



HOUSE OF LORDS

Science and Technology Committee

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3rd Report of Session 2008–09

# **Pandemic Influenza: Follow-up**

Report with Evidence

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### *Contacts for the Science and Technology Committee*

All correspondence should be addressed to:  
The Clerk of the Science and Technology Committee  
Committee Office  
House of Lords  
London  
SW1A 0PW

The telephone number for general enquiries is 020 7219 6075.  
The Committee's email address is [hlscience@parliament.uk](mailto:hlscience@parliament.uk).

## CONTENTS

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	<i>Paragraph</i>	<i>Page</i>
<b>Chapter 1: Introduction</b>	1	5
Background	3	5
Original purpose of the inquiry	3	5
Swine flu outbreak	7	6
Shift in focus of the inquiry	9	6
Acknowledgements	12	7
<b>Chapter 2: Some Principal Issues</b>	15	8
Preparation for the current pandemic	15	8
Longer-term planning	18	9
The National Pandemic Flu Service	22	10
Critical care and surge capacity	30	11
Advice to high-risk groups	37	12
A national reference point	37	12
“Flu parties”	38	13
Other outstanding issues	39	13
Next steps	41	14
<b>Appendix 1: Members and Declared Interests</b>		15
<b>Appendix 2: List of Witnesses</b>		17
<b>Appendix 3: Summary of Seminar</b>		18
<b>Appendix 4: Recent Reports</b>		32
<b>Oral Evidence</b>		
<i>Department of Health, Cabinet Office, Department for Food and Rural Affairs, Department for International Development</i>		
Written evidence from Department of Health		1
Oral evidence, 25 November 2008		12
Supplementary written evidence from Department of Health		27
<i>Department of Health, Cabinet Office</i>		
Oral evidence, 17 March 2009		48
Supplementary written evidence from Department of Health		62
Second supplementary evidence from the Rt Hon Alan Johnson MP, Secretary of State for Health, Department of Health		73
<i>Department of Health</i>		
Oral evidence, 2 July 2009		79
Supplementary written evidence from Department of Health		94
<b>Written Evidence</b>		
Royal College of General Practitioners		99
Royal College of Physicians		101

NOTE: References in the text of the Report are as follows:  
(Q) refers to a question in oral evidence  
(p) refers to a page of written evidence.



# Pandemic Influenza: Follow-up

## CHAPTER 1: INTRODUCTION

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1. Follow-up inquiries, whether undertaken soon after publication of a report or after a more substantial period of time has elapsed, are a significant part of the scrutiny activity of the Science and Technology Committee. Given the current outbreak of swine flu, the decision of the Committee last session to undertake a short follow-up inquiry into pandemic influenza is an example of the importance of such activity.
2. This is a short report based principally on evidence submitted by the Government but also informed by an expert seminar (see paragraph 5 below). Given the rapidity at which the swine flu pandemic is developing, we took the view that it would be helpful to publish the evidence we have received to date, with a commentary setting out some key issues, without further delay. We acknowledge that in doing so, given current circumstances, we run the risk of at least some of our comments being overtaken by events. We believe however that our observations, and the questions we raise, will be of value either immediately or in the future when, in due course, the Government evaluates their response to the swine flu pandemic.

### Background

#### *Original purpose of the inquiry*

3. The original purpose of the inquiry was to revisit issues raised in our earlier report entitled *Pandemic Influenza* (4th Report (2007–08) (HL Paper 88)) published in December 2005. It was clear to us that UK preparedness and pandemic influenza was of enduring interest to the House and that the House would welcome a further report. We did not know at that time that the interest and concern of the House and also the wider public would increase markedly as a result of the outbreak earlier this year of swine flu.
4. Our intention had been to conduct the follow-up inquiry by way of a single evidence session with the then Minister for Public Health, Dawn Primarolo MP, and her officials. That evidence session took place on 25 November 2008. Both the written evidence submitted by the Department of Health (DoH) before and after the oral evidence session (pp 1–12 and 27–47) and the transcript of oral evidence are printed with this report (pp 12–27).
5. Whilst we acknowledge the thoroughness of the answers of the Minister and her officials, their evidence left us with a number of serious questions about the state of UK preparedness. We therefore decided to extend our inquiry further, and on 4 February 2009 we held a seminar in which we heard presentations from a range of experts in the field. The topics covered included current pandemic influenza issues, pandemic warning signs, containment and mitigation of a pandemic, development of a cross-protective vaccine and intensive care provision in the event of a pandemic. A summary of the seminar is set out in Appendix 3 to this report.
6. We then invited the DoH to attend the Committee again in order to answer further questions including those arising from the seminar. Officials attended

on 17 March. Unfortunately the Minister was unable to come on that occasion due to ill health. The officials' oral evidence (pp 48–62) and further written evidence are also printed with this report (pp 62–72).

### *Swine flu outbreak*

7. Whereas we had initially been focusing our attention on the spread of the avian flu virus H5N1 as one of the most likely causes of the next pandemic,<sup>1</sup> we now find ourselves in the midst of a H1N1 pandemic. On 18 March, a novel influenza A virus subtype H1N1 was identified, transmissible between pigs and humans and from human to human. The outbreak began in Mexico. By 24 April, the United States Centres for Disease Control confirmed that samples from Mexico contained the same virus as cases in the United States. On 27 April, the UK Government reported that cases had been confirmed in the United States, Canada and Spain, with suspected cases in New Zealand, France, the United Kingdom and Israel.<sup>2</sup>
8. As a result of the global spread of the disease, on 11 June, the World Health Organisation (WHO) moved to Phase 6 (“pandemic period”) of its classification of six phases towards a pandemic, Phase 6 being characterised by sustained community-level transmission of the virus taking place in more than one region of the world.<sup>3</sup> This is the first influenza pandemic for more than 40 years.<sup>4</sup>

### *Shift in focus of the inquiry*

9. Following the swine flu outbreak, we shifted the focus of our attention to UK preparedness in terms of the Government's response to the emerging pandemic and subsequent events. The swine flu outbreak is a “real time” test of UK preparedness. As the recently-appointed Minister for Public Health, Gillian Merron MP, commented, the Government are no longer in a “theoretical situation”—they are “very much living it day to day” (Q 104). In a letter to the then Secretary of State for Health, Alan Johnson MP, dated 14 May, we set out some of our concerns about the Government's response to the turn of events. Mr Johnson replied on 28 May (pp 73–78).
10. On 2 July, Ms Merron came before us. Her evidence is set out in this report (pp 79–93), along with further written evidence dated 10 July (pp 94–99). On the same day, the Government made a statement in which the seriousness of the current pandemic was made clear: “Scientists now expect to see rapid rises in the number of cases. Cases are doubling every week and we could see more than 100,000 cases per day by the end of August”. As a result, the Government announced a new approach to the pandemic, moving from “containment” (involving, for example, contact tracing and prophylaxis, and laboratory confirmation of diagnoses) to “mitigation” or “the treatment phase” (involving, for example, clinical diagnoses and the establishment of antiviral collection points).

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<sup>1</sup> See Professor Nigel Lightfoot's contribution to the seminar (Appendix 3 to this report) and our 2005 report referenced in paragraph 3 of this report.

<sup>2</sup> HL Deb, 27 April 2009, col 37.

<sup>3</sup> <http://www.who.int/influenza/AH1N1>

<sup>4</sup> HC Deb, 12 June 2009, col 1052.

11. The total number of cases of swine flu is increasing each day. According to the European Centre for Disease Prevention and Control, by 15 July, 125,993 laboratory confirmed cases of H1N1 had been reported globally with 667 deaths.<sup>5</sup> In the UK, there have been 10,649 confirmed cases as of 15 July<sup>6</sup>—but we recognise that it is likely that there will have been many more cases which will have gone unreported. According to the Health Protection Agency, commenting for the week ending 12 July, “GP consultation rates for flu-like illness continue to increase in England. This rate (73.4 per 100,000) is now above the peak (68.5 per 100,000) reached in winter season 08/09”.<sup>7</sup> At present, in the UK, the virus “is generally mild in most people” (Q 104). There have been some deaths—as of 16 July, 28.<sup>8</sup> Of the small number of cases in the UK where the virus has been more severe or fatal, many of the patients have had “underlying health conditions” (Q 104), although some deaths have been reported in otherwise healthy people.

### *Acknowledgements*

12. The membership of the Committee and the interests of Committee members are set out in Appendix 1 to this report.
13. The circumstances of this short inquiry are exceptional. What began as a simple follow-up inquiry has taken on a more significant relevance. Because we had not intended to undertake a full-scale inquiry, we did not issue a Call for Evidence and expected to take evidence from the Government only. As the focus of the inquiry shifted we sought the views of the Royal College of Physicians and the Royal College of General Practitioners (pp 99–102). We would like to thank all those who submitted written and oral evidence, often to short deadlines. They are listed in Appendix 2. We would also like to thank those who made presentations at our informal seminar and for their clear exposition of the issues surrounding pandemic influenza. Their names are identified in Appendix 3.
14. Our Specialist Adviser for this inquiry is Sandra Mounier-Jack, Lecturer in Health Policy at the London School of Hygiene and Tropical Medicine. We are enormously grateful for her assistance.

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<sup>5</sup> [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1247728935374](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1247728935374)

<sup>6</sup> Ibid.

<sup>7</sup> [http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb\\_C/1247728933406?p=1231252394302](http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1247728933406?p=1231252394302)

<sup>8</sup> [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1247728935374](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1247728935374)

## CHAPTER 2: SOME PRINCIPAL ISSUES

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### Preparation for the current pandemic

15. When the WHO raised its pandemic alert status to Phase 6, the Secretary of State for Health, Andy Burnham MP, said that the declaration did not “of itself, trigger any material change on our domestic preparations”. They had, he explained, “been under way for several weeks” and were “at an advanced stage”.<sup>9</sup> We know from the evidence we received prior to the outbreak of swine flu that there has been a significant amount of work undertaken to ensure UK pandemic preparedness. According to Ms Merron, the WHO recognised the UK “as one of the best-prepared countries in the world” (Q 104). Professor Lindsey Davies, National Director of Pandemic Influenza Preparedness at the DoH, told us that “No other country in the world has done more than we have to ensure that we protect the population and that we minimise the pandemic’s impact”—other countries are now coming to the United Kingdom for advice (Q 50).
16. **We commend these steps that the Government has taken to prepare for the pandemic.** These include entering into advance purchase agreements which will enable the UK to purchase up to 132 million doses of pandemic-specific vaccine “sufficient for everybody in the UK when it becomes available” (Q 104),<sup>10</sup> stockpiling antivirals to enable treatment of 50 per cent of the population (the Government’s ‘worst case scenario’)<sup>11</sup> (p 67) and ensuring that there are sufficient antiviral collection points to cover the population in each Primary Care Trust (QQ 129, 155). We also note the comments of the Royal College of Physicians that the DoH “has done an excellent job of preparing for the anticipated outbreak” of influenza in the autumn (p 102) and of the Royal College of General Practitioners (RCGP) that it has formed “an excellent working relationship with the recently appointed Government ‘flu tzar’, Ian Dalton, who has been using RCGP members’ feedback on the situation to inform his discussions with Strategic Health Authority Leads in England” (p 99).
17. In making this report, our intention is not to contribute to public disquiet but rather to assist debate within the House and within the public at large. We acknowledge that it is too early to reflect on lessons learnt from the current outbreak. The evidence suggests that we are in the relatively early stages and that it is likely to become more widespread, potentially affecting a large proportion of the population. Our intention is to highlight some of the issues that have come to our attention during the course of gathering evidence. Because of the pace of events, we have chosen to focus on only a small number of issues. In doing so, we in no way intend to diminish the importance of other issues (identified in paragraph 40) about which we make no comment at this stage.

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<sup>9</sup> HC Deb, 12 June 2009, col 1052.

<sup>10</sup> See also Baroness Thornton, HL Deb, 2 July 2009, col 357: “We expect the first batches of vaccines to arrive in August, and around 60 million batches will arrive by the end of the year”.

<sup>11</sup> See footnote 14 below.

### Longer-term planning

18. By chance we have been able to take evidence on UK preparedness both before and after the start of the current outbreak. This has provided an exceptional insight into Government pandemic planning. With regard to the “pre-outbreak” evidence, we were struck by the number of activities which were only starting up or were still in train in March of this year, three years after our original report. The National Pandemic Flu Service is one very significant example (see paragraphs 22–29 below). Further examples taken from the evidence we received in March include:
  - testing communications within the NHS. Professor Davies told us that: “One of the next steps that we are currently planning is a proper exercise, a process of communication with NHS staff to make sure that they genuinely do understand everything that needs to be in place and how to do it ... So we have developed a number of educational programmes already, but we are building on those over the next year ...” (Q 76);
  - when asked about whole (or “end-to-end”) systems testing, we were advised that this was something which Janet Meacham, Deputy Director for Pandemic Influenza at the DoH, was “currently exploring” (Q 75) (see paragraph 20 below);
  - development of guidance in the event of a pandemic to assist specialists caring for drug addicts. In March, Professor Davies described this work as “already starting” (Q 94); and
  - development of adult and paediatric assessment tools to assist decisions on whether to refer to secondary care. The paediatric assessment tool, which was further advanced than the adult assessment tool, was expected to be available “this summer” (Q 92).
19. It perhaps comes as no surprise therefore that the Government’s longer-term planning for a pandemic has had to be diverted in order to meet the more immediate demands of the swine flu pandemic. For example, Ms Merron was asked about a self-assessment process across the NHS whereby all primary care trusts (PCTs) and other NHS organisations were asked to submit self-assessments of their pandemic preparedness plans. A review of the results had been expected in April (Q 51). In the event, the report of the review has not been published because, Ms Merron said, “we are in the middle of a pandemic ... so events have overtaken us” (QQ 124, 126). In place of the review, the Government has instituted a programme of testing, the results of which would “basically ... replace the audit” (Q 124).
20. We note that the Government plans to undertake a type of whole-system test, “hopefully” in September, the purpose of which would be “to push the system hard on the usual contingency planning basis of preparing for the worst and seeing how the various bits of the system, primary care, ambulances, hospitals and mental health services, actually interact in practice” (Q 129). **The Committee has long recognised the importance of advanced whole-systems (end-to-end) testing and welcomes the Government’s plan. We would however invite the Government to explain why it was not undertaken sooner.**
21. **Whilst we understand the need to divert attention to the immediate challenges of the current pandemic, we are disappointed that the assessment and testing processes and other activities connected with**

**UK pandemic preparedness were not sufficiently well-advanced so as to mitigate this need more significantly.**

**The National Pandemic Flu Service (formerly “the Flu Line”)**

22. Central to the Government’s policy for tackling a pandemic is the National Pandemic Flu Service, a telephone and web-based helpline service the purpose of which is to “ease the burden on frontline healthcare services” (p 9). It is intended “to supplement and protect existing primary care arrangements by taking much of the burden of initial assessment, triage and antiviral authorisation away from frontline healthcare services” (p 31).
23. In November 2008 we were told that the system was “being delivered and tested in early 2009”, a timetable which would have to be reviewed in the event of an increase in likelihood of a pandemic (p 9). However, on 27 April 2009, Lord Darzi, Parliamentary Under-Secretary of State at the DoH, announced that the Flu Line would be “up and running in autumn of this year”.<sup>12</sup> On 2 July, when we asked for further explanation for this delay, Ms Merron said that there were two reasons: first, “its development was ... put on hold because [the Government] felt it was important to get [an] interim solution up and running because we knew that could be done quicker” and, secondly, the service “was such a new approach that we would have been remiss not to have tested it sufficiently” to make sure it worked and also that it was value for money—it therefore needed the approval of both the DoH and the Treasury (Q 143).
24. In a paper submitted by the DoH on 10 July, following the 2 July evidence session, the proposed “scaled down” (p 95), “interim” Flu Service (to be distinguished from the “enhanced” Flu Service) is described further (p 94). The interim service, “if it is mobilised, will provide a flu assessment and where appropriate, authorise antiviral treatment to symptomatic individuals” (p 94). According to Ms Merron, it could be up and running in “about a week” (Q 143) and training of staff to use the Flu service algorithm would take about four hours for each trainee (Q 143).
25. It is anticipated that the Flu Service will have about 7,500 call centre seats. The evidence about the total call capacity of the centres is not entirely clear. The Government, in their written evidence, told us that this would be 45,000 per hour (p 34); in oral evidence Bruce Taylor, Deputy Director for Pandemic Influenza at the DoH, said that “at any one time we would be expecting at least 20,000 people to be able to access ... [the] Flu Line” (Q 98).
26. **The Committee has significant concerns about the delay in the operation of what the Department of Health describes as the enhanced National Pandemic Flu Service (NPFs) and invites the Government to provide a more detailed explanation of the reason. We also seek reassurance that the enhanced service will be able to meet anticipated demand and that it will be fully operational in the autumn, in good time to meet the challenges of the anticipated second wave of influenza.**
27. Meanwhile we note the Department of Health’s further explanation about the interim solution. We also note that, according to the DoH paper of 10

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<sup>12</sup> HL Deb, 29 April 2009, col 219.

July, with the onset of the mitigation (or treatment) phase, Flu Response Centres (FRCs) will be “slowly phased out” (p 97), their resources directed elsewhere and their work shifted to NHS staff (p 99). (The paper describes the purpose of the FRCs in terms of “taking on much of the frontline response work initially undertaken by the Health Protection Agency’s 26 Health Protection Units” and sets out in detail the work of the FRCs (p 98)).

28. **On 16 July, the Secretary of State for Health announced that the National Pandemic Flu Service in England would be activated from the end of the following week. We welcome this announcement. However, bearing in mind the Government’s assertion that “at [WHO] Phase 6 [announced on 11 June] the National Pandemic Flu Line Service will come into operation” (p 34) and given the move to the mitigation (or treatment) phase and the phasing out of the Flu Response Centres in early July, we would invite the Government to explain why mobilisation of (what we assume to be) the interim service was delayed.**
29. **We invite the Government also to provide further clarification about the design, scope and terms of reference of the interim service, and about whether the Flu Line Service, interim or enhanced, is separate from NHS Direct, a service which is already familiar to the public, or supplementary to it. If separate, we invite the Government to set out the cost-benefit analysis underpinning that decision.**

### Critical care and surge capacity

30. A presentation was given to us by Dr Bruce Taylor, Consultant in Intensive Care Medicine,<sup>13</sup> at our seminar in February in which he expressed with some force his concern about provision for critical care in the event of a pandemic and also about the ethical guidance given to healthcare workers to assist them when presented with difficult choices arising from scarcity of intensive care unit resources. In his letter of 28 May, the Secretary of State confirmed that various strategies would be introduced to increase intensive care capacity in the event of a pandemic (for example, suspending elective procedures which require post-operation intensive care capacity), and Ms Merron identified the use of agency staff and re-training staff as further means of increasing critical care capacity (Q 128). As to the extent of the potential increase in critical care capacity, the DoH is awaiting the results of the whole-system “stress tests”, to take place in September, but according to Ian Dalton, National Director of NHS Flu Resilience at the DoH, it is possible that we would see a “doubling” of critical care facilities “under a severe attack phase” (Q 131).
31. None the less, Mr Johnson acknowledged that “at the peak of a ‘reasonable worst-case scenario’<sup>14</sup> pandemic intensive care capacity may well be inadequate even after these measures have been adopted” (p 76). Professor Davies made a similar point: “There will be huge pressures on intensive care in a pandemic ... It would never be possible to provide unlimited intensive care facilities, ... that is not practical” (Q 87).

<sup>13</sup> For the avoidance of doubt, Dr Taylor mentioned here and Mr Taylor mentioned in paragraph 25 above are not the same person.

<sup>14</sup> The reasonable ‘worse case scenario’ of how many people could be expected to require treatment is, according to the DoH, 50 per cent of the population (p 36).

32. Mr Johnson indicated that the DoH was aware of the consequent ethical implications of patient prioritisation during a pandemic and stated that guidance to staff had been issued along with clinical assessment tools specifically for an influenza pandemic. Ms Meacham thought that clinicians would look to each other for support “so they are assured that they are making the right decisions within an ethical framework ...” (Q 88).
33. Dr Taylor, when speaking to us in February, thought that the ethical framework was unsuited to times of disaster and argued that healthcare workers should be given formal assurance that they would not face professional criticism or litigation.<sup>15</sup> Mr Johnson would not go as far as supporting universal indemnity but offered what he described as the reassurance that the “extraordinary pressure” which staff would be facing during a pandemic “would be taken into account in any subsequent legal action” (p 77). We are concerned about how this would be done.
34. **A pandemic could place extraordinary pressure on critical care capacity. We invite the Department of Health to provide more detailed information about the current basis on which critical care contingency arrangements for a pandemic have been made and, in due course, to explain any changes in the Department’s assessment following the whole-system “stress tests” in September or following lessons learnt from actual experience. We would, in particular, welcome more detailed information about how it would be possible to “double” critical care facilities.**
35. At our seminar on 4 February, we received evidence that, in the United States, in a pandemic situation, healthcare workers might opt not to volunteer for tasks outside their usual professional competence, and that if they were asked to do this, some would refuse to come to work at all. Partly this was for fear of litigation, but mainly, it appeared, because they were reluctant to undertake tasks for which they felt they were neither trained nor qualified.
36. **We invite the Department of Health to say whether they are aware of this risk and, if so, what steps they are taking to avoid this happening in the UK. We also ask whether the Department is satisfied that clinicians feel confident about the effectiveness of, support from, and clarity for decision-making provided by the current legal and ethical clinical framework.**

### **Advice to high-risk groups**

#### *A national reference point*

37. There are a number of high-risk groups for whom contracting swine flu would be potentially more serious than for those who are not in high-risk groups. They include pregnant women and people with chronic lung, kidney or heart disease. It is particularly important that there is clear advice available to these groups so that appropriate action can be taken and their anxieties allayed. We acknowledge that advice is available from, for example, the Internet. We believe however that it would assist general practitioners in becoming better and more easily informed if a central source of up to date

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<sup>15</sup> See Appendix 3.

advice were available. **We recommend that the Government should put in place a national reference point, for use by general practitioners, from which they can request advice on the treatment of high-risk groups. We would expect that advice to be based on knowledge gained from activity within the UK and also from knowledge acquired by treatment centres abroad.**

### *“Flu parties”*

38. Media coverage of the current pandemic has included reference to “flu parties” whereby parents send their children to gatherings with the intention of them contracting a mild form of the H1N1 virus in the hope that they will develop immunity to a possibly more virulent form in the autumn. We asked Ms Merron about the Government’s advice on “flu parties”. She said:

“the Chief Medical Officer ... gave a very clear line on swine flu parties, which was that ‘we would never recommend intentional exposure of anyone to swine flu’, and he goes on to describe swine flu parties as ‘seriously flawed thinking’, ‘the fact that we do not know enough about the risk profile’, ‘the fact is that in some parts of the world young, but previously healthy, adults have died’ and ‘parents’, and I think this is a strong point, ‘parents would never forgive themselves if they exposed a vulnerable child to serious illness’ ...” (Q 137).

**We welcome the advice of the Chief Medical Officer against “flu parties” and support the Government in maintaining their efforts to ensure that this message is communicated effectively.**

### **Other outstanding issues**

39. We do not underestimate the complexity of the issues and the organisational challenges associated with a pandemic attack, not least because of the uncertainty about the numbers likely to be affected by the current outbreak (whether as a result of infection or as a result of consequential action such as school closure) and about the severity of the continuous spread of the disease and a possible second wave.
40. A number of issues emerged during this short inquiry which relate to more general pandemic influenza preparedness and which we have not been able to address thoroughly but are important to note for the purposes of future assessment of UK preparedness in present circumstances. They include:
- the operational aspects of ensuring a fair and sensible distribution of antivirals and the implications of a shift to a targeted antivirals approach;
  - the need for a consistent and clear strategy on how and to whom antivirals should be distributed;
  - the importance of a robust communications strategy so that the public at large are aware of the pandemic and of what to do (both to prevent infection or in the event of infection) but, at the same time, are not unduly alarmed;
  - the vital importance of streamlined and consistent communication to frontline healthcare workers on clinical guidelines and organisational arrangements;

- frontline support mechanisms, including the steps that should be taken to identify frontline healthcare workers and whether they should be given a course of antivirals in advance, so that they could start to take them at the first sign of infection;
- the need to prepare for the uncertainty of antiviral resistance, including decisions about stockpiling a strategic reserve antiviral and the implications of a prophylaxis strategy on the development of resistance (pp 67 and 71); and
- provision for the prompt development of a pandemic-specific vaccine, factoring in time for the appropriate clinical trials to take place to ensure its safety and effectiveness and, once proven, decisions about its fair and sensible distribution, including decisions over the upper and lower age limits, given the risk from infection in infants and children.

### Next steps

41. We anticipate that when the current pandemic has finished, the Government and other organisations, both international and domestic, will be considering in detail issues—including those listed above—that have emerged during the course of the pre-pandemic, the pandemic and its aftermath, and will carry out a thorough review of how well their preparedness plans worked in practice. As part of its scrutiny activity, the Committee will also return to this subject at an appropriate time.

## APPENDIX 1: MEMBERS AND DECLARED INTERESTS

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### Members:

- Lord Broers
- Lord Colwyn
- Lord Crickhowell
- Lord Cunningham of Felling
- † Baroness Finlay of Llandaff (co-opted)
- Lord Haskel
- † Lord Jenkin of Roding (co-opted)
- Lord Krebs
- Lord May of Oxford
- Lord Methuen
- Baroness Neuberger
- Earl of Northesk
- Lord O'Neill of Clackmannan
- Earl of Selborne
- Lord Sutherland of Houndwood (Chairman)
- Lord Warner
- † Baroness Whitaker (co-opted)
- † Co-opted Members

### Specialist Adviser:

Sandra Mounier-Jack, Lecturer in Health Policy, Department of Public Health and Policy, Communicable Diseases Policy Group, London School of Hygiene and Tropical Medicine

### Declared Interests:

- Lord Broers
- Lord Colwyn  
*None*
- Lord Crickhowell  
*None*
- Lord Cunningham of Felling  
*None*
- Baroness Finlay of Llandaff  
*Consultant Physician*
- Lord Haskel  
*None*
- Lord Jenkin of Roding  
*President Parliamentary and Scientific Committee*
- Lord Krebs  
*Employee of Jesus College Oxford*  
*Member of staff at Department of Zoology, Oxford*
- Lord May of Oxford  
*None*
- Lord Methuen

Baroness Neuberger

*Hon Fellow, Royal College of General Practitioners*

*Hon Fellow, Royal College of Physicians*

*Hon Fellow, Faculty of Public Health Medicine*

*Former Chief Executive, the King's Fund*

Earl of Northesk

Lord O'Neill of Clackmannan

Earl of Selborne

*None*

Lord Sutherland of Houndwood

*None*

Lord Warner

*None*

Baroness Whitaker

*One World Trust (examines accountability of IHOs) Vice President*

*UNICEF UK Trustee*

*Overseas Development Institute Director and Trustee*

*UNA-UK Advisory Panel Member*

A full list of Members' interests can be found in the Register of Lords Interests:  
<http://www.publications.parliament.uk/pa/ld/ldreg.htm>

## **APPENDIX 2: LIST OF WITNESSES**

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The following witnesses gave evidence; those marked with \* gave oral evidence:

Cabinet Office

\* Dr Becky Kirby, Head of Human Health, Civil Contingencies Secretariat

Department for Environment, Food and Rural Affairs

\* Mr Richard Drummond, Deputy Director, Food and Farming Group

Department of Health

\* Mr Ian Dalton, National Director for NHS Flu Resilience

\* Professor Lindsey Davies CBE, FRCP, FFPH, National Director of Pandemic Influenza Preparedness

\* Professor Sir Gordon Duff, Chairman, Scientific Pandemic Influenza Advisory Committee

\* Rt Hon Alan Johnson MP, Secretary of State for Health

\* Ms Janet Meacham CBE, Deputy Director for Pandemic Influenza

\* Ms Gillian Merron MP, Minister of State for Public Health

\* Rt Hon Dawn Primarolo MP, Minister of State for Public Health

\* Mr Bruce Taylor, Deputy Director for Pandemic Influenza

Department for International Development

\* Mr John Worley, Acting Head of Profession—Health

Royal College of General Practitioners

Royal College of Physicians

## APPENDIX 3: SUMMARY OF SEMINAR

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### 4 February 2009

Members of the Select Committee present were Lord Broers, Lord Colwyn, Lord Crickhowell, Baroness Finlay of Llandaff, Lord Jenkin of Roding, Lord May of Oxford, Lord Methuen and Lord Sutherland of Houndwood.

Participants were Dr Nimalan Arinaminpathy (Postdoctoral research fellow (James Martin 21st Century School), Department of Zoology, Oxford), Professor Neil Ferguson (Professor of Mathematical Biology (Director, MRC Centre for Outbreak Analysis and Modelling, Imperial College, London), Imperial College), Professor Nigel Lightfoot (Chief Adviser to the CEO and Head of Influenza Programme, Health Protection Agency), Dr Bruce Taylor (Consultant in Intensive Care Medicine, Portsmouth Hospitals NHS Trust), Professor Alain Townsend (Professor of Molecular Immunology, Oxford) and Professor Jonathan Van Tam (Professor Health Protection, University of Nottingham).

### Overview of the current pandemic influenza issues in the United Kingdom (Professor Nigel Lightfoot)

Professor Lightfoot explained that the Health Protection Agency (HPA) was responsible for providing advice and guidance to Government, professionals and the public about pandemic influenza. Diagnosis, recognition, surveillance and monitoring cases were important aspects of its function, alongside helping the NHS.

The Government's pandemic influenza planning was based on a maximum 50 per cent clinical attack rate (CAR)—higher than other countries—giving rise to 750,000 excess deaths. It was anticipated that there would be a marked difference between the rate of increase in the number of cases locally and nationally, with the number of cases locally rising sharply at an early stage compared to national figures.

In terms of the World Health Organisation (WHO) classification of the six phases towards a pandemic, the UK was currently at Phase 3: the pre-pandemic phase. There had been 404 cases of human H5N1 infection reported to the WHO, with 254 deaths. Most had occurred in south east Asia. There had been no H5N1 avian outbreaks in Europe since May 2008 although some had occurred in other parts of the world. There had been seven avian influenza outbreaks in the UK since 2003, two of which were H5N1, one H7N3 (including one transmission to a worker) and another H7N2 (with four cases of transmission to humans). Each had been contained effectively.

Planning for an influenza pandemic held a number of challenges: avian influenza; recognising human transmission, in the UK or elsewhere, at an early stage; recognising the first cases to come into the UK; diagnosing and confirming those cases; monitoring the first cases and contacts; preparing the surge capacity of the NHS; developing a system of distribution for antivirals; planning for public health interventions (particularly, hand-washing and masks); managing social disruption and business continuity, and planning for vaccine availability.

Avian influenza was a severe disease in chickens and swans. It had been endemic in the far east for at least 10 years and had recently spread to Europe. Human transmission tended to occur where humans had been in close contact with

poultry. There had been no reported cases of human-to-human transmission save one or two cases in Indonesia.

Responsibility for addressing the challenges of a pandemic influenza outbreak rested with the Department of Health (DH) (government response, antivirals, vaccines, antibiotics, the Scientific Advisory Group and communication with the public through the Chief Medical Officer) and the HPA (maintaining global awareness, providing systems for recognition of first cases, surveillance, modelling and real time prediction, laboratory diagnosis and confirmation, reference virology, vaccine strain development, advice and guidance to the DH and NHS, communication with professionals and the public, development programme of exercises, maintain a watch on the science evidence base).

Turning to surveillance, Professor Lightfoot said that UK cases were expected to be reported through contact with “Flu Line”. The Royal College of General Practitioners also had an established surveillance system and Q Flu at Nottingham University looked at every general practice and recorded diagnoses. NHS Direct also provided a line for the public to call. Using these systems, it was possible to monitor seasonal flu, the results of which were published every week on the HPA website. Two exercises had been conducted to enable this to progress to a daily reporting system which would support the DH and COBR (Cabinet Office Briefing Room). Importantly, monitoring information and the emerging picture would be fed back to the local level.

Detailed knowledge about the first few hundred cases was critical to understanding a new virus. A system for recording had therefore been set up to enable modelling of the course of an outbreak. Data collection for this exercise would be onerous—it would take about an hour for each patient. The information would be put into a database, which was near completion, and made available to the modellers as quickly as possible. This would be done, with NHS help, at local level through Health Protection Units. This system was seen as an exemplar by the WHO and the European Communicable Diseases Centre.

A system of diagnosis and laboratory confirmation had been put in place using a network of 14 UK laboratories, each using the same tests. We could therefore be confident that we would be able to recognise the new viruses in whatever part of the country they might occur in. The UK reference laboratory was one of four WHO collaborating centres. It undertook confirmation, typing and genetic analysis. Importantly, it also undertook antiviral resistance monitoring and participated in vaccine research.

The HPA produced guidance documents on how to control infection for a range of sectors, including hospitals, prisons and funeral directors, and on clinical treatment guidelines. They were all available on the HPA website.

Public health interventions were about understanding the transmission characteristics of the virus. The essential message was stay at home if you were ill but there were doubts about whether people would follow that advice. Hand-washing and mask use had to be considered, as did restricting unnecessary travel, school and university closures and limiting large social gatherings. The evidence suggested that the virus would be transmitted through large droplet and contact routes. The virus would survive 24 to 48 hours on surfaces and 4 hours on skin. Therefore hygiene and containing sneezes were critical.

It appears from the evidence to date that a pandemic could not be stopped but only delayed by a short time—perhaps two weeks. Border closures would have a wider impact on the continuous supply of medicines and food into the country.

Screening at borders would be an alternative approach and perhaps a popular one but screening would only detect cases in WHO Phases 4 and 5 and would not detect incubating cases. Japan had already implemented screening and the United States was committed to implementing screening in Phase 5. The US had admitted that this would be very difficult, that it would only detect 50 per cent of cases and that they would do it only for two or three weeks. The UK had a policy of no border closures and no screening.

