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House of Commons
Science and Technology
Committee

Science in emergencies: UK lessons from Ebola

Second Report of Session 2015-16

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House of Commons Science and Technology Committee

Science in emergencies: UK lessons from Ebola

Second Report of Session 2015–16

Report, together with formal minutes relating to the report

Ordered by the House of Commons to be printed 13 January 2016

Science and Technology Committee

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Contents

Summary		3
1	Introduction	6
	Our inquiry	7
2	Increasing the UK's preparedness for major disease outbreaks	10
	Disease surveillance	10
	Financing vaccine, treatment and diagnostic developments	11
	A diagnostic test for Ebola	13
	Vaccine manufacturing capacity	15
3	Responding to major disease outbreaks	17
	Science advice	17
	Convening SAGE	17
	Membership and co-ordination of SAGE	18
	Scientific Advisory Groups	20
	Research during an outbreak	21
	Research coordination	21
	Data sharing	22
	Clinical trials	23
	Regulation and licencing	24
	Communication	26
	Giving advice to the public	26
	Screening at ports of entry	27
4	Governance of emergencies	29
	International governance	29
	National governance	30
	The National Risk Register	30
	UK global health policy	31
	UK volunteer response	33
Co	nclusions and recommendations	35
An	nex	40
	Committee seminar, University of Oxford	40

2 Science in emergencies: UK lessons from Ebola

Formal Minutes	43
Witnesses	44
Published written evidence	45
List of Reports from the Committee during the current Parliament	46

Summary

Ebola is a rare and deadly disease. It is spread through direct contact with the bodily fluids of infected people and with objects and materials contaminated with these fluids. Since late 2013, West Africa has experienced the largest Ebola outbreak ever recorded. It was, first and foremost, a human tragedy. We pay tribute to all those who worked tirelessly to tackle this outbreak, some of whom gave evidence to this inquiry, and many of whom continue working to avert similar crises in the future. We also commend the Government on its leading contribution to the fight against Ebola, and the financial, and personnel, commitments that it made, from constructing and staffing Ebola treatment centres in Sierra Leone to deploying troops, helicopters, aircrew and an aviation support ship to provide much needed logistical support.

Examples of UK successes in tackling Ebola, however, must not allow complacency to set in. Despite this impressive deployment of resources to combat Ebola in Sierra Leone, the UK response—like the international response—was undermined by systemic delay. The biggest lesson that must be learnt from this outbreak of Ebola is that even minor delays in responding cost lives. Rapid reaction is essential for any hope of success in containing an outbreak. Yet delays were evident at every stage of our response, from escalating Public Health England's disease surveillance data to those with the capacity to act, to convening a Scientific Advisory Group for Emergencies—the main mechanism for channelling scientific advice to Government in an emergency—which failed to be established until October 2014, three months after 'Cobra', the Government's emergency response committee, first met. In the absence of established mechanisms, ad hoc approaches emerged to fill the gaps. Inevitably, these were not as effective, or as targeted, as they should have been.

We recognise the enormous efforts made by governments, universities, regulatory bodies, humanitarian agencies, pharmaceutical companies and others to ensure that clinical trials for Ebola vaccines, treatments and diagnostics were launched in record time. But such efforts do not obscure the fact that the UK and other countries were not 'research ready' when the outbreak began, prompting a less than optimal and uncoordinated research response. The failure to conduct therapeutic trials earlier in the outbreak was a serious missed opportunity that will not only have cost lives in this epidemic but will impact our ability to respond to similar events in the future.

Research during an outbreak must be initiated rapidly, while still being designed and conducted to the highest possible standards. While we recognise the difficulties that arose in this outbreak, they are inherent to all epidemics; therefore, if we want to improve our response, we must address the weaknesses in our research readiness that this epidemic exposed. We are not convinced, however, that the Government has looked ahead and considered how a more timely, co-ordinated and robust response could be achieved when the next epidemic emerges.

Rapid and reliable communication is integral to delivering an effective response to a disease emergency. And yet, throughout the Ebola outbreak, we saw that systems to share advice, expertise, epidemiological and clinical data—particularly between the UK and Sierra Leone—were inadequate. We were concerned that this had harmful repercussions including a failure to undertake basic, yet important, research about the

efficacy of Ebola treatments, as well as undermining the robustness of transmission modelling work. We recommend that the Chief Medical Officer urgently establishes new processes and protocols to ensure that knowledge and data are communicated effectively throughout an outbreak and that research is embedded into an emergency response from the outset.

The Government's communications on Ebola with the UK public were accurate and balanced, making it all the more disappointing that the Government failed to explain why it went against guidance from the World Health Organization and Public Health England and introduced screening for Ebola at UK ports of entry. We recommend that when interventions like screening are instigated during an emergency, the Government makes the evidential basis for the intervention explicit.

Ebola also highlighted structural weaknesses in the UK's capacity to absorb and withstand shocks to the system arising from emergencies. Despite hosting world-leading experts in immunology, epidemiology and tropical medicine in the UK, there are currently no licenced treatments for, and vaccinations against, Ebola. This situation has arisen, in part, due to a long-term market failure to invest in interventions for rare but potentially catastrophic epidemics. While we welcome the Government's recent announcements of much needed research funds in this area, we recommend that it works with leading experts to publish an emerging infectious disease strategy, setting out the 'priority threats' the UK wishes to address, so that these funds can be effectively targeted and their benefits maximised.

We are also concerned that, in the unlikely but possible event of a domestic outbreak, the UK lacks the capability to go further and manufacture enough vaccines to vaccinate UK citizens in an emergency. Existing facilities are degraded and new plant will take years to build, leaving the UK in a vulnerable position. There is a need for the Government to do more than simply encourage inward investment in advanced manufacturing. We recommend that it acts now and negotiates with vaccine manufacturers to establish pre-agreed access to manufacturing capabilities that can be called upon quickly in an emergency.

The willingness of Government agencies, third sector organisations, health and aid workers, universities, and pharmaceutical companies to go above and beyond to help tackle the outbreak was phenomenal. The swift pace at which clinical trials were approved and conducted particularly stood out. The Defence Science and Technology Laboratory's rapid diagnostic test for Ebola—which was developed, manufactured and latterly trialled on patients in Sierra Leone by January 2015—exemplifies the gamechanging innovations that can be achieved by Government research and development facilities collaborating with private partners and clinicians. We were therefore dismayed to learn that, despite the promise shown by this test, and the production of 10,000 testing kits, it was not released for general use by the Government. Instead, we received different explanations, from different Government departments and agencies, about why the test was not operationalised. We are concerned that this is indicative of a worrying lack of cross-Government co-ordination, as well as an accountability deficit, for key aspects of the UK Ebola response. We ask the Government to clarify urgently why the rapid diagnostic test for Ebola was not released for use.

Prior to the Ebola outbreak, the Government had remained largely silent on its policy towards global health since it published its *Health is Global* framework in 2011. While we hope that the world will never experience an Ebola outbreak of this magnitude again, it would be naïve to assume that epidemics with the potential to cause death and devastation, and cross national borders, can be consigned to the past. Our global health policy will have a profound impact on the lives of people in the UK and beyond. It is therefore vital that the Government clearly sets out what would trigger an in-country response to a disease emergency and what capability the UK should be able to deploy readily overseas.

1 Introduction

- 1. Ebola virus disease is an acute, severe illness in humans which is often fatal if left untreated. Transmission can occur via contact with "the blood, secretions, organs or other bodily fluids of infected people, and with surfaces and materials (e.g. bedding, clothing) contaminated with these fluids". In late 2013, an outbreak of Ebola began in Guinea. It was to become the largest, and most complex, on record. The World Health Organization (WHO) estimates that there have been over 28,500 confirmed cases since the start of the outbreak and more than 11,000 deaths.
- 2. Almost all of these cases occurred in the West African states of Guinea, Liberia and Sierra Leone; three countries which had only recently emerged from long periods of conflict and political instability (see map)³. The outbreak was, first and foremost, a human tragedy. Ebola ravaged communities, causing untold suffering while placing local health systems, services and infrastructure under extreme strain. Amidst this turmoil, people throughout the affected region and beyond put their lives at risk to help others tackle a disease for which there is no licensed vaccine or treatment. We wish to pay tribute to all those who worked tirelessly to tackle this outbreak, many of whom put their own lives at risk, and many of whom are continuing their work today, fighting to avert similar crises in the future.



- 1 World Health Organization, 'Ebola virus disease', Fact sheet N°103, Updated August 2015, accessed 14 December 2015. The WHO is the international body responsible for the promotion and protection of health globally.
- 2 World Health Organization, Ebola situation reports, December 2015
- 3 Outbreak distribution map produced by the US Centers for Disease Control and Prevention based on data from the World Health Organization Ebola Situation Report, 6 January 2016.

- 3. The Ebola outbreak, however, also exposed serious shortcomings in the international community's emergency response to a global health crisis. Criticism has been primarily targeted at the performance of the WHO and its failure to act sooner. As far back as March 2014, Médicins sans Frontières (MSF Doctors Without Borders) established its first clinic in Guéckédou, Guinea and warned that its volunteers were "facing an epidemic of a magnitude never before seen in terms of the distribution of cases in the country". By June 2014, MSF reported that the epidemic was "out of control" and that the organisation had "reached the limits" of what its teams could do. Nearly two months later, on 8 August 2014, the WHO declared a Public Health Emergency of International Concern' for only the third time in its history and began to mobilise an international response to address the Ebola epidemic.
- 4. In the 2010-15 Parliament, the House of Commons International Development Committee (IDC) examined *Responses to the Ebola crisis*, focusing on the Department for International Development's (DFID) actions to tackle the outbreak, as well as the role of the WHO more broadly.⁶ The IDC has since followed up on this work, conducting detailed scrutiny into what DFID, the WHO, and the international community more generally, are now doing to improve the international response to future disease outbreaks. Less attention, however, has been focused on the UK's response to Ebola either domestically, or in Sierra Leone, where the UK took the international lead in providing assistance, committing £427million to combat Ebola.⁷

Our inquiry

- 5. The UK should be proud of its efforts in responding to the Ebola crisis, from establishing treatment centres and training frontline healthcare workers, to fast tracking human trials of an Ebola vaccine and boosting the capacity of burial teams to respond quickly, while ensuring dignified burials. Complacency on the part of the Government, however, must not be allowed to set in. While there were certainly 'success stories', these should not obscure the fact that Ebola damaged communities, compromised essential public services, weakened economies, and led to thousands of deaths in West Africa. It is vital that we learn lessons now if we are to take the necessary steps to prevent an outbreak causing such havoc and devastation in the future.
- 6. We therefore decided to examine the UK's response to Ebola focusing particularly on the mobilisation of treatment, research, scientific advice and of expertise in tackling this type of overseas disease emergency.
- 7. On the 20 July 2015, we announced our inquiry and sought written submissions addressing the following points:
- a) How prepared is the Government for a similar type of emergency? Is it effectively mitigating and increasing resilience to the disease hazards identified in the National Risk Register?

⁴ Guinea: Mobilising against an unprecedented Ebola epidemic, Médicins sans Frontières Press release 31 March 2014

⁵ Ebola in West Africa: "The epidemic is out of control", Médicins sans Frontières Press release 25 June 2014

⁶ House of Commons International Development Committee, Eighth Report of Session 2014–15, Responses to the Ebola crisis, HC 876

⁷ HL Deb, 21 July 2015, HL1280 [Lords written answer]

- b) What lessons were, or should have been, drawn from the Ebola emergency for gathering, assessing, using and communicating scientific advice across Government during this type of emergency?
- c) How successful was the Government in communicating advice to the UK public about the emergency?
- d) Since the Ebola emergency, how well has scientific advice been used to inform or revise the Government's planned response to similar emergencies in future?
- e) Could the evidence base and sources of scientific advice to Government on emergency mitigation, planning and response be improved? If so, how?
- f) What are the strengths and weaknesses in the system for weighting the risk of a future Ebola-type emergency, including the possible scale of impacts for the UK and their likelihood?

