in 2018 with the support of the Wellcome Trust and the GloPID-R will need to be repeated in the aftermath of COVID-19 to determine what lessons can be drawn from this global catastrophe.

While the initial stages of an epidemic (especially from a previously unknown agent) are always characterized by alarm and confusion, there should be no need to reinvent the data-sharing wheel every time the world is faced with another infectious disease challenge. We can learn lessons from past outbreak and do more than just write about them (which does serve the important purpose of awareness raising). We also need governments and funders to implement these recommendations. The academic publishing community is getting the picture and changing their publication practices during emergency situations. If an institution as steeped in tradition as academic publishing can adapt, then there is hope that others can too.

189. MERS-CoV Case Study, *supra* note 8.

190. West Africa Ebola Case Study, *supra* note 9.

191. Michelle Rourke et al., *Policy Opportunities to Enhance Sharing for Pandemic Research*, 368 SCIENCE 716 (2020).