In the past, closure of schools for the Christmas break has halted the spread of a seasonal influenza outbreak. So school closures could provide an effective measure but there were other considerations: for example, would the children congregate elsewhere? would there be an effect on health care workers who might have to stay at home to look after their children? when should the schools be re-opened?

Antivirals provided a strategy to reduce morbidity and mortality. They were currently used as a post-exposure prophylaxis for avian influenza. The UK stockpile was being built up and was expected, by April 2009, to reach a level that would enable 50 per cent of the population to be treated.<sup>16</sup> This was greater than the stockpile in France and Canada. An antiviral had to be given within 48 hours—12 hours was the target. Distribution presented a significant logistical problem. The DH had considered various options when letting the “Flu line” contract. Household prophylaxis was not current DH policy.

Vaccine procurement was difficult because of uncertainty about the identity of the outbreak strain. H5N1 was a likely candidate and 3.4 million H5N1 vaccine doses had been manufactured in the UK, with a sleeping contract for 120 million doses. Research in generic vaccines was essential, as was global co-operation.

Business continuity measures would have to be considered: for example, more home-working, developing a culture of surface cleaning and personal hygiene, and considering public or visitor handling policy.

### *Conclusion*

To sum up the achievements in UK preparedness, we had in place global influenza intelligence monitoring and systems of first cases recognition; there was a good network of laboratories and an effective surveillance programme; guidance documents for all sectors were available and a review of the science evidence base was ongoing; exercises were being undertaken for the UK, EC and WHO and real-time modelling was being developed by teams in the Health Protection Agency, and in the MRC Centre directed by Professor Ferguson at Imperial College.

### *Questions*

In questions, Professor Lightfoot said that the role of the Cabinet Office was to co-ordinate planning. At the beginning of a pandemic, COBR meetings would be called on a daily basis and those meetings would be informed by the data gathered by the HPA. Professor Lightfoot was asked whether tests had been carried out to determine how the frontline medical services would cope in the face of staff being unavailable because they or their families had fallen sick. He confirmed that tests would be carried out—the contract had only just been put in place. He agreed that they would need to be done and that they should be full-blown practical tests.

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<sup>16</sup> Professor Ferguson suggested that this figure may be further increased with stockpiles of both Tamiflu and Relenza now being acquired. He said that the DH had not ruled out a household prophylaxis strategy.

## Evolution and emergence of pandemic influenza (Dr Nimalan Arinaminpathy)

Dr Arinaminpathy described work that he had done with Professor Angela Mclean of the Department of Zoology, Oxford. The focus of the work was to define the events which we could expect to observe in the run up to a pandemic. A difficulty was that the nature of the virus—its virulence and transmissibility—was unknown. This made policy planning very difficult. So the strategy adopted was to use simple mathematical models to demonstrate different contingencies which may be faced in the run up to a pandemic and to use the results from the modelling to give an indication of the possible warning signs of a pandemic.

The H5N1 virus was the subtype of avian influenza that was causing the greatest concern. H7N7 and H9N2 were also pandemic candidates. There were many barriers to an avian influenza virus becoming adapted to human transmissibility. The biology of adaptation was complex and our understanding was partial at best. There were two mechanisms by which a virus could overcome species barriers: “viral adaptation” (an incremental process driven by mutation and selection) and “viral reassortment” (where an individual is infected with both a human virus and an avian virus and the two viruses mix genetic material and potentially produce a hybrid, novel virus).

Since 1997, we have been at Phase 3 of the WHO phases of pandemic alert where we have no or very limited human-to-human transmission. Increasing levels of alert correspond to increasing levels of transmission. The WHO scheme was an intuitive picture which suggested a gradual transition through the six phases. But we had to ask ourselves under what circumstances we might jump, say, from Phase 3 to a full-blown pandemic at Phase 6. Focusing on “viral adaptation”, Dr Arinaminpathy had applied simple mathematical models to discover patterns of human cases which we might expect to see before a pandemic.

In explaining the models, Dr Arinaminpathy referred to the notation “ $R(\text{zero})$ ”. It was the “average number of secondary infections produced when one infected individual is introduced into a host population where everyone is susceptible” (Anderson and May, 1992). A human-adapted virus was where  $R(\text{zero})$  was greater than one. A poorly adapted virus had a  $R(\text{zero})$  value far less than one. By adaptation, a virus with an initially low  $R(\text{zero})$  could, by incremental mutations, achieve pandemic-capability.

### *Punctuated and gradual route to emergence*

Dr Arinaminpathy explained two possible scenarios for the development of a pandemic with a virus undergoing a series of adaptations. First, there was the “punctuated” route to emergence. This was characterised by  $R(\text{zero})$  remaining well below one through several adaptations and only the fully-adapted virus having any appreciable increase in  $R(\text{zero})$ . By contrast, the “gradual” route to emergence was characterised by every successive adaptation conferring an increase in  $R(\text{zero})$ . It was not possible to say which of these two scenarios was more likely. They were equally plausible, as the genomics and microbiology of the H5N1 virus were not sufficiently well-understood. The virus that adapted gradually was the one which would be more likely to afford warning of a pandemic in the form of large but self-limiting outbreaks. The virus which adapted in a punctuated manner was more likely to emerge without any prior warning. This distinction was important to bear in mind in terms of pandemic preparedness planning because each scenario would involve different degrees of observable warning signs.

The different character of the punctuated and gradual emergence routes was reflected in the numbers of “false alarms” associated with each. The punctuated scenario tended to exhibit fewer false alarms while the gradual scenario would present far more. The gradual scenario therefore created the particular difficulty of identifying when an outbreak was genuinely self-resolving (a false alarm) or the start of a pandemic.

There were practical, resource consequences arising from these different scenarios. Because of the relatively low level of false alarms with the punctuated scenario, intervention would be likely to be triggered in respect of a genuine pandemic and therefore only the once. However, containment of a fully-adapted virus would pose significant challenges. With the gradual scenario, an outbreak may be sufficient to cause alarm and trigger an intervention but may in fact be a false alarm. At each intervention, containment would be comparatively easier than for the punctuated scenario. However, the multiple interventions elicited by the gradual scenario could drain valuable resources for when the pandemic eventually took off.

### *Summary*

In summary, Dr Arinaminpathy made the following points: (1) pandemic preparedness plans should acknowledge that although a pandemic might be heralded with repeated and large outbreaks, it was also possible that it could happen without warning; (2) each scenario posed unique challenges for preparedness and for containment, and (3) in the absence of sufficiently detailed knowledge of the steps an avian virus may take to adapt to humans, early warning systems could benefit from analysis of past outbreaks.

Professor Townsend pointed out that the three pandemics of the last century came without any warning. In addition in the 1970s, when fear of swine flu re-emerged, it turned out to be a false alarm but a huge effort was made to immunise in the US with highly damaging results.

### **Recognising the warning signs of an influenza pandemic (Professor Jonathan Van Tam)**

Professor Van Tam said that he would describe some of the practical issues relating to recognising the warnings signs of a pandemic outbreak.

#### *Pre-requisites for a pandemic*

The pre-requisites for pandemic influenza were: that the influenza virus was a novel influenza A subtype with an H value unrelated to an immediate (pre-pandemic) predecessor; that there was little or no pre-existing population immunity; that the virus caused significant clinical illness, and that there was efficient human-to-human transmission.

During the last century there had been three pandemics, two originated in south east Asia and one may have originated on the on the east coast of the US. In 2003, H5N1 re-emerged. Although the human H5N1 “hotspots” were still concentrated in south east and central Asia, there had been some incidents closer to the UK. Outbreaks in Africa had a particular importance because of the implications of its poor health infrastructure. Historically, the only influenza A subtypes which had caused human pandemics had been H1, H2 and H3. H5 was a leading candidate for the next human pandemic, although many eminent biologists believed that H2, for example, was a likely contender.

### *The sequence of detection*

In trying to detect warning signs for a pandemic, what would we be looking for in practical terms? The sequence would begin with “recognition” of (unexplained) single cases or clusters of moderate or severe acute respiratory infection. For obvious reasons, disease severity and number of cases occurring in an area were inversely related factors in triggering recognition by healthcare workers—if the illness was mild, it was less likely that a healthcare worker would recognise it as influenza at an early stage. After the influenza virus had been recognised, “diagnostics” would be applied to identify the novel virus, followed by “epidemiological investigation” to develop a pattern of human-to-human transmission. Finally, the pandemic event would be “declared”.

The WHO pandemic phases were under review and might be changed in the next two to three months. The current scheme was a rather stylised escalation to a pandemic outbreak. The phases were theoretical and there was some doubt that the phases would, in reality, translate into a smooth sequence of events.

Professor Van Tam summarised his views on the likely origins of pandemic influenza: (1) the possibilities for the site of emergence were far wider than south east Asia, especially in relation to H5N1 disease activity in birds and humans; (2) there was a very low possibility of emergence in the UK (but not zero); (3) there should be an emphasis on the international collective vulnerability: “we are as vulnerable as the weakest part”, and (4) there was no certainty that emergence would accord with the ordered, escalating picture set out in the WHO plan.

### *Recognition*

There were a number of practical difficulties in recognising cases or clusters: there was huge international variability in health systems and public health infrastructures; there was often huge variability within countries, and Africa and central Asia posed significant risks of delay. On the other hand, the International Health Regulations were now in place, which would increase the likelihood of effective monitoring. Also, once alerted, we could be confident about the effectiveness of most parts of the UK health system.

### *Diagnostics*

After recognition, there was diagnosis. The first stage was a rapid diagnostic test to determine whether the virus was influenza and, if so, whether it was A or B. Then the specimen would be interrogated to determine as rapidly as possible the likely identity of the novel subtype—the “leading suspect”. Finally, platforms for diagnosis of other subtypes would be developed.

### *Clinical-epidemiological investigation*

The next stage, clinical-epidemiological investigation, was intended to provide an understanding of the syndromic picture of the new virus. Mathematical modellers would attempt to quantify the secondary spread of the infection—the patterns of transmission—and this would inform the decisions of NHS managers about clinical management pathways and the efficacy of treatments. All these aspects of clinical-epidemiological investigation still required testing and evaluation in the UK.

To assist in data collection in the event of a suspected pandemic, the Health Protection Agency would enter information about the first few hundred cases on the avian influenza database and clinical information network—a web-based tool

(FF100)—during the early weeks of the pandemic. It would then be necessary to switch over to a system that focused more centrally on clinical information from the NHS to drive the treatment pathways. This system was currently the subject of a tender. It would probably take 12 to 18 months work-up time before we were in a position to test it on normal, seasonal respiratory illness.

### *Questions*

Professor Van Tam was asked about monitoring from sentinel general practices and routine virology of those who presented with symptoms, and whether anything had emerged from such routine data collection. He said that there were two big systems in the UK (Royal College of General Practitioners (RCGP) Unit in Birmingham and Q Flu research system in Nottingham) which recorded patients who present to GPs with a syndromic picture of flu-like symptoms. Each system reported clinical evidence. A subset of the RCGP network also took virology specimens. In addition, another set of GPs sent specimens of flu-like illness directly to the HPA.

Professor Ferguson commented that the sensitivity of a sentinel system to pick up new viruses was very, very low. In a severe pandemic, hospital-based surveillance was far more likely to pick up abnormal, severe respiratory disease.

## **Pandemic containment and mitigation (Professor Neil Ferguson)**

### *Emergence*

Professor Ferguson described a simulated emergence in Anhui in China using mobility data collected for the purposes of the model. The modelling indicated rapid spread within about 90 days, working on the assumption of a punctuated evolution of the pandemic. It appeared that intervention could interrupt the rate of transmission but action would have to be taken very, very quickly. Action to block transmission would include treating isolated cases with antivirals, public health measures such as school closures, travel restrictions around the region, mass use of antivirals prophylaxis in the population and possible use of vaccines (stockpiled by the WHO).

### *Vaccination for containment*

In recent years, work had been done with the WHO to try to understand the role of a pre-pandemic H5N1 vaccine. The political difficulty was that the WHO stockpile was only in the region of 100 million courses. The initial plan had been to give each country a small amount of vaccine for, say, critical healthcare workers. But given the relative scarcity of vaccine, researchers have considered whether it could be used more effectively. One option would be to vaccinate at the source of an outbreak. This would incentivise countries to report. On the other hand, it was not an obvious policy to use because of the effect of the time delay between vaccination and protection—in a fast-moving outbreak, that delay could be critical to undermining the effectiveness of the policy. Evidence suggested that mass vaccination would make a very substantial difference if the vaccine were 60 per cent efficacious after 7 days. The usefulness of mass vaccination diminished as the period before reaching 60 per cent efficacy lengthened—but even with the lengthening period, it remained significant. Given this, the WHO had reserved half of its stockpile of vaccine for use for containment operations.

Like Dr Arinaminpathy and Professor Van Tam, Professor Ferguson had considered whether, once  $R(\text{zero})$  equalled one, the pandemic would go through WHO Phases 2 to 6 incrementally or whether there would be a sudden jump. For mutation rates of only one per cent per infected individual per day—quite a pessimistic assumption of how fast an influenza virus might evolve—then the different scenarios about the percentage transmissibility increase per mutation made relatively little difference to the chances that containment would succeed. If containment operations were going to succeed then it would be at the stage where 100 or less cases of human influenza had accumulated. For that reason it was pessimistically assumed that the virus would take a punctuated path—the hardest situation to deal with from a policy point of view.

### *Travel restrictions*

There were doubts about the efficacy of travel restrictions to slow spread. Ninety per cent travel restrictions would slow the spread by about one to two weeks, and 99 per cent would slow the spread by two to four weeks. According to the modelling, travel restrictions would probably be useful only at a very early stage when the cluster of cases was still very small. Border screening was predicted to be almost completely ineffective. Some more nuanced work had been done, looking at different types of traveller. Some people—the “jet-set”—travelled a lot and SARS had taught us that an infection would be transmitted more quickly if it got into the “jet-set”.

### *Spread of a pandemic without intervention*

A pandemic which began in south east Asia is expected to take one to four months to reach Europe, with the uncertainty being due to the intrinsic variability in the early course of epidemics and the unknown effect of seasonality in transmission. With a value  $R(\text{zero})$  (viral reproduction rate) of about two, the epidemic would peak between eight and 12 weeks after the first case in Europe. Based on data collected during past epidemics, it was estimated that about one-third of people would fall sick, with about 1,700 cases per 100,000 population during the worst week. There would be significant local variation as to timing, with up to a four to five week variation in the timing of the peak of the epidemic between countries. There would also be timing variations between regions within the same country and regional variations in the peak daily case incidence, with local incidence likely to be considerably higher at the district level (about 2,500 cases per 100,000 population in the worst week) compared with the national average. This would have significant consequences, in particular on local absenteeism which, in the worst week, could be as high as 15 per cent (and even higher with the closure of schools because of childcare ramifications).

### *Effectiveness of interventions*

The results described above assumed no interventions. The effectiveness of single interventions at reducing attack rates was as follows:

- (1) Treatment: if given within 24 hours of symptoms, antivirals could lower transmission (as well as reducing severity of disease) and thus reduce attack rates by about one eighth.
- (2) Prophylaxis: household prophylaxis could reduce attack rates by a third but this would need a larger stockpile than a pure treatment strategy. The planned UK stockpile (50 per cent of population size) was predicted

by modelling to be enough for household prophylaxis to be used, but prophylaxis was not current UK policy.

- (3) School closure: because of the social networks associated with schools, school closure could reduce the peak incidence by 40 per cent and it might also prevent about one seventh of cases but it would have a significant impact on absenteeism.
- (4) Vaccination: it was difficult to predict its efficacy but 20 per cent coverage of low efficacy vaccine might prevent one third of cases.

### *Combining interventions*

There were benefits to combining interventions. The results were not linear in that it was not just a matter of adding together the various percentage reductions in rates of attack. The total net benefit from multiple interventions could exceed the sum of percentage reductions from individual interventions. But this advantage depended on the multiple interventions not “overlapping” (that is, not targeting the same location or aspect of transmission). Interventions could be directed at susceptibility (vaccines, prophylactics), infectiousness (antivirals) and infectious contacts (social distance or public health measures—non-pharmaceutical interventions). To get the maximum reduction in transmission, it was necessary to combine interventions so that they would not target the same place twice.

On the other hand, there was the secondary policy demand of a “failsafe” approach. This also favoured a policy of multiple layered interventions—even perhaps including overlapping interventions with the same target. Failsafe policies were needed because of the uncertainties associated with pandemic influenza. For example, a high level antiviral-resistant strain of H1N1 seasonal influenza had spread around the world very rapidly in the last 18 months—hence the need for a diversified antiviral stockpile. Another uncertainty was the identity (and, critically, the lethality)<sup>17</sup> of the specific strain which might cause the next pandemic. Finally, we would be relying principally on public health measures and the level of compliance was uncertain.

### *Questions*

In discussion, Professor Ferguson was asked why we did not have a policy of vaccination of frontline health workers. He explained that there was currently an intense debate going on about the ethical issues associated with advance use of vaccines, in part because of adverse health effects of vaccines and in part because of the cost-benefit analysis. A related issue arose from the fact that a portion of the world stockpile was about to expire—the question was being asked whether they should be deployed rather than disposed of. Professor Van Tam commented that it was DH’s intention that if a H5N1 pandemic were to breakout then the UK stockpile would be used to vaccinate frontline health staff in a schedule of two doses 28 days apart. There was strong immunological evidence to suggest that if individuals were primed now by giving them one or possibly two doses of an H5N1 vaccine, then if they were to encounter the same antigen again, either through wild challenge or through booster dose, their immune responses would be very dramatic. Evidence suggested that the booster dose could be effective if given up to eight years after the first two primer doses.

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<sup>17</sup> A matter which has concerned the Government Chief Scientist, John Beddington, was the DH planning assumption of two per cent morality as a reasonable risk scenario whereas that of H5N1 was more like a 60 per cent case mortality rate.

## What is the prospect for a broadly cross-protective vaccine for Influenza A viruses? (Professor Alain Townsend)

Professor Townsend said he would review a small part of the biology of the virus and immunity reactions to it with a view to describing how those reactions could be harnessed to create vaccines.

### *The influenza virus*

The virus was relatively simple, with eight genetic segments and 10 proteins expressed in those segments. It had a lipid envelop which had to fuse with the host cell in order for that cell to become infected. The virus would be bound to the host cell by the protein haemagglutinin, assisted by Ion channels—another protein which maintained the acidity required for the fusion to occur. The virus then infected the host cell. It uncoated and replicated itself, and would then leave the cell. In order to do that, it had to prevent the haemagglutinin remaining bound to the cell—as a result, another protein, neuraminidase, would cleave off the receptor to which the haemagglutinin was bound. The drugs used at the moment to treat the virus had the effect of rendering the neuraminidase ineffective so that the virus was prevented from leaving the cell.

### *Immunity and cross-protection*

To what extent would an infection with a type A strain give rise to protective immunity? Humans who had recovered from a particular strain of type A virus would be immune to that strain. As for viruses which were of the same subtype (that is, the same haemagglutinin value (say H1 or H5)) but had been subject to some strain drift within the previous year or two, there was evidence of some cross-protection. But the key question was whether, if a person had been infected with a strain some years ago, that person would be protected against all type A strains. The evidence was very unclear save that it seemed to be the case that there was no cross-protection in children. By contrast mice that have recovered from infection by one A strain are protected from lethal infection by any other A strain.

Professor Townsend then turned to the mechanisms for Immune protection. Some were well understood, others less so. “Antibodies” to haemagglutinin were well known. They offered complete protection. They had the effect of preventing the influenza virus binding and fusing with the host cell. “Cell Mediated Immunity” was a mechanism which operated after the host cell had been infected, whereby the conserved internal proteins of the virus could be recognised by lymphocytes causing the infected cells to be killed and growth of virus thereby halted. It could, in animals, be truly cross-protective against all A strains, but was not proven in man. However In some circumstances where the virus had infected a large area of lung before the lymphocytes arrived, it could make matters worse since the effect of the mechanism was to destroy infected tissue.

There were other immune mechanisms—for example, “innate immunity” and antibody to the (M2) Ion channel protein—about which less was known.

### *Current vaccines*

Most current vaccines were based on inducing antibodies to partially purified haemagglutinin and neuraminidase proteins. This had been done for some years now, very successfully with about a 25 per cent reduction in death rates. But, to be effective, the haemagglutinin had to be well-matched to the infective strain and, without using any other stimulus to make the immune response stronger, the

vaccines were very, very strain specific. The question was whether it was possible to get antibodies which cross-reacted across HA drift. Trials indicated that it was possible, particularly with H5 haemagglutinin, when combined with an adjuvant. Another problem was that it often took several months to develop the amount of vaccine needed.

The second form used “live attenuated influenza viruses” as vaccines. This has several significant advantages. The vaccine is a live influenza virus that infects and replicates in the lining of the nose but does not cause pneumonia. As a result it can in principle stimulate all of the immune responses that are induced by seasonal or pandemic influenza. Extensive trials had taken place in Russia and the United States and there was no doubt that live attenuated viruses were significantly better than subunit vaccines in the context of strain specificity. They definitely induced some immunity across HA drift in humans, even in children. There had also been examples in mice and ferrets where the vaccine cross-protected from seasonal influenza against a challenge by an H5 virus. Live attenuated virus vaccines were not yet available in Europe but were due to be licensed next year.

### *Experimental vaccines*

There was a range of experimental vaccines, all of which were years away in development but offered some hope. At the moment, subunits were produced by growing them in chicken eggs. It could also be done in live cultures of human cells although there were worries that the cells would harbour unknown viruses. However, the new technologies might eventually enable subunit vaccines to be produced more quickly. Other developing areas included genetically modified viruses (such as Smallpox vaccine or Adenovirus engineered to make selected components of influenza) and DNA vaccines. The engineered viruses can result in very powerful stimulation of cell mediated immunity against the conserved internal proteins of influenza. In animal experiments this can result in limitation of virus replication in the lung with cross-protection between all A strains. However, as discussed above, caution is required as this mechanism if mis-timed has the potential to worsen tissue damage rather than prevent it. The advantage of DNA vaccines was that DNA was very quick to make and easy to transport—the disadvantage was that it did not work in man efficiently enough to be reliable—yet.

### *Conclusion*

In conclusion, Professor Townsend said that the best candidates for pre-pandemic immunisation were the live attenuated vaccines and also subunit HA with adjuvant where there was clinical evidence that they worked and would be likely to afford some protection within an HA subtype. There was no universal vaccine for human influenza at the moment.

### **How will NHS hospitals deal with the sickest of patients during an influenza pandemic? (Dr Bruce Taylor)**

Dr Taylor said that although his talk would focus on intensive care, there were implications for the wider NHS. He would be raising points for which he did not have answers. He was concerned about how the NHS would cope in the event of an influenza pandemic—the availability of intensive care beds was a constant struggle even in normal circumstances.

Dr Taylor said that he first became involved in the issue when he contributed to the development of a policy on critical care contingency planning. He helped to

produce a report which focused on “planning for an emergency where the number of patients substantially exceeds normal critical care capacity”, and the guidance had been accepted by and large by the intensive care community.

### *Availability of healthcare workers (HCWs)*

As a result of the SARS outbreak, studies had been done in New York about the ability and willingness of HCWs to report to duty during catastrophic disasters (Journal of Urban health: Bulletin of the New York Academy of Medicine. Vol. 82, No. 3). The results showed that 40 to 70 per cent of HCWs were either unable or unwilling to report to duty. It was clear from the SARS outbreak that staff morale and staff confidence were absolutely critical. If staff believed that they would be protected and looked after—and perhaps more importantly that the risk to their families would not be increased, they were more likely to come to work.

### *Triaging during a disaster*

The most important effort should be in preventing hospital referrals in the first place. But the likelihood was that there would still be plenty of patients in any event. Patient care depended on the ability to flow through the “primary care—secondary care—complex care” pathway. But even in normal NHS circumstances patient flows may be limited by bed availability and so forth and, in the peak of a pandemic pathways were likely to become blocked because of limited resources. If there were a complete blockage, then patients who might normally have had a reasonable chance of survival might not have access to the treatment they required.

This then led to the difficult concept of triaging patients in the face of limited bed capacity. Dr Taylor had written a draft policy document on triaging suggesting that “increasing age, chronic disease and co-morbidities may have to be accepted as appropriate triage criteria”. He argued that this was not ageism but a realistic recognition that as we get older our health deteriorate and intensive care unit beds may need to be limited to patients more likely to have a good outcome. His proposal had not been accepted.

The current guidance was that “the priority is to reduce the impact on public health, ie to reduce illness and save most lives in a way that is fair and in accordance with the ethical framework”. When Dr Taylor met the Committee on Ethical Aspects of Pandemic Influenza (CEAPI), he had suggested that, where there was only one intensive care unit (ICU) bed available, the choice between a 90 year old and a 9 year old would not be difficult. This was held to be “completely unacceptable” by the CEAPI. But the difficulty for HCWs was that they had to make these sorts of decisions on a daily basis in any event.

The Cabinet Office and DH had now published a document entitled *Responding to pandemic influenza: the ethical framework for policy and planning*. In a way it was perfect: everyone mattered, everyone mattered equally—but this did not mean that everyone would be treated the same way, and so forth. The individual principles underlying the policy—respect, minimising harm caused, fairness, working together, reciprocity, keeping things in proportion, flexibility and good decision-making—were all fine in normal circumstances. But they were not relevant to dealing with a pandemic. A pandemic would require disaster-management, as happened during the London bombings, and it would be unrealistic to focus on ethical principles when overwhelmed with patients and trying to identify those most likely to survive. There was a gap between reality and expectations because resources were limited.

### *Sequential organ failure assessment*

To address the reality gap, the DH had produced a document entitled *Pandemic Influenza: surge capacity and prioritisation in health services*. It was based on “sequential organ failure assessment” (SOFA), an approach advocated by a paper from Canada. As demand for beds increased, then a patient’s organ failure would be assessed and the severity scored. If the SOFA score totalled 11 or more, then the patient would not be accepted for critical care.

There was a practical difficulty with this system. If a patient was taken into an ICU because he was below 11 but after 48 hours he was worse and exceeded 11 or if he remained in the eight to 11 bracket after 48 hours, then he would be taken out of the ICU and put back on to the ward where he would die. However, under normal circumstances he might have been expected to have survived. This action of having to remove critical care from patients would cause emotional and ethical difficulties for staff. Dr Taylor also provided anecdotal figures which confirmed that the SOFA score approach would lead to patients, who in normal circumstances would probably have survived, being left to die.

### *Deploying scarce ICU resources in a pandemic and the blame culture*

So how should ICU referral decisions be made during a pandemic? Perhaps a lottery system was the only realistic way of meeting the ethical expectation of fairness. The fact was that, at some point, ICU services may have to be closed because of lack of resources. Dr Taylor’s worry was that the implications of the ethical guidance which clinicians were expected to meet put them in an impossible position. They were required to apply an ethical framework unsuited to times of disaster.

During what would effectively be a disaster scenario, clinicians would have to make decisions based on current guidance that would not be sufficient to meet the excess demand. This would inevitably result in significant numbers of potentially preventable deaths occurring. The NHS had a “blame culture”. The concern was that although it was hoped that people would want to do their best to help others, this culture—in a period of disaster—would discourage them from reporting to duty. Without adequate staff attendance the plans to expand capacity (or even just to maintain existing services) would not be successful. HCWs needed formal assurance that they would not face professional criticism or retrospective litigation for doing the best they could under very difficult circumstances. It was also necessary to address public expectations in an open and honest way. We had to make it clear that the current standards of intensive care which we currently expected would not be achievable during a pandemic.

### *Questions*

It would be difficult to persuade staff to undertake tasks which they deemed outside their competence. In times of disaster, it would be necessary to develop a sense of immunity from prosecution. The question was raised whether we should have a concept of a state of emergency which would include strategies for handling the consequences of the blame culture.

### **General discussion**

A key theme was “complexity”. One aspect was the evident inability of the public services to handle complexity. Another was that, as a result, it was essential that practical solutions had to be developed which had been thoroughly road-tested.

There had to be confidence that the contingency planning worked. More positively, there were clear indications of the routes that had to be taken in order to develop an evidential base on which to establish an effective contingency arrangement. Ministers should ask themselves where and how they could make a difference.

The DH and its agencies had come a long way but tended to focus on individuals. They found abstracts like “herd immunity” difficult to deal with. They had had four years but were still only thinking about targeted local prophylaxis.

If closing boundaries gained us one to two weeks, why was it dismissed? Also, socially it would be difficult to stop the public call for border closures. In answer, it was suggested that whether border closure was a reasonable policy critically depended on how long it would take to make vaccine. A cordon sanitaire around a local cluster which was then treated robustly could be highly effective. Screening, on the other hand, had very little value, in any circumstances, since it would capture almost nobody.

Front line staff preparedness seemed to be poor.

## APPENDIX 4: RECENT REPORTS

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### *Session 2005–06*

- 1st Report Ageing: Scientific Aspects
- 2nd Report Energy Efficiency
- 3rd Report Renewable Energy: Practicalities and Energy Efficiency: Government Responses
- 4th Report Pandemic Influenza
- 5th Report Annual Report for 2005
- 6th Report Ageing: Scientific Aspects: Follow-up
- 7th Report Energy: Meeting with Malcolm Wicks MP
- 8th Report Water Management
- 9th Report Science and Heritage
- 10th Report Science Teaching in Schools

### *Session 2006–07*

- 1st Report Ageing: Scientific Aspects—Second Follow-up
- 2nd Report Water Management: Follow-up
- 3rd Report Annual Report for 2006
- 4th Report Radioactive Waste Management: an Update
- 5th Report Personal Internet Security
- 6th Report Allergy
- 7th Report Science Teaching in Schools: Follow-up
- 8th Report Science and Heritage: an Update

### *Session 2007–08*

- 1st Report Air Travel and Health: an Update
- 2nd Report Radioactive Waste Management Update: Government Response
- 3rd Report Air Travel and Health Update: Government Response
- 4th Report Personal Internet Security: Follow-up
- 5th Report Systematics and Taxonomy: Follow-up
- 6th Report Waste Reduction
- 7th Report Waste Reduction: Government Response

### *Session 2008–09*

- 1st Report Systematics and Taxonomy Follow-up: Government Response
- 2nd Report Genomic Medicine

# Minutes of Evidence

TAKEN BEFORE THE SCIENCE AND TECHNOLOGY SELECT COMMITTEE

TUESDAY 25 NOVEMBER 2008

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Present	Colwyn, L	Patel, L
	Crickhowell, L	Selborne, E
	Finlay of Llandaff, B	Sutherland of Houndwood, L
	Haskel, L	(Chairman)
	Jenkin of Roding, L	Warner, L
	Krebs, L	Whitaker, B
	Methuen, L	

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## Memorandum by the Department of Health

### FOLLOW-UP INQUIRY INTO PANDEMIC INFLUENZA

#### WRITTEN RESPONSE TO QUESTIONS

##### WORLDWIDE SURVEILLANCE OF THE H5N1 VIRUS

1. *The Government response to the recent report by the Select Committee on Intergovernmental Organisations (Cm 7475, paragraph 194) acknowledged the need to improve disease surveillance and reporting systems in developing countries. What is the current level of UK funding for pandemic influenza surveillance in these countries, and how is the effectiveness of this funding evaluated?*

In addition to our share of the substantial contributions that the European Commission has made, the UK has pledged £35 million towards the international effort to tackle highly pathogenic avian influenza (HPAI) and to prepare for a future pandemic. This pledge is in three parts: to deliver £20 million from DFID over three years through multilateral channels; to reprioritise DFID's country aid programmes if requested to by partner governments; and to provide significant technical resources such as laboratory testing of viral samples, technical support for monitoring and surveillance, and vaccine development, through other Government Departments.

From the £20 million pledge, DFID has already provided:

- £7.0 million to the World Bank Multi-Donor Trust Fund for the Avian and Human Influenza (AHI) Facility;
- £500,000 to the International Federation of Red Cross and Red Crescent Societies' Avian Influenza Preparedness, Mitigation and Response appeal;
- £3.5 million to the World Health Organisation (WHO);
- £3.5 million to the Food and Agriculture Organisation (FAO); and
- £1.3 million in technical support to the Pandemic Influenza Contingency Support Teams (PIC) in the UN Office for the Coordination of Humanitarian Affairs (OCHA), the World Organisation for Animal Health (OIE) and the UN System Influenza Coordination Unit (UNSIC), headed by Dr David Nabarro.

In addition to the £20 million multilateral pledge, DFID has already reprioritised bilateral programmes in China, Ethiopia, Kenya, Malawi, Nigeria and Uganda to focus about £3.3 million on animal and human influenza projects and has approved a research project on the socio-economic impacts of avian influenza control strategies, worth £3.9 million over three and a half years. Most of this funding has also gone through international organisations.

All the organisations to which money has been committed provide detailed regular reports on the use to which the money is put and the effectiveness of the operations financed. In addition, UNSIC and the World Bank prepare specific progress reports across the board every six months. There are also global macro indicators which show that the number and spread of outbreaks in poultry and the incidence of human cases and human deaths are both declining. In addition, DFID can also call upon the staff in its Overseas Offices to gauge the effectiveness of individual programmes in-country.

*2. In the same response, the Government expressed support for the notion that surveillance for pandemic flu should be integrated with generic surveillance activity in developing countries. How have the Government's preparedness planning activities led to improvements in the capacity to detect and respond rapidly to pandemic flu outbreaks in developing countries?*

The Government has made its own National Framework for responding to an influenza pandemic very widely available, including on the web. We have also worked very closely with the European Centre for Disease Prevention and Control (ECDC) in Stockholm to promote the exchange of best practice on pandemic planning within the European Community, and similarly with the WHO, particularly in the revision of the WHO pandemic preparedness guidance and indicators. The Government has also initiated workshops and seminars to facilitate this exchange.