We received 18 written submissions and took oral evidence from 17 witnesses from a variety of backgrounds including:

- academics with expertise in international development, tropical medicine, vaccinology
 and public health, including a doctor who had worked on the ground in Sierra Leone
 throughout the outbreak;
- the pharmaceutical industry;
- science media;
- officials from Public Health England and the Defence Medical Services;
- · the Government Chief Scientific Adviser;
- the Government, represented by Jane Ellison MP, Parliamentary Under-Secretary of State for Public Health (hereafter "the Minister"), the Chief Medical Officer, and the Civil Contingencies Secretariat in the Cabinet Office.

We also held a seminar at the University of Oxford (see Annex). We would like to thank everyone who contributed to this inquiry.

- 8. In our inquiry, we have been primarily concerned with the science aspects of the UK's response to the Ebola emergency and the lessons that we must learn for the future. We have not focused on the role of DFID and the humanitarian response as this has been scrutinised on multiple occasions by the IDC. Instead, steps to increase the UK's preparedness for major disease outbreaks are considered in Chapter 2, while Chapter 3 examines the strengths and weaknesses of the UK's response, both domestically and in Sierra Leone. Finally, Chapter 4 looks at how emergencies are governed, from both an international and national perspective, the latter focusing particularly on the UK's global health policy.
- 9. While our report is focused on how the UK can improve its response to 'disease emergencies', our recommendations do not suggest that the UK's longstanding efforts to reduce the global burden of chronic and endemic diseases should be accorded a lower priority. Affected West African states began to be declared Ebola-free by the WHO during

the course of our inquiry, yet chronic and endemic diseases persist globally. Diarrhoeal disease, for example, is one of the leading causes of death in children under 5 years old, killing an estimated 760,000 annually across the world. Most of these cases could have been prevented through access to safe drinking water, better sanitation and improved hygiene.8 The recommendations in our report should be pursued alongside such interventions.

2 Increasing the UK's preparedness for major disease outbreaks

10. This chapter considers measures that the UK could instigate, or develop further, to improve our capacity to withstand global disease outbreaks. Increasing the UK's emergency preparedness involves taking steps to ensure that, as a country, we are better able to anticipate, absorb, and accommodate 'shocks' to the system, such as extreme events, while also recovering rapidly, and continuing to develop.

Disease surveillance

- 11. Disease surveillance and early diagnosis are vital components of controlling the spread of diseases. Public Health England (PHE), which manages the UK's national and international systems for detecting disease threats, was praised by witnesses for the strength, quality and effectiveness of its surveillance capacity. There was also a consensus across the evidence we received that the Government must work to strengthen surveillance capacity and capability *globally*, especially in emerging infection 'hot spots' that tend to be located in less economically developed countries. The Government appeared to have taken a similar view, announcing in March 2015 a £195 million investment in the Fleming Fund "to build laboratory capacity, surveillance networks and response capacity in lowand middle-income countries".
- 12. Surveillance data loses its value, however, if it fails to reach those who have the ability to act upon it. As Dr Jeremy Farrar from the Wellcome Trust explained, "surveillance on its own without the capacity, willingness and leadership that allow you to respond is not stamp-collecting, but it is not far from it". We raised concerns with PHE that while it was publishing the information gleaned from its disease surveillance capabilities in a "whole range of different reports", that information was not making its way into the hands of those who had the power to escalate the situation and intervene. When asked if, rather than circulating published papers, PHE communicated directly with the Government it was hard to get a clear answer. Professor Paul Cosford could not categorically confirm that Ministers had been alerted, instead concluding that:

The specific answer to your question about whether we talked to advisers to the Secretary of State is that I am sure we must have done, but it was not flagged as being a major problem for the UK at that point.¹⁴

13. Similar concerns were raised at the international level about the ability to share surveillance data and ensure that it was effectively communicated. The Medical Research Council stressed that "monitoring spread of disease [and its] transmission dynamics [...]

⁹ Q57; Wellcome Trust (EME015)

¹⁰ Wellcome Trust (EME015) para 13; Medical Research Council (EME014); Microbiology Society and the Society for Applied Microbiology (EME013) para 12; The Academy of Medical Sciences and The Royal Society (EME011) para 6; Department of Health (EME008) para 31

¹¹ Fleming Fund launched to tackle global problem of drug-resistant infection, Wellcome Trust Press Release, 18 March 2015

¹² Q100

¹³ Q124

¹⁴ Q127

can only be properly investigated using real time data collection, sharing and analytics". 15 Yet, as a report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola highlighted, "reliable systems for rapid transmission of epidemiological, genomic, and clinical data were not established during the Ebola epidemic".16

- 14. Witnesses were clear that the slow communication of, and action upon, real-time data comes at the cost of thousands of lives in outbreaks of this ferocity. A study by researchers at the London School of Hygiene and Tropical Medicine, for example, recently calculated that while setting up nearly 3000 treatment beds in Sierra Leone by the UK and Sierra Leonean Governments saved 56,000 lives, an estimated 12,500 more cases could have been averted had this intervention occurred only a month earlier. 17 The Wellcome Trust confirmed that a "lack of real time data of infection rates [...] significantly impacted on both the ability to make decisions regarding treatment and prevention of spread of the disease."18 The Chief Medical Officer (CMO), Professor Dame Sally Davies, was more explicit, stating that delays by the international community in responding "probably meant that lives were lost".19 The Medical Research Council and the Academy of Medical Sciences indicated that the CMO was now working with the WHO "to develop a new, more advanced system to share data on a disease with health agencies and doctors and nurses on the frontline".20
- 15. The rapid transmission of disease surveillance data to those with the ability to interpret and act upon it is a vital component of disease control. In its absence, we have seen, in the case of Ebola, how quickly an outbreak can spread and the devastation it can cause. The lines of reporting of surveillance data must, therefore, be clear and well-understood by those involved to ensure a co-ordinated and timely escalation. We are not convinced that the systems in place for interpreting, sharing and escalating disease surveillance data across the Government operated effectively during the early stages of the Ebola outbreak. We discuss later in this report how a lack of clarity about which diseases, or types of diseases, are covered in the National Risk Register, may have contributed to this situation.
- 16. We recommend that the Government sets out, in its response to this report, how surveillance data is escalated, both within Public Health England and across Government, and identify the triggers that would prompt warnings to reach ministers and senior officials with the capacity to act. We also ask for an update on the Chief Medical Officer's work with the World Health Organization to develop systems to share disease data.

Financing vaccine, treatment and diagnostic developments

17. In the absence of rapid diagnostic tests for Ebola, or any licenced drugs and vaccines, health workers in affected West African countries struggled to diagnose patients and provide effective care. Dr Jeremy Farrar from the Wellcome Trust expressed his frustration

¹⁵ Medical Research Council (EME014)

¹⁶ Suerie Moon et al, "Will Ebola change the game? Ten essential reforms before the next pandemic. The report on the Harvard-LSHTM Independent Panel on the Global Response to Ebola", The Lancet, volume 368, (2015), pp 2117-2226

¹⁷ Adam J. Kucharski et al., "Measuring the impact of Ebola control measures in Sierra Leone", Proceedings of the National Academy of Sciences of the United States of America, vol 112 (2015), pp 14366-14371

¹⁸ Wellcome Trust (EME015) para 8

¹⁹ Q167 [Dame Sally Davies]

²⁰ Medical Research Council (EME014); The Academy of Medical Sciences and The Royal Society (EME011)

that, nearly four decades after the virus was first discovered, we still understand very little about how to treat Ebola patients effectively.²¹ This situation is not unique to Ebola, nor is it indicative of a general poverty of ambition to do more. Witnesses repeatedly explained that the slow progress in tackling emerging infectious diseases related, in large part, to the funding mechanisms for drug and vaccine development globally.

- 18. The majority of funding for drug and vaccine research and development originates from private sector bodies, particularly pharmaceutical companies. However, as Professor Adrian Hill from the Jenner Institute explained, "the business case for large pharma becoming involved in marketing or developing vaccines [for Ebola and other outbreak pathogens] is very weak". Typically, outbreaks of emerging infectious diseases tend to be both small and rare. As a result, the market for interventions targeting these diseases has been considered too limited for pharmaceutical companies to justify the costs of shifting their resources "away from more commercially viable projects to work on tools for epidemics that may not happen".²³
- 19. This lack of "commercial viability", 24 alongside a scarcity of alternative funding mechanisms, were identified as key reasons for a repeated failure to take promising vaccines and treatments for Ebola through 'Phase 1' clinical trials. 25 As a result, when an Ebola epidemic did materialise, vaccines were not even 'on the shelf', ready to be tested further in humans who were at risk of becoming ill. Dr Jeremy Farrar from the Wellcome Trust described this as a "fundamental error". 26
- 20. To avoid a similar situation occurring when the next outbreak strikes, Professor Hill advocated establishing an alternative model of funding. He stressed that a system was needed "whereby public and foundation money is used to work with academics and industry to develop Ebola vaccines and other vaccines for which the business case is weak".²⁷ The British Society of Immunology made a similar recommendation, adding that this type of public-private collaboration would be "best achieved [...] under a common programme and following a nationally agreed framework".²⁸
- 21. During last six months, the Government has made several announcements that suggest such a shift towards more public investment in 'neglected diseases'. In June 2015, the Prime Minister announced the creation of the UK Vaccine Research and Development Network with the aim of bringing together "the best expertise across the country [...] to focus on the most threatening diseases including Ebola, Lassa, Marburg and Crimean-Congo Fever". The Network "will invest £20m over the next 5 years to develop new vaccines" with additional investment anticipated from the private and research sector. Two additional funds were outlined in the Spending Review: a £1 billion 'Ross Fund',

^{21 &}quot;Diseases spread in weeks. Epidemic research takes years. This must change", The Guardian, 10 June 2014

²² Q50

²³ Bill Gates, "The Next Epidemic — Lessons from Ebola", New England Journal of Medicine, vol 372 (2015), pp 1381-1384

^{24 051}

²⁵ Phase one trials aim to test the safety and efficacy of a new drug or vaccine. A small number of people, usually healthy volunteers, are given a small dose of the drug or vaccine and are monitored for side effects. This is normally the first time that the intervention has been tested on humans.

^{26 099}

²⁷ Q50

²⁸ British Society for Immunology (EME004) para 2.3

²⁹ Prime Minister calls for 'wake-up to the threat from disease outbreak', Prime Minister's Office News Story, 7 June 2015

³⁰ Medical Research Council (EME014)

in partnership with the Bill and Melinda Gates Foundation, to support "the global fight against malaria and other infectious diseases." A further £1.5 billion over the next 5 years was committed by the Chancellor to establish a 'Global Challenges research fund' to ensure "UK science takes a leading role in addressing the problems faced by developing countries". 32 We welcome the Business Secretary's reassurance that the Global Challenges fund will include support for health research programmes "including vaccines and emerging and current viral threats". 33

- 22. Part of the suffering seen throughout the Ebola outbreak resulted from a long-term market failure to invest in interventions for rare, but potentially catastrophic, disease epidemics. Through a combination of public and private investment, the UK now has the opportunity to capitalise on its world-class strengths in the field of tropical medicine, and reverse decades of underfunding in vaccine, treatment and diagnostic R&D in emerging infectious diseases. We welcome the Government's recent announcements of much needed research funds in this area.
- 23. To maximise the effectiveness of these funds, we recommend that the Government works with leading experts to publish an 'emerging infectious disease strategy'. This should set out a long-term plan identifying the 'priority threats' the UK wishes to address, how much funding will be directed to each threat, as well as how action will be delivered and outcomes evaluated. The strategy should outline how coordination across funding streams will be achieved, so that there is no unnecessary duplication of research. Open knowledge and data sharing should be set as default conditions for those receiving public funds.

A diagnostic test for Ebola

- 24. The need for a much more strategic approach to research and development funding was demonstrated by Dr Oliver Johnson of the King's Sierra Leone Partnership in his account of the events surrounding the trial of a new diagnostic test for Ebola early in 2015. Diagnosing Ebola quickly was highlighted as important for "protecting health workers and allowing [...] patients either to get Ebola treatment or move on and get other care" but existing tests required a blood sample to be sent to a specialist lab. Dr Johnson told us that "at some stages it was taking up to a week to get results".³⁴
- 25. Working in partnership with Public Health England, a new diagnostic test for Ebola—the 'rapid diagnostic antigen test' (RDT)—was subsequently trialled in Sierra Leone by the King's Sierra Leone Partnership and others. Developed by the Government's Defence Science and Technology Laboratory (DSTL), and its industry partner BBI Detection, the RDT enabled a result to be obtained at the 'point of care' within 20 minutes.³⁵. Data from the study were "very positive"³⁶: the test was found to be "highly sensitive, specific and

³¹ Chancellor George Osborne and Bill Gates to join forces to end malaria, HM Treasury News Story, 22 November 2015

³² HM Treasury, Spending Review and Autumn Statement 2015, Cm 9162, November 2015, p 29

³³ Correspondence from Sajid Javid MP to Nicola Blackwood MP on The Science Budget and the Spending Review, 7 January 2016

³⁴ Q110

³⁵ Defence scientists support efforts to defeat Ebola, Press release, Ministry of Defence and Defence Science and Technology Laboratory, 21 May 2015; N F Walker et al, "Evaluation of a point-of-care blood test for identification of Ebola virus disease at Ebola holding units, western area, Sierra Leone, January to February 2015", Eurosurveillance, vol 20 (2015)

³⁶ Q110

[performed] well in an operational setting". Though an additional, confirmatory blood test was "probably" still required, Dr Johnson considered that DSTL's test "would be very useful overall in bringing outbreaks under control". He saw it as a "real success" and something that "Britain [could] be proud of". 39

- 26. Notwithstanding the promising results, and the production of "about 10,000" of these rapid diagnostic tests, Dr Johnson stated that he had "not been able to operationalise them". 40 Despite our questioning, we did not receive clear answers as to why this failed to occur. Initially, when we asked PHE and the Defence Medical Service to clarify what had happened, both were unable to shed light on the situation. 41 Subsequently, both PHE and the Ministry of Defence informed us that for a test of this type to be made available, the following would need to be in place:
- a) The device in question to have received the necessary clearance for emergency use by the World Health Organization.
- International consensus on how best to deploy antigen RDTs.
- c) The approval of the relevant health body in the country where the test will be used.⁴²
- 27. PHE stated that these requirements had not yet been met: "This particular antigen RDT does not have regulatory clearance for emergency use and has not been through the [Emergency Use Assessment and Listing Procedure] process which is, de facto, a prerequisite for wider deployment". It added that there was also "a lack of [international] consensus about where and how [antigen rapid tests] should be used". None of these requirements, however, were referred to by the Department for International Development in its response to a question, tabled in June 2015, about when the rapid diagnostic test would be made available:

The device has been evaluated in Sierra Leone by PHE to determine its utility in the outbreak setting, and the decision on whether to proceed with production now rests with the manufacturer.⁴⁴

28. Different reasons for not deploying the test were subsequently heard by the International Development Committee (IDC). Giving evidence to the IDC, Dr Johnson speculated that the reason lay in wrangling and disagreements across the UK Government about funding.⁴⁵ This speculation was not confirmed by Justine Greening MP, Secretary of State for International Development, when she appeared before the IDC. Instead, she raised concerns about the accuracy of the test, and the potential for disruption to arise from re-training health care workers to use the new testing process.⁴⁶

- 38 Q110
- 39 Q110
- 40 Q110
- 41 Q116; Q162
- 42 Supplementary written evidence Public Health England (EME019); Supplementary written evidence from the Ministry of Defence (EME020)
- 43 Supplementary written evidence Public Health England (EME019)
- 44 HL Deb, 22 June 2015, HL288 [Lords written answer]
- 45 Oral evidence taken before the International Development Committee on 10 November 2015, HC (2015-16) 338, Q46 [Dr Johnson]
- 46 Oral evidence taken before the International Development Committee on 30 November 2015, HC (2015-16) 338, Q137 [Secretary of State]

³⁷ N F Walker et al, "Evaluation of a point-of-care blood test for identification of Ebola virus disease at Ebola holding units, western area, Sierra Leone, January to February 2015", Eurosurveillance, vol 20 (2015)

- 29. The rapid diagnostic antigen test is an example of the innovations that can be achieved in Government research and development facilities, working in conjunction with private partners and clinicians. The UK should be proud of the efforts made by all of those involved. We were therefore disappointed to learn that, despite the promise shown by the test, and the production of 10,000 test kits, it has not been operationalised. The different explanations advanced for not deploying the test suggest a worrying lack of co-ordination across the key Government departments and agencies that were at the forefront of delivering the UK's response to Ebola. Along with other evidence we received, we are concerned that this is indicative of more systemic co-ordination problems, and an accountability deficit, for key aspects of the UK Ebola response.
- 30. The Government must clarify, it its response to this report, why the rapid diagnostic antigen test was not released for use during the Ebola outbreak, distinguishing any technical, commercial and budgetary factors involved. We ask that the Government also sets out what steps it will take to ensure a joined-up, cross-departmental approach, with clear lines of accountability, to address future outbreaks.

Vaccine manufacturing capacity

- 31. Throughout our inquiry, we heard about the UK's strengths and expertise in emerging infectious disease research and treatment. Both Professor Chris Whitty of the London School of Hygiene and Tropical Medicine, and former Chief Scientific Advisor at DFID, and Dr Jeremy Farrar from the Wellcome Trust stressed that the UK is "world-leading" in vaccinology, that "the academic base for understanding immunology [...] is as strong in the UK as it is anywhere in the world" and that "our tropical epidemiology and tropical public health is among the best in the world, if not the best, in many diseases". Yet both witnesses, and others who gave evidence, highlighted that we lack the capacity to go further and manufacture vaccines. Professor Adrian Hill from the Jenner Institute described this capacity gap as a "national security issue" while Dr Farrar stated that "if something dreadful happened on a regional or global scale, getting vaccines from other countries would be incredibly difficult". The UK, he added, would "be on [its] own. That is a very worrying situation to be in". 49
- 32. The Chief Medical Officer, Dame Sally Davies, told us that the UK has some vaccine "manufacturing capability" but that "it is degraded and we are looking at how we can try and attract companies back [to the UK] to do some manufacturing". The Vaccine Research and Development Network, for example, is seeking to identify the vaccine "manufacturing [...] gaps". Professor Hill suggested that another way to tackle this problem was through establishing "investigational stockpiles"—storing tens of thousands, rather than millions, of doses of vaccines that have not been fully licenced, so that:

once there is an outbreak, not only do you have the opportunity to control it when it is tens of people, not thousands, but you also get a chance to test your vaccine and show that it is efficacious.⁵²

⁴⁷ Q96

⁴⁸ Q75

⁴⁹ Q92

^{50 0183}

⁵¹ Supplementary written evidence submitted by Jane Ellison MP, Parliamentary Under Secretary of State for Public Health (EME021)

⁵² Q55 [Professor Hill]

- 33. Professor Hill cautioned, however, that even small stockpiles cannot be created in the UK "in weeks" since "you need years to build manufacturing plant". ⁵³ Dame Sally disagreed with this approach, emphasising that "we do not stockpile vaccines" on the grounds that we would need to have the right vaccine for the right strain which, she told us, was "quite difficult". ⁵⁴ The Minister highlighted that while any stockpiling decision would need to be made in collaboration with the WHO, it does not currently consider there to be a strong national or international consensus on the effectiveness of investigational stockpiles. ⁵⁵
- 34. The lack of capacity to manufacture vaccines places the UK in a vulnerable position when the next epidemic strikes, whether for use overseas or at home. We urge the Government not simply to encourage private sector investment in vaccine manufacturing capacity, but to negotiate with vaccine manufacturers to establish preagreed access to capabilities that can be called upon quickly when the next epidemic emerges. In the longer-term, this may not be sufficient. We recommend that the Government commissions the UK Vaccine Research and Development Network to:
- a) identify the actions required to address the UK's deficiency in manufacturing capacity and;
- b) investigate the public health, economic and regulatory feasibility of establishing investigational stockpiles of vaccines that would be ready for Phase 2 trials during an outbreak.

⁵³ Q75

⁵⁴ Q182

⁵⁵ Supplementary written evidence submitted by Jane Ellison MP, Parliamentary Under Secretary of State for Public Health (EME021)

3 Responding to major disease outbreaks

Science advice

35. The main mechanism for channelling scientific advice to Government in an emergency is intended to be a Scientific Advisory Group for Emergencies (SAGE). According to the Government, a SAGE is responsible for "ensuring that timely and coordinated scientific advice is made available to decision makers to support UK cross-government decisions in COBR (Cabinet Office Briefing Room mechanism)". While a SAGE is usually chaired by the Government Chief Scientific Adviser (GCSA), each SAGE is emergency-specific and has a flexible structure. The Ebola SAGE was co-Chaired by the GCSA and the Chief Medical Officer. Its establishment marked the fifth occasion that a SAGE had been convened, yet witnesses expressed concerns about the slowness with which it was assembled, the make-up of its membership, and shortcomings in its interaction with existing scientific advisory committees.

Convening SAGE

- 36. According to the Government's 2011 Enhanced SAGE Guidance, a SAGE can only be activated by the Cabinet Office Briefing Room mechanism (COBR or 'Cobra') in support of collective cross-government responses to and/or recoveries from 'serious' or 'catastrophic' emergencies. ⁵⁷ Though COBR was convened in response to Ebola in July 2014, a SAGE was only convened three months later, in October 2014. ⁵⁸ Public Health England noted that, by this stage, "the outbreak in West Africa was out of control". ⁵⁹
- 37. In evidence given to our predecessor Committee in January 2015, the Government Office for Science stated that one of the lessons that the SAGE secretariat learnt following the winter flooding crisis in 2013/14 was "providing more challenge to the Government process on when and how to provide scientific advice during an incident". 60 Evidence from several witnesses to our current inquiry, however, raised questions about whether this lesson had been implemented in time for the Ebola outbreak. Professor Melissa Leach from the Institute of Development Studies and a member of the Ebola SAGE, spoke in positive terms about what the SAGE achieved, yet commented that:

because of the lateness of the response [the formation of the SAGE], this sciencepolicy interface had to operate in emergency mode in a context of extreme uncertainty. [...] An earlier response would have enabled more measured use of evidence, and more timely planning and response.⁶¹

⁵⁶ Scientific Advisory Group for Emergencies (SAGE), gov.uk. accessed 14 December 2015

⁵⁷ Cabinet Office, Enhanced SAGE Guidance. A strategic framework for the Scientific Advisory Group for Emergencies (SAGE), October 2012

⁵⁸ Department of Health (EME008) para 16

⁵⁹ Public Health England (EME012)

⁶⁰ Supplementary written evidence submitted by the Government Office for Science (LEG0019) [Science and Technology Committee, Ninth Report of Session 2014–15, Legacy—Parliament 2010–15, HC 758]

⁶¹ Institute of Development Studies (EME017) para 3

- 38. In a similar vein, the Wellcome Trust told us that "in the event of a future emergency, the mechanisms for triggering the establishment of expert groups and determining who is responsible for these should be activated more quickly".⁶² Sir Mark Walport, the Government Chief Scientific Adviser, conceded that one of "our learnings from this is that we probably would have established [SAGE] a bit earlier".⁶³ The Chief Medical Officer, Dame Sally Davies, however, was very defensive when questioned on this point, stating that she did "not think we needed to do it [establish SAGE] earlier, because the science advice was coming in and being acted on. [...] That is what matters".⁶⁴ She also questioned how setting up SAGE "a little earlier" could have been achieved in practice.⁶⁵
- 39. We agree with Sir Mark Walport that the Ebola Scientific Advisory Group for Emergencies (SAGE) should have been established earlier. Convening a SAGE, however, currently requires a request from COBR in the Cabinet Office. It is not clear how, and when, COBR makes an assessment of whether there is a need for a SAGE to assist its response. We recommend that the trigger for the formation of a SAGE should be a formal recommendation from the Government Chief Scientific Adviser. This would ensure a more robust, evidential basis for convening a SAGE.