In addition, DFID is helping to fund the WHO and PIC OCHA, to support their work to monitor and help improve the pandemic plans of UN Country Teams, International Humanitarian Agencies and of individual countries. The Cabinet Office also seconds a full-time member of staff to the UNSIC team, and the Health Protection Agency provides training, exercise and other preparedness material and expertise to help developing countries. Last November, the Department of Health donated £2 million to the WHO Global pandemic influenza Action Plan (GAP) to improve vaccine supply.

The UK launched its cross-government Pandemic Flu International Preparedness Strategy last month

(see [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_089527](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089527)).

This document sets out the priorities and actions that the Government will take over the next three to five years in its international approach to pandemic preparedness. One of its four objectives is to “support detection and surveillance activity in countries at risk”.

*3. What is the Government's view on progress in implementing the World Health Organisation's (WHO) International Health Regulations (IHR)? Is the UK supporting the implementation of IHR in developing countries?*

The new IHR were adopted by the World Health Assembly in 2005, and came into global effect in June 2007. In the UK the key requirements of the new IHR were put in place in June 2007. The UK has designated the Health Protection Agency as its IHR National Focal Point (IHRNFP) (Article 4).

As at November 2008, the new IHR have thus been in full effect for just over a year. Happily, they have not been put to a serious test in an emergency during that time, so it may be premature to reach conclusions on their effectiveness. However, a continuing concern has been the failure of Indonesia to provide timely reports on all human cases of H5N1, and to share the influenza virus samples with the WHO.

The Government strongly supports the IHR, and is satisfied with the functioning of the UK's IHRNFP, which has exercised the procedures laid down in the IHR on a number of occasions. All parties to the IHR are to carry out a self-assessment review within two years of implementation, and are required to be in a position to fully implement the core requirements within five. The WHO has reported regularly on progress. This time next year we should have a more fully informed and developed picture as to progress.

The UK has contributed to support the implementation of the IHR by core funding and voluntary contributions to the WHO. Also, by means of our pledges, in-kind support and the objectives and actions detailed in our International Strategy (see Answers 1 and 2 above) we have, and shall continue to, support the IHR implementation. We are also actively working with the WHO and partner countries to resolve the influenza virus sharing and access to benefit discussions and consider full reporting and sharing of virus samples essential to global health security.

4. *What is the Government's assessment of the effectiveness of the United Nations Food and Agriculture Organisation in funding the early detection of and response to outbreaks of disease?*

FAO's global response to HPAI is being evaluated through a series of independent real-time evaluations. The first evaluation was in 2007 and UK expertise was employed in both the evaluation and its peer review.

The Government supports the conclusions of that evaluation and its review, the principal messages of which were that:

- FAO did reasonably well in mobilising a large amount of new funding for the detection and response to outbreaks throughout the world, working in close cooperation with other international bodies such as the World Organisation for Animal Health and the bilateral and multilateral funding agencies.
- FAO was criticised for not defining robust objectives and establishing performance measures in the rush to fund HPAI programmes, so relatively little is known about the quality and impact of this major mobilisation of funds.
- The evaluation questioned the culture at the centre of FAO's management of its response to HPAI, which has been focused largely on veterinary and technical aspects. The evaluation suggested that important social, economic and developmental issues also need to be incorporated into FAO's response and recommended a management structure that reflected this imperative. This recommendation was not accepted by FAO.
- The evaluation also recommended that FAO move from an "emergency" mode of managing and funding its response to HPAI, suggesting that its role must evolve to one of supporting the longer-term policy, institutional and financial efforts that must underpin prevention and control of avian influenza in birds in the long term. FAO accepted this in principal, but made the point that the predominance of short-term "emergency" and project-specific funding is largely determined by FAO's donors' preferences. The Government has made clear to FAO that this is not its preferred way of operating and has made available flexible funding over a reasonably long term.

A second round of the Real Time Evaluation of FAO's global response to highly pathogenic avian influenza will be conducted in early 2009 and will focus on impact at country level.

5. *What measures are in place within Europe to enable information on animal influenza outbreaks to be shared with interested parties such as poultry producers, and to control exports from countries where there is a suspected outbreak?*

Measures to prevent and control avian influenza are coordinated at EU level by DG SANCO of the European Commission. Prescribed measures, including prevention of trade in live poultry and poultry products from infected zones, must be enacted by national authorities if there is a suspected or confirmed case of highly pathogenic avian influenza in either wild birds or domestic flocks in their territories. EU import bans have also been placed on potentially risky birds and products from third countries with outbreaks.

Pre-emptive risk reduction measures include surveillance, vaccination and biosecurity, these inevitably require communication with the industry which each Member State (including the UK) has implemented in its own way. The Commission has produced a factsheet in several languages. [http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/ai\\_factsheet\\_2006\\_en.pdf](http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/ai_factsheet_2006_en.pdf).

When an outbreak occurs within the EU, the affected country must immediately notify the Chief Veterinary Officers of all Member States and other European countries. They will then distribute the information to their industry as they see fit and advise whether any additional precautions are required.

The Commission provides a detailed explanation of the measures in place and legislation on its website: [http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/index_en.htm)

6. *What action is the Government taking to ensure that influenza virus samples and information about their genetic sequence are shared between countries in order to facilitate research and drug development?*

Currently, discussions are ongoing in the WHO to find consensus between countries on a revised WHO system for sharing of influenza viruses and a more equitable access to benefits. Indonesia has stopped sharing its influenza virus samples with the WHO until a resolution is reached, in particular on establishing access for developing countries to vaccines, capacity benefit and other benefits.

The UK is playing an active part in both the design of the new virus tracking system and the revised strategic arrangements. An Inter-Governmental Meeting (IGM) in Geneva in December will take this forward. It is essential that viruses are shared for both risk assessment and vaccine development purposes.

Current practice should involve the WHO laboratories depositing the gene sequences obtained from original samples in publicly accessible databases if the originating country does not object to such publication. These laboratories share viruses and derived materials with other laboratories world-wide as long as the originating countries do not impose restrictions on distribution of materials.

*7. Should H5N1 virus samples be patented to protect their use and to ensure equitable access to vaccines derived from them?*

H5N1 viruses themselves should not be patented/patentable as they are naturally occurring biological materials and the isolation of viruses is not an innovative process. Patenting does however have an important role to play in stimulating the innovation that is needed to create new and better influenza vaccines. Without patents in place to protect new or improved ways of making vaccines, commercial investment to make these a reality is unlikely.

Patenting of virus would not help ensure more equitable access to benefits, which should be based on public health need and not any link to giving the virus. These issues are being taken forward in the WHO IGM (see above).

#### GLOBAL DRUG STOCKPILES AND PRODUCTION CAPACITY

*8. The WHO has made the decision to stockpile doses of a pre-pandemic H5N1 vaccine. Will the Government be contributing to this stockpile? On what basis will the vaccine be distributed?*

The WHO has a current virtual stockpile of 110m doses of H5N1 vaccine—50 m doses promised from GSK and 60m doses from Sanofi Pasteur. These vaccines are currently still in the manufacturing process with the first batches being available next year. Currently the WHO through its expert SAGE group (see Question 23), with the Gates Foundation and Wellcome Trust is reviewing the size and use of the stockpile, as well as preparing operational guidance. Progress on this will be presented to the December WHO IGM. Current thinking regarding use is that 50m doses would be used for containment purposes and 60m doses for use in vulnerable countries for support of critical infrastructure (precise use to be determined by the country).

*9. What is the current size of the global antiviral stockpile? What arrangements are in place for their deployment? Given antivirals are, like vaccines, likely to be a scarce resource globally in the event of a pandemic, what is the Government doing to ensure equitable access internationally?*

The current global antiviral stockpile consists of 5m treatment courses and is at strategic locations around the world. The WHO has produced guidance for their deployment. Roche donated the stockpile—3m treatment courses to contain the pandemic, and 2m for current use in avian influenza outbreaks. Manufacturing capacity of antivirals has increased considerably over recent years and many countries have and are purchasing them. For developing countries, pledged funds can be used for their provision (over \$3 billion global pledge has been made to date). There is not the same problem regarding available capacity of antivirals as with vaccines.

*10. In the event of a pandemic, resources for the manufacture of doses of pandemic-specific vaccine are concentrated in more wealthy countries. What arrangements are in place to ensure that poorer countries are also able to secure supplies of this vaccine?*

This issue is currently being addressed as part of the WHO discussions on influenza virus-sharing and more equitable access to benefits (see Questions 6 and 7). It is one of the benefits that will be considered at next month's IGM. One of the objectives of the UK-supported GAP (see Question 2) is to build capacity and transfer vaccine manufacturing technology to help developing and vulnerable countries become more self-sufficient.

## UK AGRICULTURAL POLICY

11. *What systems of surveillance are in place to allow the rapid detection of an outbreak of avian flu in UK poultry?*

There are a number of steps taken to allow the rapid detection of an outbreak of avian flu in UK poultry and these are set out below.

The National Survey for Avian Influenza Viruses of Subtypes H5 and H7 in Domestic Poultry is used to detect the incidence of infections with avian influenza virus subtypes H5 and H7 in different species of poultry. A random list of poultry premises is selected from across the UK and includes chickens, turkeys, ducks, geese and quail. Blood samples are taken from a number of birds on each premises by Animal Health staff. The birds are then screened for the presence of antibodies to avian influenza viruses of subtypes H5 and H7. Over the last five years only a few serologically positive samples of avian influenza H5 or H7 subtypes have been found in poultry during the survey. When this occurs, veterinary inquiries may be carried out and further samples taken to ascertain whether avian influenza viruses are present or not. Previous positive findings were all due to previous infections with LPAI viruses, and following further investigations, no active infection was found to be present in those flocks. Final survey results are submitted to the Commission.

The Great Britain Wild Bird Survey is used to detect a change or increase in risk to domestic poultry due to HPAI H5N1 incidents in wild birds. The Survey focuses on the patrolling of designated reserves by skilled wild bird ecologists and wardens. This is active all year round and provides enhanced screening and assessment of dead wild birds suitable for testing for Avian Influenza (AI). Sampling of live caught wild birds also takes place at designated reserves. The results of this surveillance help us assess the risk and decide if consideration should be given to enhancing industry biosecurity measures (eg housing birds).

We have a system and publicity in place to encourage anyone to report mass mortality incidents (ie 10 or more dead birds found together).

In addition to these steps, Defra's International Disease Surveillance team monitors occurrence of major animal disease outbreaks worldwide as an early warning to assess the risk these events may pose to the UK.

Surveillance is also enhanced by rapid investigation of reports of suspect cases of AI or Newcastle Disease made by bird keepers or their vets.

12. *In the event of such an outbreak, what is the Government's culling policy? Is it in line with current scientific knowledge about the spread of the flu virus in bird populations?*

Early reporting, rapid action, biosecurity, culling of poultry and other captive birds on infected premises (under the Animal Health Act 1981) and surveillance remain the most effective ways of protecting domestic poultry and other kept birds against an avian influenza outbreak, as well as controlling it if it does occur.

The Government does have powers to kill other poultry and captive birds in order to prevent the spread of disease (a preventive or "firebreak" cull). The use of this power would be used only where this is justified by the possibility of disease spreading and on the basis of sound veterinary, epidemiological and scientific advice.

A major factor in using this power is to get ahead of the disease. Under legislation, the Secretary of State is required to ensure that poultry and other captive birds on infected premises must be killed without delay. Other poultry and captive birds would only be killed based on an assessment of the risk they pose to the spread of disease if they were not killed. Such action might be deemed appropriate to protect areas of dense poultry population. The slaughter will include those flocks (and, if necessary, other birds) which, should they become infected, would present a significant risk to the farming and poultry community more generally by contributing to onward spread. It is in such circumstances that effective preventative action may be necessary to safeguard the wider public interest. Species, geographical area and, if appropriate, type of farming would be relevant.

Any decision to use the wider powers of slaughter would be taken in the light of an overall assessment of the risks, costs and benefits in a given situation. This could include not only risks of transmission but also the potential social and economic costs that would arise if effective and timely action were not taken.

A Veterinary Inspector would be required to explain the reasons to the owner and give him an opportunity to provide evidence if he believed the poultry should be exempted. A slaughter notice would be issued that states the powers under which slaughter is required and the reason why the owner's stock is included (with reference to the criteria for slaughter to prevent the spread of disease).

Government policy is to detect a change in risk for domestic poultry from avian influenza in wild birds and take steps if the H5N1 form of the virus is confirmed in such birds. These steps do not include the cull of wild birds: eradicating avian influenza H5N1 in wild birds is not the objective.

13. *What is the Government's current assessment of the scientific case for the vaccination of poultry stocks?*

Influenza viruses have the potential to change their characteristics and the disease they cause. For preventative vaccination, achieving highly sustained levels of protection requires prior knowledge of the likely field strains of virus to which birds could be exposed. Vaccines against avian influenza are less easy to administer to large numbers of birds—this limits their usefulness in normal conditions of husbandry. Development of full immunity in the face of an outbreak can take up to six weeks, which severely constrains the use of AI vaccines where one is seeking rapid protection to halt advance of disease. Moreover, currently available vaccines have not been shown to be effective in species such as ducks, turkeys and geese.

There is a place for use of AI vaccine in small numbers of birds with high economic and/or genetic value where the issues of individual administration are less important. Since December 2006, zoos in England have been allowed to vaccinate their birds against AI because they can contain the disadvantages of vaccines through their high levels of biosecurity and veterinary surveillance, ensured by annual inspections required by law.

AI vaccination is not used routinely in other EU Member States. Like other Member States, Defra's preparation for handling AI outbreaks includes ensuring we have access to vaccine to use against the highly pathogenic H5 and H7 strains were it to be needed in response to an outbreak. A vaccination delivery plan for use outside zoos has been developed with stakeholders, through the Vaccination Technical Working Group. In the event of a decision to vaccinate being taken, this delivery plan (designed to be adaptable to different circumstances) would have to be submitted for approval to the European Commission.

#### UK PREPAREDNESS—PRE-PANDEMIC VACCINES

14. *What size is the current UK stockpile of pre-pandemic vaccine, and how quickly could more be produced?*

We have already purchased a stockpile of H5N1 vaccine totalling some 3.3m doses which would be used for health-care workers in a pandemic.

We continue to monitor scientific developments and advice and will use this to inform any future decisions about the procurement of additional stocks of pre-pandemic vaccine.

15. *Have priority groups for pre-pandemic vaccination been identified and, if so, on what basis?*

The current stockpile has been purchased specifically for the protection of healthcare workers. More widespread vaccination strategies are being considered.

The success of pre-pandemic vaccine will depend on how much protection is offered by the vaccine. This is something which cannot be known in advance. The science underpinning the further development and potential use of pre-pandemic vaccine is cutting edge and has just been reviewed by UK, and other international experts. We are actively considering their findings and the implications for our policy to inform future decisions.

#### UK PREPAREDNESS—ANTIVIRAL POLICY

16. *What is the current UK stockpile of antivirals, and how many additional doses, if any, do the Government plan to acquire? What is the overall cost of the UK stockpiling strategy?*

We currently have enough antiviral medicines to treat 25 per cent of the population, which would be sufficient to manage all those who became ill in a pandemic of similar magnitude to those of the 20th century. The Secretary of State for Health announced that we would be increasing our stockpile to meet the needs of 50 per cent of the population, so that there would be an antiviral course available for every person infected during a pandemic, even in our reasonable worst-case scenario. Procurement has been subject to an EU Tender process under the Restricted Procedure which was advertised in August 2008 in the Official Journal of European Union. Final tenders have been returned and will be subject to an evaluation and award process. We cannot currently provide information on costs in the light of this procurement.

17. *The Committee recommended in its 2005 Report (paragraph 8.10) that the Government clarify their policy on how antiviral drugs would be used in the event of a pandemic reaching the UK. How will these drugs be used? Will they be used preventatively, by relatives of those infected, and by front-line NHS staff? What scientific advice has the Government used in order to make decisions regarding prioritisation of supplies?*

The current policy is based on the treatment of clinical cases only. With a 50 per cent stockpile, the need for prioritisation of antivirals is likely to be small. There are currently no plans for pre- or post-prophylaxis of household contacts or healthcare workers. However, the Government is studying the options for a prophylaxis policy and related procurement, bearing in mind the scientific and logistical issues associated with prophylaxis on such a large scale, and the need for additional antivirals. The government obtained scientific advice from the Scientific Pandemic Influenza advisory group (SPI, formerly SAG), paper of which are available on: <http://www.advisorybodies.doh.gov.uk/spi/minutes.htm>.

18. *In January 2008 the Government confirmed that they will stockpile a second line antiviral.<sup>1</sup> Has this begun? How many doses will be stockpiled, and over what timescale? For which population groups is this intended?*

The procurement of the additional antivirals mentioned in question 16 will include a second antiviral, Relenza. Scientific advice has been sought on the specific groups which should receive Relenza rather than any other product (ie pregnant women, patients with severe renal impairment) and on which groups should receive Relenza if resistance to other antiviral medicines emerged (those normally receiving seasonal influenza vaccine, children and health care workers). The exact amount of Relenza to be purchased is dependent on both this advice, and the current procurement process, but it should be sufficient to form a strategic reserve if problems such as resistance emerge with other antiviral medicines.

#### UK PREPAREDNESS—PANDEMIC-SPECIFIC VACCINES

19. *Advance purchase agreements (“sleeping contracts”) for the manufacture of pandemic-specific vaccine have been made with GlaxoSmithKline (GSK) and Baxter. How many doses of vaccine will be provided for under these agreements?*

The advance purchase arrangements allow for the purchase of up to 132m doses of pandemic-specific vaccine. Up to 72m of these will be provided by Baxter, and up to 60m by GSK.

20. *In the event of a pandemic, once the strain of virus has been identified, made safe and passed on to these manufacturers, how long would they take to develop a vaccine and to complete production of the doses ordered? Has there been any progress since the original inquiry in speeding this process up?*

The process from the identification of the virus to the manufacture and delivery of initial supplies of vaccine is expected to take between four to six months. While work is on-going to ensure that there are no undue delays in this process (due for example to regulatory issues) this time period is unlikely to be reduced significantly.

21. *In order to avoid licensing delays were a pandemic flu strain to emerge, the European Medicines Evaluation Agency (EMEA) allows manufacturers to gain authorisation for a “mock-up” vaccine before a pandemic occurs. Have any “mock-up” dossiers been acquired by vaccine manufacturers in the UK? How has this been funded?*

A number of manufacturers are developing pandemic-specific vaccines and all must seek regulatory approval in line with specific guidelines on licensing mock-up vaccines to be used in a declared pandemic situation. The Government is not made aware as a matter of course when applications for a licence are made as this is “commercial in confidence” information. However, the information on the issue of the licence is publicly available. In May 2008 the EMEA granted a licence to GSK for its pandemic specific vaccine named Pandemrix. The fees associated with this process were paid by GSK.

<sup>1</sup> Letter from Baroness Royall of Blaisdon to Lord Soulsby of Swaffham Prior, 23 January 2008.

22. *Given the advance purchase agreements which have already been made, is there any value in the acquisition of “mock-up” dossiers from the EMEA by other vaccine manufacturers?*

This is a commercial issue. If a company was developing a mock-up pandemic-specific vaccine and wished to market the product for use in a declared pandemic situation the company would need to consider the acquisition of a licence during the development of its marketing strategy.

23. *In the event of a pandemic, research would be greatly facilitated by the sharing of information between pharmaceutical companies. What is the Government doing to encourage sharing arrangements? What is the position of the WHO and the EU with regard to such arrangements?*

The Government cannot force companies to share commercially sensitive information or to put such information into the public domain. Nevertheless, the DH meets regularly with influenza vaccine manufacturers to discuss their scientific progress on pandemic influenza vaccine development. Under such bilateral arrangements, the manufacturers have been open with the Department in revealing their progress on product development and their timelines to obtaining licences. The WHO has held regular open meetings to consider progress on development of H5N1 vaccines and manufacturers for all over the world take part in these meetings and again are open, even in the presence of their competitors, in sharing scientific and technical progress.

The WHO Director General has asked SAGE (Strategic Advisory Group of Experts on immunisation—with UK/DH Chair) to advise her on use of H5N1 vaccines from the WHO stockpile. Manufacturers are collaborating with this review that SAGE will complete by April 2009. The Wellcome Trust is providing the scientific support for this review and will be working with all appropriate vaccine manufacturers to gather the evidence of safety and likely effectiveness of these products.

24. *To what extent are findings from the ongoing modelling work by the Scientific Pandemic Influenza Advisory Group and the Health Protection Agency being incorporated into the Government’s planning on the issue of which groups of the population should be prioritised in the distribution of pandemic vaccine doses?*

The modelling work, which is based on assumptions obtained from seasonal influenza experience, is one of the sources that informs the default planning assumptions that we make about potential prioritisation. Practical and ethical considerations, as well as other scientific advice such as potential efficacy and risk considerations from the Joint Committee on Vaccination and Immunisation, also feed into these deliberations.

Once pandemic-specific vaccine becomes available, actual prioritisation decisions will need to take into account information that can only be obtained in the course of a pandemic. This will include the nature of the pandemic virus, impact on specific population groups, severity of the illness and its transmissibility once it has appeared. Much of this will be obtained via real-time modelling of clinical and surveillance data during the pandemic. In this current planning phase, the emphasis must be on ensuring the appropriate mechanisms for seeking advice are robust and effective.

#### UK PREPAREDNESS—GOVERNANCE AND ORGANISATIONAL ISSUES

25. *Primary Care Trusts (PCTs) are scheduled to finalise their local preparedness plans by December 2008. Have any PCTs already completed their plans and tested them in simulation exercises? Are arrangements in place to ensure that PCT plans are consistent with national guidance and coherent with one another? How will the plans be evaluated?*

As part of the Operating Framework requirements; all PCTs have to have a plan in place to respond to an emergency such as pandemic flu. The Strategic Health Authority has responsibility to ensure that the PCT plans comply with the National Framework for responding to an influenza pandemic. A self assessment of existing plans was undertaken in January 2008 to support PCTs in their planning. A reviewed self-assessment tool, developed by the NHS Implementation Team in line with national guidance, is now available to support organisations and will be used in January 2009 by Strategic Health Authorities to review preparedness throughout their regions.

A comprehensive schedule of exercises has taken place following the Winter Willow Exercise in February 2007. A further series of national exercises to test all aspects of pandemic flu plans, is being developed to roll out 2009–10 and 2010–11.

26. *During the preparedness stage, how do Local Resilience Fora interact with PCTs and has collaboration been tested and evaluated?*

Representatives from the health community are effectively integrated into local resilience work and PCTs, in particular, play a key role in the development of local pandemic flu contingency arrangements.

Following production of the National Framework for responding to an influenza pandemic, Local Resilience Forums (LRFs) were tasked with the production of multi-agency pandemic flu plans to ensure that at the local level the UK is as well prepared as possible to respond to the challenges of an influenza pandemic.

The Cabinet Office is currently in the process of completing a thorough evaluation of LRF multi-agency pandemic flu plans. To date this has included:

- validation of all LRF multi agency pandemic flu plans;
- a national pandemic flu workshop to aid local planners in the development of their plans; and
- publication of supplementary guidance to assist local planners in the production of their plans.

Cabinet Office has prepared an exercise programme to test one LRF's multi agency pandemic flu plans per government office region. The first of these exercises is scheduled to take place in late November with the last to take place during April 2009. In time all LRFs' multi-agency influenza plans will be exercised.

This evaluation programme is closely aligned with the audit of NHS pandemic influenza arrangements.

27. *How does devolution impact on the development of a pandemic response in the UK?*

The Devolved Administrations are represented on all pandemic flu cross-Government working groups and committees including MISC 32, the Cabinet Committee which oversees and guides UK pandemic flu preparations.

#### UK PREPAREDNESS—NHS LOGISTICS

28. *The Government's plans for antiviral distribution rely on a "National Flu Line" phone and web service, to be activated when pandemic cases are confirmed in the UK.<sup>2</sup> Has the target of October 2008 for completion of the National Flu Line been achieved? What is its estimated cost?*

Plans are ongoing to deliver a National Flu Line Service to be available in the event of a pandemic, with the aim to ease the burden on frontline healthcare services. The flu line system has not yet been completed. Current plans are based on the system being delivered and tested in early 2009. This timetable would be subject to review if the likelihood of a pandemic increases in the meantime, with the announcement of WHO Phase 4. The estimated cost for the development of such a service for England is approximately £10 million.

29. *What is the current estimate of the risk of fraudulent demand for antivirals, which could diminish the stocks available for true cases of infection? What measures are in place to prevent fraudulent claims?*

It is recognised that there is a risk of fraudulent demand for antivirals. The communications strategy with information being made available at WHO Phase 4 and WHO Phase 5 will be critical in explaining what antivirals will and won't do, and also how the process/controls for accessing antivirals will operate. We are also planning to increase the current stockpile of antivirals to allow for treatment of up to 50 per cent of the population, in line with the clinical attack rates in the worst case scenario as set out in the national framework for responding to an influenza pandemic.

Controls to mitigate against fraud have been built into the design for the National Flu Line Service. These aim to minimise the number of people who are able to acquire more than one dose of antivirals by linking identity details to the allocation of a system-specific reference identifier for anyone who is confirmed as being symptomatic. Plans for the distribution of antivirals take account of the requirement to secure stocks of antivirals to minimise any risk of theft.

<sup>2</sup> Letter to Lord Jenkin of Roding from the Parliamentary Under Secretary of State (Lords) Professor the Lord Darzi of Denham (14 February 2008).

30. *How will the antivirals be physically distributed so as to ensure that the risk of transmission of infection is minimised?*

Planning has been underpinned by a “homecare model” for antivirals which encourages symptomatic patients to stay at home, therefore minimising the risk of transmission of infection. The National Framework for responding to an influenza pandemic includes the proposed model of care from a patient’s perspective. This assumes that a friend or relative will be available to collect the patient’s antiviral treatment course from the designated collection points on production of authorisation from the National Flu line service. The communications in the build-up to a pandemic will ask everyone to try to arrange for people to be available to act as their “flu friends”.

31. *Concerns about primary care preparedness have been raised by both national<sup>3</sup> and European<sup>4</sup> organisations. How will primary care services be involved in the pandemic response?*

PCTs are responsible for ensuring local health plans and arrangements are in place in advance of a pandemic and for managing the local health response during a pandemic. Guidance to support PCTs in the development of their plans was released in November 2007. PCT guidance is currently being updated to reflect new information, particularly with regards to the Antiviral Strategy and Command and Control guidance. The guidance will be published in November 2008. In addition guidance for General Practice to support the primary care response is currently in draft which will be published in December 2008.

32. *A number of exercises in testing preparedness, including simulation exercises for the distribution of drugs, have been conducted since December 2005. What was the outcome of these? Have simulation exercises included tests of the National Flu Line system?*

Since 2005, across the UK, there have been a significant number of exercises at national, regional and local level, in health and non-health sectors, which have helped to drive forward planning for a flu pandemic. In particular the outcome of the Winter Willow national exercise in January and February 2007 informed the development of the National Framework and subsequent preparedness activity.

We are building dress rehearsals into the testing plan for the flu line service. This will form an integral part of the contract. Integration testing is also critical for the success of the antiviral implementation strategy. This has been stressed as part of the testing plans for the individual system and is also critical for the hosting arrangements for the different systems. Some of the elements of the antiviral distribution such as the operation of individual collection points can only be tested at a local level.

To continue to strengthen our preparations there are plans for a number of future exercises to close the remaining gaps:

- We are in discussion with HPA about developing a further off-the-shelf exercise to test responses at the peak of a pandemic and as recovery begins, drawing on the experience of Exercises New Day 5 and Phoenix. These discussions have also included proposals to develop an exercise for social care. This is planned for 2009, with the working title of Exercise Prometheus.
- Towards the end of 2008, a series of LRF exercises are being conducted across England and Wales, following the review of LRF plans recently undertaken by Cabinet Office. This exercise programme will contribute towards the overarching objective, agreed by MISC32, of delivering “a suite of fully audited and tested UK multi-agency pandemic influenza operational plans from the national to the local level inclusively by December 2008”. The exercise programme will test the required elements of plans (as set out in “Preparing for a pandemic influenza—guidance to local planners” issued in December 2007 and “Preparing for Pandemic Influenza: Supplementary Guidance for Local Resilience Forum planners” issued May 2008) in one LRF from each region, plus London.
- Scotland are running Exercise Cauld Crow, due to take place in late 2008 or early 2009, which will develop their own preparations by briefing, training and exercising the Government.
- In 2011, DH has the option of conducting another Tier 1 command-post exercise on pandemic flu, similar in scale to Winter Willow. Options for this are currently being developed.

<sup>3</sup> Pandemic Influenza: report of follow-up symposium. Royal Society and Academy of Medical Sciences, November 2007.

<sup>4</sup> Pandemic Preparedness in the European Union, Autumn 2007. European Centre for Disease Prevention and Control.

33. *Have the resource needs beyond antivirals and vaccines been estimated and, if so, are there sufficient for given expected scenarios? Are adequate stockpiles of medical supplies in place, including protective equipment, and materials necessary for the safe disposal of infectious material in the event of a pandemic?*

In accordance with the National Framework we are planning at the upper ends of possible clinical attack and complication rates. Some consumables are within the scope of the current procurement, including personal protective equipment and disposal materials. Exercise Chain Reaction helped us to look at how the supply chain which delivers medical supplies would be affected by a pandemic. We are using this information to model our likely needs and plan solutions.

34. *Have the Government considered the need for emergency contingency powers in the event of a pandemic, and to what purpose?*

As part of the lessons learned from Exercise Winter Willow, the Pandemic Flu Implementation Group (the cross government officials levels pandemic flu working group) has considered a raft of legislation that may need relaxation or where emergency powers may need to be invoked to ensure the UK is in the best possible position to respond to an influenza pandemic whilst maintaining essential services. This work has had the input from all Government Departments and the Devolved Administrations.

#### UK PREPAREDNESS—CONTINUITY OF SERVICES

35. *In 2007, the European Centre for Disease Prevention and Control recommended that further work be undertaken to establish across the EU business continuity plans for an outbreak of pandemic influenza. Has any action been taken?*

The most recent overview of preparedness across the EU is provided by the French Presidency's report of a seminar in September which aimed to identify critical weaknesses in the pandemic preparedness and plans of Member States of the European Union and the European Economic Area. This indicated substantive preparatory work by Member States on planning, acquisition, training, information and plan implementation in public health; by the European Commission on issues of coordination and on the holding of exercises; and by the European Centre for Disease Prevention and Control on self-assessment of national preparedness, scientific and technical expertise, preparedness evaluation, and the development of guidance.

However, there was variation in preparedness among Member States in the public health sector but to a greater extent in the non-health sectors, which could complicate the inter-operability of their pandemic plans. The Presidency's seminar report called for current efforts in public health to be sustained and deepened. It recommended also that the European Commission and the Member States should improve inter-sectoral coordination and preparedness so as to ensure economic continuity and essential service provision among the general public, in the private sector, and across borders. Further official discussion of European Union pandemic influenza issues of this kind would be expected to take place in the Health Security Committee and its specialised sub-group on influenza, and to bear in mind that the legal competence of Member States and of the European Commission varies across sectors.

36. *What is the level of preparedness of sectors of the economy which may be particularly affected by a pandemic influenza outbreak—for example, in food distribution where “just in time” operations are vulnerable to problems in transport and haulage, banking, particularly maintaining the supply of cash, cemeteries and crematoria?*

The National Risk Register assesses pandemic flu as one of the major risks facing the UK. The Government's aim is to ensure that all sectors of the UK are as well prepared as possible to respond to and recover from an influenza pandemic. Pandemic influenza plans are in place in key sectors:

The Government's strategic approach and national cross cutting planning assumptions and presumptions are set out in the guidance document National Framework for Responding to an Influenza Pandemic.

All Government Departments are directly or indirectly involved in preparing for an influenza pandemic and play an active role in informing and supporting contingency planning in their areas of responsibility, including public and private sector organisations. Departments work closely with these sectors to promote business continuity management and facilitate robust and resilient planning to deal with a wide range of emergencies, including an influenza pandemic.

To further assist emergency planners in the development of pandemic flu contingency arrangements, the government has also published advice for a range of sectors / issues, including (among others):

- Health services.

- Sector specific infection control material for organisations.
- Guidance to local emergency planners.
- A framework for planners to manage deaths.
- A checklist for business.
- Public health advice to encourage high standards of respiratory hygiene.
- Guidance for the education sector.
- Guidance for the justice system.
- An international strategy.

The Government is currently driving forward the implementation of this advice at the local level and ensuring the quality of arrangements through a validation procedure.

The evidence that supports the statement that pandemic flu plans are in place in most key sectors includes:

- The National Capabilities Survey (NCS). The confidential survey goes out to organisations providing essential services; as well as local emergency responders, regional government offices and central government departments. This includes the private sector. The results of the last NCS survey in 2008, showed that, in the main, the essential services had well established business continuity plans, which were designed to prepare for, respond to, and recover from, a whole range of risks including an influenza pandemic.
- The Cabinet Office recently completed a review of all Local Resilience Forum's (LRFs) multi-agency pandemic flu contingency plans as part of its ongoing validation programme and can confirm that all LRFs have flu plans in place.
- CNI (critical national infrastructure) industries took part in the Winter Willow exercise in 2007. The Government has also been advised by the Business Advisory Group on Civil Protection (BAGCP). The group works to support an open, constructive and representative relationship between government and business in the area of civil protection as a whole, ensuring that business plays its part in identifying and managing the risk of emergencies, and maintaining world-class capabilities to respond to and recover from a wide range of emergencies.

13 November 2008

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### Examination of Witnesses

Witnesses: RT HON DAWN PRIMAROLO, a Member of the House of Commons, Minister of State for Public Health, Department for Health, PROFESSOR LINDSEY DAVIES CBE, National Director of Pandemic Influenza Preparedness, Department for Health, DR BECKY KIRBY, Head of Human Health, Civil Contingencies Secretariat, Cabinet Office, MR RICHARD DRUMMOND, Deputy Director, Food and Farming Group, Defra and MR JOHN WORLEY, Acting Head of Profession—Health, Department for International Development, examined.

**Q1 Chairman:** Minister, may I, in the distance, welcome you and your colleagues to this committee meeting. We appreciate your willingness to give us time. The room is embarrassingly large. Fortunately, we are not doing macular disease or something of that sort, there would be too many unfortunate jokes. We know that ministers have a very busy schedule, but I think you will agree with us that this topic is one of the highest importance. It is one to which the committee, as you know, is returning, having already done some, we believe, significant work in this area. We are named around the table, if you can read the signs at a distance, but perhaps it would be very helpful if you and your colleagues would like formally to introduce yourselves and we will take it from there.

*Dawn Primarolo:* Thank you very much. I am very grateful for the opportunity to speak to you and answer your questions this morning. I do not take

this symbolism of discussing pandemic, we are all down here and you are up there, to mean anything. I am hoping to be able to give you all the answers on this very important subject, both the work of the UK and our international work. If I can just put a personal plea in before I introduce my officials. I have been working in Libya over the weekend for the Department, and I returned late last night so I am hoping that my brain will stay connected with what I want to say, but please forgive me if something fails me and I ask an official to provide the detail. Perhaps if I can introduce those with me this morning. On my right is Professor Lindsey Davies, she is from the Department for Health leading the preparedness. Next to her is Dr Becky Kirby, she is from the Cabinet Office, and that will be for the details perhaps around the civil contingency on emergency preparedness. On my left, I have, firstly, Richard Drummond, he is from Defra. We are very grateful for the opportunity

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

to hear from the officials directly in other departments. It is not unusual for a Treasury minister to speak for all departments at the moment, but it is unusual for a health minister. Next to him is John Worley from Dfid and again, the specific issues, perhaps, around animals, the poultry industry, et cetera, Defra will be picking up the detail on those.

**Q2 Chairman:** Thank you very much indeed. Just as a technicality, since this is being recorded, as and when your colleagues do speak for the first time, if they could say who they are for the sake of the record and those who transcribe it, that would be very helpful. We look forward to hearing from all of you. We are interested in information and understanding rather than minister baiting, I can assure you of that. I wonder if I might start with a question about the preparedness of the health sector should such a pandemic alight on us. How well prepared is the UK hospital system? It would be very helpful if you could also relate particularly to local hospitals because inevitably that is where many of the cases will emerge and turn up. Do they have adequate support available in terms of ventilatory support through the intensive care unit, and so on? It would be very helpful if you could tell us a little bit about that.

*Dawn Primarolo:* Certainly, my Lord Chairman. I think you have touched on the importance for hospitals—in fact, the local health service, primary and secondary care, but concentrate specifically at the moment on hospitals—of needing to be very clear on increased workloads, depletion of workforce, critical care and discharge of patients. They will also need to be very aware of the required ongoing care that could be necessary in the patient's home, the medical supplies, including pharmacy and equipment, the full range, regrettably including sufficient mortuary provision. We also expect them to be very clear on the stockpile of antivirals including collection points, and I know we will come on to that later.

**Q3 Chairman:** Indeed.

*Dawn Primarolo:* In addition to all of the guidance and some of the issues we will touch on in other questions—capacity, preparedness, guidance—the operating framework for the National Health Service for 2008–09 required as a priority that NHS preparedness and all NHS organisations have robust pandemic influenza plans in place by December 2008, and to forward those to the Department covering all of the areas that you would expect us to touch on. Obviously that cannot be perfect because there are a number of disruptive challenges that will be very difficult to actually forecast—and I need to be careful as I say this because the operating framework for next year has not been published yet, it is to be

published soon—but I think it would be appropriate for me to tell the Committee that on receipt of the plans for every hospital tied in to the priorities that will be in the operating framework for next year will be a detailed look at each of those plans and their resilience and, if necessary, discussions—I hope that will not be necessary because I hope they will be prepared—with each hospital. It is quite soon that the framework will be out, in the next week or so, so I would be able to send the specific details of how we intend to push it forward as a priority in the next year but, regrettably, I am not able to pre-announce it, even though I would have really liked to and I pressed the Department quite hard but there are other issues around, so I hope your Lordships will forgive me on this point. By the time we have the plans in December 2008, a consideration and an assessment of those plans and their resilience and, if necessary, return to the hospitals' local providers, the Department will have formed an opinion on the preparedness of all these issues.

**Q4 Chairman:** It would be very helpful to receive a copy when the public announcement is made. I am sure we can distribute it to members of the Committee. Can I press a bit on how wide-ranging hospital plans are expected to be? Are they detailed or are they simply general saying, “well, we are ready to go?” For example, will it involve change of practice, isolation rooms are not that numerous but they might be in great demand or in heavy use, training of staff in advance, equipment and so on?

*Dawn Primarolo:* This is now cascading, the questions you are asking about what if we have a shortage of medical professionals, what do we do about that, surge capacity, supply chains. I think what might be helpful, if you allow me, is to ask Professor Davies to link that with the surge capacity work that is going on. It will then lead us into some of your other questions about securing enough health professionals to be able to deliver what might be considered to be the necessary intensive care, et cetera.

*Professor Davies:* I am Lindsey Davies, I am the National Director of the Pandemic Influenza Preparedness at the Department of Health. We have worked very closely with hospitals across the UK over the last few years to develop their plans and the plans we are expecting from them at the end of the year are comprehensive ones. They certainly are expected to go well beyond just a few platitudes explaining that they are planning, we know that they can do that and write back to us, what we want to know is what those plans entail. We want to know that they are robust implementable plans, that is what has been required. They are expected to answer a whole range of questions. They have already seen

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

the self-assessment tool and the assessment tool we will be giving to them and we are certainly happy to supply you with that if you would find that interesting. The sorts of plans we would expect them to have in place will include how they are going to develop extra capacity within their hospitals should the need arise. To help them with this we have published recently some surge capacity guidance. It is currently in its final draft form for discussion, it has not been quite finalised yet, but we do not expect it to change very much from the draft they have seen already. The responses have been very positive. What that guidance includes is a comprehensive approach to how hospitals could, in the early stage of a pandemic, begin to get their services in order, look at those that they need to prioritise as an assessment tool which enables them to think in advance now about in what order they would prioritise services, what is really crucial for them and what is less so and for the population they serve. So, to look in the early stages as the pandemic wave arises and passes through their community to have planned which will create capacity which will then make best use of that capacity and staff they have got and that may mean, initially, as I say, perhaps looking at postponing elective operations, cancelling them, cancelling outpatient appointments and things like that, and then moving through to prioritising patients for admission, who really needs to come in and who does not, who have got life-threatening illnesses and who have not. Then moving again beyond that to the recovery phase where you then think, “Well, how are we going to put services back in order in a systematic way?” We are very clear that we expect people to look at all phases of that and not just to think how are we going to stop, but also how are we going to restart in a measured way being sensitive to the fact that staff, of course, will have had quite probably their own quite traumatic experiences over a period of time. We have had a number of conversations, and very helpful ones, with professional bodies, the medical royal colleges, GMC, BMA and so on, who have been very actively engaged. It has been a pleasure for me over the last couple of years to work with them so constructively to respond to the challenges.

**Q5 Lord Crickhowell:** I think that is very helpful and an encouraging introduction, Minister. The guidance says that the challenge during a pandemic is to ensure as far as possible there is sufficient appropriate staffing and levels of competencies in the areas most in need. You, Minister, referred to possible depletion of workforce, you talked about surge capability, and so on. I must say reading Exercise Winter Willow, which identifies a number of things that can go quite smoothly, communication for example, we will come back to the importance of relations with the devolved

bodies, there is a concentration on the availability of medical supplies, masks, antibiotics, and so on, but I did not get any clear picture out of that that the personnel issue was being examined in that exercise as I would have liked it. I have been encouraged by hearing what Professor Davies said, but there is nothing like a real emergency to suddenly show up things. It just so happened—different circumstance—when I was Secretary of State for Wales we had a massive blizzard on a Sunday and all the plans had worked on the assumption that people would be in their offices. Well, of course, the officials in local government and the health service, everywhere, were not in their offices, they were at home, they could not get to their offices, so the entire communications system broke down. What is likely to happen here—could happen here—is that the people on whom the whole thing will depend are actually smitten quite severely themselves, and it may happen, particularly severely in particular health authorities or particular hospitals and the people simply will not be there to deliver the services. In a sense, you began to answer because you talked about the robust plans and the way you are examining them, but it does seem to me that on this question of the availability of people, if the people who are providing the service are ill themselves or become ill and there are shortages, can you develop a little further on what seems to me to be a very critical issue?

*Dawn Primarolo:* Perhaps I should ask Lindsey to give more detail with regard to the work we have done with the royal colleges, the RCN, the BMA, specifically around three big sets of issues and more. Firstly, unavailability of some staff, whether there are retired medical staff, the level perhaps of student staff that we can bring in, that requires then a working through, which I know they are doing about appropriate care, how that could be provided and by whom if we did not have exactly the staff that we would normally be used to having and a re-casting, if you like, of the clinical team, drawing in skills and abilities that we might not necessarily have used in normal times. That did come up recently in the flooding and the issues we had around that, particularly in Gloucestershire. There were issues about getting staff to work, which we have seen, but these are new, where we have seen a high level of absenteeism of critical staff and that is also where a great deal of work has been done. Lindsey, again, could you unpack that, please, and give some examples of where we are.

*Professor Davies:* We are very sensitive to the fact that unlike some of the emergencies we are perhaps more used to responding to, a bomb or something, and we see masses of medical staff coming and wanting to help, this will be very different. It will take its course over a period of time and will be something which will

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

potentially directly affect the families of those involved, so this is a very new and different set of circumstances which we have had to explore very carefully with the professions. We have issued some guidance on staffing and employment, the Human Resources Guidance, which sets out a lot of this in more detail, but I think our response covers a number of areas. Firstly, talking to staff now and helping them understand and think through for themselves what the specific challenges will be that they as individuals will face, and how they might respond to those, whether domestically or whatever, to enable them to get to work. A clear expectation that if anybody is ill they should not soldier on and come to work, but they must go home as soon as they are ill, because once they are better they will be absolute treasures to the health service, and we will need to use them wherever we can. That is a really important message, and, again, it is counterintuitive to much of the way that many staff will want to soldier on whatever in normal circumstances, so we want to be very clear about that. The other, of course, is the surge preparations, which we were mentioning earlier so that staff and hospitals understand and have really thought through what they will do if up to a third of their staff are off at any one time. There is no simple answer to that, each hospital will have their own challenges and resources, but we are encouraging them to think about that and develop the capacity as far as possible. One way of developing capacity is to look at who else you have got in the area you might be able to use, and in some areas there will be medical students at different levels of preparation. We spoke to the GMC and medical schools about how that might best work. Obviously we will need students to have appropriate supervision and support but, on the other hand, there are many practical things they could usefully do to release others to get on with other things. Similarly, retired doctors, the BMA have a retired doctors' group, they have encouraged them to sign up to offer to be prepared to help in the pandemic, and we are exploring with them ways in which we could make it easier for this to work. There are obvious issues about registration and about training and being up-to-date, but there will be a range of things that retired doctors might do. One area, for example, is death certification. Again, we might touch on that later on. So, availability, encouraging people to think through what they would do, but then, within the hospital now and in a continuing way, looking at how one might use staff who perhaps work in one specialty area in another way during the pandemic, making sure that as far as possible we have got those who know how to use the ventilatory equipment and things which are there should that be required. I think one has to be realistic about that because in a pandemic situation, of

course, people will still be getting the other illnesses that they normally get and one cannot divert the whole and one should not divert the whole of the hospital towards flu because there will be people who get their appendicitis or get their heart attacks and who have their babies who will equally need to be looked after. We are conscious of that in the planning and doing what we can to take an holistic approach. We are supporting it nationally where we can with training packages. We have even got a quiz which hospital staff can use to get themselves up to speed at the moment.

**Q6 Lord Patel:** Mine is a simple question: would it not be more helpful if there was a generic guidance issued rather than each PCT or hospital developing their own plans as to which services they must continue with, a generic guidance that these core services need to continue, but others may not, so that there is a plan nationally of which services? You mentioned maternity and cardiovascular, heart attacks, yes, they continue, but everybody knows pandemic flu occurs and shuts those services down.

**Professor Davies:** In the draft surge capacity guidance we have a priority service assessment tool which takes people through a series of questions and steers them towards the sorts of generic answers you are talking about. We did not say this must continue or that must continue because different hospitals have different pressures on them and their own context is different. In developing the surge guidance we wanted to be as useful to everybody across the UK as possible. It really is a UK, "This is a tool, work it through." That said, within England, each Strategic Health Authority will be working with its local hospitals, its local communities to ensure that there is a proper package across the patch to ensure there is the best possible balance of services to serve that whole population. Again, looking at any individual hospital in isolation, there is a limit to what they can do. In some areas, for example—and we are encouraging this—the tertiary very specialist hospitals are looking at ways in which their own very specialised consultants can use telephone support more actively to enable people in the field to perhaps look after more complex cases than they would normally do. It is about a balance and ensuring that over a community you get the right mixture, but we are looking to those who have an overview of those communities to get the balance right.

**Chairman:** Of course we have got a few superannuated doctors here in the House of Lords, but I will not press that point.

**Lord Patel:** My Lord Chairman, they will all be recruited.

**Lord Colwyn:** What about superannuated dentists!

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

**Q7 Baroness Finlay of Llandaff:** As an active practising employed doctor could I just ask, before I get on to my main question, a very simple short question: when you are asking for the reports in, are you monitoring how the training of staff at ground level, all the junior staff as well as the senior staff, is currently happening?

*Dawn Primarolo:* The short answer is yes, but perhaps you would want to be reassured on how we were doing that.

**Q8 Baroness Finlay of Llandaff:** I ask it because I have a concern from talking to junior doctors that some of them have not had any pandemic flu training for a time, but I would like to move on to my main question, if I may.

*Dawn Primarolo:* Perhaps we should take note of that and come back to that.

**Q9 Chairman:** That would be helpful.

*Dawn Primarolo:* It is quite a big issue and it is important.

**Q10 Chairman:** If there are any written answers you want to send us afterwards, that would be very helpful.

*Dawn Primarolo:* Of course.

**Q11 Baroness Finlay of Llandaff:** With the extensive national guidance which describes how the UK would respond, early containment does not seem to be clearly addressed. Has the Government planned for an early containment of a possibly highly pathogenic avian influenza human outbreak with things such as buffer zones, antiviral prophylaxis, social distancing, closing down social movements and so on at an early stage before the pandemic has actually taken hold?

*Dawn Primarolo:* The short answer is yes. Although the expert advice is that it is incredibly unlikely to originate in the UK, the Government clearly has to plan for that early containment regardless, particularly of an outbreak, as you say, of a highly pathogenic avian influenza. Such situations will be dealt with in line with the health protection agencies' national incident and emergency planned response where there is guidance on treatment algorithms for clinicians on handling cases, obviously the suspected cases going through isolation, prophylaxis planning, to make that containment if it is required and, of course, for the local assessment about what level of information we would then also be making available in that community in terms of advice on what individuals should do. We do have that within the planning process and if it has not been made clear enough to the Committee perhaps we should provide

more detail of how that would work. Even though it is considered to be unlikely we cannot rule it out.

**Q12 Baroness Finlay of Llandaff:** Could I push you a little bit further and ask you, if the estimates are right that there may be between 50,000 and 750,000 deaths in the UK, at what point would you say that a curfew should be imposed to minimise the number of deaths so that there would be no movement between different cities and each area within the city, and places that people congregate would no longer be used as potential places of cross-infection?

*Dawn Primarolo:* We would not go as far as curfews in terms of the management and containment. We are already preparing and the health advice we give out now is pushing all the time to "stay at home, services will come to you" which will be the Flu Line because this has to be a balance between the expectations of the population and panic and being able to continue the work. This is obviously a difficult area but having curfews is counter to the two messages that we very clearly need to put out. We need to put out a "business as usual" wherever we can, otherwise how do we get people to work and keep the supply but, equally, for those infected we need to be getting a very clear message through to them which is "Stay at home if you are sick. Contact the Flu Line and assistance will come to you". The early containment regardless of where it breaks out is about encouraging those and supporting those who need to be isolated without bringing a whole community to an absolute grinding halt with catastrophic conditions or circumstances being caused elsewhere. All our planning is predicated on those two very important principles: how do you manage that and keep those who are sick isolated and those who are well still providing all the systems that we need in order to support those who are sick, and a curfew is not seen at the moment as a sensible way forward. I hope that answers it. I am happy to provide more in writing about how we came to that decision. We looked at the evidence and the challenges.

**Q13 Baroness Finlay of Llandaff:** One of the concerns is about people being infected before they develop symptoms in that presymptomatic phase, but I think we need to move on with our questioning.

*Dawn Primarolo:* Lindsey could just touch on that point.

**Q14 Chairman:** Briefly that would be helpful and then we will move on.

*Professor Davies:* I think that is a very valid concern. All the scientific advice that we have had suggests that people are most unlikely to be infectious before they are showing symptoms because of the way that flu is spread, as far as we know, which is in droplets

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

which come out when you cough or sneeze, so if you are not coughing or sneezing the droplets are not coming out, and therefore as long as people go home and stay at home the moment they start coughing and sneezing and as long as they catch their coughs and sneezes in a tissue and throw it away and wash their hands a lot—hence our huge message to people now to get into good hygiene practices—so long as that happens then that really goes a long way to minimising the risk.

**Q15 Lord Jenkin of Roding:** This leads on very nicely to a question which I have been very concerned about for some time which is the question of the availability and distribution of antivirals in the case of a major flu pandemic. I raised this at the time of the last report of the Committee in the debate on the Report. At that stage there had only been table-top exercises, this was apparent, so I read the report on Winter Willow, which Lord Crickhowell mentioned, with great interest until I got to the sentence on page 15 of that report: “The system of access and UK-wide distribution to the public of antivirals was not tested as part of the exercise scenario.” Could I ask when you intend to test it?

*Dawn Primarolo:* The answer is next year on an end-to-end process. The information will be supplied in the plans that we have for us to test that in December 2008.<sup>1</sup> It is the relationship between the local collection points and how that fits into the distribution that will go from the local collection points and how those local collection points fit into where we will hold additional stocks, and the movement between those if we see greater demand in one area than another, or if we need to intervene in order to change slightly the availability and the use of them because there is greater pressure or there is more information around as we are in the pandemic.

**Q16 Lord Jenkin of Roding:** I get the impression not only from what you have just said about but also from the report that a great deal of attention is being devoted to, as it were, the top-down organisation and administration and communication of all that. I have got very little impression as to what is being done to make sure that it works locally on the ground. I am not allowed to give evidence but I discussed this recently with an extremely able pharmacist from whom I get my supplies—I am kept alive by the pharmaceutical industry—and he is worried that he will have riots outside his shop because people will not know how or where to get it. One other question, you mentioned the Flu Line a moment ago and the papers make it perfectly clear that the Flu Line is not yet up and running. What testing is going to be done with that?

*Dawn Primarolo:* There are quite a lot of points there which I am happy to pick up. On the Flu Line it is straightforward; we are in the final negotiations for the Flu Line to be set up. That is imminent and is dependent on contracts. In terms of the supply chain and the availability, firstly, where the local collection points will be (and we will know as part of these plans how they will interact) part of the consideration is that we will then test in exercises next year. We are going to come on to the question of exercises done and what we have learned and exercises still to do and where we will end up. The last point when you were talking about the pharmacist, that is part of a wider discussion on the supply chain as well. It is necessary for us to complete some other discussions that we are also having with the industry at the present time on the PPR. That has concluded so the wider discussions about how we ensure a supply so the pressures do not arise as you are indicating are taking place now. We will be in a position to test all that, including the Flu Line, with the public in the next year. That is the preparation that is necessary in order to get us to test those.

**Q17 Lord Jenkin of Roding:** Chairman, it is three years since this Committee looked at this problem and produced a comprehensive report which was debated in this House and in which I took part. This was identified as a key issue. Here you are three years later saying it is still being studied and you have not got any plans. I do not understand what you have been doing on this. Distribution and availability at the local level is going to be absolutely the key to the initial treatment and maybe also to the prophylactic effect of antivirals. Am I unjustified in feeling this concern?

*Dawn Primarolo:* It is not for me to say. I think it is for me to say perhaps I have not answered it clearly enough that we are at the stage of testing the arrangements rather than speculating what they may be, which is exactly the point that you are raising, and perhaps as another attempt to answer the question in a better-informed way I will ask Lindsey to actually come back and reassure you that since three years of this report actually a great deal has gone on and we have moved on considerably to actually having in place what we think the distribution would be and testing it, which is a bit more than just thinking about the necessity of it.

**Q18 Lord Jenkin of Roding:** We are going to come back to testing. When is this going to be tested on the ground?

*Dawn Primarolo:* Next year. We are going into December, we are talking about 2009 and that is when we plan to test it to see that it works.

<sup>1</sup> This is clarified in Paper C.

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

*Professor Davies:* We are. We share those concerns entirely and have been working very closely with those in the field, particularly the PCTs whose job it is to make sure that there are the arrangements in place to supply and distribute the antivirals to their population, but it is very complicated. In order to get an effective system of distribution which we have confidence will work at all stages of the pandemic and will get the antivirals from their distribution centres right out to individual collection points in the right amounts, depending on demand in that local community at the time, we need not only to have the distribution system set up, and we are a very long way towards doing that, but we also need to have effective information and surveillance procedures. There is another whole workstream to put these in place so that we will get the information from the collection points about how much they have got, what the demand is, and how quickly it is going so that we can adjust the supplies accordingly. That whole system is at a very advanced level of preparation now. We hope that we will have the Flu Line in place probably in early summer next year. That is what we are working towards but again it is taking us time to get that in place. We do not want to have something that is going to fail. We are very conscious of the need for public confidence and for the confidence of staff in all of this as well, so when we do have something in place we want it to be robust, and that is why we are taking the time to plan it properly, but we are also planning and testing in various stages both with the public and internal systems themselves. In the meantime we have been asking the NHS in its plans to plan for now. In the knowledge that the Flu Line is not there, it is not operational yet, they have had for the last couple of years a clear expectation on them to consider how they would do things and what they would do in the absence at the moment of the Flu Line. Having given you the timetable of next summer I think we would also say that if a pandemic were announced now we would work as quickly as we could to get a Flu Line system in place absolutely as quickly as we could do that so we would get the best we could do in place. We have asked the Health Service and Social Services and all local partners to be honest in their planning. That is what Winter Willow started with. It was to say do not plan for some ethereal “maybe it will be like this”; plan for what is actually there on the ground. After Winter Willow, although we did not include the Flu Line within that, we have subsequently been asking them to think exactly how they would do this and what they would do. There will not be ideal solutions but in their plans in December they are expected to tell us exactly how they would do it.

**Q19 Lord Jenkin of Roding:** Forgive some probing questions from, if I might describe myself, a superannuated Secretary of State, but I think I would

find it extremely helpful if we could have some more specific information describing what Professor Davies has been putting to us because at the moment I have to say I have very little confidence in what is currently being told us.

*Dawn Primarolo:* Okay, absolutely.

**Q20 Chairman:** If we could ask for something in writing that would be immensely helpful.

*Dawn Primarolo:* We will get that and hopefully we will deal with it and if not we could have another question session.

**Q21 Lord Krebs:** I have a small follow-up question to Lord Jenkin’s question which is to do with the plan and when you do the trial to practise it. As I understand it, it is very important that the antiviral is taken by the patient within 24 hours of becoming symptomatic, so in your trial run how are you going to evaluate whether you can achieve that?

*Dawn Primarolo:* I think you should just answer that. I do not want to tread into areas that I do not answer correctly.

*Professor Davies:* We are currently developing how we are going to do the pilot so I cannot give you a detailed answer for how we are going to do that. We do know that we need to get antivirals to people ideally within 12 hours and definitely within 48, so in testing the system we will be looking at how quickly we can get people individually through the whole process. I cannot give you the details of exactly how we are doing it because we are currently working that up at the moment to make sure that it does test exactly what you are asking.

**Lord Patel:** I have one or two supplementaries but also another one on the answer that you just gave. This is the crucial issue: according to the paper, we have 38 million doses of antivirals that the Government has ordered, and it is important that this drug is used appropriately and at its most effective. We know that it will be most effective if it is administered within 48 hours of the symptoms and it is no use after that, so the right people have to get it at the right time, and that is going to be a tall order and require the best organisation to do that. Some of the other things are peripheral issues. What are the plans to make sure that that happens? Secondly, what other assessment has been done, if it is the Tamiflu that has been ordered whether that is the right drug for all of the people? What if there is a high level of resistance that comes about by the time the pandemic occurs? Have we got plans to use other antivirals such as Relenza? Is oral medication the most effective way or is vapourised medication more effective for some people? What about children, how will they get the drug given to them? Also, antivirals can be used for treatment not just for prophylaxes, so how would

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

antivirals be delivered for therapy purposes and would we have a stock of them? I have two more supplementaries after that.

**Q22 Chairman:** That is the first bite. You will need to move on, I have to say, but let us take this one.

*Professor Davies:* Shall I pick up some of those detailed points and again we are happy to come back in writing or further questioning if you wish. We are setting up a Clinical Information Network which will enable us to get as much information as we can about the effect of the virus on individuals in reality and on what works and what does not, so we will have a number of clinicians who will be sharing information on a day-to-day basis with ourselves so that we can advise and adjust the recommendation on how to respond, both in terms of antivirals and how well they are working but also in terms of other treatment modalities and how they are doing. We are also putting in place a surveillance system for incidents to see how it is around the country based largely, but not entirely, on the existing flu surveillance systems. We are developing those and for the first few hundred cases the HPA has developed a systematic approach for identifying them as clearly as we can but really working very closely with the clinicians looking after them so that again we get as much information as possible from those first few hundred cases to advise us on how this virus is working and affecting the population in the UK, so we will be bringing those various bits of information together, both at the beginning of the pandemic in the UK and also as things progress, so that we can see if resistance is developing or it is not and where that is. We have looked at the pros and cons of a range of different antivirals and we are mindful of the advice that we have had from a range of bodies and committees about the need to get a mixture. At the moment we are in the process of procuring a mixture of antivirals with exactly the intent in mind that you say; that there may be resistance or people may find some easier to take than others, so we are doing our best at the moment to get the right balance of that in place as we develop the stockpile. Also, as I said, we want to ensure that our surveillance and distribution systems are sensitive enough to be able to alter the way that we distribute things and look at the balance of the antivirals going down the chain should that be necessary. In terms of children, yes, we have got advice for clinicians on children. Again, we can give you the details on this, but for older children it is fine for them to use the normal Tamiflu. There is also an oral solution for the much younger ones, for the under-ones, and that is going to be made up by a number of specific hospital pharmacies. They know how to do it and we will have separate distribution arrangements for little ones. We are just finalising the

details of that because obviously it is important that GPs or health professionals see those very vulnerable babies. We have got a whole piece of work just finalising that at the moment.

**Q23 Lord Patel:** Knowing that there is some evidence scientifically already that a generic vaccine to H5N1 might give some protection to key workers, are there any plans to have a generic vaccine developed for H5N1 which might be used for key workers in the hope that some of them get an immune response to that?

*Professor Davies:* We do already have a stock of H5N1 vaccine which we have bought.

**Q24 Lord Patel:** How big a stock?

*Dr Davies:* 3.3 million doses, which is enough for front-line healthcare staff, and that is the plan: it should be offered to them if a pandemic were to break out now. We do not know how effective that would be (it is to a specific strain) but we would certainly be offering it. We are really interested in the new research that has come out and in our thinking about the pros and cons of that, we are looking at the science, we are looking at the potential costs, and we do think it is definitely worth exploring, so we are looking at that energetically at the moment. We have not come to any conclusions yet because we want to make sure that we are testing the evidence as fast as we can and at the same time we are not delaying unnecessarily so there is a balance there, but we are currently collecting the data and will be advising ministers.

*Dawn Primarolo:* It might be appropriate to deal with the question of protection of care staff and health staff beyond that baseline.

*Dr Davies:* Vaccine is one way in which staff might be protected but they will also want to be reassured that when they are coming to work they are not going to be unreasonably exposed to catching a virus which could have an impact on them and their families if they took it home and transmitted it to them, so we are committed to purchasing a stockpile of face masks for healthcare and social care workers, and again that procurement is in the process of being taken forward at the moment. The plan there would be that any worker coming within a metre (so in close contact) with a patient with flu would be advised to wear just an ordinary surgical face mask because it is the droplet transmission that we think is the problem. For aerosol-generating procedures then staff would be advised to wear special bigger respirators and those are going to be stockpiled as well.

**Q25 Lord Patel:** On what basis did you make the assessment that only 50% of the population at the most will get infected?<sup>2</sup>

<sup>2</sup> Please see letter.

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

*Dawn Primarolo:* I was advised by the science. We took the top range and we looked at the worst case scenarios coming from previous pandemics. It is not an absolute guarantee but through discussions and assessments of the science and working very closely with the WHO, who by the way think that the UK is the most advanced and prepared country, whatever our frustrations about the speed—

**Q26 Lord Patel:** —That is because the others are so awful!

*Dawn Primarolo:* Well yes. The question and the point about scientific evidence is also to ensure that it is considered by a scientific advisory group that guides us in that. Wherever possible, we are trying to follow what the science informs us of the likelihoods, including the possible infection rate, in order to predicate our plans and testing and, frankly, I think that is the best that we can do. We can only stay vigilant, as Lindsey has already said, about any newly developing evidence that we are able to take on board and adjust our plans if necessary.

**Chairman:** A last one on this specific topic and then we must move on. Lady Finlay?

**Q27 Baroness Finlay of Llandaff:** Quite specifically going back to the vaccine, given that you are stating that you have a number of doses of potential vaccine already available, are you planning to give that now to front-line staff and replenish that stock so that you begin to build up a degree of herd immunity in the ones who are probably going to have the maximal exposure to sick people (who would probably be those in A&E medical admissions units and some GPs)?

*Dawn Primarolo:* We are not planning to give it now but the wider question of replenishment is also being dealt with on two levels, which is a contract that has gone through the process of the *Official Journal of the European Union*, and that is covering replenishment on use and replenishment on the dating of the stocks that we hold so that we keep it both up-to-date and at the levels that we want, and those contracts are nearly at their conclusion. Sorry, I am talking about the wrong thing again so go on.

*Professor Davies:* We are replacing the antivirals. We have already got 25% of the antivirals and some of that will be going out of date in the next year of two so we are looking at the best ways in which we replenish that sensibly as well as expanding to cover 50% of the population. On the vaccines, the H5N1 that we have got at the moment, we are testing it regularly to see if it is still active or whether there is any chance of it being less effective than it might have been. As long as it stays okay we are keeping it. As I say, we would offer it to staff once we knew that a pandemic was imminent, so that is when that would

work. We are again looking at the possibility of offering it to staff sooner. There was this interesting paper recently which showed that having a bit of a boost now might make it even quicker to boost the immunity in a pandemic, so again we are just looking at that. It is early stages because the paper is relatively new and again we have got to explore it properly but we are asking our Scientific Advisory Committee and the JCBI to look at it for us. That is where we are getting our advice.

**Q28 Lord Methuen:** Looking at currently available resources in the healthcare system, where do you think there will be major gaps in these resources, for instance in pharmaceuticals, medical equipment, infrastructures, isolation facilities, staff?

*Dawn Primarolo:* The biggest challenge perhaps is the question of supplies and the supply chain. We have the drugs in the system and that is an issue which we are addressing ourselves about securing that supply chain. I am not talking about the distribution centres but actually getting hold of the drugs in the first place and replenishing them at a rate and also the alternatives. The second area of priority would then be the isolation and how we would manage that and then, of course, followed very quickly with staff and the sort of things that we talked about at the beginning—realistic assessments of what we can expect and not expect in the demand on the Health Service regardless of the pandemic. I suppose that is the way that we are cascading it. Lindsey has touched on that very extensively in terms of the testing of the system and the points that Lord Jenkin rightly made, feeling his frustration that we should be further ahead on this.

**Chairman:** We have been dealing largely with human ill-health but animal health is relevant, too. I wonder if Baroness Whitaker would like to take up the discussion.

**Q29 Baroness Whitaker:** Minister, we had some conversation about this in the Intergovernmental Organisations Committee and I am glad to be able to continue it. Of course, pandemic flu comes almost certainly from outside our boundaries. I understand that there has been criticism by the poultry industry that current EU information on animal outbreaks is not very widely or speedily shared. I know that there is an EU Framework DG-SANCO for notification and control but perhaps you and your colleagues could tell us how you respond to the criticism. Is it well-founded and what sort of links are there between DG-SANCO and the European Centre for Disease Control, because when we talked to them they told us that they had no remit to pick up information about animal outbreaks? Perhaps you could give some

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

examples of how it is working well; that would be helpful.

*Dawn Primarolo:* I am going to ask Defra to deal with this. We have had some discussions on this in another committee but they are going to deal with the detail.

*Mr Drummond:* Thank you and good morning. I am Richard Drummond, a Deputy Director in the Veterinary Science Team in the Food and Farming Group in Defra. The first thing to say is that there is a well-established mechanism for sharing information about outbreaks of disease not just within the EU but worldwide through the OIE which is the world animal health organisation, and that is well established and the 172 countries of the OIE who are members contribute information, and that information is shared and disseminated very quickly. Within the EU each of the EU Member States has a responsibility for letting both the OIE and, more importantly, the European Commission know very quickly about suspected outbreaks of disease. Even at the point before we have confirmed the disease through laboratory testing, we will have informed the Commission and they will usually send information round to the other Member States' chief veterinary officers. When we hear about outbreaks of disease, either in another Member State or in a third country, we usually would carry out a veterinary risk assessment which goes into our evaluation of the threat posed by that outbreak and we would construct that quickly and make it available on our public website. Where we believe the risk is assessed as exceeding the normal low background level, we would expect to hold urgent meetings with the key representatives of the poultry industry bodies, and this is something that we have actually done in practice in the past. What we cannot do, mind you, is to act on the basis of informal information that we might receive through industry contacts about a disease that may be breaking out in one of the Member States. We do need to wait for official notification before we can take action to make sure of course that we are not raising anxiety unnecessarily and therefore the impact that that would have on trading links. In cases where we have identified a higher level of risk that would require some urgent action to be taken, we have an established network through what we call our Poultry Database which is essentially a collection of the information of all of those owners of flocks greater than 50 birds. We can communicate with these owners through text messages and again this is something that we have done to keep them informed about our assessment of any increased risk. The final thing to say is that we do work very closely with industry representatives. We have regular meetings between outbreaks and of course during outbreaks and we do look to them and work with them in getting information out to their members as quickly as possible.