Membership and co-ordination of SAGE

- 40. For unforeseen emergencies, the *Enhanced SAGE Guidance* is clear that the "SAGE secretariat will need to define SAGE membership".⁶⁶ Many of our witnesses emphasised that establishing the 'Ebola Anthropology and Social Science sub-Group of SAGE', and ensuring that the membership of SAGE included social scientists, were "extremely important in controlling [the] outbreak".⁶⁷ Professor Chris Whitty described social science as "important in almost every aspect of what we did" in West Africa.⁶⁸ This included understanding the "history of inequalities and economic policies that left people distrustful of foreigners and the state in many areas" as well as the "social routes", such as burial practices, through which Ebola was transmitted.⁶⁹
- 41. The importance of multidisciplinary research feeding into emergency responses was emphasised in Sir Paul Nurse's review of the UK Research Councils, *Ensuring a successful UK research endeavour*. To support research proposals aimed at addressing "cross-cutting societal needs, including grand challenges, and responses to emergency situations", Sir Paul recommended the establishment of a "common research fund" which, he proposed, would be administered by a new organisation called "Research UK": a partnership of the seven Research Councils.⁷⁰
- 42. While Professor Melissa Leach was "impressed by the breadth of expertise" included in the SAGE membership,⁷¹ others pointed to a lack of front-line clinicians represented on SAGE, particularly from "aid organisations providing emergency medical assistance in-

⁶² Wellcome Trust (EME015) para 12

⁶³ Q169

⁶⁴ Q170

^{65 0178}

⁶⁶ Cabinet Office, Enhanced SAGE Guidance. A strategic framework for the Scientific Advisory Group for Emergencies (SAGE), October 2012, para 37

⁶⁷ Q174 [Sir Mark Walport]. See also Q80, Qq132-133

⁶⁸ Q80 [Professor Whitty]

^{69 022}

⁷⁰ Paul Nurse, Ensuring a successful UK research endeavour. A Review of the UK Research Councils, November 2015, p28

⁷¹ Q22

country, such as MSF [Médicins sans Frontières]".⁷² In the absence of such representation, Dr Oliver Johnson from the King's Sierra Leone Partnership found that the transmission of scientific advice between the UK and Sierra Leone was problematic:

My impression is that there was some very thoughtful good science and scientific discussion taking place within the British Government. The challenge was that a lot more of it was happening here in London than out in the field, and sometimes the partners in the field were not aware of the discussions that were going on. ⁷³

- 43. Referring to the anthropology research work, Dr Johnson highlighted that there were "colleagues on the ground, some who were involved in [...] decision making, [who] did not know it existed". Professor Paul Cosford of Public Health England suggested that there was a "mismatch between what [Dr Johnson] was observing [...] and what the international community was doing in response". Dr Johnson suggested that "planning should be more local", adding that he believed treatment facilities in Sierra Leone "could have been up and running more quickly [...] if more of the planning had been done in Freetown rather than in the UK". To
- 44. Compounding these problems was a lack of clarity about how those with valuable expertise, but without a seat on SAGE, could communicate evidence to the Government. Professor Tom Solomon, the Director of the NIHR Health Protection Research Unit in Emerging and Zoonotic Infections,⁷⁷ complained that while his Unit had conducted research on Ebola, there was "no formal process for Government to request of us the research felt to be needed, and no formal mechanism for us to feed in the results of relevant research we had done".⁷⁸ The Microbiology Society reported that its members had similar experiences, noting that they "had limited knowledge of the Government processes for collating and processing expert advice" and that it was "unclear how they could proactively submit ideas or information for consideration".⁷⁹
- 45. The Chief Medical Officer told us that she was surprised by claims that experts did not know how to feed in to the scientific response. She stressed that she was "very clear publicly, in many places, that we wanted to hear all views and that they could come directly to me, my office or through [Sir] Mark [Walport]".80 The Government told us that it was examining how, through SAGE, it could "further rationalise processes" to ensure it gets "access to a range of opinion and advice in a health emergency".81
- 46. The Government should review its Enhanced SAGE Guidance to establish a clear mechanism for experts on the ground, in affected countries, to participate in a two-way exchange of information during a disease emergency originating overseas.

⁷² Welcome Trust (EME015), para 12; see also The Academy of Medical Sciences and The Royal Society (EME011)

⁷³ Q134

⁷⁴ Q134

⁷⁵ Q126

⁷⁶ Oliver Johnson, "A view from the frontline", Journal of the Foundation for Science and Technology, Vol 21 (2015) pp 10-12

⁷⁷ One of 13 such Research Units established in 2014 with £47.5m of funding from the Department of Health.

⁷⁸ National Institute for Health Research (NIHR) Health Protection Research Unit in Emerging and Zoonotic Infections (EME007), para 5

⁷⁹ Microbiology Society and the Society for Applied Microbiology (EME013), paras 16-17

^{80 0173}

⁸¹ Department of Health (EME008) para 42

47. If the Government sets up the new 'Research UK' body advocated by Sir Paul Nurse in his review of the research councils, it should include in its remit a responsibility to act as an evidence conduit between academia, industry and Government when a SAGE is established. This should provide a single point of entry for expert advice and evidence, beyond the SAGE membership, to feed into the Government's emergency response.

Scientific Advisory Groups

- 48. Well-established networks and relationships, developed over the course of many years, can be crucial to delivering an effective emergency response, as Dr Jeremy Farrar from the Wellcome Trust highlighted from his personal experiences.⁸² Reflecting on the importance of existing networks in responding to the Ebola outbreak, he advocated the establishment of a standing advisory body on emerging infectious diseases. This, he suggested, could meet regularly, "even in the absence of an epidemic", to ensure that the UK is ready to respond to the next disease outbreak.⁸³ When asked about the merits of this suggestion, the Chief Medical Officer told us that it was important "to be aware of what we already have".⁸⁴ She pointed to the current structure of "standing advisory committees which meet regularly, to make sure that the advice is updated and they scan what is out there".⁸⁵
- 49. Both the Chief Medical Officer and the Minister highlighted the work of the standing Advisory Committee on Dangerous Pathogens (ACDP), an arms-length body. During the Ebola outbreak, however, this particular scientific advisory committee did not appear to have been fully integrated into the SAGE process. The Code of Practice for Scientific Advisory Committees states that "SACs should consider having procedures for providing advice in a national emergency", while the Enhanced SAGE Guidance states that existing advisory groups should be utilised, though "SAGE should not seek to replace or duplicate" them. But when we asked how the Ebola SAGE interacted with the ACDP, and avoided duplicating its work, the ACDP's chair during the outbreak—Professor George Griffin—revealed that "there was no formal interaction between SAGE and the ACDP". 88
- 50. The CMO stated that there had since been discussions about how scientific advisory committees "fed in"⁸⁹ to the Ebola response. Public Health England was more explicit, stating that:

How the various advisory committees and other sources of scientific expertise link with SAGE, and also what their remits are in response mode, needs further consideration.⁹⁰

⁸² Q85 [Dr Farrar]

⁸³ Q85 [Dr Farrar]

⁸⁴ Q176 [Dame Sally Davies]

⁸⁵ Q176 [Dame Sally Davies]; a list of standing advisory committees can be found at: http://foiwiki.com/foiwiki/index. php/Scientific_advisory_committees

⁸⁶ Q176 [Dame Sally Davies]; Q198

⁸⁷ Government Office for Science, Code of Practice for Scientific Advisory Committees, 2011, para 143; Cabinet Office, Enhanced SAGE Guidance. A strategic framework for the Scientific Advisory Group for Emergencies (SAGE), October 2012, para 38

⁸⁸ Q27

⁸⁹ Q176 [Dame Sally Davies]

⁹⁰ Public Health England (EME012)

- 51. One of the strengths of the UK science advisory system is its depth and breadth, with over 70 standing scientific advisory committees and councils, tasked with helping Government departments interpret, understand and make judgements about scientific information. Exactly how these committees operate during an emergency situation, however, is currently covered by a single paragraph in the Code of Practice for Scientific Advisory Committees. Furthermore, despite the Enhanced SAGE Guidance encouraging such advisory committees to be utilised by a SAGE, there was no formal interaction between the Advisory Committee on Dangerous Pathogens and the SAGE during the Ebola outbreak. We are concerned that this may be indicative of a broader failure by the Government to access, and use, the range of high-quality scientific advice available to it.
- 52. To take full advantage of the work and knowledge of a scientific advisory committee during an emergency, we recommend that its chair is invited to sit on the SAGE as a full member. The Code of Practice for Scientific Advisory Committees should be expanded to provide guidance on the procedures that these bodies should put in place, so that they are in a position to provide advice rapidly in an emergency.

Research during an outbreak

- 53. During emergencies, it may be necessary to conduct further research to ensure an optimal response and learn lessons for the next time. The Wellcome Trust identified undertaking research "in the field", in "real-time" during an outbreak, as a critical means of trialling vaccines, treatments and diagnostics. Professor Trudie Lang of the University of Oxford agreed, noting that in the case of Ebola, where we "know little about how to manage patients [...] and have no proven therapies," it was vital that research "is embedded fully and from the outset into the response". Professor Trudie Lang of the University of Oxford agreed, noting that in the case of Ebola, where we "know little about how to manage patients [...] and have no proven therapies," it was vital that research "is embedded fully and from the outset into the response".
- 54. We heard, however, that the UK, and the international community more generally, had not been 'research ready' when the outbreak occurred. As Professor Lang explained, this lack of preparedness made a difficult situation even more challenging. Testing treatments on the ground, during an outbreak, was highlighted as particularly problematic because researchers:

did not know how long [the outbreak] was going to last, or how many patients would be available for the studies [...] This is why there have never been trials in an outbreak before, because you have a very narrow window within which to answer your question.⁹³

Reflecting on her experience, Professor Lang concluded that the "challenges [...] faced in the design, implementing and reporting of the Ebola drug trials were not scientific, but political and administrative". Limited research coordination and data sharing on the ground, as well as longer-term problems with drug and vaccine licensing, were particularly singled out by witnesses.

⁹¹ Wellcome Trust (EME015) para 26

⁹² Professor Trudie Lang (EME010)

⁹³ Qq60-61

⁹⁴ Professor Trudie Lang (EME010)

Research coordination

- 55. By the end of 2014, five research groups (including Professor Lang's) were ready to start trials for possible Ebola treatments. Speaking with the "huge benefit of hindsight", Professor Lang suggested that having "five different groups testing five different things" was "not an overly sensible approach" 95 since it resulted in an "absurd situation" whereby a disorganised and "unorchestrated throng of researchers" were each "negotiating for access to patients" on the ground.96 She stressed that "better co-ordination" was needed in the future, combined with a more obvious prioritisation of research studies.97
- 56. Other witnesses emphasised that in the absence of any clear prioritisation of research, important gaps in the knowledge base were not addressed. Professor Whitty stated that this included answering very basic research questions such as "how much fluid should you give people, and should you give them antibiotics?"98 Dr Johnson noted that while there was "a lot of focus on [...] novel therapeutic drugs",99 what health workers on the ground "really wanted to know was which was more effective: oral fluids versus intravenous fluids? These were the sorts of things that day to day we needed a simple study on to reach a conclusion".100
- 57. Professor Whitty acknowledged that loading an additional study onto UK and Sierra Leonean health workers was "probably not realistic" during the first few months of the outbreak. He reflected, however, that "once the outbreak had peaked [in December 2014] we could easily have done that and got big enough numbers to get a serious answer, and we did not". 101 Dr Johnson stressed the importance of better cross-country co-ordination, and communication, of the scientific response. He noted that "there was a challenge in translating some of the science going on internally to things in the field", adding that he was unsure, even afterwards, "who the co-ordinator of the scientific element of the response was". 102 To improve research prioritisation, co-ordination and communication in the future, the Wellcome Trust suggested that:

a mechanism needs to be identified which will enable the best people to undertake the appropriate research in an emergency situation, with appropriate coordination to ensure a joined up approach between research, public health and clinical expertise. 103

Data sharing

58. Co-ordination difficulties extended to data gathering and sharing. The Wellcome Trust had funded transmission modelling work, which was presented to the SAGE, but its robustness suffered from a "lack of real time data" and from a "lack of data sharing amongst groups". 104 Similarly, the Academy of Medical Sciences pointed to "several studies of the

^{95 060}

⁹⁶ Professor Trudie Lang (EME010), para 5

⁹⁹ Black's Medical Dictionary defines therapeutics as "the general name applied to different methods of treatment and healing".

¹⁰⁰ Q134

^{101 089}

¹⁰² Q134-Q135

¹⁰³ Wellcome Trust (EME015) para 9

¹⁰⁴ Wellcome Trust (EME015) para 13

epidemic (including some making use of virus genome sequences) that could potentially have informed the public health response," but which "took too long to complete due to delays in obtaining specimens and data sharing". 105

59. The Wellcome Trust emphasised that data disclosure should not be delayed by journal publication timelines, adding that research groups needed to recognise that "sharing to address an immediate humanitarian emergency should be paramount to maintaining data for academic outputs". Clarity regarding "who is responsible for directing and coordinating such research in an emergency" was also needed. The Academy of Medical Sciences recommended that the Government "work with partners to develop an appropriate system to collect and share real-time data to enable effective outbreak research modelling and clinical studies". The Academy of Medical Sciences recommended that the Government "work with partners to develop an appropriate system to collect and share real-time data to enable effective outbreak research modelling and clinical studies".

Clinical trials

60. Professor Piot, co-discoverer of the Ebola virus in 1976, stressed that the Ebola outbreak was the first time that trials for vaccines and treatments had taken place "in the midst of an epidemic". Witnesses attributed this to the exceptional nature of the situation and the unprecedented efforts made by a wide range of people to expedite trial approval processes. Under 'normal' circumstances, the Medical Research Council stated that it "can take as long as a year" to establish "an early trial of a vaccine candidate" and "get in place peer reviewed funding, ethics approval and volunteer recruitment". According to Dr Farrar, delays arise from "the bureaucratic challenge of securing multiple ethical approvals for trials, and putting contracts between institutions in place". Testing the safety of a candidate Ebola vaccine, however, was completed in record time during the outbreak. Professor Hill from the Jenner Institute told the Committee that:

An application was made to the regulator in London, the Medicines and Healthcare Products Regulatory Agency, who turned this around in four business days [...] four days is absolutely exceptional. The ethical committee met specially to review the application, and I think it made a decision that day. There was lots of work on formulating the vaccine, transporting it, relabelling it and so on, all of which happened in a few weeks, and we were able to start about a month after that telephone call, which is quite exceptional.¹¹¹

61. Trial approval processes were also expedited for candidate Ebola treatments. Professor Lang noted that while it "usually takes 18 months to set up a clinical trial", her team "managed to do it [for a potential Ebola treatment] within six weeks [...] but that was everybody pulling out all the stops and making it incredibly agile and streamlined". Professor Hill told the Committee that he "would like every trial that we do to take that short period of time" adding that there "may be a case for further investment so that trials happen faster". 113

¹⁰⁵ The Academy of Medical Sciences and The Royal Society (EME011) para 29

¹⁰⁶ Wellcome Trust (EME015) para 13

¹⁰⁷ The Academy of Medical Sciences and The Royal Society (EME011)

¹⁰⁸ Ebola response: The Lancet Audio 22 November 2015 (Peter Piot discusses new recommendations for health agencies and public health systems in response to the 2014-15 Ebola outbreak)

¹⁰⁹ Medical Research Council (EME014)

^{110 &}quot;Diseases spread in weeks. Epidemic research takes years. This must change", The Guardian, 10 June 2014

¹¹¹ Q63

¹¹² Q51

¹¹³ Q64

62. Some countries already have processes in place to facilitate faster regulatory reviews. Canada's Health Products and Food Branch, for example, has a "Priority Review Process" that allows for a faster review to make available "promising drug products for life-threatening or severely debilitating conditions [...] for which there are few effective therapies already on the market". 114 We are encouraged that the Government's Accelerated Access Review is considering many of these issues and look forward to receiving its final report later this year.

Regulation and licencing

- 63. The Ebola outbreak showed a readiness on the part of pharmaceutical companies to divert resources quickly towards developing treatments and vaccines. Dr Ripley Ballou of GSK stated, however, that the "small market" for such products was not the only, or the main, factor that had previously resulted in limited development, instead pointing to the "fact that there is not a clear path to licensure". 115 He explained that absence of a "clear path" mattered because "if you cannot license a vaccine, you cannot commercialise it". 116
- 64. The problem, as Dr Ballou saw it, was a mismatch between the type of clinical trial design that could be initiated and conducted during an outbreak, and the kind of evidence that regulators required to register vaccines or drugs as safe and effective. Recalling meetings with regulators during the outbreak, Dr Ballou reported how "the regulators pleaded that [randomised control] trials were the only way to know if these vaccines were going to work".117 He described a "tremendous resistance" to randomised control trials from stakeholders, with "very impassioned arguments coming from parts of the community who felt that any study that involved the use of a placebo or a control vaccine or drug was inherently unethical". 118 Professor Lang explained that, in other circumstances, researchers "would randomise and say 'you get the drug, but you will get something else'," but in the case of the Ebola outbreak:

you had very sick, frightened people, and there was no other treatment to give [...] Médicins sans Frontières and local ethics committees said, 'We cannot let you sit there and say that the mother gets the drug and the daughter doesn't'. 119

65. We heard how, during the outbreak, discussions between scientists and regulators about 'optimal' trial designs took place under very difficult circumstances. Dr Ballou recalled that:

The message was essentially: 'If it goes the way we are seeing, we are talking about the depopulation of West Africa by 2015'. It was incredibly sobering. [...] This scenario contributed to a sense of desperation which I believe impeded normal scientific debate, especially around study designs. 120

¹¹⁴ Health Canada, How Drugs are Reviewed in Canada, February 2015, accessed January 2016

¹¹⁵ Q52

¹¹⁶ Q52

¹¹⁷ Ripley Ballou, "Learning the lessons of the Ebola outbreak", Journal of the Foundation for Science and Technology, Vol 21 (2015) pp 8-9

¹¹⁸ Ibid; Q70

¹²⁰ Ripley Ballou, "Learning the lessons of the Ebola outbreak", Journal of the Foundation for Science and Technology, Vol 21 (2015) pp 8-9; Q70

Professor Lang added that "we need to be able to have that debate in a rational scientific way, which was not always the case" for Ebola. 121 There is, however, no clear process for approving a novel trial format (such as one without random control trials) or for providing indemnity against legal liability for producers and distributors of the vaccine or treatment. 122

- 66. The Chief Medical Officer noted that an additional SAGE 'Clinical trials subgroup' was established during the height of the outbreak "bringing in the MRC clinical trials group and industry partners, and [the US Centers for Disease Control] dialled in from the States, to look at trial methodologies". Longer-term, the Wellcome Trust recommended developing "standardised clinical trial protocols covering clinical trial design, data sharing protocols and ethical review for infectious disease outbreaks" in the inter-epidemic period. Such pre-agreed protocols would then be ready "for roll out in outbreaks", enabling research to be "initiated within days" during a future public health emergency. The UK Vaccine Research and Development Network is examining the scope for advance protocols for a range of diseases, though any protocols that might emerge from such work would require the agreement of international as well as UK regulatory authorities.
- 67. We recognise the enormous efforts made by governments, universities, regulatory bodies, humanitarian agencies, pharmaceutical companies and others to ensure that clinical trials for Ebola vaccines, treatments and diagnostics were launched in record time. But such efforts do not obscure the fact that the UK and other countries were not 'research ready' when the outbreak began, prompting a less than optimal and uncoordinated research response. The failure to conduct therapeutic trials earlier in the outbreak was a serious missed opportunity that will not only have cost lives in this epidemic but will impact our ability to respond to similar events in the future.
- 68. Research during an outbreak must be initiated rapidly, while still being designed and conducted to the highest possible standards. While we recognise the difficulties that arose in this outbreak, they are inherent to all epidemics; therefore, if we want to improve our response, we must address the weaknesses in our research readiness that this epidemic exposed. We recommend that the Chief Medical Officer urgently takes forward the work of the UK Vaccine Research and Development Network to negotiate new processes for embedding research into the emergency response. This should establish protocols for facilitating research that positively contributes to the emergency response, and should address the following questions:
- a) Where do the key gaps in our knowledge of emerging infectious diseases lie and what research questions or projects need to be prioritised before the next epidemic?
- b) What types of trial design can be readily used during an outbreak, and will be accepted by regulators as producing data that reliably demonstrates the efficacy of vaccines, treatments and diagnostics, thereby providing a pathway to licensing?

Health (EME021)

¹²¹ Q71

¹²² Ripley Ballou, "Learning the lessons of the Ebola outbreak", Journal of the Foundation for Science and Technology, Vol 21 (2015) pp 8-9

¹²³ Q176 [Dame Sally Davies]

¹²⁴ The Wellcome Trust (EME015) para 28

¹²⁵ The Wellcome Trust (EME015) para 27; The Academy of Medical Sciences and The Royal Society (EME011) para 28
126 Supplementary written evidence submitted by Jane Ellison MP, Parliamentary Under Secretary of State for Public

- c) What ethical and cultural issues need to be considered before going into the field? Discussions should include patient consent, the use of placebos, and equitable access to the outcomes of the research, such as new drugs or diagnostics. These matters will need to be revisited and adjusted at the start of an outbreak to take specific local circumstances into account.
- d) Who is best placed to coordinate the research effort, prioritise studies, and ensure that researchers are adhering to the agreed research plan during the outbreak?
- e) How can a mechanism be established that enables open data sharing in real-time during a disease emergency?
- 69. Through the Chief Medical Officer's membership of the World Health Organization Global Advisory Committee on Health Research, this work package should feed in to, and learn from, discussions taking place at the international level about research governance during an outbreak.

Communication

Giving advice to the public

- 70. Clear and balanced communication with the public is vital during an emergency. Public Health England described the Government's communications during the Ebola outbreak as having learned particularly from missteps in the US, where "excessive previous reassurance led to significant loss of public confidence in the national agencies when [Ebola] transmissions did occur". PHE thought that the UK message—delivered primarily by the Chief Medical Officer—that "a 'handful' of cases should be expected in the UK" was important in "setting realistic public expectations". Physical Physica
- 71. Witnesses were broadly in agreement with PHE's assessment and were mostly positive about the Government's public communications on the level of risk posed to the UK by the Ebola outbreak. The Academy of Medical Sciences was "pleased with the guidance and information provided by the Government", adding that risks were "communicated well" which, in turn, helped to avoid "creating unnecessary panic". The Microbiology Society thought the Government's public communications were "measured and appropriate, given the level of threat posed to the UK". The Wellcome Trust pointed to the "good" quality health information provided by the Government through NHS Choices, noting that it was "easy to understand" and that it appropriately rated "the risk of infection to the UK as low".
- 72. The UK media's reporting of the situation unfolding in West Africa was similarly judged by witnesses to have been balanced. According to the Science Media Centre, the overall "UK media coverage of the Ebola outbreak was accurate and evidence-based" which, they suggested, was assisted by Government departments playing "a key role in fielding media enquiries from journalists and informing them of developments". 132 Professor

¹²⁷ Public Health England (EME012)

¹²⁸ Public Health England (EME012)

¹²⁹ The Academy of Medical Sciences and The Royal Society (EME011) para 20

¹³⁰ Microbiology Society and the Society for Applied Microbiology (EME013) para 44

¹³¹ Wellcome Trust (EME015) para 15

¹³² Science Media Centre (EME009)

Whitty told us that the UK media "did a very good job on this occasion", particularly in comparison to other countries where, he suggested, "the media got seriously in the way of events by making hysterical claims about the risk to well-developed public health systems like the UK".133

Screening at ports of entry

73. Concern was repeatedly expressed, however, about the rationale behind, and the communication of, the introduction of Ebola screening at UK ports of entry. The UK's stance on implementing screening at airports changed over the course of three days during the height of the Ebola outbreak. On 7 October 2014, Public Health England issued a statement on the UK's position. It explained that while the World Health Organization (WHO) recommended that affected countries should conduct exit screening for individuals with "unexplained illness consistent with potential Ebola infection, [...] entry screening in the UK is not recommended by WHO". PHE added that:

There are no plans to introduce entry screening for Ebola in the UK. This would require the UK to screen every returning traveller, as people could return to the UK from an affected country through any port of entry. This would be huge numbers of low risk people.134

- 74. Two days later, the Prime Minister's Office issued a statement. It acknowledged that screening at airports in Liberia, Sierra Leone and Guinea had been in place for "some weeks to ensure all passengers leaving affected countries are checked". However, it explained that advice had been received from "the Chief Medical Officer today [...] that enhanced screening arrangements at the UK's main ports of entry for people travelling from the affected regions-Liberia, Sierra Leone and Guinea-will offer an additional level of protection to the UK". 135 These measures were initially rolled out at Gatwick and Heathrow airports, and at Eurostar terminals.
- 75. Many of our witnesses believed that the scientific evidence and rationale for introducing screening was missing. Professor George Griffin, former Chair of the Advisory Committee on Dangerous Pathogens, told us that "there was little clinical evidence that the screening involved, in terms of body temperature, would be either sensitive or helpful", describing it medically as "an incredibly blunt and insensitive tool". 136 This was echoed by Dr Jeremy Farrar from the Wellcome Trust who stated he did not think screening "was epidemiologically and scientifically justified". 137
- 76. Witnesses recognised, nevertheless, that the Government was subject to other pressures when making decisions about screening. Professor Griffin continued that "in terms of something that raised and kept up public awareness, [screening] was reasonable". 138 Taking into the account "the politics of the situation", Dr Johnson also thought screening "was proportionate", noting that the "organisation on the ground was polite, rapid and effective".139

¹³³ Q82

^{134 &}quot;Ebola surveillance and contingency planning ongoing in UK", Public Health England press release, 7 October 2014 135 "Ebola update: Chief Medical Officer advice on UK screening", Prime Minister's Office press release, 9 October 2014

¹³⁶ Q43

¹³⁷ Q103

¹³⁸ Q43

¹³⁹ Q156 [Dr Johnson]

77. PHE told us that the label 'screening' was partly responsible for the scientific debate around the effectiveness of the intervention. The label, it stated:

provided public reassurance but stimulated a scientific debate about the expectation that screening would prevent infected asymptomatic individuals entering the UK-which we knew it was unlikely to do. There are lessons to learn about communication to the scientific community alongside communication to the public so that all are clear on the purpose of such an intervention and its scientific basis. 140

- 78. Communication with the public is one of the most important aspects of any emergency or crisis situation. The Government provided good quality, accessible and accurate health information on Ebola, and provided balanced communications of the risk of the outbreak to the UK. It is disappointing, however, that it failed to explain clearly its rationale for going against guidance from both the World Health Organization and Public Health England by introducing entry screening for Ebola at UK ports.
- 79. When interventions are made during a future disease emergency that are intended to protect the UK, such as entry screening, we recommend that the evidential basis for—and purpose of—the intervention is made explicit. This information should be clearly communicated, especially if it goes against established guidance from trusted advisory bodies.

4 Governance of emergencies

International governance

- 80. Throughout the Ebola outbreak, there has been sustained criticism of the World Health Organization (WHO). Reviews of its performance have concluded that it was far too slow in responding to the outbreak and that lives were lost as a consequence. It was not until 8 August 2014, nearly six months after a major Ebola outbreak in Guinea was reported by the WHO, that it declared a 'public health emergency of international concern' (PHEIC) and began to mobilise a coordinated, international response to tackle the epidemic. There has since been further discussion of the WHO's responsibilities in global health governance and whether it should be more "operationally engaged". It Dr Ripley Ballou from GSK described how he contacted the WHO repeatedly in March, June and July 2014 about accelerating trials for an Ebola vaccine but was instead told that the WHO had "no policy that even contemplated the use of a vaccine in an Ebola outbreak".
- 81. The Report of the Ebola Interim Assessment Panel (the Stocking Report), the Harvard-LSHTM Independent Panel on the Global Response to Ebola, and numerous other reviews have each identified reforms to strengthen the WHO's leadership, restore its credibility, and help ensure that the international community can more effectively manage global disease outbreaks in the future. We were encouraged to hear from the Minister that she had spoken to both the Director-General of the WHO and the Chair of the WHO's Ebola Interim Assessment Panel about the need for WHO reform. 144 DFID and the Department of Health are, we were told, working with the WHO on a "blueprint for research and development for infectious diseases with epidemic potential", which could improve the WHO's capacity for managing future disease outbreaks. 145
- 82. Witnesses were careful not to lay blame solely at the WHO's door for weaknesses in the international response to Ebola. Though acknowledging that the WHO was "extraordinarily slow" in tackling the outbreak, Professor Chris Whitty suggested that it was dangerous to assume that this was "someone else's fault". He stressed that we "all have to accept that WHO is owned by all of us; it is the international community and, if there is a problem with it, it is our problem as much as anyone else's ". Professor Paul Cosford of Public Health England agreed adding that "the WHO is an organisation of member states, of which we are one, so we bear some joint responsibility" for failings in the way it responded. 148

¹⁴¹ World Health Organization, Final Report of the Ebola Interim Assessment Panel, July 2015 ("the Stocking Report");
Suerie Moon et al, "Will Ebola change the game? Ten essential reforms before the next pandemic. The report on the
Harvard-LSHTM Independent Panel on the Global Response to Ebola", The Lancet, volume 368, (2015), pp 2117-2226

¹⁴² Colin McInnes, "Changing authority in global health governance after Ebola", International Affairs, Vol 91 (2015), pp 1299-1316

¹⁴³ Qq53-54

¹⁴⁴ Qq191-192

¹⁴⁵ Supplementary written evidence submitted by Jane Ellison MP, Parliamentary Under Secretary of State for Public Health (EME021)

¹⁴⁶ Q80 [Professor Whitty]

¹⁴⁷ Q80 [Professor Whitty]

¹⁴⁸ Q128

- 83. Witnesses were clear, nevertheless, that the timing of the UK's overseas response was hindered by the WHO's delay in declaring a public health emergency. As Professor Tom Solomon of the University of Liverpool explained, "the response of individual countries, like ours, is limited if the WHO has not recognised [an outbreak] as an international emergency". The UK could not, as Professor Whitty described it, "just march in and say, 'You don't think you've got a problem but you have got a problem, and we are going to sort it out". For Professor Solomon, one of the key challenges for the future was "how to get greater international recognition so that individual countries can embark on a response". 151
- 84. We recommend that the Government supports the reforms proposed in the Stocking Report and the Harvard-LSHTM Independent Panel, as well as the WHO 'Blueprint' initiative, to ensure that the World Health Organization is fit for purpose and equipped to deliver international leadership when the next major disease emergency strikes.

National governance

The National Risk Register

- 85. Under the Civil Contingencies Act 2004, the Government has a duty "to assess, plan and advise" for emergencies. One way in which the Government exercises this duty is through its National Risk Assessment (NRA) process; a comprehensive, classified appraisal of the most significant emergencies (malicious and non-malicious) that people in the United Kingdom could face over the next five years. This information is then used to shape its plan for, and response to, such threats.
- 86. Since 2008, a National Risk Register (NRR), an unclassified version of the NRA, has been published to assist individuals, communities and local commercial organisations in their planning. Though the broad category of 'emerging infectious diseases' has featured on the NRR since it was first published in 2008, Ebola was not specifically referred to until the 2015 edition.¹⁵³ We questioned whether such a broad category was appropriate, particularly since the UK failed to anticipate the extent and severity of the Ebola outbreak in West Africa. The Academy of Medical Sciences suggested that it might "be useful to have a more detailed technical appraisal of the risks posed by specific potential emerging infectious diseases".¹⁵⁴ Professor Adrian Hill from the Jenner Institute thought it would not "be difficult to get consensus about what the top five or 10 target diseases should be. [...] That is not the difficult bit; you can get a committee to do that".¹⁵⁵
- 87. The Chief Medical Officer and the Minister both disagreed with this approach. When asked about fleshing out the 'emerging infectious disease' category with the "top 10 risks" and designing "protocols for each of those", the Minister replied that she was "a little worried" it could lead to "complacency":

¹⁴⁹ Q16 [Professor Solomon]

¹⁵⁰ Q80 [Professor Whitty]

¹⁵¹ Q16 [Professor Solomon]

¹⁵² Civil Contingencies Act 2004, section 2

¹⁵³ Cabinet Office, National Risk Register of Civil Emergencies 2015 edition, March 2015

¹⁵⁴ The Academy of Medical Sciences and The Royal Society (EME011) para 12

¹⁵⁵ Q57 [Professor Hill]

I would be a bit nervous about something as pinned down as a top 10, because if we had a plan for those we would be tempted to take our eye off surveillance and horizon scanning.¹⁵⁶

When pressed to identify ways to strengthen the detail on emerging infectious diseases in the NRR, Dame Sally stated that considering the "transmission" mechanism was key: "Is it respiratory, blood-borne, vector-borne or food-borne?" She told us that:

we try to have, and we do have, protocols in place for those groupings that we can fine-tune if something comes: "There we are, Ebola blood-borne." We have had cases of Lassa fever and Crimean Congo haemorrhagic fever before, but the basic protocols are there for different things. 158

The CMO's transmission 'groupings' do not appear in the 2015 edition of the NRR.

- 88. We appreciate the Chief Medical Officer's reassurance that protocols are in place to respond to different types of disease emergencies, according to their transmission mechanism. However, the groupings she described do not feature in the 2015 edition of the National Risk Register: Instead, the broad category of 'emerging infectious diseases' is used. This is the same broad category which has been in place since 2008, yet it did not prepare our research, science advice or political response systems for a public health crisis on the scale or time-frame of the Ebola outbreak. We are not convinced that this wide-ranging category is sufficiently detailed to enable responders without clearance to view the National Risk Assessment to prepare adequately for the next disease outbreak. Furthermore, given the far reaching lessons learnt from the Ebola outbreak, it seems extraordinary that the Government does not appear to accept the case for refining its emerging infectious disease risk assessment and protocols.
- 89. In its response to this report, we ask the Government to set out with which responders it shares its respiratory, blood-borne, vector-borne and food-borne emergency response protocols. These groupings should be used to structure the 'human diseases' section of the next edition of the National Risk Register.

UK global health policy

- 90. In an era of ever increasing globalisation, the health of UK citizens is inextricably linked to events taking place hundreds, sometimes thousands, of miles away. There is a growing recognition that while action can be taken in the UK to protect its citizens from outbreaks in other countries, it may need to be matched by the deployment of its skilled personnel and resources overseas to contain major disease outbreaks at source.
- 91. Public Health England (PHE) confirmed that its "bread and butter work" was "controlling outbreaks in the UK" and acknowledged that it was not as well equipped to respond overseas. 159 It was unclear how strong its mandate from Government was, prior to the Ebola outbreak, to establish an international epidemic response capability, and the extent to which this would become a key function of the organisation. The cross-Government Health is Global Plan 2011-15 and PHE's Global Health Strategy 2014-19

both support the principle that diseases do not respect national borders. Yet the Epidemic Diseases Research Group of the University of Oxford reported that "operationalization" of this concept had "been limited". 160 We were repeatedly told, for example, that some of the UK's interventions overseas during the Ebola outbreak were ad-hoc.161 As a result, it appears that they were not necessarily as effective, or as targeted, as they could have been.