**Q30 *Baroness Whitaker:*** All that sounds very fine so can you tell me are the poultry industry misinformed? Have they got the wrong end of the stick in their criticism? Also informal information which you feel does not have enough weight behind it to put it out on the website, do you then check that back with your colleagues in other European Union States and why can the ECDC not link in with all this?

*Mr Drummond:* I am afraid I cannot comment in detail (because I do not know) on the links between the ECDC and the European Commission but, I have to say, my impression was that those links were there. To what extent they are developed and how much they talk on a day-to-day basis I do not know. What I can say is that there is an extremely well-developed informal network of information sharing within the EU Member States. That comes about through the network of laboratories that are responsible for the diagnosis of the disease—in the UK we have the Community Reference Laboratory for avian influenza—and by the exchange of information between the scientists in these laboratories we get some very good information very quickly about what is happening in the other Member States, so there is both the formal and the informal and we are using both to good effect.

*Dawn Primarolo:* This point came up before about the connections between the reporting mechanisms particularly at a European and international level and surveillance for animals and humans. I remember it well when you asked me and I sat here explaining how it was all working fine, but afterwards we reflected and we pursued this. Obviously Defra is not in a position to answer today but I think it might be helpful if we did a note saying that yes we have noted and have attempted to raise this and take it forward and to reassure ourselves that the links in theory are working in practice.

**Baroness Whitaker:** I am sure that would be very helpful, thank you.

**Q31 *Lord Krebs:*** I just wanted to follow that up. In your written response you refer to a survey of wild birds to look for the possibility of the virus in wild birds. I wonder if you could give us a feeling for how many birds have been sampled and how big the survey is? In the cases where there have been identified wild birds affected, such as the swans at Abbotsbury, how many birds were sampled in those particular cases? What is the total sample and the sample in the case of particular identified infections?

*Mr Drummond:* I am afraid I do not have the exact figures with me on that. What I can say is that over the last two or three years we will have sampled several thousand wild birds. In 2005 when we expanded the level of surveillance in the Wild Bird Survey, we introduced some new elements which were

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

around sampling of wild birds using one of our ornithological organisations, so they were catching birds live and then releasing them. We enhanced the reporting mechanism for people who found dead birds under suspicious circumstances or circumstances believed to be suspicious so they could be collected and sampled. We even expanded it so that birds that were shot as part of the normal wildfowling activities could be submitted for examination as well. That element has now stopped but the others continue. As a result of that sampling we revealed surprisingly little in the way of avian influenza infection in general and even less so in relation to H5N1 highly pathogenic AI. We are continuing with that surveillance because we believe that it is at least an element that may—and I stress the may—give us a chance of early detection of infection but, equally, we are conscious that avian influenza viruses do circulate freely in wild bird populations, and without investing huge sums of public money it is very difficult to have a statistically valid sampling. We can only do it as a risk mitigation measure.

**Chairman:** I think we will change direction a little again and I will ask Lord Warner to take the discussion.

**Q32 Lord Warner:** Can I say to the Minister having been interrogated on the floor of the House of Lords by many of the people at this end of the table on this subject I have a good deal of sympathy for the situation she finds herself in!

*Dawn Primarolo:* Is this going to be a “but”?

**Chairman:** And I would tell you that he does not coach us on how to do it.

**Q33 Lord Warner:** I did find it reassuring earlier on that you have incorporated in the Annual Operating Framework for the NHS pandemic flu preparation as a priority area, not that I believe that the NHS always does everything that is in the operational framework but it is a good start. However, it was pretty clear in the Winter Willow exercise that there was a need to improve linkages between what you might call established regional and local resilience fora and NHS structures and bodies. To what extent do you think that local services and emergency services are now ready for a pandemic flu outbreak and how are you actually monitoring that to keep on top of that particular issue?

*Dawn Primarolo:* I absolutely agree with you, Lord Warner, about the need—and I will put it delicately because I am still a Health Minister—to ensure that plans developed are actually held to, hence the return in the next operating framework to assess them. You are quite right, the key role of PCTs in local resilience fora is very important in taking forward the preparedness but, in particular, in following the Civil

Contingency Secretariat issued guidance in 2008. I thought it would be appropriate to ask the Cabinet Office, and that means Dr Kirby, to take you through the points with regard to ensuring that there is—and I was going to say a seamless whole, but anyway—this collaboration and partnership and it is developing in the way we would expect across all of the emergency services and local authorities.

*Dr Kirby:* I am Dr Becky Kirby and I head up the Human Health Desk in the Civil Contingency Secretariat at the Cabinet Office. Part of the programme that we have been taking through since the lessons identified from Exercise Winter Willow came out is looking specifically at local and regional planning on pandemic flu and making sure not only that they have plans in place but also that they are fit for purpose. The 2008 National Capabilities Survey, which was published in January this year, showed that 86% of local resilience fora had multi-agency plans in place and that 70% of them had been exercised through multi-agency exercises. Those figures look good but it was not 100%. Also, although we knew that they had planned, how could we be sure that they were fit for purpose and implementable when a pandemic hit, so we took forward a work programme whereby my team validated and provided feedback on every local resilience forum multi-agency plan. Following that we held a large conference to enable them to share best practice and we published supplementary guidance in order to help them fill the gaps that we thought were within their plans, specifically around data collection, the management of excess deaths for example. We are now working through a process with regional resilience directors to validate those plans and to exercise them, so by the end of this year, by the end of December, all local resilience fora plans will have been validated and they will all be published on the UK Resilience website. By the end of the financial year a series of exercises will have been completed at the local level in order to make sure that we have confidence that those plans are operational. In terms of the link with the health system, I can tell you that primary care trusts, the HPA, hospitals, *et cetera* are all represented on local resilience fora multi-agency planning committees so I am confident now those links are in place and that all LRFs have those linkages in the right places. You mentioned essential services and although in the Cabinet we co-ordinate the cross-government response and take forward planning for the non-health elements of pandemic flu, it is really down to lead government departments to drive forward planning within their sectors, so for example we rely on the Department for Transport to drive forward planning in the transport sector and BERR and DECC in the energy sector. However, I can tell you that with the electricity, gas and nuclear

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

industries for example, we are confident that they have plans in place. We sit on a number of pandemic-specific sub-committees on which those groups are represented and ourselves and the lead departments for those industries feed into them on a regular basis to make sure not only that they have plans but also that they are exercised, which we see as fundamentally important. The same is true with the Department for Transport looking at those essential services.

*Dawn Primarolo:* I think you will probably recollect this: it comes into government level through the Ministerial Committee which is interdepartmental and which the Secretary of State chairs, where again there is pressure to bring all of this together both across devolved administrations and departments. I sit on that as Health because the Secretary of State is taking that forward. One of the questions we ensure that the NHS answers and part of their assessment locally is the detail of how they are working on delivery, so we are putting the pressure as best we can on the other side, on the NHS, to continue to show us where the connections are and that these inter-agency and local authority plans are working.

**Q34 Lord Warner:** Could any of you elaborate a little bit more on where the weak spots are because we know from previous exercises like the SARS experience in Hong Kong that some linkages are more critical than others and the police and healthcare system links in the SARS epidemic were very important? How reassured are you, and can you give us some examples, that the key linkages between health and some of these other agencies are really, really robust, or which are the ones where you would have some anxieties in a significant number of places?  
*Dr Kirby:* I certainly think that we are in a much better position now than we were at the start of the year and once we have completed our exercise programme we then have a feedback mechanism back up to the centre to make sure that if any continued weaknesses are identified that they are addressed. Before we started this programme, as I mentioned already, the management on the non-health side, for example the management of excess deaths, was an issue. We have published some new guidance on that including an indication of the types of legislation that we would look to amend or relax in order to facilitate planning in that area. As Lindsey and the Minister have said, those linkages across health and non-health now are in place driven from the top down but also from the bottom up in local resilience fora as well.

*Professor Davies:* I think I would agree with that. None of us could guarantee that in every location across the UK everybody is working together perfectly, but the information that we have had

through all our various networks is just incredibly encouraging. We go out and about a lot. I think all of us are on conference and workshop platforms most weeks talking to people in different regions and different parts of the UK about what they are really doing and the conversations over lunch there I think are most pertinent where people say, "How is it really for you?" I really have noticed a sea change certainly in the couple of years that I have been doing this. I was working to a region before and I knew what it was like to be there and linking. I now know that the feedback that I am getting and even the body language from the people round the table is much more positive. They know each other, they know who is who and they know what is supposed to be happening.

**Chairman:** I think this leads very easily to Lord Crickhowell who has some further questions in this general area.

**Q35 Lord Crickhowell:** Can we just have a look at the devolved administrations. Again in the Winter Willow report you say fairly that there are some policy areas where there might be differences of approach in dealing with local need. On the other hand, as we heard in the opening evidence session, there clearly are some very important planning and testing of planning processes going on at a national level, and it seems to be absolutely vital to me with the fact that we have got devolved administrations that we do not open up a gap between the two. No-one will actually be very sympathetic, even those enthusiastic for devolution, to the whole process if it is found that things are less good in Wales or Scotland than they are in England or vice versa. As some problems were identified in Winter Willow, particularly making sure that there was a real understanding of where responsibilities are, can you elaborate on how far we have got in sorting that one out?

*Dawn Primarolo:* You are quite right that it is a national plan and they are taking forward within the devolved administrations their work in delivering to the same level, but they are also integrated in terms of communication between ministers in making sure that we are agreed that this is a sensible way forward. In terms of them being represented, it is at every level in the policy development or discussions, from the MISC 32 Committee, the Ministerial Committee, through to using the expertise that they have to develop for the whole of the plan some particular advice. For instance, I think it was Scotland which did some of the development work around the surge capacity at each point to make sure they are fully involved in development of policy exercises, guidance, frequent discussions and communication between ministers about directions of policy

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

development, response to new research, and in their own cases taking forward the delivery for their administrations. However, it is clearly set within a UK-wide response and everybody is at the same place doing the same thing to the same standards and we are following the same guidelines, so I hope that the national framework and the practice has now—and that is certainly the advice to me—delivered that very clear and close working at all levels.

**Q36 Lord Crickhowell:** And just to follow up, I live quite close to the English border in the south but if you take particularly North East Wales and Cheshire and so on, when I had responsibility for health in Wales we always had pretty close co-operation between hospital services on both sides and we were using facilities in the English hospitals when we had not got them in the Welsh hospitals and so on. Are you satisfied that in the event of this kind of emergency there could be effective cross-border co-operation and that we will not get into a wholly absurd separation “that is nothing to do with us because it is a different country or different administration”?

*Dawn Primarolo:* No absolutely, what you are describing in terms of the UK response with UK resources, and making sure that across the devolved administrations as well that we are seeing the response to a pandemic and that there is not a demarcation line saying “that is England” or “that is Wales”. Those partnerships, as you are rightly describing, have gone on for some time in terms of planning capacity anyway with regard to the Health Service and still do. I think we are satisfied on that. We would pay attention to that and certainly in the discussions (mainly done in writing because there is agreement) with the ministers in the devolved administrations, we are all on the same page on this and are all progressing in the same way.

**Q37 Lord Crickhowell:** Can I go down to PCTs. You talked about the availability of resources and so on in answer to the previous question. What about consistency of response between local PCTs? Some are very good; some are rather less good. In Wales I happen to have a simply marvellous local service and I am full of the highest praise for it but there are others I know that are rather less good. Are you satisfying yourselves that at that level there is a consistency of approach and standards?

*Dawn Primarolo:* Yes we are. Perhaps I should ask Lindsey to detail how we are progressing through what might be considered as a delicate area in terms of the standards being provided across all PCTs and making sure that happens.

**Q38 Lord Crickhowell:** How?

*Professor Davies:* In a number of different ways. Firstly, by issuing not just the UK National Framework but a whole suite of different sets of guidance. One of those sets is for PCTs and we are in fact refreshing that and going to be publishing a revised PCT guidance imminently, so that is one thing. That is there to guide them. How do they interpret that in practice and can we ensure consistency there? Firstly, regarding the expectations around the NHS plans there is a whole set of self-assessment questions for PCTs that set out quite clearly what is expected of them and how they might do it, so their response to that is important, but at the local level we are encouraging PCTs to work closely with their own community within their boundaries—it depends on the size of the PCT a bit—but also with local PCTs to share plans. On some occasions a local resilience forum will have several PCTs as part of it so that forces the engagement. We have asked each strategic health authority as the head of the NHS in their area to nominate a pandemic influenza lead and also each PCT to nominate a pandemic influenza lead. The SHA flu leads meet with me monthly to talk about plans and expectations and what they are doing and to share what they are doing, and that is obviously an important forum for consistency across the country at that level. They have similar meetings with their PCT leads and are going out regularly with them engaging with them to talk one-to-one, to talk at conferences, workshops, whatever, so that is another route. Finally, I send every month out to the NHS through the flu leads a publication called *Flu News* which keeps people up to date with expectations and points them to guidance that is happening but also identifies any new links, any new things of which they should be aware. We have a whole web-based information forum service for them that people can just ask to have their names put on and they get access to all the guidance and everything they need to know, and they can also talk to each other through that and share experience, so we hope the range works.

**Chairman:** Thank you very much. Dr Kirby mentioned in her last question an issue that I think we want to go back to and I do not want to lose, which is legislation, and Lord Selborne will take the discussion.

**Q39 Earl of Selborne:** The Civil Contingency Act 2004 allows in the case of an emergency for the appointment of regionally nominated co-ordinators. Would you expect in the event of a pandemic event this part of the Act to be activated? Would there be other provisions of the Civil Contingency Act that might be activated or would you simply rely on the

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

established linkages between the regional and local resilience structures?

*Dr Kirby:* As mentioned already, one of the lessons coming out of Exercise Winter Willow was to identify now a whole host of legislation that we might need to amend or relax during a pandemic, and obviously Part II of the Civil Contingencies Act forms part of those considerations. However, emergency powers under the Civil Contingencies Act should be viewed as a last resort. When the Bill went through Parliament it was agreed that there was a triple-lock mechanism and that three particular pieces of criteria needed to be met before it could be considered to be used. One of those was that an emergency was imminent. Although we do not know when a pandemic could happen, I do not think I could say it was imminent, so what we are doing now is identifying other legislative vehicles, for example amendments to primary and secondary legislation, that we can draft and have on the stocks now ready to go through Parliament or if there is a particular bill that is going through Parliament that is there is scope so that these preparations are made in advance of a pandemic and therefore would negate the need to use emergency powers once a pandemic emerged. However, that said, it is there and emergency powers should be used if they are needed in order to facilitate the response to a pandemic, but only if the criteria upon which it was agreed are fully met and if we have exhausted all other possibilities.

**Q40 *Earl of Selborne:*** Could you give us some hint as to what these different legislative opportunities are other than the Civil Contingency Act? You referred in your written evidence to a raft of possible legislation which may need changing; what is this?

*Dr Kirby:* I can give you a few examples and I can provide more examples in writing afterwards. I can give you examples about the ones that we have already made public. However, we are keen that planners plan on the basis that we are not going to use emergency powers because otherwise their plans might just assume that we will and therefore will not be particularly robust. If I take excess deaths for example and just give you some examples about the legislation that we are looking at in order to facilitate the response there, we are looking at ways of increasing capacity for coroners by making specific changes to the Coroners Act 1988 and the Coroners Rules of 1984 which increase the flexibility for example of who can hear coroner cases, where post mortems can be carried out, arrangements for investigating deaths from abroad, who can sign death certifications, extending the amount of time to register stillbirths, in order to improve or increase the capacity of coroners. Those changes can be made by making amendments to bills that have already been

passed rather than by having to use emergency powers and there are others that we have identified where we would make changes to existing legislation rather than put something through using emergency powers.

**Q41 *Earl of Selborne:*** If we could go back to the regionally nominated co-ordinators which, as you say, might be the last stop, what powers would such co-ordinators have? For example, we have heard earlier that curfews are not seen to be a sensible way forward. Supposing the regional co-ordinator thought that that might be an appropriate way forward in that particular region, would there be powers to enforce that curfew?

*Dr Kirby:* I would prefer to come back to you on that in writing if you do not mind. What we have established is linkages and information flows so that any issues arising at a regional or a local level are fed back through the system so that centrally we can look across the piece to know if the South West are having a particular problem and are thinking about the need to implement curfews so that we can have a UK-wide joined-up approach rather than one region acting in a different way to others, so by ensuring that those information flows are in place I hope that we would negate the need for one region to act in isolation in such a way.

**Earl of Selborne:** Thank you.

**Q42 *Lord Haskel:*** The Minister spoke about business as usual in the event of a pandemic and this means, of course, keeping the essential services going. It means keeping transport, food distribution, electricity, the Internet and telephone services going. In your paper you say that the Government is working closely with the private sector to strengthen business continuity planning. Dr Kirby said that the departments have got plans in place and that you have been working with the various sectors of industry. Can you tell us where you expect the greatest challenges to take place? Where do you think the failures are going to be? Where do you think the problems are going to lie outside the Health Service but in the central services that will need to keep going?

*Dr Kirby:* As you already mentioned, we have been working hard with all of the essential services and especially with category one responders because they have a duty under Part I of the Civil Contingencies Act to make sure that they have business continuity plans in place so that not only can they respond to the emergency but also do what else they should be doing as well. In terms of liaising with business we have the Business Advisory Group on Civil Protection and a standing agenda item for that meeting is pandemic flu preparedness. Representation includes the CBI, the

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

Federation for Small Businesses and also some of the other large industry groups, and through that mechanism and by individual meetings with businesses we are helping them to drive forward their business continuity planning. In fact, some essential services and some businesses have agreed that we can publish their business continuity plans on the UK Resilience website so that we can share that best practice across the piece. You asked where we think the biggest challenges will be outside of the health sector. It has already been mentioned at this meeting that staff absenteeism is going to be one of the biggest challenges because it will impact across the piece. I could not tell you which particular industry would be most impacted by that but I can tell you that they all have business continuity plans in place to deal with the highest staff absenteeism rates which involve looking at their priorities, looking at staff training, making sure that they have identified the particular functions that they could curtail during a pandemic because they are non-essential, identifying those that are essential and making sure that more staff are trained to do those roles to build in that contingency. The National Capability Survey, which the Civil Contingencies Secretariat runs every two years, does indicate a significant increase in the number of not only category one responders but other essential services and businesses that have business continuity plans which are specific for pandemic flu.

**Q43 Lord Haskel:** Following on from the previous question then, if an essential service or a business falls down on the job and fails to continue providing the essential service, is the Government prepared to legislate to mitigate the damage or disruption? How would you deal with that?

*Dr Kirby:* Firstly, I hope that through the information and data collection networks that we have established now that we would find out that there was a problem before anything fell over. I think that is really key, so the mechanisms feeding into the COBR mechanism during a pandemic, that a particular essential service or group of businesses is struggling would be our first mitigation strategy, identifying that early on and then putting something in place, and if that requires legislative changes then we would have to be prepared to be able to do that.

**Chairman:** That is very helpful. We are running very close against time but there is one further question that I would like to take a few minutes on and, if that is acceptable, would Lord Colwyn take up the discussion.

**Q44 Lord Colwyn:** This is a question about finances. We are aware and we have seen in your written evidence details of the contributions you have made via the European Commission and of the UK pledge

of £35 million towards the international effort to tackle avian influenza and for the preparation for a future pandemic. We are also aware of the ways in which some of this money has already been spent. What is the overall estimated cost of the Government's contingency planning and has this been subject to a cost/benefit analysis?

*Dawn Primarolo:* The Government has already committed £350 million. That includes the purchasing of medicine and securing supplies. You have mentioned in addition the monies that we are committed to internationally, and that is a dimension that we have not been able to touch on very much today in terms of surveillance and capacity in other countries, particularly in the most vulnerable ones. In addition, DFID—and perhaps I could ask John here—in terms of working with countries in reprioritising projects and looking at the work that could be done there, the Government's approach is that we need to contain those costs in normal spending arrangements within government. Again, we mentioned the concluding of contracts soon both on the Flu Line and on future purchase for ourselves of increased stocks, but I wonder whether on the international issue, John, you can touch on some of the issues and the costs and continuing costs.

*Mr Worley:* My name is John Worley and I am the acting Head of Profession for Health in DFID. DFID focuses its health spending essentially in supporting poor countries strengthen their health systems. That does not overlap necessarily with those countries where pandemic flu is the greatest risk, so we also provide significant amounts of multi-lateral support to the UN system and particularly the work of the WHO and the FAO and support for the UN Systems Influenza Co-ordinator, Dr Nabarro. Through our country programmes increasingly we are supporting as part of our health system strengthening approach the strengthening of capacity and systems for disease surveillance in a number of countries that have asked for that, including China, Kenya and Uganda, as well as countries that more recently have suffered disease as a result of earthquakes and other natural disasters such as Pakistan where avian flu is now one of the sentinel markers in the disease early warning system that we are supporting there. As the Minister said, we intend to continue to support the international response through our usual programme and budgeting mechanisms as well as to consider, when they are presented to us, the options for supporting a global vaccine stockpile. That will probably be discussed at the forthcoming December inter-governmental meeting that the WHO will hold.

**Q45 Lord Colwyn:** The Minister mentioned £350 million I think and I am not quite sure how that is allocated.

25 November 2008

Rt Hon Dawn Primarolo, Professor Lindsey Davies CBE,  
Dr Becky Kirby, Mr Richard Drummond and Mr John Worley

*Dawn Primarolo:* That is for the purchase to which we are already committed in terms of spending for the antiviral medicines and supply of vaccines. Over and above that there are costs not included in that which we are concluding now with the business cases for procurement on the additional counter-measures, so that is spending here in the UK and then these are the monies that we are devoting through international co-operation particularly if there is surveillance and resilience in other countries as we respond to the requirements for the WHO. I can tell you that it is £350 million now but when those contracts are concluded, which is imminent, I will be able to tell you the next level of committed expenditure I cannot tell you that at this point in time beyond the £350 million.

**Q46 Chairman:** We have covered a lot of ground. There is much more that my colleagues want to cover. I am being inundated with bits of paper and questions that they would like to ask. We will certainly be continuing our discussion of this. It

would be very helpful to have fairly soon the various written follow-ups that you have indicated we could have. I know people are busy but it would be appreciated. What we would like to do is withdraw into our Committee, talk further about what we have heard and about what people send to us and possibly send some more questions, and then it may be that further discussion would be useful and helpful. I appreciate that we have given you a lively time and I thank you very much for giving up your time, all five of you.

*Dawn Primarolo:* Thank you very much. We did not touch on GPs' guidance either. We will certainly do our best to get the information that we have already promised to you as quickly as possible. I am absolutely happy to facilitate responses in writing and should your Lordships wish to return to this in an evidence session such as today's I am more than happy on this biggest challenge to public health, frankly, that we face, and I am sure that you will give us a great deal of help and guidance on this. Thank you very much for your time.

**Chairman:** Thank you very much indeed.

### Supplementary memorandum by the Department of Health

#### A. NHS PREPAREDNESS

The NHS Operating Framework for 2008–09, which sets out the priorities for the NHS, requires all NHS organisations to have robust pandemic influenza plans in place by December 2008.

These plans will be assessed early in 2009. A web based assessment tool will be released in January 2009 to allow Trusts to complete the formal survey of preparedness based on the plans that they have put in place for December. SHAs will carry out a review and challenge process to ensure consistency of approach and that they are content with the way that the assessments have been completed. Information should be available to the NHS Chief Executive by the end of March to confirm current levels of preparedness.

#### *Support for the pandemic preparedness planning*

The DH Pandemic Influenza team is providing support for the development of pandemic preparedness. This includes:

- Publication of guidance and “how to” information for NHS organisations. Recently published documents include draft guidance on maternity services, vulnerable groups and surge capacity, and final guidance on human resources, dental practices, primary care dentistry, management of death and cremation certification, recovery etc. All guidance is available on the DH website. (See below for further information about guidance for GPs and primary care.)
- Implementation guidance and tools, in a modular form, for adult social services.
- Monthly Flu News.
- A web-based Pandemic Flu Forum.
- Implementation workshops including a mental health workshop (24 September), ambulance services (15 October) and forthcoming regional social care workshops, to be held jointly with NHS colleagues attending.

- A competency based e-learning tool for health care staff is in development.
- Communications road shows to support PCT communications planning.
- Frequent ongoing support at Regional and local workshops and events.

#### *Guidance to GPs and Primary Care*

We expect that the use of our stockpile of antivirals will reduce the number of seriously ill people, which in turn would reduce the pressure on the NHS. However, advance planning for these challenges is essential.

The key issues for GPs and Primary Care will include increased workload, depletion of workforce, critical care, the discharge of patients, (some of whom will require ongoing care at home), medical supplies including pharmacy and equipment, and sufficient mortuary provision.

Operational Guidance for GP Practices has been developed in conjunction with the Royal College of General Practitioners (RCGP) and The British Medical Association (BMA). It focuses on business continuity planning, dealing with symptomatic and asymptomatic patients and access to antivirals. It also explains the use of Flu Line Professional, which allows GPs and other healthcare workers to validate users, update the system and process patients whom they have diagnosed directly. The guidance will be released in January 2009 via the RCGP and BMA, supported by the DH.

To preserve GP capacity and enable practices to deliver care in the community setting, it is planned that non-essential activity will cease (but continuing to make essential care available for emergencies and patients with chronic or other illness), and GPs and those with higher clinical skills or experience will focus on those patients who may be at particular risk.

We are encouraging GP practices to work in clusters to support each other in the event of a pandemic. This is to ensure no GP practice is left isolated.

Guidance for dental practices was issued in September 2008, focussing on infection control, dealing with symptomatic patients, and business continuity planning. Another document entitled "Guidance on the Delivery of and Contract Arrangements for Primary Care Dentistry in a Pandemic" was also issued in September 2008 to provide guidance more specific to NHS Primary Care Dentistry.

In May 2008 the DH published a summary of responses to its paper entitled "Possible Amendments to Medicines And Associated Legislation during an influenza pandemic", which was an initial consultation on outline ideas to ensure continuity of access to medicines and healthcare products during the event of an influenza pandemic. We continue to work with various stakeholders to study these responses.

Revised guidance for PCTs and primary care professionals in a community setting was published in December 2008; this revision reflected changes in antiviral strategy.

#### *Communication and Training for Frontline Staff*

The responsibility for communicating business continuity and pandemic influenza plans to staff lies with NHS Trusts. As part of their pandemic flu preparedness, Trusts are expected to develop communications plans for all stakeholders including staff.

The Department is undertaking a number of initiatives to support NHS Trusts in this, as outlined above. There is currently a cascade system to communicate information via regional "flu leads". The Department is reviewing whether and how this should be extended.

Chief Medical Officers have an important professional leadership role in a pandemic. In conjunction with expert groups, professional bodies and health protection agencies, they will provide multidisciplinary advice and information and may need to adapt initial guidance as the characteristics of the emerging influenza virus become more apparent or if pressures on capacity, pharmaceuticals or other supplies make tactical changes necessary.

Training will play an important part in alleviating the pressure on staff during the peak of the pandemic, as the availability of sufficient human resources is critical to the maintenance of all health and social care. We are developing a number of "training modules" that can be used locally to raise awareness of pandemic influenza and related issues among frontline staff.

One such resource is a training package that we are developing for the GP Vocational Training Scheme (VTS) which may also be used in practices. It takes the form of an off the shelf exercise using a scenario set at WHO pandemic level 6. The aim is to raise awareness and familiarise key stakeholders with the wider impacts of an outbreak of infectious disease on the contingency planning and service continuity of general practitioner

services, and also to rehearse the impact and management of such incidents at organisational, team and individual levels.

A pilot exercise was run as part of the Oxfordshire VTS scheme in October and feedback from the trainees and tutors is being used to refine the material to be used in a second pilot course in Southampton in February. Initial feedback from both GPs and tutors on this form of training tool is positive.

In addition, doctors.net have had a flu module internet training package that has been available to doctors for some time. We are looking at e learning as a training tool for other professionals too.

While at the present time there are no national plans to give frontline staff operational training for pandemic influenza, DH is exploring the development of such training from next year and how best to make it available to staff. We plan to discuss this further with the post graduate deans and others in the new year.

## B. EARLY CONTAINMENT PLANNING

Avian influenza outbreaks amongst poultry and wild birds can be expected to occur from time to time in the UK.<sup>5</sup> At present, no subtypes of avian influenza with the potential to spread readily from person to person have been identified. There have been a limited number of well-documented cases involving H7N7 and H5N1 in which limited human-to-human transmission has occurred but to date there is no evidence that any avian influenza viruses have adapted to spread easily in humans.

An outbreak of avian influenza in humans, whether high pathogenic or low pathogenic in birds, would indicate greater ease of transmission from birds to humans and raise the possibility of sustained human-to-human transmission. Because such an event could prelude the emergence of a pandemic strain, the measures developed for preventing spread of infection in pandemic influenza would then be applied. Although experts think it unlikely that a pandemic will start in this way in the UK, the Government has planned for early containment of an outbreak of any avian influenza capable of causing human disease.

Situations such as this would be dealt with in line with the Health Protection Agency's National Incident and Emergency Response Plan. The HPA and Department of Health would be immediately notified by Defra, given the animal health link. The DH would in turn notify WHO, depending on the avian influenza subtype and outbreak situation.

We now have experience of dealing with seven avian influenza outbreaks in the UK; in two of these incidents human infections were identified, treated and appropriate controls put in place. Guidance and treatment algorithms for clinicians on handling cases or suspected cases of avian influenza has been produced and is published on the HPA's website<sup>6</sup>. The measures put in place for patient care and follow-up of contacts of cases and suspected cases are designed to prevent further spread of infection:

- Suspected and confirmed cases would be managed in strict isolation. Where hospitalisation is deemed to be clinically necessary, patients would be looked after in a negative pressure room and staff would wear full personal protective equipment; high filtration masks, gowns, gloves and eye protection.
- Prophylaxis with antivirals would be offered to those who had been determined to have significant contact with the sick individuals and the source of the infection (assumed to be birds). Each local health protection unit of the HPA has a local stock of antivirals for this purpose, which could be rapidly augmented by neighbouring units.
- Contact tracing would identify as many as possible of those who had been in contact with suspected and confirmed avian and human cases.
- Contacts (or their responsible carer) would be given information about the illness and active health surveillance would be undertaken—daily telephone calls for up to seven days after last exposure in order to detect the onset of febrile respiratory or other unexplained illness. Contacts would also be offered antiviral prophylaxis and would be asked to minimise social contact—the definition of “contact” in this situation would be determined by the HPA, based on epidemiological evidence.
- Measures to prevent further spread of infection are also in place for diagnostic and research laboratories, with appropriate guidance on biological containment measures in place.

<sup>5</sup> As a precautionary measure against the possibility of a new virus emerging as a result of mixing between human flu and avian flu viruses, vaccination against human flu is made available free of charge to poultry workers and others who might be at risk of exposure to avian flu.

<sup>6</sup> This guidance has already been implemented in dealing with suspected cases of H5N1 amongst travellers returning from areas where this infection is endemic, and in dealing with possible cases of infection amongst those who have been exposed to infection during outbreaks of HPAI amongst poultry in the UK.

In addition, information developed by the Health Protection Agency would be made available to people in the surrounding area by the local primary care trust (PCT) through the NHS, the media and a dedicated helpline. This would give advice on the disease, signs and symptoms and action to take in the event that an individual develops symptoms or they considered themselves at particular risk.

These arrangements would apply in the event of an outbreak in humans linked to disease in birds, when there would be a focus around which a containment strategy could be developed. In the event of sustained human-to-human transmission,<sup>7</sup> we would need to implement the WHO rapid containment protocol using our existing incident and emergency response framework. The logistical issues of getting antivirals from WHO that many countries face in their planning can be discounted in the UK because we have sufficient stockpiles already. In addition, PCTs are developing plans for antiviral receiving and forward distribution. The rapid containment protocol includes widespread prophylaxis, establishment of containment and buffer zones and restrictions on movement. Depending on the nature of the virus, vaccination may also be offered, if available.

The Health and Social Care Act 2008 updates the Public Health (Control of Disease) Act 1984 by providing powers to make regulations, both on a standing and ad hoc basis. Such regulations could, if necessary and proportionate, enable the establishment of containment zones or restrictions on movement.

We are conscious that surveillance will have a key role in the containment strategy as both the WHO rapid containment strategy and our own strategy are the more effective the earlier an outbreak is detected.

We are keeping these plans under review and will develop them further, if necessary, in the light of the revised WHO planning guidance and any further scientific evidence.

### C. PLANS FOR DISTRIBUTION OF ANTIVIRALS AND TESTING OF PLANS

There is international consensus that using antivirals to treat the symptoms of pandemic influenza could play a key part in mitigating the impact of a pandemic and mitigate the severity of the disease. This position is set out clearly in the WHO “Guideline on the use of Antivirals and Vaccines” (2004). It recommends the stockpiling of antivirals as part of national pandemic preparedness planning.

In order to minimise the impact of the illness and maximise individual health benefits, patients should take an antiviral medicine as soon as possible after the onset of symptoms—ideally within 12 hours but in any case within 48 hours. Therefore, rapid antiviral provision is an important planning aim in the National Framework for responding to an influenza pandemic.

This paper sets out:

- I. The rationale for the decision to implement a National Pandemic Flu Line Service.
- II. An overview of how the service will work.
- III. Progress to date on the development and implementation of the service.
- IV. Operational considerations that have been taken into account.
- V. Plans for testing the antiviral distribution strategy.

#### I. *Rationale for the National Pandemic Flu Line Service*

In order to support the decision to adopt antivirals as a countermeasure, a mechanism to distribute these antivirals needed to be developed. Options considered for the distribution of antivirals were:

- Primary care distribution via GPs.
- Distribution of antivirals via post to the entire general population immediately in advance of an influenza pandemic.  
This would mean that people had antivirals to hand should they become symptomatic and need medication.
- Automated distribution through a multi-channel FluLine to symptomatic individuals only.

<sup>7</sup> It is important to note that it is very possible that such transmission could be of a low pathogenic virus, with relatively mild symptoms, rather than a highly pathogenic virus.

These three options were assessed against quantitative criteria of cost and risk, and also against ten key qualitative criteria:

- i. *Reduce the impact of the pandemic on primary care services*  
Primary care services will be under immense strain during a pandemic, therefore it will be important to divert as many people as possible to alternative means of care, enabling primary care to focus on providing services to those who need it most.
- ii. *Easy and widespread access to the general public*  
It is important to provide a service that can be accessed by as large a proportion of the UK population as possible.
- iii. *Enable symptomatic individuals to stay at home*  
In order to reduce the spread of the influenza and avoid the creation of flu “hot spots”, it will be important to encourage symptomatic individuals to stay at home. As a result, a service that provides assessment and antiviral authorisation and provision to people which they can access from their homes will be essential to helping to reduce the spread of the virus.
- iv. *Rapid assessment and antiviral access (less than 48 hrs from onset of symptoms)*  
In order to be effective, a key requirement of the antiviral is that it is taken by the symptomatic individual within 48 hours, and preferably within 12 hours, of the onset of symptoms. Once past this timeframe, the antiviral ceases to be effective in reducing the severity of symptoms experienced.
- v. *Control over the antiviral stockpile*  
Given the high costs of purchasing antivirals and the fact that sufficient antiviral will be purchased to cover one dose each for the general public (plus additional amounts for wastage and UK visitors) it is essential that a high level of control be maintained over the purchased drugs. This is to ensure that it is available to symptomatic individuals as and when they need it, as well as to minimise the risk of profiteering from illegal sale of the drug.
- vi. *Scalability*  
Given the anticipated level of demand based on a 50 per cent attack rate for the whole population and the speed with which a pandemic could spread, any service of providing assessment, authorisation and distribution of antivirals to the UK population will need to be able to rapidly scale up to the required volumes and be able to cater for the high level of demand placed on it.
- vii. *Reliable and robust solution*  
As the system will be used to provide antiviral to symptomatic individuals within 48 hours of the onset of symptoms, it is vital any mechanism can be relied upon to be available to people when they need it.
- viii. *Security*  
Given that any service would be required to hold personal data, it is imperative that it is compliant with Cabinet Office security standards. The service will also need to be secure from fraud such that it is able to authorise antiviral release fairly and equitably.
- ix. *National service providing coherent UK response*  
In the event of a pandemic, it is important that the UK’s response is coordinated, across all four United Kingdom Countries (UKCs).
- x. *Support national decision making through surveillance and other information*  
In order to be able to understand the impact of the pandemic and make informed decisions based on the impact on the population and the health economy, it is vital that key management information is available throughout its duration.

Of the three options considered, the third option of a multi-channel automated distribution system (the National Pandemic Flu Line Service) best meets the critical success criteria and is the lowest cost option.

## II. *Overview of National Pandemic Flu Line Service*

The National Flu Line Service is intended to supplement and protect existing primary care arrangements by taking much of the burden of initial assessment, triage and antiviral authorisation away from frontline healthcare services. This is also in accordance with the message to “stay at home if ill” as it allows patients to contact the Flu Line from their own home, over the telephone, or by web.

On contacting the Flu Line, members of the public will gain an initial assessment of their symptoms (using a clinically-based algorithm), advice, triage, and if appropriate (if they are symptomatic and able to take the antivirals within 48 hours of onset of symptoms) authorisation of antiviral medicines. On having their identity verified and being given a unique reference number, they will then be asked to send a “Flu Friend” (eg friend, family member, carer) to a local collection point to collect their antiviral medicine for them.

The National Pandemic Flu Line Service will act as the “first port of call” to those who become symptomatic during an influenza pandemic, and will be the mechanism through which the majority of the public subsequently access antivirals.

The service will be supported by stock management and storage and distribution arrangements (see below). It is recognised as being critical to the Government response to an influenza pandemic.

### III. *Development and implementation of the antiviral distribution strategy*

In order to take forward the development and implementation of the service, the Pandemic Influenza Preparedness Programme has drawn up a comprehensive antiviral implementation strategy to ensure that there is a coherent, well-planned approach for the entire distribution process. This encompasses all of the key components that are required to implement the solution: the National Pandemic Flu Line Service, local arrangements (including collection points), stock management, and storage and distribution.

The strategy has three focal areas:

- To provide assessment and authorisation of antivirals during a pandemic (National Pandemic Flu Line Service).
- To ensure that there is a robust system in place to distribute the antivirals locally (collection points and local arrangements).
- To ensure that there is a robust system in place to effectively manage, store and transport AV stock during a pandemic (Stock Management, Storage and Distribution).

This is clearly a major endeavour and the government has placed great importance on ensuring that the proposals have the support of all the critical stakeholders and are subjected to the most rigorous scrutiny, both in terms of feasibility and value for money.

#### National Pandemic Flu Line Service

The primary objective of this project is to analyse, design, develop, test and implement the National Flu Line Service, which will provide access to antiviral medicine to people with the influenza virus who have been symptomatic for less than 48 hours. The service must remain operational until the impact of the pandemic and the threat of further waves subside.

Related objectives for the project are as follows:

- Assessment of symptoms using a national clinical algorithm;
- Authorisation of antiviral as appropriate (ie to those that are symptomatic with the influenza virus and within 48 hours of onset of symptoms);
- Allocation of a unique reference number to those that receive authorisation (which can be used to reconcile the patient with the authorisation at point of collection);
- Manage fraud/wastage by identifying those who would benefit from antiviral and validating that they have not already received them;
- Gather and report on data on the spread of the Influenza virus to inform surveillance during a pandemic; and
- Provide integration with the DH stock management system to ensure stocks are monitored and distribution arrangements are maintained.

Extensive and exhaustive work to assure the quality of the project and secure proper value for money has been undertaken as follows:

- In August 2006 an initial consultation paper on the plans for operating a flu line to support the distribution of antivirals to the public was published on the DH website. The consultation paper led to a period of extensive engagement with key stakeholders such as the BMA and the RCGP to inform the development of a proposed solution that was acceptable to the professions.

- In 2007 NHS Direct was commissioned to lead on the development of proposals for the National Flu Line Service system, working in partnership with NHS 24 (Scotland) and NHS Direct Wales. The launch of the National Framework in November 2007 confirmed the plans for introducing the National Flu Line system and the home care delivery model. Plans to increase the antiviral stockpile and to establish an antibiotic stockpile were also announced at this time. Public engagement research in early 2008 was used to test some of the key planning assumptions for the Flu Line.
- The project for the development of the Flu Line system was reviewed by the Office of Government Commerce in March 2008. This considered both the project planning for volumes and costs and also the ongoing work to develop clinical algorithms which could be used by non-clinicians.
- British Telecom was confirmed as the preferred supplier in July following a procurement exercise using the OCG Catalyst framework for Specialist Solutions. The contract between NHS Direct and British Telecom, and the agreement between NHS Direct and the Department of Health were signed in December 2008.

The process for obtaining the necessary approvals to satisfy the assurance arrangements for the Flu Line Business Case to be submitted to HMT has been a lengthy one. We are breaking new ground internationally in developing the National Flu Line system: no other country has an equivalent system for making antivirals available to the public.

Signing the contract in December should mean that the National Flu Line Service system is available for use in the event of a pandemic by April/May 2009. If Phase 4 was announced in the meantime (meaning that a pandemic is more likely) DH would review the development timescales with the contractor.

### Local Arrangements

In parallel with the work outlined above to procure the Flu Line service, work to ensure that the local arrangements are in place is underway at local level. Guidance on the local arrangements for establishing collection points—where the public can pick up antivirals if they have been authorised to do so by the Flu Line—was made available to PCTs in July 2008. PCTs are now finalising plans detailing the locations they would use as collection points during an influenza pandemic.

The key objectives for Collection points will be:

- To store supplies of antivirals.
- To verify the unique reference number given to a patient and reconcile on the Flu Line system.
- To physically issue antivirals to the person collecting the antiviral.
- To support stock management—monitoring reports and manual checking.

Minimum requirements for Antiviral collection points are specified in detail in the Pandemic influenza “How to” guide for primary care trusts on local arrangements for antiviral collection points including details of technical and operational considerations. PCTs have also been provided with a modelling tool to enable them to identify their local capacity requirements based on potential surge patterns of the pandemic.

In line with the NHS Operating Framework, the target date for identification of Antiviral Collection Points is the end of December 2008. At this point, our information suggests that PCTs are on track with the identification of collection points and are carrying out the risk assessment to ensure the locations selected are fit for purpose. The Department will be working with SHAs to assure pandemic preparedness planning between Jan-March 2009. This will include checking that all PCTs have identified their collection points and carried out the risk assessments.

### Stock Management, Storage and Distribution

For the efficient distribution of antivirals, the National Flu Line service needs to be underpinned by an antiviral stock management system that provides near real-time national interface with local distribution points to ensure people are directed to where stocks are available.

Additionally, the antiviral stock management system needs to provide visibility and traceability of the stock to the management team so that appropriate decisions can be taken regarding the distribution of national stockpile.

There is no existing stock management system that can be easily enhanced to meet the requirements for the antivirals distribution arrangements. Hence, a stock management system needed to be built, initially focussing on the distribution of antivirals so that it can support the National Flu Line service. Sapient is leading the development of this system.

Storage and distribution arrangements have been made for the current stockpiles in the event of a pandemic, with antivirals being provided directly to PCTs. These arrangements are being updated to take account of the plans to increase the levels of stockpiles.

A correctly designed warehouse and distribution network is key to the effective management of the stockpiled products. Before the pandemic, it will provide secure management of products worth many hundreds of millions of pounds. In the event of a pandemic the outbound Distribution and distribution will be on the critical path to the point of use of the Antivirals.

The aim of the workstream is to deliver the contract with a third party logistics supplier to house the countermeasures being procured by the programme and move them from warehouse to required location.

The geographical scope of storage and distribution is to deliver:

- Storage and Distribution facilities, including secondary distribution to the point of care for England and Wales.
- Primary distribution to their national warehouse for Scotland and Northern Ireland. Arrangements for secondary distribution to point of care are being put in place by the respective administrations.

The product scope for Storage and Distribution includes all countermeasures being procured by PIPP.

#### IV. *Operational Considerations*

In order to ensure that the overall system is robust, detailed analysis and specification has been undertaken of all elements the system design.

##### Demand

We have modelled the peak demand for Flu Line over the course of the pandemic. The technical infrastructure will be built to a scale that can deal with this demand. The Flu Line solution is a multi-channel service (web, telephony, automated telephony) with contacts redirected to the most appropriate channel to serve their needs. Should call centre capacity be exceeded, contacts will be directed to automated telephony.

The contract we will sign with the service provider requires them to conduct re-performance testing whenever there are modifications or additions to the Flu Line system. This will ensure that should any modifications be required as a result of the simulation tests these can be incorporated and the system re-tested.

We are securing call centre capacity from a range of external call centres from both the public and private sector. We aim to have around 7,500 call centre seats—and so these agents will be able to deal with up to 45,000 calls an hour.

Equally important to meeting the expected demand is the role an effective communications plan will have in articulating the role of Flu Line and directing the “worried well” to the Info Line instead. These plans are currently being developed and tested.

At WHO Phase 4 there will be a leaflet drop to every household providing information on the pandemic and the systems that will come into place as and when pandemic hits. This will be supported by launching the information line. At WHO Phase 5 there will be a further door drop including any further information that we have ascertained about the pandemic. At Phase 6 the National Pandemic Flu Line Service will come into operation. Also at this Phase, the information line will be updated with new information about the pandemic. TV and press advertising will support communications at each WHO Phase.

##### Flu Friends

We are aware of concerns that people may not be willing to act as “flu friends” to collect the antivirals on behalf of affected persons. We have tested the proposal through a public engagement research programme and the results suggest the public accepted the reasoning behind the need for a flu friend, although there were some reservations. We continue to work to identify and address any specific issues as we take the programme forward.

Flu Line will advise patients on the preferred collection point to use, as determined by the stock management system using the patient's postcode. However patients will not be denied antiviral if their flu friends go to other collection points.

PCTs are responsible for considering the needs of those who are, or who are likely to become, vulnerable during a pandemic. This includes those who may be isolated, or who are unable to use Flu Line. PCTs may arrange to provide flu friends for example through the agreements with voluntary organisations, or put in place other delivery arrangements for those who would otherwise be unable to access antivirals, according to local circumstances.

### Fraud and security

There is inevitably a potential risk of fraud in relation to the Flu Line. We are addressing this in four ways:

- The Flu Line service will only permit one course of antivirals per individual for treatment.
- Personal information used in the patient identification process will meet Cabinet Office regulations required for security.
- Monitoring and reporting at the Flu Line operations centre will be carried out to patterns of fraud.
- Anybody collecting antivirals will require an approved means of identification.

Effective public communications will be key to reducing the risk of fraud and a communications strategy has been developed for this. However, we recognise that the risk cannot be completely mitigated: there is an inevitable tension between the need to make antivirals available as quickly as possible to large numbers of people in need, and the extent of the checks that can be put in place to avoid the risk of fraud.

### V. *Testing of the antiviral distribution strategy*

A testing strategy for antiviral implementation has been produced and this has informed the requirements that have been included in the proposed contract for the development and implementation of the Flu Line service, and also the agreement for the development of the stock management system.

Because the systems will be dormant until a pandemic occurs it will be essential that tests and dress rehearsals are used on a regular basis to ensure that functionality is tested and that we have the assurance that the systems would operate in the event of a pandemic. This consideration has also been built into the contract negotiations.

### System Testing

The development of new business processes and technical infrastructure for pandemic preparedness, particularly in relation to the delivery of countermeasures, require a comprehensive system testing strategy. The purpose of the different testing phase is to ensure that the systems meet all requirements—specifically:

- Fulfilment of Scope (Requirements).
- Fulfilment of Functional Specifications.
- Fulfilment of Acceptance Criteria.

System testing will involve a number of different components to include:

- Integration testing—An end-to-end Integration Test will be carried out on the entire delivered solution.
- System testing—To ensure end-to-end business testing of all components in the integrated environment and to verify the functional dependencies.
- User Acceptance testing—see below.
- Performance testing—to validate the system performance during various possible conditions for server response times as load/capacity is increased measure against the non-functional requirements.

### User Acceptance Testing

A significant programme of public engagement has been used to test some of the key principles and plans for pandemic preparedness. This has informed both pandemic policy development and the communications strategy.

Further public engagement research is being used to focus on how the public are able to access antivirals using the National Flu Line service and in particular going through the questions in the clinical algorithm. The research will consider how flu friends, family members and children are able to answer the questions on behalf of someone else. The research should also be used to provide a steer on question wording, and in particular the usage of medical terms.

### Delivery Testing

Some PCTs are planning tests to assess how collection points could operate, how the process should be managed from flu friends entering the collection point to receiving the antiviral, how many staff are required and the potential issues that could limit the effectiveness of the process. We expect more PCTs to be undertaking similar exercises as they maintain and review their pandemic plans.

Dress rehearsals have been included as a key requirement in the contract for the flu line for the dormancy period in order to provide assurance that the flu line operations could be started as soon as a pandemic is confirmed in the UK.

The arrangements for the storage and distribution contract arrangements includes the requirement for biannual operation testing. This will be also be aligned with the biannual testing for the stock management system.

## CONCLUSION

A project of this size and scope is a major challenge with inherent risks. The rigorous reviews undertaken by the Office of Government Commerce, the Major Projects Review Group and HM Treasury have been highly valuable in testing and confirming our approach. We welcome the continuing external scrutiny and challenge from the Pandemic Influenza Programme Board and the Department of Health Board and OGC. We are working closely with the NHS, professional and other bodies to secure successful implementation at the local level and we have firm plans in place for public engagement and communication, which we will continue to refine in the light of relevant research. In addition, we have in place the necessary detailed analysis, risk mitigation, programme management and programme controls to maximise the likelihood of successful delivery.

## D. ANTIVIRALS: CHOICE AND USAGE

### Introduction

When used to treat seasonal influenza, antiviral medicines reduce the length of symptoms (by around a day) and usually their severity, as long as treatment starts within two days of the onset of symptoms. Whilst it is impossible to predict whether antiviral medicines will be equally effective against a new or modified pandemic virus, it is reasonable to anticipate a similar effect and associated substantial reductions in severe morbidity.

The prompt use of antiviral medicines will benefit individual patients and may also produce public health benefits by decreasing the overall clinical attack rate, shortening the period that individuals are able to shed virus and thus able to pass on the infection to others. Although there is considerable uncertainty over the level of reduction possible, one model suggests a relative lowering of the attack rate by up to one-third over the course of a pandemic.

The UK has established national stockpiles of oseltamivir (Tamiflu), a neuraminidase inhibitor that works by preventing the influenza virus from reproducing and leaving the host cell. We have enough oseltamivir to cover 25 per cent of the population, which would be enough to cover all those who fall ill in a pandemic of similar proportions to the 20th century. We are currently in the process of doubling our antiviral stockpile to treat up to 50% cent of the population (the reasonable “worst case scenario” of how many people could be expected to require treatment). We have invited manufacturers to tender for contracts to supply these additional antivirals. We are also considering the appropriate mix of antivirals (oseltamivir and zanamivir) based on expert scientific advice.

### Choice of Antivirals for Specific Population Groups

Both oseltamivir and zanamivir are licensed medicines. Data supporting their licence applications gives a clear summary of likely interactions with other medicines and contra-indications. This information is key to the development of the countermeasures policy. There are few significant drug interactions with oseltamivir or zanamivir. Patients with severe renal impairment cannot metabolise oseltamivir and zanamivir is the preferred treatment for these patients. In view of the very rare occurrence of severe bronchospasm or decline in respiratory function, patients with severe asthma or COPD, are not advised to use zanamivir unless under close medical supervision. While neither product is licensed for use in pregnant or lactating women, there is a clinical view that a non-systemic product (such as zanamivir) is the preferred drug for treatment for these groups.

Oseltamivir is licensed for use in children over one year old and low dose capsules are available for children under 13. The existing stockpile now includes sufficient low dose capsules to treat children in this age range up to a 25% population coverage. Any future procurement will include the right proportions of capsules for these groups.

Oseltamivir is not licensed for use in children under one. There is, however, published evidence from Japan that it has been used safely at a dose of 2 milligrams per kilogram twice daily in children under one year of age. The Government has purchased the active ingredient powder for the manufacture of a solution in licensed Hospital Pharmacy Manufacturing Units. There are currently sufficient drums of powder to make up antiviral solution to treat the UK population of under-ones at a clinical attack rate of 25 per cent. Any future procurement will include additional oseltamivir powder for this group. Separate discussions are under way regarding the best place from which to distribute the antiviral solution. This will depend in part on the clinical pathway that is chosen for this group.

Zanamivir is not licensed for children under five years old and is not available in a suitable paediatric presentation.

Unless there is clear clinical need detected by the algorithm, it is unlikely that callers to the Flu Line would be able to select their antiviral (making a choice between oseltamivir and zanamivir). However, patients who had difficulties swallowing capsules could break them open and mix them with a sweet sugary solution. The legality and practicality of this option is currently under consideration.

### Antiviral Resistance

Genetic mutations of the virus leading to reduced susceptibility or resistance to antiviral medicines has been recognised as a potential issue with all antivirals. The way that antivirals are used will depend on the emerging viral resistant profile but their use could also influence the overall resistance pattern that may limit the treatment options available on an individual or population basis.

Resistance could develop after exposure to the antiviral medicine (drug-induced resistance) or could be fully resistant right from the start (*de novo* resistance). Resistance has an impact both on the balance of the two different types of antiviral needed, and on the distribution arrangements for antivirals. Although it is impossible to predict if or when resistance might emerge, scientific and clinical advice can inform strategies for coping with the emergence of resistance.

Specific advice from the SPI (Scientific Pandemic Influenza Advisory Group), has been sought on this issue. If resistance were to emerge, it could still be desirable to offer antivirals to influenza patients if the clinical effectiveness or the overall susceptibility to treatment was not impaired by the mutation of the virus<sup>8</sup>. Increasing the dose of the antiviral could also be considered. However, if the clinical effectiveness of the antiviral was severely impaired, this would require a change in strategy, with the deployment of a second antiviral if one was available.

There are different ways of approaching this scenario. Equal amounts of both antiviral could be stockpiled but there are significant cost and logistical issues with this approach as large numbers of antivirals would be needed. Alternatively, a primary antiviral and a secondary antiviral could be stockpiled. This strategy would involve identifying and assessing numbers of likely target groups who might receive the strategic reserve. SPI has considered this issue, looking at the use of zanamivir as the strategic reserve antiviral, and identified a number of likely target groups. We are currently considering the impact of this advice.

Scientific advice is that amantadine should not be stockpiled because resistance to this product develops easily and there are a range of side effects associated with it.

<sup>8</sup> This can occur when the virus is resistant to one antiviral but not the other, or where the virus has fragmented into multiple strains with some resistant and others not.

The National Influenza Centre (NIC) at the Centre for Infections (CFI)-Health Protection Agency (HPA) carries out antiviral susceptibility testing on positive specimens obtained through routine or enhanced virological surveillance schemes.

### Prophylaxis

It is possible to use antiviral medicines as a preventive measure to protect against infection, a course of action called prophylaxis. Although some prophylactic use may help contain spread from initial cases and thus slow the development of the pandemic, protecting significant numbers of people for its entire duration would consume large numbers of treatment courses and still leave those treated susceptible to infection as soon as they stopped taking the medicine. An alternative may be “household prophylaxis”, which provides post-exposure prophylaxis to immediate contacts at the same time as treating a symptomatic patient on the grounds that some of the contacts may already be incubating the infection. This could mitigate and delay the progress of a pandemic, particularly when combined with measures such as school closures. However, such a strategy would consume significantly greater stocks of antiviral medicines and mean that some people would need multiple treatment courses initially to prevent and then possibly treat infection.

Both oseltamivir and zanamivir are licensed for prophylaxis based on clinical trial data submitted to the regulatory authorities. There are a number of options for using two products in multi-drug stockpiles:

- Random allocation.
- Prophylaxis with one product and treatment with another.
- “Consecutive” use of one product until the stockpile is exhausted and then transfer to a second product.

The Department of Health is currently examining these different approaches as part of its analysis of prophylaxis. The logistical challenges, as well as the scientific issues, need to be investigated fully.

### Expiry of Antivirals

The shelf life of antivirals is determined by scientific data submitted at the time of licensing and can only be varied if further data is submitted by the company. This is an international issue, given that there has been global stockpiling.

The current stockpile was purchased in 2004–05 and has a five-year shelf life so will expire during 2009–10. As it was bought in batches over a period of time the products in the stockpile do not all expire at the same time.

The replacement of the stockpile was covered in the public procurement exercise which started with an announcement in the Official Journal of the European Union in August 2008. We have asked bidders to include proposals for the replenishment of the existing stock as well as new products in their responses.

## E. INTERNATIONAL STRATEGY AND ANIMAL HEALTH

### International Funding Commitments

The Government is fully committed to funding and implementing its new cross-government international strategy. It is the first international strategy of its kind and focuses our international efforts in the medium term. It is very fair to say that the UK is highly regarded internationally in its pandemic planning efforts and we have much to offer in leadership and example globally. We intend to fund the strategy through our usual budgeting mechanisms.

At the intergovernmental ministerial conference in Sharm el-Sheikh in October, we announced that we would reserve our pledging position pending detailed consideration of the new “One World, One Health” strategic framework prepared for consultation by the intergovernmental agencies<sup>9</sup>. This will be the subject of further technical discussions organised by WHO and hosted by Canada in Spring 2009. We will therefore see how the international situation develops before deciding how further to fund the strategy.

We have already pledged £35 million to the international effort to improve preparedness (most of which has now been spent) and a further £2 million to the Global Action Plan to improve pandemic vaccine supply. We also second staff to the United Nations System Influenza Co-ordinator’s office—known as UNSIC—for pandemic and avian influenza work.

<sup>9</sup> WHO, FAO, UNICEF, OIE, UNSIC and the World Bank.

DfID has recently extended its commitment to support the Pandemic Influenza Contingency Support Teams in the UN Office for the Coordination of Humanitarian Affairs for a further 12 months until December 2009. DfID also provides considerable direct funding to WHO to, among other things, support the implementation of the International Health Regulations.

#### Prioritisation of International Funding

We will seek to maintain some flexibility in our future financial contributions to allow us to respond to new challenges and priorities, in pursuit of the objectives in our international strategy.

Generally speaking, the UK will continue to do this through multilateral channels, as it has the capacity to deal globally with issues relating to the control of the avian virus and pandemic preparedness, addressing priority needs, as they arise.

DfID's bilateral aid programme is widely praised for its concentration of resources on the poorest countries, but it is not necessarily these countries that pose the most serious threats relating to influenza. Where we do have substantial bilateral programmes and where our partner governments have asked us to help, we can and have provided funds, though even in these cases funds have usually been channelled into multilateral programmes (for instance FAO and WHO) in-country.

At a global level, earlier this year we announced in the National Security Strategy our intention to bring together international organisations and partners to clarify roles and responsibilities and to improve the coordination of the global response to a pandemic. This is a key part of the first objective in the strategy and will be a priority during the next 18 months.

We will also continue to provide materials and expertise, particularly in encouraging a cross-sectoral and cross-border approach to pandemic planning (the second of our four objectives).

Our third objective focuses on supporting detection and surveillance in countries at risk and we are committed to working with partners to find a consensus to the WHO deliberations on influenza virus-sharing and more equal access to benefits.

The inter-governmental meeting next month will be taking this forward. In order to improve surveillance and detection in vulnerable countries it's essential that all influenza viruses are shared through the WHO.

#### Global Animal Outbreak Preparedness

As set out in the Written Response, the rush to fund Highly Pathogenic Avian Influenza (HPAI) programmes was a learning experience for FAO, as it was for the other national and international bodies concerned. However, as a result of the work of the FAO, and of the World Organisation for Animal Health (OIE) with which the FAO works very closely, it is fair to say that there is now a much greater international awareness of the threat posed by avian influenza. There is also better disease surveillance, better reporting of outbreaks and faster and more effective handling of such outbreaks.

The challenge going forward is to improve capacity to control the infection in those countries where it has become entrenched, whilst maintaining vigilance by stamping out any new or recurring outbreaks elsewhere. 2007 was the first year for four years in which cases of H5N1 in birds (and humans) showed a decline. 2008 is on track to follow this trend.

We will continue to encourage the FAO, working with OIE, to move towards a role that supports the longer-term policy, institutional and financial efforts that must underpin prevention and control of avian influenza in the long term. We will pursue this through the ongoing work in relation to the independent evaluation process, with which the UK has been closely involved, and through ongoing discussions of the One World One Health concept established at the Sharm el-Sheikh conference.

DfID has also commissioned a research project (costing £3.9 million over three and a half years) examining risks and risk management in avian influenza, which will hopefully lead in the long term to a clearer understanding of best-practice in HPAI control—effectively reducing risk while promoting equitable growth and poverty reduction. This research project is being carried out by a consortium including FAO, the International Food Policy Research Institute (IFPRI), the International Livestock Research Institute (ILRI), the Royal Veterinary College and the University of California at Berkeley.

While the situation still presents serious risks, strategies for control and containment have evolved and have been tested in a range of developing countries using national resources or funds from the World Bank. HPAI is now better understood and the problems more manageable. FAO and OIE's engagement is now less intense, as much of the burden already rests with the strengthened veterinary services of the countries experiencing

outbreaks. A more hands-off relationship for FAO with national authorities reflects the current situation and is also permitting FAO to return to its work on other animal health problems that had to be neglected in the early stages of the spread of H5N1.

#### Sharing of Information Between ECDC and Member States

There is a free flow of information between the Commission and the Member States. This is achieved through both planned and ad hoc communications in both directions (chiefly by e-mail). The Commission informs Member States about cases of notifiable Avian Influenza once these have been confirmed in one or more country. This is done electronically very soon after the appropriate national reference laboratory and/or the Community reference laboratory have supplied information about the detailed characteristics of the AI virus causing the outbreak.

In Great Britain, once we have received this information it is customary to carry out a veterinary risk assessment which examines the level of risk to our own poultry in the light of the new information received from the Commission. These risk assessments are published on Defra's external web site. Where it is believed that the assessed risk exceeds the background level (described as low), Defra will make contact with key stakeholders in the poultry industry to discuss joint tactics for raising awareness about the disease situation and the need for flock owners to report if they suspect that their birds have become infected.

Information is also shared between the Member States at meetings such as the Standing Committee for the Food Chain and Animal Health and at Commission Working Groups which are established to discuss the detail of EU animal health policy formation.

#### Role of Community Institutions such as EFSA and ECDC

Surveillance information on matters of animal health are the responsibility of the European Food Safety Authority (EFSA). To ensure that the system works effectively, it is critical that EFSA works closely with partners and stakeholders, and is a proactive member of important networks. Partners include bodies and risk managers working within the European Commission, the European Parliament and the Member States, and stakeholder groups and individuals or groups who feel they can contribute to the Authority's work. Examples of this would be the EFSA Advisory Forum which brings together the national food safety authorities of all 27 EU Member States and the EFSA stakeholder consultative platform which brings together EU-wide stakeholder organisations working in areas related to the food chain.

EFSA also organizes and participates in many events annually on scientific topics within its mandate. These include workshops, conferences and roundtables. These enable EFSA to update partners and interested parties on new developments on scientific subjects within its remit as well as to gather feedback, information and different points of view on ongoing work such as the development of guidance documents or risk assessments.

In the European food safety system, risk assessment is done separately from risk management. As a result, EFSA is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States. EFSA's scientific work informs the decisions of the European Commission, the European Parliament and other EU institutions.

EFSA works with other EU agencies and institutions active in closely related fields by exchanging information and cooperating on matters of mutual interest. To reinforce these relations EFSA seeks to sign Memoranda of Understanding with other EU agencies on enhancing cooperation and information exchange. EFSA has signed a Memorandum of Understanding with the ECDC to increase cooperation and exchange scientific information on topics of mutual interest including food safety, control of communicable diseases, infectious diseases prevention and emergency response.

EFSA has also signed a collaboration agreement with the European Commission's Joint Research Centre to strengthen cooperation in the field of food and feed safety, animal health and welfare, plant health and nutrition. Surveillance is also a core activity of the European Centre for Disease Prevention and Control (ECDC), through the operation of dedicated surveillance networks and the provision of technical and scientific expertise to the Commission and Member States, and through supporting the networking activities of the competent bodies recognised by the Member States. Its primary means of support is providing quality assurance by monitoring and evaluating activities of surveillance networks through maintaining the database(s) for such epidemiological surveillance, communicating the results of the analysis of data to the Community network and harmonising and rationalising the operating methodologies.

By encouraging cooperation between expert and reference laboratories, the Centre fosters the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health.

The Health Communication Unit is charged with efficiently communicating the scientific and technical output of the ECDC to professional audiences.

The main scientific output from ECDC is disseminated through technical reports authored by internal and external experts. To give maximum visibility to the reports, there is often a launch event with an interactive “webinar”, in which scientists and journalists around Europe have the opportunity to ask questions from and comment to a panel of authors having produced the report.

As of March 2007, the journal *Eurosurveillance* is hosted by ECDC. *Eurosurveillance* is published online with short, timely articles published weekly and longer articles monthly. All longer and most shorter articles are also published on paper in a quarterly print compilation. The journal covers all aspects of communicable disease epidemiology, prevention and control from a European perspective, and the electronic releases have more than 10,000 subscribers.

ECDC not only works actively with the media but also has in place procedures for timely consultations with the European Commission (including EFSA) and the Member States to promote coherence in the risk communication. ECDC has a number of obligations (eg issuing opinions and evaluating current and future health threats) towards the various EU institutions. In more detail:

#### *European Commission*

The ECDC has daily contacts with staff of the European Commission. The closest links are to the Directorate General of Public Health and Consumer Affairs (DG SANCO), in particular the Directorate C (Public Health and Risk Assessment) and its Health Threat Unit (C3), but on the issue of zoonoses also with Directorate E (Food safety: Plant Health, Animal Health and Welfare, International Questions). ECDC also advises the Commission on research issues within the Framework Programmes of the Research Directorate General (DG RTD).

#### *Other EU agencies*

The remits of ECDC are complementary to those of some other EU agencies, eg the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the European Monitoring Centre on Racism and Xenophobia (EUMC), and the European Environmental Agency (EEA). Close links have been established with EFSA on issues concerning reporting under the Zoonoses Directive (2003/99/EC) and avian influenza.

ECDC also works closely with the 27 EU Member States, and also with the EEA/EFTA countries (Norway, Iceland and Liechtenstein), candidate countries (Croatia, Former Yugoslav Republic of Macedonia and Turkey) and potential candidate countries (Albania, Bosnia and Herzegovina, Serbia and Montenegro, and Kosovo).

Being a small agency, ECDC relies heavily on the expertise and infrastructures (for example microbiological laboratories) in the Member States. The ECDC has the role of co-ordinating EU resources and being the focal point for information related to communicable disease. The pooled expertise of the ECDC will also be offered to those countries in need of enhancing specific aspects of their communicable disease control systems.