92. Dr Oliver Johnson from the King's Sierra Leone Partnership commented that "at times there were not senior public health officials as part of the leadership team in Freetown [in Sierra Leone] who could help to understand what was happening. A colleague out there described the British response as a bit deaf and blind as a result". 162 The lack of British epidemiologists in Sierra Leone was particularly singled out:

From my perspective, there was not the same epidemiological footprint from Public Health England on the ground [...] To compare it with the US Centres for Disease Control, they had perhaps 70 people on the ground; at every meeting I went to, a senior public health specialist from the US would be present informing US decision making. 163

Professor Paul Cosford from PHE recognised that "myriad CDC personnel [were] present all across the world", but added that this level of "capacity is not the sort of numbers we have".164 In the case of epidemiologists, he clarified that PHE had "one person" in Sierra Leone "leading our epidemiology and other work at the moment; we have had people plugged into some of the district emergency response centres, but it has been ad hoc". 165

93. Dr Johnson maintained that a decision needed to be taken by the Government as to whether the UK needs a domestic capacity that can be deployed overseas or whether, as a country, we are content to rely on the WHO and US Centres for Disease Control. 166 The Minister suggested that a more international outlook to disease control was being contemplated:

One of the big lessons we learned within the Government and as a nation is that our best protection at home is helping to fight disease abroad. Thinking of it like that was quite a turning point for the nation [...] We will look back on that as the moment we really understood that our world is so interconnected that our best defence at home is by making sure we invest in and support work abroad effectively.167

94. The Chief Medical Officer also pointed to a proposal for establishing a 'rapid response force' which would be on permanent standby, ready to deploy to countries with disease outbreaks. Professor Cosford told us that the proposal was a "key part" 168 of PHE strengthening its international public health functions and would be "good for the UK reputationally", while helping "to protect our own health as well". 169 The Head of the Civil

¹⁶⁰ Epidemic Disease Research Group, University of Oxford (EME016) para 3.6

¹⁶¹ Qq137-137, Qq173-174

¹⁶² Q142

¹⁶³ Q134

¹⁶⁴ Q138

¹⁶⁵ O136

¹⁶⁶ O144

¹⁶⁷ Q186 [Minister]

¹⁶⁸ Q140

¹⁶⁹ Q137

Contingencies Secretariat, Campbell McCafferty, told us that the "rapid response team [was] about identifying that we did not have capability that could deploy quickly and looking to fill that gap as we move forward". The also highlighted additional provisions announced in the *National Security Strategy and Strategic Defence and Security Review 2015*. The Review stressed that the UK has learned lessons from major incidents overseas, including Ebola, and promised the publication of "a national bio-security strategy in 2016". This, it stated, would address the "threat of natural disease outbreaks, as well as the less likely threat of biological materials being used in a deliberate attack".

- 95. The Government's 'Health is Global' plan states that the Government will "protect the health of the UK proactively by tackling health challenges that begin outside our borders". It is not clear, however, what would prompt the UK to intervene overseas, or what level of capability and capacity the UK should be able to deploy in such situations.
- 96. We recommend that the forthcoming National Bio-security Strategy sets out what would trigger an in-theatre response by the UK to a disease outbreak overseas. In addition, the Strategy should make clear what level of capability and capacity the UK should be readily able to deploy overseas in the event of a disease epidemic or pandemic. This should include details of the roles and responsibilities of relevant Government departments and how they would deploy sufficient resources.

UK volunteer response

- 97. In addition to Public Health England staff being deployed overseas, we also heard about the NHS staff, including GPs, nurses, clinicians, psychiatrists and consultants in emergency medicine, who volunteered to assist in Sierra Leone during the height of the Ebola outbreak. By November 2014, over "1000 NHS staff and 185 staff from Public Health England [had] put their names forward" to volunteer. Our evidence, however, suggests that the call from the Government for volunteers came late and was poorly communicated. The Pirbright Institute stated that the request was "not well publicised or co-ordinated" which, in turn, "resulted in difficulty in the rapid recruitment of appropriately skilled scientists for deployment". He Microbiology Society agreed that "the initial call for volunteers from the wider microbiology community could have been made earlier and advertised more widely". The Society went on to recount some of the difficulties faced by volunteers both in negotiating a period of absence from their 'day job' as well as reacclimatising on their return. It thought that a much clearer framework for volunteering in future disease emergencies was needed.
- 98. We can only admire the courageous and selfless actions of UK volunteers, and their West African counterparts, throughout the Ebola outbreak. However, some employers lacked the capacity to release their staff or to manage their return. Some individuals were left on their own to negotiate a leave of absence from full-time clinical roles and research to assist in West Africa. We are concerned that the ad hoc nature of these

¹⁷⁰ Q186 [Campbell McCafferty]

¹⁷¹ HM Government, National Security Strategy and Strategic Defence and Security Review 2015. A Secure and Prosperous United Kingdom, Cm 9161, November 2015, para 4.131

¹⁷² ibid

¹⁷³ Ebola: Written question - 212924, answered on 10 November 2014

¹⁷⁴ The Pirbright Institute (EME002) para 5.iii

¹⁷⁵ The Microbiology Society and the Society for Applied Microbiology (EME013) para 22

arrangements made our clinical response more fragile than it needed to be. This is a structural weakness that should be addressed.

99. In some situations, Public Health England's capacity may need to be augmented by volunteers drawn from across the NHS, public sector, universities and beyond. We recommend that a clear framework facilitating the timely deployment of volunteers overseas, in response to an epidemic, is agreed and put in place now, ready for use in the future. We encourage the Government to consider the model used by NHS Trusts when employing staff with Reserve Forces commitments who may be subject to short notice mobilisation in conflict zones.

Conclusions and recommendations

Increasing the UK's preparedness for major disease outbreaks

- 1. The rapid transmission of disease surveillance data to those with the ability to interpret and act upon it is a vital component of disease control. In its absence, we have seen, in the case of Ebola, how quickly an outbreak can spread and the devastation it can cause. The lines of reporting of surveillance data must, therefore, be clear and well-understood by those involved to ensure a co-ordinated and timely escalation. We are not convinced that the systems in place for interpreting, sharing and escalating disease surveillance data across the Government operated effectively during the early stages of the Ebola outbreak. (Paragraph 15)
- We recommend that the Government sets out, in its response to this report, how surveillance data is escalated, both within Public Health England and across Government, and identify the triggers that would prompt warnings to reach ministers and senior officials with the capacity to act. We also ask for an update on the Chief Medical Officer's work with the World Health Organization to develop systems to share disease data. (Paragraph 16)
- 3. Part of the suffering seen throughout the Ebola outbreak resulted from a long-term market failure to invest in interventions for rare, but potentially catastrophic, disease epidemics. Through a combination of public and private investment, the UK now has the opportunity to capitalise on its world-class strengths in the field of tropical medicine, and reverse decades of underfunding in vaccine, treatment and diagnostic R&D in emerging infectious diseases. We welcome the Government's recent announcements of much needed research funds in this area. (Paragraph 22)
- 4. To maximise the effectiveness of these funds, we recommend that the Government works with leading experts to publish an 'emerging infectious disease strategy'. This should set out a long-term plan identifying the 'priority threats' the UK wishes to address, how much funding will be directed to each threat, as well as how action will be delivered and outcomes evaluated. The strategy should outline how coordination across funding streams will be achieved, so that there is no unnecessary duplication of research. Open knowledge and data sharing should be set as default conditions for those receiving public funds. (Paragraph 23)
- 5. The rapid diagnostic antigen test is an example of the innovations that can be achieved in Government research and development facilities, working in conjunction with private partners and clinicians. The UK should be proud of the efforts made by all of those involved. We were therefore disappointed to learn that, despite the promise shown by the test, and the production of 10,000 test kits, it has not been operationalised. The different explanations advanced for not deploying the test suggest a worrying lack of co-ordination across the key Government departments and agencies that were at the forefront of delivering the UK's response to Ebola. Along with other evidence we received, we are concerned that this is indicative of more systemic co-ordination problems, and an accountability deficit, for key aspects of the UK Ebola response. (Paragraph 29)

- 6. The Government must clarify, it its response to this report, why the rapid diagnostic antigen test was not released for use during the Ebola outbreak, distinguishing any technical, commercial and budgetary factors involved. We ask that the Government also sets out what steps it will take to ensure a joined-up, cross-departmental approach, with clear lines of accountability, to address future outbreaks. (Paragraph 30)
- 7. The lack of capacity to manufacture vaccines places the UK in a vulnerable position when the next epidemic strikes, whether for use overseas or at home. We urge the Government not simply to encourage private sector investment in vaccine manufacturing capacity, but to negotiate with vaccine manufacturers to establish preagreed access to capabilities that can be called upon quickly when the next epidemic emerges. In the longer-term, this may not be sufficient. We recommend that the Government commissions the UK Vaccine Research and Development Network to:
 - a) identify the actions required to address the UK's deficiency in manufacturing capacity and;
 - b) investigate the public health, economic and regulatory feasibility of establishing investigational stockpiles of vaccines that would be ready for Phase 2 trials during an outbreak. (Paragraph 34)

Responding to major disease outbreaks

- 8. We agree with Sir Mark Walport that the Ebola Scientific Advisory Group for Emergencies (SAGE) should have been established earlier. Convening a SAGE, however, currently requires a request from COBR in the Cabinet Office. It is not clear how, and when, COBR makes an assessment of whether there is a need for a SAGE to assist its response. We recommend that the trigger for the formation of a SAGE should be a formal recommendation from the Government Chief Scientific Adviser. This would ensure a more robust, evidential basis for convening a SAGE. (Paragraph 39)
- 9. The Government should review its Enhanced SAGE Guidance to establish a clear mechanism for experts on the ground, in affected countries, to participate in a two-way exchange of information during a disease emergency originating overseas. (Paragraph 46)
- 10. If the Government sets up the new 'Research UK' body advocated by Sir Paul Nurse in his review of the research councils, it should include in its remit a responsibility to act as an evidence conduit between academia, industry and Government when a SAGE is established. This should provide a single point of entry for expert advice and evidence, beyond the SAGE membership, to feed into the Government's emergency response. (Paragraph 47)

- 11. One of the strengths of the UK science advisory system is its depth and breadth, with over 70 standing scientific advisory committees and councils, tasked with helping Government departments interpret, understand and make judgements about scientific information. Exactly how these committees operate during an emergency situation, however, is currently covered by a single paragraph in the Code of Practice for Scientific Advisory Committees. Furthermore, despite the Enhanced SAGE Guidance encouraging such advisory committees to be utilised by a SAGE, there was no formal interaction between the Advisory Committee on Dangerous Pathogens and the SAGE during the Ebola outbreak. We are concerned that this may be indicative of a broader failure by the Government to access, and use, the range of high-quality scientific advice available to it. (Paragraph 51)
- 12. To take full advantage of the work and knowledge of a scientific advisory committee during an emergency, we recommend that its chair is invited to sit on the SAGE as a full member. The Code of Practice for Scientific Advisory Committees should be expanded to provide guidance on the procedures that these bodies should put in place, so that they are in a position to provide advice rapidly in an emergency. (Paragraph 52)
- 13. We recognise the enormous efforts made by governments, universities, regulatory bodies, humanitarian agencies, pharmaceutical companies and others to ensure that clinical trials for Ebola vaccines, treatments and diagnostics were launched in record time. But such efforts do not obscure the fact that the UK and other countries were not 'research ready' when the outbreak began, prompting a less than optimal and uncoordinated research response. The failure to conduct therapeutic trials earlier in the outbreak was a serious missed opportunity that will not only have cost lives in this epidemic but will impact our ability to respond to similar events in the future. (Paragraph 67)
- 14. Research during an outbreak must be initiated rapidly, while still being designed and conducted to the highest possible standards. While we recognise the difficulties that arose in this outbreak, they are inherent to all epidemics; therefore, if we want to improve our response, we must address the weaknesses in our research readiness that this epidemic exposed. We recommend that the Chief Medical Officer urgently takes forward the work of the UK Vaccine Research and Development Network to negotiate new processes for embedding research into the emergency response. This should establish protocols for facilitating research that positively contributes to the emergency response, and should address the following questions:
 - a) Where do the key gaps in our knowledge of emerging infectious diseases lie and what research questions or projects need to be prioritised before the next epidemic?
 - b) What types of trial design can be readily used during an outbreak, and will be accepted by regulators as producing data that reliably demonstrates the efficacy of vaccines, treatments and diagnostics, thereby providing a pathway to licensing?
 - c) What ethical and cultural issues need to be considered before going into the field? Discussions should include patient consent, the use of placebos, and equitable access to the outcomes of the research, such as new drugs or diagnostics. These