#### *World Health Organization (WHO)*

WHO is the most important of the international organisations with which ECDC forms a partnership. In particular, with the WHO Regional Office for Europe (WHO/EURO), which has a set of tasks and responsibilities which aligns with the mandate of ECDC, eg in surveillance. It is therefore important that ECDC works in concert to avoid duplication of efforts and making the best use of limited resources. A detailed Memorandum of Understanding between ECDC and WHO/EURO has been signed.

### Communication between DEFRA and UK Poultry Industry

DEFRA has established a sound working relationship with leaders of the poultry industry. Risk assessments of Avian Influenza outbreaks occurring internationally are carried out as quickly as possible once a risk becomes apparent—these are posted on DEFRA’s external website. Where risk is assessed as exceeding the background level (low), DEFRA would expect to hold urgent meetings with key industry stakeholders to apprise them of the position.

There is a responsibility on EU Member States to let the Commission and the OIE know when an outbreak has officially been confirmed. There is also an obligation on the member countries of the OIE (who are not members of the EU) to inform OIE HQ without delay and this information is then disseminated to other member countries including the UK.

DEFRA cannot act on basis of informal or anecdotal information that Industry may receive through its contacts. Instead, it must wait for official notification from Cion (or OIE in some cases) before it can launch action. In cases of identified higher level risk that would require urgent action (for example “housing” of birds) DEFRA can communicate via text message with all registered members on the poultry database.

DEFRA does expect the poultry industry to take some responsibility for keeping its membership informed and they have been helpful in suggesting some additional channels of communication. This will include news and general press information in journals and magazines which reach lifestyle (hobby) farmers.

### F. EMERGENCY POWERS AND LEGISLATIVE CHANGES

Part Two of The Civil Contingencies Act 2004 (CCA) allows for the making of temporary special legislation (emergency regulations) to help deal with the most serious of emergencies. An influenza pandemic outbreak may generate exceptional circumstances within the UK whereby new legislation is needed or existing legislation needs to be suspended or amended in order to support the response.

Where possible these potential legislative changes should be identified and implemented in advance of an influenza pandemic. Alternatively they can be addressed at the time of a pandemic in light of the emerging circumstances. There are a number of options available to achieve the relevant legislative changes as detailed below.

#### In Advance of an Influenza Pandemic

If a Bill is passing through Parliament with scope relevant to the issues being considered, clauses can be inserted to address the risk. Departments are encouraged to explore opportunities to include the relevant pandemic influenza text, therefore negating the need for a Bill at the time of the pandemic or for Emergency Powers under the CCA (see Appendix 1 for details).

#### At the Onset of an Influenza Pandemic

There are likely to be a number of weeks between WHO raising its alert level (or receiving intelligence that pandemic is imminent) and pandemic influenza reaching the UK (we assume for all other planning purposes that pandemic influenza will originate overseas) and then further delays between the first few cases in the UK and the need for certain legislation to be in place or suspended. As a result there should be time to push through Parliament the relevant legislative changes either in the form of one overarching pandemic influenza Bill (covering all the possible changes that may need to be implemented over the duration of the Pandemic), or a series of smaller Bills on specific issues. Experience suggests that it is feasible to push straightforward legislation of this sort quickly through Parliament should the need arise, particularly if there is a demonstrable need and cross-party support.

With this in mind, officials across government have been considering which regulations might need to be relaxed during an influenza pandemic and have been working with lawyers to identify the appropriate legislative vehicles and to draft the relevant “stand-by” legislation (see Appendix 1 for details).

#### During an Influenza Pandemic

If there is insufficient time to push through the changes using the above method or Parliament is in recess, then it may be appropriate to take Emergency Powers under Part Two of the Civil Contingencies Act 2004 (CCA), where the tests laid down in the Act have been met.

## Emergency Powers

Emergency Powers are for use in only the most serious of emergencies when existing powers are insufficient, and there is not time to take new powers through the usual route of new legislation. Use of Emergency Powers is a last-resort option.

By taking forward the programme of work detailed above, we hope to negate the need to use Emergency Powers during a pandemic. However, until the characteristics of the virus emerge and the ability of the UK to cope becomes apparent, their use cannot be ruled out.

A number of robust safeguards exist to prevent the powers being used inappropriately. At the centre of these is the “triple lock” mechanism which ensures that Emergency Powers will only be available if:

- An emergency that threatens serious damage to human welfare, the environment or security has occurred, is occurring or is about to occur.
- It is necessary to make provision urgently in order to resolve the emergency as existing powers are insufficient and it is not possible to bring forward a Bill in the usual way because of the need to act urgently.
- The emergency regulations are proportionate to the aspect or effect of the emergency they are directed at.

Emergency Powers may extend to the whole of the UK or to any one or more of the English regions and/or the devolved administrations. The decision on whether to implement changes to legislation across the whole of the UK or within specific regions will need to be taken at the time of a pandemic based on the information available. However, feedback from local and regional planners suggest a strong preference for a UK wide approach to legislative changes given that many responders (for example those dealing with excess deaths) are likely to work across more than one border and could therefore be subject to differing controls resulting in considerable additional burdens.

## The Role of Regional Nominated Coordinators

As dictated by the Act a Regional Nominated Co-ordinator (RNC) must be appointed to all English regions to which emergency regulations apply. RNCs are appointed only if emergency powers are used and only to the regions where emergency regulations apply. In Scotland, Wales and Northern Ireland, the person taking this post will be known as the Emergency Coordinator. The post-holder will be appointed to facilitate co-ordinated activities under the emergency regulations in line with the response strategy and objectives set by central government. This will also play a wider co-ordinating role. Co-ordinators will be appointed by a senior Minister from the LGD, and must comply with any direction or guidance issued by the Minister. The level of discretion permitted to co-ordinators during an influenza pandemic will vary according to the strategy adopted by the Lead Government Department. Co-ordinators will be directly accountable to the Minister, who retains ultimate decision-making authority and, in England will be supported by Regional Resilience Teams.

If emergency regulations are implemented during a pandemic RNCs will be identified as laid out in the Act.

## G. PRIMARY CARE TRUST PLANNING

All PCTs are expected to have pandemic influenza preparedness plans in place. However, it is for PCTs to decide whether or not to make emergency preparedness plans, such as those for pandemic influenza, publicly available.

Since the research in the PLoS One report was undertaken, the NHS Operating Framework for 2008–09 has required all PCTs, together with local partners, to produce robust pandemic plans by December 2008. Guidance has been issued to PCTs<sup>10</sup> and others to support the development of pandemic influenza plans. The plans will be assessed in an audit process during the first three months of 2009.

Both the guidance issued to PCTs and the self-assessment tool for the audit process emphasise the need to have in place arrangements for both pre-pandemic vaccine and pandemic-specific vaccine when it becomes available.

<sup>10</sup> “Pandemic influenza: guidance for primary care trusts and primary care professionals on the provision of healthcare in a community setting in England”: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_080757](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080757)

### Pre-pandemic Vaccine

Pre-pandemic vaccine will be available for frontline NHS staff. Whilst PCTs would provide the necessary vaccine, oversee the suitability and completeness of local arrangements, and ensure monitoring of vaccine coverage among healthcare workers, occupational immunisation is primarily an employer responsibility. NHS occupational health departments will therefore provide the professional lead in planning for, and ensuring the delivery of, immunisation of those NHS staff groups for whom they are responsible, building on existing arrangements for healthcare workers to be immunised against seasonal influenza. PCTs are expected to work with NHS occupational health departments to ensure that suitable arrangements are in place.

The guidance highlights a number of practical issues that will need to be considered at the preparatory planning stage when planning for the pre-pandemic immunisation of healthcare workers employed by NHS trusts. These include identifying an adequate number of staff to provide this service, the training needs of those staff, and clerical support to the vaccination team.

### Pandemic-Specific Vaccine

PCTs have overall responsibility for the protection of public health within their geographical area and are responsible for planning the response to an influenza pandemic in that area, including the delivery of vaccination. Local planning for delivering vaccination should be undertaken in liaison with local stakeholders, particularly colleagues in primary care, under the direction of a designated lead. PCTs have also been advised to establish a planning group to support and advise the designated lead in establishing arrangements. This would include:

- taking lead responsibility for ensuring that local health response plans would be able to deliver population-wide immunisation in the event of a pandemic;
- agreeing arrangements for reporting progress to the PCT, focusing on any areas of concern;
- assigning roles and responsibilities to group members and list personal actions;
- ensuring that planning is coordinated with relevant local stakeholders, particularly primary care colleagues;
- considering the needs of vulnerable or hard-to-reach groups;
- developing contingency plans in the event that particular general practices or other services are unable to deliver the immunisation programme in the event of a pandemic; and
- ensuring that there is proactive dissemination of information that comprehensively covers the likely questions the public will ask about local vaccination arrangements. This includes providing clear information about how to access vaccination locally, the nature of the vaccination, and making clear any vaccine contraindications.

The primary-care-based vaccination delivery model builds on normal arrangements, particularly those of general practice, where providing vaccination clinics is a routine activity. Whilst this may mean that specific live exercises involving local practices are not needed, it is nonetheless particularly important that primary care teams are involved in the discussion about the delivery of this plan locally.

PCTs' plans for pandemic vaccination programmes will be assessed through the pandemic influenza plans assessment process to be undertaken between January and March 2009.

## H. DEVOLVED ADMINISTRATIONS

Representatives from Northern Ireland, Scotland and Wales have been fully engaged throughout Cabinet Office's review of legislation that might need to be amended to help the response and recovery to a pandemic. Any product from this review will be on a UK basis wherever appropriate.

The plans of the Devolved Administrations (DAs) are monitored at Cabinet Office level in order to ensure compatibility across the whole of the UK. However, pandemic influenza planning is a devolved issue and it is therefore the responsibility of the devolved Ministers to ensure that planning is conducted and reviewed appropriately.

The DAs are full members of both the officials and Ministerial level planning committees, including the Pandemic Flu Implementation Group (pFIG) and the Ministerial Committee on Pandemic Influenza Planning (MISC32). Both the Department of Health and the Cabinet Office meet with representatives from the DAs on a regular basis to ensure a joined-up approach to planning.

Primary care is administered differently in the DAs, so while they have adopted similar principles for dealing with an influenza pandemic, they have tailored their primary care guidance to suit their local circumstances. We are working closely in agreeing the principles to adopt in managing a pandemic while leaving the DAs to adopt practical measures that meet their own needs.

## I. PRE-PANDEMIC VACCINATION

We understand from the French Ministry of Health that they do not, in fact, plan to vaccinate their whole population. They currently have two million doses of generic H5N1 vaccine but given the available data, no vaccination strategy, in particular those including the use of a pre-pandemic vaccine has been validated or is currently favoured<sup>11</sup>.

However, it is an important question and one to which the UK government has given careful thought. The Government decision on pre-pandemic vaccine coverage is based on scientific, logistical and risk management considerations. Although scientific evidence indicates H5N1 vaccines are now likely to offer some level of protection across H5N1 variants, there is no evidence that these products would offer any protection against a different H-type virus (with H2, H3, H7 and H9 viruses all containing potential candidate strains). It is impossible to calculate the likelihood of any one strain mutating to cause a pandemic, but there is no reason to believe that H5N1 is more likely to do so than any other. Investment in this line of defence thus needs to be balanced against more broadly applicable defences. Timing and logistical issues would also make a 100 per cent coverage policy challenging to implement.

Therefore, the Government has procured 3.3m doses of generic H5N1 vaccine to supply front-line healthcare workers in the event of a pandemic against which it is effective. This is because of their proximity to symptomatic patients and to reflect the need to ensure the continuity of essential services.

In light of discussion with various stakeholders including the Joint Committee on Vaccination and Immunisation (JCVI), the government is considering options around pre-pandemic vaccine, including increasing this stock to cover those identified by the JCVI as most likely to spread the disease and those likely to suffer most complications and deaths.

The specific groups identified are front line health and social care workers, children, as they are among those who are most likely to spread the disease, and at-risk groups, based on the vulnerable groups identified for seasonal flu vaccination.

## APPENDIX 1

### WORK OF CIVIL CONTINGENCIES SECRETARIAT TO DATE ON LEGISLATIVE PROVISIONS

As part of the lessons learned from Exercise Winter Willow, the Cabinet Office (in conjunction with other government departments) has considered legislation that may need relaxation or amendment to ensure the UK is in the best possible position to respond to an influenza pandemic and maintain essential services.

The overarching aims of this work have been to:

- Identify legislation that may need to be amended during a pandemic to facilitate the response or ensure the continued delivery of essential services.
- Work with lawyers to identify the appropriate legislative vehicles and where appropriate draft relevant “standby” legislation for use at the onset of a pandemic.
- Identify the potential need to use Emergency Powers.

This has included looking at the impact of a pandemic on the following broad sectors:

- Healthcare.
- Education.
- Excess Deaths.
- Finance.
- Maintenance of essential services and supplies.
- Workplace.
- Audit and inspection.

<sup>11</sup> Fiche C6: Stratégie et modalités d'organisation de la vaccination contre une grippe à virus pandémique [http://www.grippeaviaire.gouv.fr/article.php3?id\\_article=305](http://www.grippeaviaire.gouv.fr/article.php3?id_article=305).

## RESULTS

In many cases legislative changes have not been necessary as current flexibilities within regulations have proved adequate to cope with the potential challenges that a pandemic may pose. Where this is not the case relevant legislative vehicles have been identified and lawyers are currently drafting legislation which would allow for the changes to be implemented either now or after the onset of a pandemic.

Whilst the need to ensure open and transparent planning at all levels is recognised, it is important that planning is not taken forward on the assumption that all of the potential legislative changes identified will be implemented. Each change will need to be considered on a case by case basis as the impacts and consequences of the pandemic emerge. Planning is therefore continuing on the basis that, where possible, a pandemic influenza is managed within the current legislative framework.

However, where judged appropriate (by both the cross-government planning committee and ministerial committee), some proposed legislative changes have been made public as detailed below.

## DEATHS

Legislation may be amended to:

- Increase the capacity of coroners to allow greater flexibility about;
  - who can hear coroners cases;
  - where post mortems/inquests can be carried out;
  - arrangements for investigating deaths abroad;
  - whether to have a jury at the discretion of the coroner; and
  - Simplifying the arrangements for the appointment of deputy coroners.
- Adjust the requirement that a death must be referred to the coroner if the registered medical practitioner who certified the cause of death had seen neither the body after the death or the patient within 14 days of their death. This may be extended to 28 days.
- Relax the requirement to receive the original, signed MCCD or coroners forms.
- Allow information for a death or still-birth registration to be given by telephone.
- Allow still-births to be registered more than three months after a child has been still born.
- Allow a streamlined version of the cremation Form B and to suspend the requirement for the cremation Form C.
- Increase the number of medical practitioners that can sign a death certificate.

## JUDICIAL

Legislation may be amended to:

- Extend the time a defendant remains in custody prior to court disposal (Vehicle—Prosecution of Offences Act 1985).
- Extend the power to conditionally caution/fine without the need for a court appearance (no legislative changes required—current flexibilities would allow for the appropriate changes).
- Allow for the prioritisation of court cases (no legislative changes required—current flexibilities would allow for the appropriate changes).
- Visiting rights—existing Prison Rules provide for the Secretary of State to alter prisoners visitation rights on a temporary basis.

## SCHOOLS

If the Government decides that closing schools and childcare settings for child welfare reasons is advisable, we expect to issue advice to schools and childcare providers, and do not expect to use Emergency Powers under the Civil Contingency Act 2004 (see Annex A) to oblige services to close. We believe that all concerned will share the desire to safeguard children's health, and will want to comply with advice based on children's welfare.

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**HEALTH**

Legislative changes being considered are:

- Provision of a new statutory gateway which provides for the Secretary of State (DWP) to supply social security information to the Secretary of State (DH) and persons providing services to him for the purposes of the flu line, to be included in an appropriate legislative vehicle and introduced in the nearest available bill session. Civil Contingencies Act 2005 to allow data sharing if the above are not possible.
- New regulation-making powers inserted in to the Public Health (Control of Diseases) Act 1984 by the Health and Social Care Act 2008 would enable provision to be made in regulations to manage a pandemic, including to close or restrict public gatherings. DH is not actively seeking these powers and amendments to legislation are not envisaged, this would only be used as a last resort.
- Altering the period during which a patient subject to a Community Treatment Order may be detained in hospital following recall.
- Altering the time limits during which a patient may apply to the Tribunal for his discharge.
- Increasing the range of persons capable of acting as a responsible clinician for the purposes of the Mental Health Act 1983.
- Supply of medicinal products and relaxation of pharmacy terms of service and control.

*11 December 2008*

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TUESDAY 17 MARCH 2009

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Present	Crickhowell, L Haskel, L Jenkin of Roding, L May of Oxford, L Methuen, L	Neuberger, B Selborne, E of Sutherland of Houndwood, L (Chairman) Whitaker, B
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**Examination of Witnesses**

Witnesses: PROFESSOR LINDSEY DAVIES, CBE, National Director of Pandemic Influenza Preparedness, MR BRUCE TAYLOR, Deputy Director for Pandemic Influenza, Ms JANET MEACHAM, CBE, Deputy Director for Pandemic Influenza, and DR BECKY KIRBY, Head of Human Health, Civil Contingencies Secretariat, Cabinet Office, examined.

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**Q47 Chairman:** May I say welcome to the four witnesses, two of you at least coming back, and we appreciate your taking the trouble to do so. Our regrets that the Minister is unwell. I do hope you will send her our good wishes. We anticipate her getting better and coming in at a later date, which we would find very helpful to the work of the Committee. Can I simply remind you that everything is on the record, the microphones are voice activated and you know the implications of that, and we have a series of questions we want to put to you over the next hour or so. If there are some matters that we do not get to that we are very keen to have a comment on, we may ask for a written response, but knowing that we will be inviting the Minister in, there is a bit of leeway for us to follow up there. So again thank you very much for coming. I wonder if you could introduce yourself simply for the oral record?

*Professor Davies:* Certainly. I am Lindsey Davies, I am the Director of Pandemic Preparedness at the Department of Health.

*Mr Taylor:* I am Bruce Taylor, I am one of the deputy directors of the Pandemic programme.

*Dr Kirby:* I am Becky Kirby, I am the Head of the Human Health desk in the Civil Contingencies Secretariat of the Cabinet Office.

*Ms Meacham:* I am Janet Meacham, another deputy director of the Pandemic Flu programme and my area of responsibility is NHS and social care implementation.

**Q48 Chairman:** Thank you very much indeed. We wanted to start with a few questions about preparedness UK, and the first one which I want to raise is to ask you about the emerging outcomes of the review of preparedness in the NHS following the primary care trusts' preparedness survey. What has come out of that, and have there been gaps identified and possible remedies if they have?

*Professor Davies:* I would be very happy to talk about that in a moment. The Minister very much regrets that she is unable to be here, and we did have one or two words that she was hoping to say to you had she been here, so if I could just perhaps take a moment or two?

**Q49 Chairman:** Yes, please. Sorry, I should have asked. Do put that on the record, that would be helpful.

*Professor Davies:* Thank you. She does very much regret that she is unable to be here today due to ill-health, and this of course is not a decision that she took lightly. It is a very difficult one for her.

**Q50 Chairman:** We understand.

*Professor Davies:* She was very pleased that she was able to meet you last November, and I think we are conscious that you have taken evidence from a number of experts since then. As she mentioned when she appeared before your Lordships last year, the Government's national risk register of 2008 highlights pandemic flu as one of the biggest risks facing the UK, and to address this very real risk, the Government has concentrated on putting in place effective plans across the entire NHS, but also on ensuring that other sectors of commerce, industry and public services are well prepared. Now having developed these plans over the last few years in fact, we have largely moved on now from formulating strategy into the operational phase, and that is really where we are positioned at the moment, in terms of the programme. Our plans are really firmly rooted in the best available evidence, and we are constantly refreshing those. They are, wherever possible, based on existing services and systems, and in fact, we are already finding that the work we have done on preparedness is strengthening many of those systems across the NHS and elsewhere, so that is a very nice side effect. Our plans are also proportionate, we are very conscious of the context of the many other

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

pressures facing government and society and indeed the NHS, but above all, our plans are very practical. We are taking implementation of the plans very seriously indeed, and we have made a lot of progress. We tested our plans in Winter Willow in 2007, we have a suite of further exercises planned for 2009, but we do remain very vigilant and we recognise the need for challenge, so we very much welcome this sort of opportunity. We are also taking forward now our procurement of countermeasures, including antivirals, pre-pandemic vaccine, antibiotics and face masks, and also the infrastructure to make sure that all of these things get to the right people at the right time. We are not interested in just having stockpiles that sit there, they are for use, and we want to make sure that we have confidence in the way they are going to be used. This year we are also planning to update the national framework. As you know, this was prepared in 2007, a lot has happened since then, so we will be refreshing and revising it, and we hope to be able to publish the revised framework by the end of this year. We are, of course, also very aware of the pressures on the NHS, this year and every year, but particularly the concerns about the pressures a pandemic will put on NHS services, and that is why we have been taking the advice of a whole range of experts in the field, including some of those who came along to see you, I think, in February. We are really grateful to all these people for the help they have given us, we could not do it without them, and we do want to put our thanks on the record, because without them, as I say, we could not have made the great strides that we have. So on behalf of the Minister I really would like to assure the Committee that we are equipping the UK to respond to the pandemic quickly and effectively. The UK is recognised as being at the forefront of preparedness internationally. In fact, other countries are now coming to us for advice. No other country in the world has done more than we have to ensure that we protect the population and that we minimise the pandemic's impact, and we are delighted to have this opportunity to talk to you about that this afternoon. Thank you.

**Q51 Chairman:** Thank you very much, and we share with you the gratitude for the generosity of specialists who have come along, not least our own specialist adviser, Sandra Mounier-Jack. We had a very important and worthwhile seminar. All that you have reported, so to speak, on behalf of the Minister I am sure are points that will come up in the discussion as we go through that are fundamental to many of our concerns, but perhaps we could simply go back to the review of preparedness, and the questions I raised

about that in relation to primary care trusts, and identifying gaps and so on.

*Professor Davies:* Indeed. As we mentioned before, we have just been undergoing a self-assessment process across the NHS, where all primary care trusts and other NHS organisations have been asked to submit their own self-assessments. They submitted those by mid-February, and they are currently being reviewed by the relevant strategic health authority for their area. Once those reviews are complete, because obviously we want to make sure that the self-assessments are suitably challenged, to be honest, we will then be reviewing those with each SHA during April. So I will be meeting each SHA with a colleague from the NHS performance management side to explore with each strategic health authority how things have gone in their patch, and part of that process is ensuring consistency in the assessment across the country. So by the end of April, we should have a clear picture of where the strengths and weaknesses are. We do not have that picture for you yet, but as soon as we do, we will be able to reflect more effectively on it. We did go through a similar process last year. The questions were not exactly identical, we have revised them in the light of experience, but we did have some learning from that, and we have been using that to inform our plans, and we know that within the NHS the whole process of self-assessment this year is helping all NHS organisations to improve the plans they already have in place. It really crystallises the mind when you see the questions that you perhaps are not able to answer as strongly as you would like. So that is the overall picture. We can give you more detail about how we used last year's assessments if that would be helpful, and how we plan to use these.

**Q52 Chairman:** So effectively you are saying of this year's assessment, it is too early to tell yet. I wonder if the most useful thing to do therefore would be to ask if you can put together a report when you have the results in that we could share with the Committee, because we have had the opportunity to talk about last year's assessment, but it is whether there was progress being made was really the interesting point. So I wonder if that is the best way to handle that one, to ask you for your own reflections perhaps at the end of April, when you have looked at all the evidence?

*Professor Davies:* We will happily do that.

**Chairman:** Because I am keen to move on, we have a lot of ground to cover, and I will ask Lord Selborne to pick up the discussion.

**Q53 Earl of Selborne:** I was going to ask how many local authorities have held joint testing of preparedness between resilience fora and the

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

National Health Service, and have any lessons been learned from this?

*Dr Kirby:* I will take this question on behalf of the panel. I can tell you that 35 out of 43 local resilience forums in England and Wales have taken part in joint testing of preparedness between the health and non-health strands of pandemic planning. If you do the maths, this equates to approximately 350 local authorities, which I think was what your question specifically asked. I do need to caveat that figure slightly, the 350 figure, in that we cannot be sure that every local authority in the 35 LRFs I mentioned actively took part in the exercise. All of those exercises have lessons identified reports. As a result, those are owned by the LRFs themselves and so they are not held centrally by the Cabinet Office or the departments. There is also a Cabinet Office led exercise programme which is underway which is exercising one local resilience forum in each of the nine English regions, and these are multi-agency exercises which test NHS alongside local authority colleagues and others involved in the multi-agency response. These exercises include 94 local authorities by the time the exercise programme is complete, which is the end of this week. We are heavily involved in the lessons identified process from this programme, and we are planning on publishing a summary of the lessons identified from each of those exercises, and also some details on how we plan to address those nationally.

**Q54 *Earl of Selborne:*** Could you just give us a feel as to the lessons learned from the fora? Is there an overarching theme which comes out of it?

*Dr Kirby:* The overarching theme that comes out of the exercises we have been involved in is a need for a clearer defined decision-making process around the management of excess deaths and how strategic co-ordination groups move from phase one to phase three, different ways of working to cope with excess deaths. Off the back of that, we have developed a question and answer document which aims to address those issues which we plan to circulate to local resilience forums within the next few weeks. Communications messaging is coming out as a clear gap for them, and the need for us centrally to provide them with an indication of what the Government's messages would be at different WHO phases, again work is underway to address that; and finally, the sort of key lesson coming out is our social care planning and linking up between local authorities and primary care trusts in order to address that social care need. Again, I think that particular gap is the result of the fact that guidance was issued but issued quite recently, so it did not have time to embed before we started our exercise programme, but we are certainly seeing advances in that area now.

**Q55 *Lord Jenkin of Roding:*** Could you give us an impression of roughly how many people in each of the local authorities that you have described to us have actually been involved in this? How far down does it go? Is this at the management level, or has it involved anybody below that?

*Dr Kirby:* The local resilience forums have clear guidance about who should sit on their planning committees and who should be involved in exercises. In terms of local authorities, our guidance is it should be people who are involved in deaths management, social care and forming those linkages between health and non-health response. I could not give you a clearer picture than that on the exact level of engagement.

**Q56 *Lord Jenkin of Roding:*** Are we talking about 20 or 200 or 2,000? How far down does this go?

*Dr Kirby:* The level of awareness within local authorities goes very far down, and the level of engagement on planning committees would be much fewer, sort of individuals, key leads within local authorities for each local resilience forum.

**Q57 *Lord Crickhowell:*** A very quick supplementary on that. You referred to the lessons from English regions. Is the Cabinet Office co-ordinating the same lessons from Wales and Scotland, and if so, are there any additional lessons?

*Dr Kirby:* Yes, Wales has a regional level exercise planned for later this year, which will involve local resilience forum equivalents in Wales, and those lessons identified will also be made available in the public domain. Scotland also have their own exercise programme and will be conducting their own lessons learned process on that, but we are engaged in those exercises and we will be engaged in the lessons identified processes as well.

**Q58 *Lord Methuen:*** What account has been taken of the probability that some drivers in the logistics chain will become ill or for pandemic-related reasons may not turn up for work? What sort of contingency planning have you done for this?

*Professor Davies:* Well, this is clearly a very important matter, and it is one which we have taken really seriously. We have a number of workstreams in place.

*Dr Kirby:* I think the key thing to note is we are making proportionate preparations for the disruption that pandemic influenza will have in terms of staff absenteeism on the logistics, drivers and the whole of the supply chain. Firstly, we have been engaging with all Government departments that have a stake in this, in order to drive forward business continuity planning in the relevant sectors. That includes providing specific guidance, providing checklists and also one-to-one support if requested in

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

order to help them drive up their planning on the whole of the supply chain, not just on the drivers element. Many of the people that we have engaged with are actively taking this forward. For example, the retailers have looked at their supply chains; all of them that I have spoken to have plans to prioritise their supply chains for essential services, food, milk, et cetera, rather than clothing or luxury goods, which is definitely a step in the right direction. In addition, we have also looked at the legislative framework within which our logistics operations and supply chains operate. They are also on an end-to-end basis. So, for example, HGV drivers will be able to work longer hours to deliver goods to supermarkets if we utilise the flexibilities that we have in place under drivers' hours regulations. At the other end of the chain, supermarket staff will be able to work longer hours to receive goods by utilising the flexibility under the Working Time Directive. So we have taken an end-to-end process, looking at the business continuity framework and the legislation framework, in order to give ourselves the confidence that this will not fall down in the pandemic.

**Q59 Lord May of Oxford:** This is a question that Lord Broers, who could not be here today, was keen that we ask, and it is based on his understanding that Australia and New Zealand and, for all we know, other countries are planning to (or at least thinking about discussing whether to) close their borders in the event of a pandemic, perhaps in the case of Australia and New Zealand motivated by the fact that they did avoid the worst effects of the 1918 pandemic by virtue of remoteness, admittedly in a different world. I appreciate that it is a different world, and I also realise that some of the reasons for not considering it are that it is not merely inconvenient but maybe infeasible, but none the less, it is in my view (and Alec's) certainly something that ought to be considered, and I just wonder to what extent we have.

*Professor Davies:* We definitely agree it needs to be considered. It is probably again better for Becky to give you the details, because a lot of thought has gone into this already.

*Dr Kirby:* To address this policy, we looked at it back in 2005, again more recently in 2007, and it is constantly under review to sort of take advantage of any sort of scientific breakthroughs that we get. The fundamental thing is a balancing act between knowing what the positive result of border closures or international travel restrictions would be, in terms of delaying the pandemic, but weighing those up against the specific impacts that the UK are likely to face, which may be different from Australia and New Zealand, as a result of these closures, and that is the balancing act that we have tried to do. Our SPI

modelling paper, which is in the public domain, shows that neither border closures nor more limited specific restrictions on international travel would delay the pandemic for a significant amount of time, and the key thing is not an amount of time which will allow for a pandemic-specific vaccine to be manufactured.

**Q60 Lord May of Oxford:** With respect, this is my subject, it is a subject that Roy Anderson and I are largely responsible for creating, and one of those studies at least shows that a combination of targeted local prophylaxis is far more effective than closing borders, but the original and still one of the best studies by the Imperial College group shows that if in addition to that you close borders, then in some of the simulations it is not so much just delaying it, you halve the total number of cases below—it is much more effective to be targeted local prophylaxis, but none the less, added to that—I do not think it can be dismissed on the basis of modelling saying it does not work. There are larger questions furthermore in that you have to think, if you postpone it, then you have more time to be developing a vaccine, and it gets much more complicated than that. I would have been myself much more convinced by the argument that it is a mixture of infeasible and dreadfully inconvenient, but I would like to hear it said. But you cannot invoke the models as the reason, in my opinion.

*Professor Davies:* We totally would share that. It is balancing risk, as everything is in pandemic management. Having looked at the practicalities of closing the borders, and you would need to get at least a 90% secure closure in order to have really any significant impact at all, that would divert so many people to closing the borders away from the things that they might profitably otherwise be doing, that we think feasibility arguments are very powerful, in terms of doing it. Equally, to get a 99.9% closure, which would really give us a significant delay, as we understand it, we just do not think that would be doable, given the number of ports we have, and the situations that we have in the UK, but Becky can talk about the implications.

**Q61 Lord May of Oxford:** The Australia/New Zealand experience in 1918 did not get 99.9% closure. That is an interesting thing worth looking at. Admittedly, there was much less travel, so that you are trying to diminish something that was smaller. But I do not want to pursue this any further, I just think it is the sort of thing that I think has been brushed aside because it is too anti-prevention.

*Dr Kirby:* We have mapped out the impacts, we have not just looked at modelling and how long it will delay. We do weigh that up against the impacts it will have, not only on the economy but on businesses; our

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

ability to import essential medical supplies, for example, which save lives regardless of the pandemic, which the UK is reliant upon. So it is a case of managing all of those issues. My understanding on the Australian situation specifically is that for a future pandemic, they are proposing to restrict travel from what they are calling high risk countries rather than implementing a full border closure, which modelling a map of the UK suggests that because people reroute via other countries and come into the UK indirectly from south-east Asia or other places which we might consider high risk, then it really would not have significant impact in delaying the pandemic, hence why our policy is so different to Australia.

**Q62 Lord Haskel:** Just very quickly, have you taken public perception into account? Surely the public would expect us to close the borders?

*Dr Kirby:* I think border closures is one of the first decisions which will need to be taken once WHO raise their alert level to alert level 4 and I think it would be naive to expect us not to come under some pressure from the public to close borders. However, the general public are quite savvy nowadays and also the media. I do not think it would take them long to realise what the impacts of border restrictions would be, or to look at the scientific papers that we have published and independent scientists have published which suggest that border closure policy would not necessarily work. Similarly, if we were to adopt a position like Australia, I do not think it would take long for the public or the media to realise that people were coming to the country from infected areas, routed via other large hubs, Paris for example.

**Q63 Chairman:** Presumably there would be a difference between a short-term closure to buy some time to develop, if one possibly can, a new vaccine, and clearly the maleffects of longer term closures, where you have—well, we are not a self-feeding country, just for a start.

*Professor Davies:* The time involved in developing a pandemic specific vaccine and having enough of it to distribute to us and other countries would be a number of months, and even if the technology moves on, our understanding is it still takes some considerable time. So yes, it is an attractive concept, but we cannot see that it would work because of the risks to our own supplies at the same time.

**Chairman:** You can see we have elements of scepticism about that, but we will move on with Lord Haskel to another question.

**Q64 Lord Haskel:** We move on to the preparedness of the NHS and we wondered what is going to happen to the 3.3 million doses of the H5N1 vaccines

when they pass their shelf-life, when they are beyond their sell-by date. What is the cost of the recurrent provision of the vaccines and the antivirals, and will they be used for key frontline workers?