- matters will need to be revisited and adjusted at the start of an outbreak to take specific local circumstances into account.
- d) Who is best placed to coordinate the research effort, prioritise studies, and ensure that researchers are adhering to the agreed research plan during the outbreak?
- e) How can a mechanism be established that enables open data sharing in real-time during a disease emergency? (Paragraph 68)
- 15. Through the Chief Medical Officer's membership of the World Health Organization Global Advisory Committee on Health Research, this work package should feed in to, and learn from, discussions taking place at the international level about research governance during an outbreak. (Paragraph 69)
- 16. Communication with the public is one of the most important aspects of any emergency or crisis situation. The Government provided good quality, accessible and accurate health information on Ebola, and provided balanced communications of the risk of the outbreak to the UK. It is disappointing, however, that it failed to explain clearly its rationale for going against guidance from both the World Health Organization and Public Health England by introducing entry screening for Ebola at UK ports. (Paragraph 78)
- 17. When interventions are made during a future disease emergency that are intended to protect the UK, such as entry screening, we recommend that the evidential basis for—and purpose of—the intervention is made explicit. This information should be clearly communicated, especially if it goes against established guidance from trusted advisory bodies. (Paragraph 79)

Governance of emergencies

- 18. We recommend that the Government supports the reforms proposed in the Stocking Report and the Harvard-LSHTM Independent Panel, as well as the WHO 'Blueprint' initiative, to ensure that the World Health Organization is fit for purpose and equipped to deliver international leadership when the next major disease emergency strikes. (Paragraph 84)
- 19. We appreciate the Chief Medical Officer's reassurance that protocols are in place to respond to different types of disease emergencies, according to their transmission mechanism. However, the groupings she described do not feature in the 2015 edition of the National Risk Register: Instead, the broad category of 'emerging infectious diseases' is used. This is the same broad category which has been in place since 2008, yet it did not prepare our research, science advice or political response systems for a public health crisis on the scale or time-frame of the Ebola outbreak. We are not convinced that this wide-ranging category is sufficiently detailed to enable responders without clearance to view the National Risk Assessment to prepare adequately for the next disease outbreak. Furthermore, given the far reaching lessons learnt from the Ebola outbreak, it seems extraordinary that the Government does not appear to accept the case for refining its emerging infectious disease risk assessment and protocols. (Paragraph 88)

- 20. In its response to this report, we ask the Government to set out with which responders it shares its respiratory, blood-borne, vector-borne and food-borne emergency response protocols. These groupings should be used to structure the 'human diseases' section of the next edition of the National Risk Register. (Paragraph 89)
- 21. The Government's 'Health is Global' plan states that the Government will "protect the health of the UK proactively by tackling health challenges that begin outside our borders". It is not clear, however, what would prompt the UK to intervene overseas, or what level of capability and capacity the UK should be able to deploy in such situations. (Paragraph 95)
- 22. We recommend that the forthcoming National Bio-security Strategy sets out what would trigger an in-theatre response by the UK to a disease outbreak overseas. In addition, the Strategy should make clear what level of capability and capacity the UK should be readily able to deploy overseas in the event of a disease epidemic or pandemic. This should include details of the roles and responsibilities of relevant Government departments and how they would deploy sufficient resources. (Paragraph 96)
- 23. We can only admire the courageous and selfless actions of UK volunteers, and their West African counterparts, throughout the Ebola outbreak. However, some employers lacked the capacity to release their staff or to manage their return. Some individuals were left on their own to negotiate a leave of absence from full-time clinical roles and research to assist in West Africa. We are concerned that the ad hoc nature of these arrangements made our clinical response more fragile than it needed to be. This is a structural weakness that should be addressed. (Paragraph 98)
- 24. In some situations, Public Health England's capacity may need to be augmented by volunteers drawn from across the NHS, public sector, universities and beyond. We recommend that a clear framework facilitating the timely deployment of volunteers overseas, in response to an epidemic, is agreed and put in place now, ready for use in the future. We encourage the Government to consider the model used by NHS Trusts when employing staff with Reserve Forces commitments who may be subject to short notice mobilisation in conflict zones. (Paragraph 99)

Annex

Committee seminar, University of Oxford

On Thursday 19 November 2015, the Bodleian Library, in collaboration with the Department of Politics and International Relations at the University of Oxford, hosted a one day event for Oxfordshire Sixth Formers to learn more about parliamentary representation and the work of select committees. It formed part of 'Parliament Week', a programme of events and activities that connect people across the UK with Parliament and democracy.

Members of the Committee joined the seminar in the Divinity School of the Bodleian Library, with four Oxford academics discussing the UK's response to, and their experience of, the Ebola outbreak. The sixth formers present were also able to ask questions.

Members present:

- Nicola Blackwood MP, Chair
- · Chris Green MP
- Carol Monaghan MP
- Derek Thomas MP
- Valerie Vaz MP

The panel comprised:

- Dr Laura Merson, Head of Data Sharing Initiatives, Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine, University of Oxford
- Dr Amanda Rojek, Field Project Manager, RAPIDE TKM Ebola Trial and DPhil candidate, Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine, University of Oxford
- Professor Sarah Gilbert, Group Head and Professor of Vaccinology, The Jenner Institute
- Dr Tom Rawlinson, Clinical Research Fellow, The Jenner Institute.

The topics covered during the discussion included:

Ebola vaccine and drug trials

The panel outlined how the Ebola vaccine and drug efficacy trials were conducted on the ground in West Africa and discussed some of the practical challenges that they faced. These included coping with running a trial in a very hot region while wearing protective clothing, as well as difficulties with getting patients to come forward for treatment during the early stages of the trial. It was suggested that this reluctance was linked to a suspicion of local medical staff, and Western agencies, combined with a cultural preference for keeping and treating unwell family members at home.

Funding for trials

Essential funding for the Ebola response in West Africa came from the Wellcome Trust, the Medical Research Council and DFID, with the Ministry of Defence providing logistical support, including transport, medical care, infrastructure and storage. Medical staff also volunteered from the NHS. Panellists noted that there was not a huge incentive for pharmaceutical companies to invest in drugs and vaccines for Ebola, and similar diseases, and that this problem needed to be addressed through alternative funding mechanisms. As a result, licensing processes had to be fast-tracked during the Ebola outbreak with sufficient trialling to establish their patient safety, to establish the immune response for given intended dosages, and their efficacy.

Co-ordination of trials and volunteers

Coordination of multiple trials taking place in West Africa was described as ad hoc and informal, with an overall lack of high-level oversight. There was a suggestion that while some trials were prioritised by the World Health Organization, researchers went away and 'did their own thing', taking patients from prioritised trials without any repercussions.

Data collection and results

Systems for data collection on Ebola cases were set up in theatre, with NGOs and local government departments. While the treatment field trials had good monitoring data, the response plans for tackling new outbreaks were described as less well-developed. Since the treatment regimes varied between the trials, panellists also described how it was difficult to produce hard conclusions about the efficacy of particular treatments and interventions. Monitoring patients and providing follow up was also highlighted as difficult.

Trial protocols

Looking to the future, panellists were clear that treatment protocols needed to be agreed in advance, so that they were ready to use before the next disease outbreak, and that this required phase 1 trials to be undertaken too. It was suggested that 'ring vaccination' could provide a good model for future trials during disease outbreaks. There had been discussion during the outbreak about the ethics of particular trial designs and the use of placebos. Trial protocols included a commitment to ensuring the local population had access to the results. Many NGOs and agencies were therefore content to use new drugs in trials during the outbreak on the basis that they were very inexpensive (or free) and would continue to be so. Ethical questions may have been raised if the drugs involved were expensive for local people.

Following the scientific method

Since there were very few clinicians with knowledge of Ebola before the outbreak began, when scientists differed in their opinions about optimal treatments and interventions the solution was to adhere, as much as possible, to well-founded scientific principles for producing and interpreting evidence. It was also stressed that they undertook a lot of public engagement with the local population.

Global health

Ebola was described as a global health problem that required a global response, our understanding of which suffered from a historic neglect of tropical diseases. For future disease outbreaks, it was suggested that all those involved needed to recognise that the cost of preventative measures, including vaccines, would be cheaper (both in financial terms as well as the human cost) than responding once an outbreak occurs. However, there appears to be a continuing lack of international interest in preventing some tropical diseases.

Formal Minutes

Wednesday 13 January 2016

Members present:

Nicola Blackwood, in the Chair

Chris Green

Graham Stringer

Dr Tania Mathias

Derek Thomas

Carol Monaghan

Matt Warman

Draft Report (Science in emergencies: UK lessons from Ebola), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 99 read and agreed to.

Annex and Summary agreed to.

Resolved, That the Report be the Second Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

[Adjourned till Tuesday 19 January at 3.30 pm

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the Committee's inquiry page at www.parliament.uk/science.

Tuesday 20 October 2015	Question number
Professor Tom Solomon, Director, National Institute for Health Research, Health Protection Research Unit in Emerging and Zoonotic Infections, University of Liverpool, Professor Melissa Leach, Director, Institute of Development Studies, University of Sussex, and Professor George Griffin, former Chair, Scientific Advisory Committee on Dangerous Pathogens	Q1-49
Dr Ripley Ballou, Vice President and Head, GSK Vaccines Research and Development Centre, Rockville, Maryland, Professor Adrian Hill, Director, T Jenner Institute, University of Oxford, and Professor Trudie Lang, Head, The Global Health Network, University of Oxford	
Dr Jeremy Farrar , Director, Wellcome Trust, and Professor Chris Whitty , Professor of Public and International Health, London School of Hygiene and Tropical Medicine	d Q79-106

Tuesday 24 November 2015

Dr Edward Sykes, Senior Press Manager, Science Media Centre, Professor Paul Cosford, Director for Health Protection and Medical Director, Public Health England, Lily Makurah, Ebola Screening and Returning Workers Scheme Programme Manager, Public Health England, and Dr Oliver Johnson OBE, Programme Director, King's Sierra Leone Partnership	Q107-160
Professor Sir Mark Walport, Government Chief Scientific Adviser, Government Office for Science, Professor Dame Sally Davies, Chief Medical Officer, Department of Health, and Brigadier Timothy Hodgetts, Medical Director, Defence Medical Services	Q161-184
Jane Ellison MP, Parliamentary Under-Secretary of State for Public Health, Department of Health, Professor Dame Sally Davies, Chief Medical Officer, Department of Health, and Campbell McCafferty, Director of Civil Contingencies Secretariat, Cabinet Office	Q185-201

Published written evidence

The following written evidence was received and can be viewed on the Committee's inquiry web page at www.parliament.uk/science. EME numbers are generated by the evidence processing system and so may not be complete.

- 1 Academy of Medical Sciences and The Royal Society (EME011)
- 2 Academy of Social Sciences (EME006)
- 3 British Society for Immunology (EME004)
- 4 Epidemic Diseases Research Group at the University of Oxford (EME016)
- 5 Department of Health (EME021)
- 6 HMG Department of Health (EME008)
- 7 Institute of Development Studies (EME017)
- 8 Medical Research Council (EME014)
- 9 Microbiology Society and the Society for Applied Microbiology (EME013)
- 10 MicroPharm Limited (EME003)
- 11 Ministry of Defence (EME020)
- 12 NIHR Health Protection Research Unit in Emerging and Zoonotic Infections (EME07)
- 13 Pirbright Institute (EME002)
- 14 Professor Adrian Hill, The Jenner Institute, University of Oxford (EME018)
- 15 Professor John McCauley (EME005)
- 16 Professor Trudie Lang (EME010)
- 17 Public Health England (EME012, EME019)
- 18 Science Media Centre (EME09)
- 19 University of Worcester (EME001)
- 20 Wellcome Trust (EME015)

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the Committee's website at www. parliament.uk/science.

Session 2015-16

First Special Report	Royal Botanic Gardens, Kew: Government Response to the Committee's Seventh Report of Session 2014–15	HC 454
Second Special Report	Current and future uses of biometric data and technologies: Government Response to the Committee's Sixth Report of Session 2014–15	HC 455
Third Special Report	Advanced genetic techniques for crop improvement: regulation, risk and precaution: Government Response to the Committee's Fifth Report of Session 2014–15	HC 519
First Report	The science budget	HC 340







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