*Professor Davies:* We currently have a stockpile, as you say, of 3.3 million doses which we purchased in 2006 from two different suppliers, Baxter Healthcare and Chiron Novartis, and these vaccines are not currently licensed. At the time of their purchase, there were no licensed vaccines. When we bought them, we thought it was definitely the best way; it was again balancing the risks, we would rather have a vaccine than no vaccine, so that is where we are. At the moment, we are testing them regularly and they are standing up well, so we have not seen any decrease in potency as yet, but we are continuing to keep that very much under review.

*Mr Taylor:* Essentially we work with the National Institute for Biological Standards and Control, who carry out the tests for us, as well as with the actual companies. We bought them over a staged basis during 2006, and actually that also helps us; as the tests happen, if they do start to get early indications that the stability is becoming less beneficial, then actually we will get early warning to that. Really at that stage we probably have two main options. One is to use it as originally intended and make it available to frontline healthcare workers. As Lindsey has referred to, the fact that it is a use of an unlicensed vaccine does increase potential risks, particularly given that there had been no increase in the pandemic alert at that stage, but what we are doing on that is that we are actually now seeking advice today, at a meeting of the Joint Committee on Vaccination and Immunisation, around their views on the safety issues of if we did choose to go down that line at some point in the future, what their view would be. The other part would have to be in terms of our ongoing review of pre-pandemic vaccine anyway, and therefore to be looking at the replacement strategy for healthcare workers and potentially others as well, as part of that strategy. So therefore, it is a two-pronged approach that we are now taking.

**Q65 Lord Haskel:** But do you have a replacement strategy? How long do you expect these current doses to last: years, months?

*Mr Taylor:* This is the thing, we genuinely do not know, because buying a vaccine and keeping it for that long is actually quite a novel thing to be doing, because normally people buy vaccines and then use them within the year of expected use. So what we are doing is keeping these monitoring tests going because of the fact that actually that enables us to be able to see how long we could be able to keep them for. As I say, because it was staged, we will get an early view of when it starts to become a potential issue. What we

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

are having to look at very closely though is also then the manufacturing timescales. With the current manufacturers of our pre-pandemic vaccine, there is now one licensed product, but there are a number of other products on the market as well, in order to see the windows of opportunity that provides, so if we were then looking to a situation of replacement, when we would have to be making those commitments in order for it to happen. As I say, it is balancing that monitoring against actually having the plan to be ready if things start to suggest that we need to look for a replacement.

**Chairman:** Thank you for the clarity, we genuinely do not know, that is refreshing. We move now to Lady Whitaker.

**Q66 Baroness Whitaker:** Turning to new work, can you tell us how you ensure that recent advances in pandemic and pre-pandemic vaccine developments and new information on the resistance to antivirals become incorporated into policy?

*Professor Davies:* We have a Scientific Pandemic Influenza Advisory Committee, which is a large committee, and which advises not just the Department of Health but all departments across government on matters related to pandemic influenza, and we look to them for considered advice on every scientific aspect that we can, including antivirals and vaccines and so on. On the vaccine side, we do also look to the JCVI, the Joint Committee on Vaccination and Immunisation, that we were referring to earlier, for their very specific advice. They really are the experts in the field and we take their advice, as we are today, very frequently. We also do have a range of experts who we talk with, as I was saying earlier, individually, to make sure that we really are keeping abreast of what is happening in the field and at the cutting edge as far as we are able to. In terms of the system that we have in place to translate the advice of those committees into policy, and to seek their advice, Bruce, do you want to talk about that?

*Mr Taylor:* Yes. Just to give you a couple of examples of it working in practice, you will probably be aware that we are now increasing our stockpile of antivirals to cover 50% of the population. Following on from the discussions with SPI around issues on resistance to antivirals, what we have now agreed that the part of the procurement that is taking place is to not only increase our supply of Tamiflu, which was the original stockpile that we had, but also to include within that 50% a strategic stockpile of Relenza, so that we are now buying 10.5 million courses of Relenza within that total. What that essentially means is that we will still aim to start the pandemic using Tamiflu, because that is the easiest one for people to take, the one that is recognised, but what it

also then means is if other issues arose because of resistance during the pandemic or other concerns were being raised, it does mean that we have this back-up situation of having some Relenza to be able to use on a targeted basis if that situation arose. What it also means is if there was in fact a higher attack rate in the pandemic, we would be expecting to use both Tamiflu initially and then Relenza subsequently as part of our overall responsive treatment.

**Q67 Baroness Whitaker:** So that is information from your own operations?

*Mr Taylor:* Yes.

**Q68 Baroness Whitaker:** Which obviously can be very rapidly put into policy, but your Scientific Influenza Committee, is that people from all over the world, is it British academics, who is on it?

*Professor Davies:* A bit of both actually. It is largely British academics, but we do also have a number of people from Europe and further afield, WHO—

**Q69 Baroness Whitaker:** Does it meet regularly on a standing basis, or is it ad hoc?

*Professor Davies:* No, it meets twice a year normally, and it has a number of sub-groups that meet more often. We set up ad hoc working groups to look at particular issues where we need to. It was I think set up in its current form probably about 18 months ago now, so it is just getting into its proper functioning, but it is settling down very well.

**Q70 Baroness Whitaker:** So if some really important new research emerges between meetings, how do you make sure that that is translated into policy?

*Professor Davies:* I think our first step with that would be to talk with one or two of the relevant experts on that committee, we would then discuss with them whether it was important or worth really exploring, in which case we would probably set up a sub-group of the committee to meet really quite quickly and give it as much consideration as we could. We have scientists working on the programme as well employed by the Department of Health who would be able to help with a lot of background work for that too, and they in turn link with their equivalents in other government departments, so we would bring civil service expertise along to support what the academics brought. We would then take the advice of that sub-committee and bring it to the main committee if there were a meeting at the right sort of time, but again we would not delay. We could either set up something if we really needed to with the big committee more quickly, but more likely we would move this through, speak to the chairman and talk about how we would take that. Then when we got the considered advice, we would move that into papers

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

sort of internally within the Department of Health to explore with colleagues and with ministers, so that is how it would gradually work forward, and if necessary, across government. Does that answer the question?

**Q71 Baroness Neuberger:** I think you have largely answered the question about whether you have come to a decision on options for the use of pre-pandemic vaccines, but I think it would be helpful for the Committee to know a little bit more about what you are thinking about a replacement strategy and certainly about the manufacturing timescales. I do not know what you can say about that, but it would be very useful to hear it.

*Mr Taylor:* Certainly, as I say, I think the science has become clearer around pre-pandemic vaccine, and certainly, compared to where we were in 2006, we have more options in terms of what is being produced, what has now been licensed. What we have also then done is wanted to undertake an independent research into the current market, to get a better feel, because a lot of the manufacturers work around their windows for seasonal flu production, to therefore understand on that piece, but we also have sought advice from the JCVI, the immunisation and vaccination committee, just around if we were to expand our view beyond frontline healthcare workers into other targeted groups, where they actually feel that would be best focused, whether it is around children of school age or the elderly. That is really as far as we have got at this stage, because there have not been any further commitments beyond that. It is now actually reviewing the information that has been obtained by those two actions, in order now to inform us being able to advise on a way forward.

**Q72 Baroness Neuberger:** Is that today's meeting of the joint committee that is looking at that?

*Mr Taylor:* Essentially today's meeting is more around the use of the current stockpile. At the last meeting, we talked to them about the fact of the idea on targeting and it is out of their review on that that we are now hoping to try and inform policy linked to the manufacturing piece as well.

**Q73 Baroness Neuberger:** What is roughly the timescale on that?

*Mr Taylor:* Essentially we were planning to go to Ministers within the next few months with that as a view. Clearly there are other factors to measure against this because as we are building on other stockpiles as well, like the antibiotics, it has to be set against that background of the sorts of timescales, but clearly one question would be the replacement piece may well actually need to be driven as a priority as compared to the other parts.

**Q74 Lord Crickhowell:** You have begun to mention the things that it has to be set against, manufacturing timescales. How is it affected by sudden large scale demand from other countries elsewhere in the world? Surely there is a limit on manufacturing, and your own estimates may suddenly be knocked completely sideways if there is a stampede from countries who have been rather slow on the starting line.

*Mr Taylor:* Although at the moment, the majority of countries who have gone down the line of any pre-pandemic vaccine have been on very limited procurement, there are only a couple of countries that have bought significantly more. We do through our international contacts try and keep as much information as we can around the ideas of where countries are moving. Again, I cannot deny, part of it is I think a lot of countries are watching us and therefore seeing what we are doing, where the thinking is moving, and have the same issues, whether it is around the cost or the timescales of the pre-pandemic vaccine. It is a risk, I would accept, but as I say, we tried our best by actually monitoring and mapping what is going on around the world.

**Chairman:** We wanted to pick up the issue of testing the system, and Lord Jenkin perhaps will take this on.

**Q75 Lord Jenkin of Roding:** The first thing I just would like to say on this, those who were at our previous evidence session, you remember I asked a number of questions about tests and trials, and I think the Minister's statement this afternoon referred to end-to-end testing. The first thing I would like to say is since that last session, we were sent some additional papers by the department, including a paper that was called C, and in fact it was labelled B, I think, wrongly, plans for distribution of antivirals and testing of plans, and I would like to say that was a hugely important part of your evidence, and I felt, having read that, that at least a good many of my questions were being answered. However, I do not think we have had yet what you called an end-to-end test, and the question is, if you do that, is this going to be a real test, a realtime test, with real people performing their designated roles in as realistic a situation as can be devised, or is it something less than that?

*Professor Davies:* We are addressing that in two parts. We would very much like to do something top to bottom, end-to-end, with all the bits in place. The practicalities of that are something we want to explore, and I will invite Janet to talk about that in a moment, but Bruce, do you want to just start by explaining the end-to-end bit as far as the antiviral distribution system goes?

*Mr Taylor:* Yes, because essentially what we have from the papers you have seen now are three main elements to this, in terms of the point of view of the

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

Flu Line, working through to the stock management arrangements and therefore having control on that, through to the storage and distribution arrangements. So what we are keen to be making sure is as we are developing those systems, from the Flu Line, which comes in and will be available to us around the May point, through to things like the stock management system, and storage and distribution schedule for the summer, once we have those elements together, a critical part will be the integration testing of those pieces. So making sure that the information systems themselves, as data is fed in at one part, actually can then be recognised and reflected in the way that the systems then act to control and give us surveillance around the fact of how the take-up is then being dealt with, to the management of the stock, through to actually the performance of our contractors in delivering out to the collection points, and making sure that stock is in the right place at the right time, and using different systems, whether it is around threshold or whether it is around actually the levels of stock that we are putting out. So there is a proper control around that piece of work, so there is that understanding that as the re-ordering then takes place, there are proper controls that mean that we can have confidence in the information we are getting. So that is the element around the end-to-end system testing that we are doing, but I accept that is just part of the overall story.

*Professor Davies:* We do try to take a whole systems approach in everything that we are doing here, and put all the pieces together as reasonably as we can, but the logistics of that are sometimes a challenge, and Janet is currently exploring how we can practically do what you are looking for, which is test something which starts with somebody feeling ill and phoning the Flu Line and gets everything back round to them.

*Ms Meacham:* I guess the challenge of that is how many people do you need to then test it with, over what geographic area, and how many collection points do you use? I think we need to go and have some careful thought about this, although we can test it end-to-end with just a few people, that you would want to test it in as realistic a situation as you possibly could, and if that means over such a wide geographic area that it becomes unfeasible, then we have to go and think again. So it is a real challenge, we have not come to the end of it. We have done it in some other exercises, used real people in testing out systems, not necessarily for flu, but in doing it for the Flu Line, I think the challenge is the numbers of people and the geographic area.

**Q76 Lord Jenkin of Roding:** We are going to have a question on Flu Line later, but I am just going to repeat what I said at the previous evidence session. I

have been going round asking quite a lot of people at the hospital over the river, in my general practice, nurses that I meet, and the family and everything. I have yet to meet a single person in the health service who has any idea what they are going to be asked to do if there is a pandemic flu. They have no idea as to what their role will be. My GP simply said, "They are going to dump it all on us and we shall be completely overwhelmed", and she is a highly intelligent lady. I think you ought to take note of this. People do not know what it is they are going to be expected to do, and I do not see how you can make a system work until they do.

*Professor Davies:* Yes, we too are conscious of that, and we walk around and we hear the people too, so I share that concern. Now that we have our plans in place, and we are confident in them, and we understand better than we have before how the various bits are going to work. One of the next steps that we are currently planning is a proper exercise, a process of communication with NHS staff to make sure that they genuinely do understand everything that needs to be in place and how to do it. Now we will be looking at the self-assessments that are coming through to explore this with them, because it was an element that NHS organisations are being asked to demonstrate, that they have robust implementable plans in place, and implementable does mean that the staff know what they need to do. That said, there is a real question mark about which staff exactly need to know what and when, given turnover and movements around, but at least understanding the basic concept is a very important thing. So we have developed a number of educational programmes already, but we are building on those over the next year, and we are alongside that planning a proper communications exercise.

*Ms Meacham:* We are doing a communications exercise, a piece of research that started yesterday, to test out the different roles and responsibilities of NHS staff, whether or not the communications package that we have developed for the public is enough for them, do they need something further and specific communication tools, and then it will be to go and share pandemic flu communications with them. So that is one thing that we are doing. But we have a phenomenal number of conferences that we attend to raise awareness, both with social care and with NHS staff. We are hoping that more NHS staff will participate in the off-the-shelf exercise regimes that we are now able to give them, now they have come to the end of planning, then maybe the planners will move into players, and there will be a wider engagement with how they are testing their flu plans, with more people, and some of them are already tested over quite a large area. Then I think you must not forget what they already do in terms of baseline

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

training. Every year, we emphasise with staff routine hand hygiene, which is one of the bases of what they need to do in pandemic flu. So I think there is a lot that we are doing that is not necessarily pandemic flu badged, but still helps people to understand what they would need to do in a pandemic.

**Q77 Lord Jenkin of Roding:** What is the question I should be asking them?

*Ms Meacham:* I guess I would want to ask, if I go into an organisation, do you understand that your organisation has a plan for pandemic flu?

**Q78 Lord Jenkin of Roding:** I suspect the answer from the people that I was talking to would be that they would not have a clue.

*Ms Meacham:* That is something we need to continue to work on, because one of the other things that we recognise is the more that people who work in an organisation have a better understanding of what the plans are, the more they will realise what the organisation is doing to support them, and so internally support the organisation.

*Professor Davies:* I think our experience would be it is very variable across the country at the moment. You could equally speak, I think, to some GPs who would be very well aware of it and very conscious of it, but it is patchy, and it is the consistency that we want to improve. The BMA and the Royal College of General Practitioners together published guidance specifically aimed at general practitioners and their practice managers at the end of last year, and that is beginning to have a real impact around the country now. We want to see that and other things being used more effectively, but as Janet says, the very small exercises, the very practical gains that people can play, some PCTs already use these very effectively. Camden for example has a great very practical game where you deal a few cards out and you play and gradually people die and you suddenly realise you cannot rely on these people any more. It brings it home to people that they need to plan, and where that is used, it is used very effectively, and it does put people in mind of the need to do plans. Equally, in some regions, for example the East of England is buying a business continuity management tool for each of its general practices, and putting that in place, so that all GPs are becoming extremely conscious of the wider aspects of business continuity as well as for pandemic flu. So there are different approaches, but we want to share the good practice, and we do have a way to go, we acknowledge that.

**Q79 Chairman:** I think we are running together two or three different things here. One is clearly how far down the system communication has gone, and that is a very important question. It will be critical on the

day, so to speak, but also before the day. But there is still the question of what we have called, and you have also, end-to-end testing, and what is feasible, and what is not feasible, and you did try to draw a distinction. I can imagine, because of volume factors, it is very difficult to test that in an end-to-end context, but although it has to be tested, it is not the only thing that is tested in an end-to-end test. What is being tested are the links in the chain, so that things are not happening out of time, out of sync, and you can move from one set of decisions to another having at least some confidence that either the material is available or the people to distribute it or whatever, and it is this end-to-end bit I press back at you again. I think the only thing that would satisfy us was to see every step outlined, and yes, we have gone right down the ladder on that. Is that impossible?

*Mr Taylor:* I think the best way to make it real is actually by looking at the different parties involved, and how they interact with the systems. So therefore, from the public's point of view, essentially there are two main points of access. One is through Flu Line and one is through the Flu Friends going to collect at the collection point. Those are the elements of test that you pay for the public to be able to be involved and actually have them party to. Clearly you have an awful lot of users as part of this, whether that is within the PCT, manning the actual collection points, or whether it is actually in the call centres, taking the phone calls, or within the actual central co-ordination, whether that is within the PCT itself or at a national level, and what you can do is you can run exercises for those different elements for those perspectives. What I think has to support it and back it up is the confidence that the fact is all of those elements are being supported by systems and, therefore, to know that they can operate the processes that they have, but also to understand the systems that are operating for them, and have the opportunity to put those in practice well in advance, and I think it is how you bring those elements together. I personally do not think you can get a full end-to-end part where you would have the public ringing in, getting someone to go and collect from a collection point, to actually then seeing it all work behind the scenes, but essentially if you can play all of those pieces in individual parts to exercises, linking the dependencies where they are there, actually you can get more confidence and assurance around the fact of the system actually delivering on the day.

**Q80 Chairman:** I understand what you say, I am not sure I am convinced yet completely, because I think if it is a shortage of people phoning in, you have nine volunteers here immediately. Whatever it is, it is to see whether the bits do fit one after another, and the only way to do that is to see the linkages in operation.

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

*Mr Taylor:* Yes, I would accept that, and certainly, on things with the Flu Line, actually we have plans in place for public testing, so actually we have already started again this week the initial pieces of taking people through the scripts to understand them, and obviously their reaction, what they would have to do next in order to do it. I suppose the only thing I would question is just about the fact of to then say to them, are you to then send somebody to a collection point, or actually is it better then to run that as an independent piece, knowing that there is a direct linkage between having gone through that first call? As long as you have tested with the public their reaction to the idea of having gone through that first stage of confirming access to the antiviral that they are symptomatic, to then say the next stage is you would need somebody to go and collect, that would be very good, how do you react to that, rather than having to actually go through the process. We can certainly refine and certainly become more sophisticated, I think, as our systems and processes become more established and in place.

**Chairman:** As we discovered not a few weeks ago, if there is a very heavy snowstorm, things are suddenly disrupted and you actually need to know what could be done—I think we have made our point, and it is on the record, and we may come back to this, but now I wonder if Lord May would take us on.

**Lord May of Oxford:** Let me just lead off by saying that compared to the hearing we had on flu, I guess it is two years ago now, this has been much more reassuring. That earlier meeting was really quite dreadful. The first meeting with officials, it was unclear that the officials understood the difference between use of antivirals and antibiotics, and they had not got round to briefing the Minister, because when the Minister appeared, the Minister said the policy for the use of Tamiflu shall be that you come into the surgery and are diagnosed with flu and then we will give it to you as a patient, which brings me to the point—I mean, that was when we had 14.7 million doses of Tamiflu, which was the result of a three digit precision calculation, so lots has got better; however, in the interval, Lord Jenkin has asked a short Parliamentary question on the question of how we are going to handle the distribution, not just the distribution points, but how they are going to be used. Are they going to be used for people who now have the flu or are they going to be given to people, if you can get them early enough, in the flu cores, or are they going to be that plus giving them to the family, giving them to the kids in the school room, giving them to the thing that is technically known as targeted local prophylaxis, which is in my opinion, and that of most people, the only rational use of antivirals, because by and large, by the time someone is clearly symptomatic, it is past the point where they

are going to be a hell of a lot of use. That point was made more than two years ago, it got a waffly answer in the Lords over a year ago. When we had our little seminar, we asked Nigel Lightfoot, who gave a very good presentation, he was asked bluntly, do you think the optimum use of Tamiflu and Relenza is as a targeted local prophylaxis, and he beamed and unambiguously said absolutely. So my question is: when is this going to be your formal policy in the distribution of it? Could you reassure me on that, so that my cheerfulness on some things could be expanded?

**Q81 Chairman:** We like a cheerful Lord May. Do help us.

*Professor Davies:* Well, I think the first thing to say is that the scientific advice that we have, of which you are aware, I think, is that it is actually useful to give people antivirals, as long as you get them to people within ideally 12 hours but definitely 48 hours of their becoming symptomatic.

**Q82 Lord May of Oxford:** That is not prophylaxis.

*Professor Davies:* I am coming on to that, sorry, but it was just about that our scientific advice tells us that it is useful to give them once you are symptomatic, and I just wanted to be clear about that to start with. Again, our understanding on that, and the reason that we are working so hard to get the antivirals to people who are symptomatic, is because we want to above all reduce their chances of getting the complications of flu, and that is really the prize that we are after in getting the antiviral distribution system as effective and as robust as we can. That is what we are concentrating on at the moment. The matter of antivirals for prophylaxis and giving it to people, as you say, very, very early—

**Q83 Lord May of Oxford:** In close contact with the people diagnosed.

*Professor Davies:* I am very conscious of that, and conscious of the science, and it has been part of our considerations of our defence in depth strategy for a couple of years now. We are conscious of it, we talk about it. We certainly have seen the scientific arguments for that and we understand them very well. That said, we are very concerned to ensure that whatever plans we put in place are practical and are implementable, so what we are doing at the moment is having looked at the science, we are looking at the practicalities of implementing a policy like that, in terms of how the stockpile would be used, how you would define people in close contact, how you would reduce the chances for fraud, what sort of amount of stockpiling and the costs of that that you would need at the time. We are also conscious of the potential that if you do use it very widely like that, antivirals on

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

a very widespread basis, then the potential for resistance becomes more significant, and again that is another of the risks that we are balancing.

**Q84 Lord May of Oxford:** Can I interrupt, before going on too long, to say that you are in flat disagreement with, for example, Nigel Lightfoot, and if you actually tell me that the best advice you have is what you were on the point of elaborating at length, and could be summarised as saying not having targeted local prophylaxis in the sense I defined, then I say to you flatly you are not getting the best scientific advice, and I am in a position to say that.

*Professor Davies:* Nigel Lightfoot is a member of our scientific advisory committee and we do our best to get the best scientific advice and we will continue to do so, to talk with him and others.

**Q85 Lord May of Oxford:** So you disagree with him or you agree with him?

*Professor Davies:* Our priority at the moment is to use them for treatment, and to get the treatment actually in place and robust, because taking the consensus of advice that we have, that is where we are at the moment. We are looking at the practicalities of using antivirals for prophylaxis, but at the moment we have not explored those sufficiently to convince ourselves and others that we could implement it practically. Those are the bits we are exploring, and if we can find a way, then we will be taking the policy discussions further.

**Q86 Lord May of Oxford:** There is no point in pursuing this further. I think the best way forward here is I will find out a bit more about who the expert committee is and talk with some of the people who are really expert, and we will have another conversation, but what I have heard from you is that Nigel, for example, and I and Roy Anderson and a set of people that I would trust in this have not convinced you, and you have given me what I thought was a rather long-winded way of saying maybe/maybe not, and I find that unsatisfactory.

*Mr Taylor:* I think just the other thing to add to it is the fact that at the moment, we are not aware of any other country that equally is going down the line of household prophylaxis, and I think it is similarly the logistical and implementation issues of how you actually try and put that into practice which is causing their issues.

**Lord May of Oxford:** But on the other hand, we have now spent the better part of three years not even considering it and trying to move it forward.

**Chairman:** I think saying it is a logistic problem is a rather different response to saying it is not the right scientific answer. Well, you have heard it, again it is on the record and doubtless you will think about

what has been said and perhaps we will take it forward in other ways.

**Q87 Baroness Neuberger:** In the event that there is a pandemic, what do you think will be the pressure on access to intensive care facilities, and given the very limited resources available that we all know about, what guidelines, including guidelines I think on ethical choices, will be given to frontline workers for conducting triage? A small question.

*Professor Davies:* It is a very big question. Again, we are trying to take a really sort of whole systems approach to this. There will be huge pressures on intensive care in a pandemic, there is no doubt about that. We are entirely realistic, and we talk to colleagues in the field, not least the other Bruce Taylor, who I think was part of your discussion the other day, and he and many of his colleagues like us are concerned about the pressure that there will be, and the very real difficulties that will be faced, and the ethical challenges to be faced by people on the frontline when the pandemic arrives. So we are doing our best to provide them with the best support that we can in those circumstances, because with the best will in the world, it would never be possible to provide unlimited intensive care facilities, and that is not practical. So we have looked at providing ethical advice for this, we set up the ethical committee on influenza nearly three years ago now, in response to exactly this kind of concern. We wanted to make sure that there was a suitable basis, and that it was a consistent basis around the country. That has produced its advice, but it is still very broad brush, general principles, and we are now in the process of developing that further, articulating it in the forms of worked-through scenarios, which is what the committee will be working on over the next year or so, in order to really practically help people on the ground, so that is the important first bit about the ethics of it. Janet, I wonder whether you would like to talk a little bit about what we are doing in terms of tools, the surge management guidance and so on.

*Ms Meacham:* Yes, the next piece of guidance we are going to be issuing, Lindsey has referred to it as surge, we are actually calling it managing demand and capacity in healthcare organisations, because people seem to be a bit scared of the word “surge”.

**Q88 Baroness Neuberger:** I can imagine.

*Ms Meacham:* So we have renamed it. It is a piece of guidance that was originally developed by the Scottish pandemic influenza team, and it has been at consultation since August 2008, and I think it is the single piece of guidance that has had the most comments and the most interest from clinical staff. It says several different things. Firstly, it is reinforcing the fact that we are expecting organisations to look at

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

how they can increase capacity, and that is both in terms of facilities, their people, and to look at business continuity issues. So we recognise that that will go some way to assisting. But secondly, to set out that within the difficult situation that people may have in critical care, that they need to feel that they can work within an ethical framework that will allow them to take some difficult decisions. I think this guidance is talking about some of the tools of assessment that may be available to do that, and I think Bruce Taylor talked about one called a SOFA score, which means sequential organ failure assessment for ITU, and has been recognised in both Canada and the USA as probably the best mechanism for assessing somebody's entry into ITU. But then there is the equally difficult bit of how one can assess a patient; are they still maintaining support from ITU, or have they reached the stage that in actual fact, we can no longer give them anything that is beneficial for their care? The surge guide is suggesting that there should be very regular assessments and some practical advice to people to say that if scores—and scores can only be an indicator, they are not precise, and because of that, then clinicians may want to take advice from more than one clinician, and to work together, so they feel assured that they are making the right decisions within an ethical framework in an ethical way, so that there is equality of access for patients. So the guidance actually sets out the indicators and the principles behind that as well. The reason why Lindsey said it takes a whole system approach is because in fact, for some patients, it may well be in the community, and it could be predicted that they may well need to go into secondary care, and into intensive care, so it is sensible to try and look at what assessment criteria there are within the community, so that people can work together, and by that I mean the GPs, the acute hospital trusts, the ambulance service as well, so that if there is an increase in demand on services, people can try and get consensus of the same tool that they are assessing people against, albeit as an escalating score. So we are just beginning to do some of that work, I do not think it is going to be easy, but there is an awful lot of interest and the colleges are signed up to working with us to begin to explore that.

**Q89 Baroness Neuberger:** You are going to try and model it?

*Ms Meacham:* I think the first thing we are going to try and do is pick apart things that are there, and see if we can start from scratch to say, is there going to be any consensus on what it might look like, and then I think at some stage we will have to think about how we may well test it out, and I have some views on how

we may do that, and maybe use it as a training tool as well.

**Q90 Lord Jenkin of Roding:** The pressure is going to be intense if there is a pandemic on this. One of the messages which I have got from your papers is that there really does need to be emergency legislation to protect healthcare staff from the risk of being sued if in fact, under that pressure, they make a decision which in ordinary circumstances they perhaps ought not to have made. Is there any consideration being given to that? Because otherwise, you are going to have people not coming in. They will say, "It is not my job, I am not going to be able to do that. Therefore I am not going to go into the place at all".  
*Professor Davies:* We are naturally aware of that concern, and as a doctor, it is something that I would personally be concerned about if I were in that position, very much so. That said, we would want to look very carefully before we talked about emergency legislation to just protect any health professional from making any decision that they might make, whatever the pressures upon them, and what we are looking at at the moment, the way we are approaching this, is we are giving health professionals as much support as we can in the decisions they may wish to make. We are also working with the GMC, who have produced some very helpful guidance recently, with the other professional organisations, and some of the defence organisations, to just talk with them about how best professionals can be reasonably made to feel protected, and able and willing, and supported in coming into work. Some of that is reflected in the HR guidance for the NHS that we published last year, but others of it are part of conversations we are having at the moment, and still taking forward. So we are very conscious of this, we do want to give people reasonable levels of protection, but again it is a question of balancing risk, and there are risks to patients and risks to healthcare professionals, and we need to get that balance right in whatever advice that we give.

**Q91 Chairman:** Again, we understand that, but evidence was put to us really quite strongly about the concerns of some in the health professions about this matter, and the risk that it would have adverse effect on the behaviour and willingness to turn up and make the impossible decisions that they will have to make about who gets the treatment and who does not, and who is in the intensive care unit and who therefore will not be in the intensive care unit. So I suppose we see it not simply as a matter for further discussion, but a fairly urgent view on whether or not, and I think this is the question raised, emergency legislation at that time for a very short period, which

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

would cut out the risk of it being misused later, could be put in place. Is there a plan at least to consider that, is the point we are pressing. You have heard our concerns.

*Professor Davies:* We have heard the concern.

**Chairman:** Perhaps we could move on. Lord Selborne?

**Q92 Earl of Selborne:** Yes, in the previous evidence session where you kindly gave us some help, we discussed how the interface between primary and secondary care would be managed and I wonder if we could return to that. How will the referral system be organised, and has this been tested in local primary care trusts, and if so, what happened?

*Professor Davies:* We were talking a little earlier, Janet was describing the work that we are just putting in train, in terms of trying to get some consistency of approach across the country for enabling people to make the choices that will need to be made about who goes into which levels of care, but Janet, I do not know if you want to expand on that?

*Ms Meacham:* Yes. I think the referral system will work as normal, except as it works at the moment, I think if you are a GP and you try and refer a patient into hospital and the hospital is very busy, that very busyness may well be just for a short period of time, and how hospitals normally get by is by being able to use their own clinical networks, transferring patients to other nearby hospitals, as you get a peak of work. Clearly in a pandemic, that cannot work, because everybody is going to be under the same level of pressure, and so we think that the best thing that we can do is to try to support people to look at an assessment tool that they can all use, that they can all sign up to, so that there is communication throughout that community and beyond that they are at a particular level of assessment, and so that they know at what level patients can get access to a higher level of care, and that is what we are saying is the way forward. So it builds on the work that we are doing in demand and capacity, into access between primary and community care. We have got a little bit further with paediatrics than we have with adults, and we are expecting a paediatric assessment tool to be available in summer this year, which is looking at assessing children beneath the age of 16, and whether or not they would be benefitting from going into secondary care.

**Q93 Earl of Selborne:** So from that, do I gather that you are not going to do tests within the primary care trusts as such?

*Ms Meacham:* Well, when you talk about testing it, I think the way that we would test it would be to try and ensure that all the people who might be using it, and it may be GPs, secondary care, it may be

ambulance services, that when they assess people with that tool, that they come out with the same assessment, and it works for all of them, and they will feel comfortable about it. So that is the kind of testing that I would see happening.

**Q94 Lord Crickhowell:** Lady Finlay cannot be with us this afternoon. You have been given notice of a question which she wanted put, and that is: what measures have been put in place for those with long-term maintenance conditions? She cites those on dialysis, drug addicts, those on domiciliary parenteral or gastrostomy feeding as examples. What is the answer to her question?

*Professor Davies:* There is no simple answer to this. The most straightforward way of answering it is to say we are encouraging through the guidance every local NHS organisation to look very carefully at these vulnerable people, and all those with long-term conditions come into that. The Cabinet Office has recently produced guidance on vulnerable people in emergencies generally, but we are currently working on something more specific for people with health issues. That said, each of the medical Royal Colleges has been asked to think very carefully about the guidance that it gives to clinicians and patients which would need to be given real priority in a community or elsewhere in a pandemic, in terms of maintaining their own support, and people with long-term conditions come very much into that, as being part of their considerations. The Royal College of Physicians, for example, has done a huge amount on this, and provided a wealth of guidance to specialists to assist local planning and the exploration of that. On the drug addiction side, we are working with the National Treatment Agency, we have funded them to explore relevant aspects of preparing for a pandemic, as far as drug addicts are concerned, and that work is starting already.

*Mr Taylor:* Yes.

*Professor Davies:* It is going ahead, so we are doing what we can to take a range of approaches, but there is not any single answer.

**Q95 Lord Crickhowell:** On dialysis, it just happened a very long time ago now, I think I was the first Minister to introduce private business dialysis units into National Health hospitals in Wales with very considerable success. As far as the patient is concerned, they are simply the national health, but they are actually run by private companies, so are you consulting with private organisations in this area and in others which are working as part of the health service, or indeed outside the health service?

*Professor Davies:* We are working very closely with private healthcare organisations nationally and we are strongly encouraging the NHS locally to engage

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

with its local and further afield partners in this. That is a message that we have all given—individually and in the framework—very strongly, because we are conscious that resources need to be shared and they need to be acknowledged and we need to make the best use of whatever is out there for patients and for their families, so yes is the answer to that.

**Q96 Lord Crickhowell:** Taking my first question on the particular area a little wider then, so organisations like BUPA hospitals or others are being very much drawn in, are they, and fully involved in this process, and will play their part, right across the board?

*Professor Davies:* Absolutely, absolutely. We have spoken with them. I have regular meetings with private health and social care providers as a group, to make sure that they understand exactly what our planning is, and also in developing policy, we explore with them some of the ideas that we are coming up with, so that we can be sure that it makes sense all round. We speak to the national representatives, as well as encouraging people locally to make these moves from the NHS perspective; we listen to them, and where occasionally they have told us that they are not getting the engagement with their local private sector colleagues that they would ideally like then we have brought that to the attention nationally of the relevant organisation, because we are really determined that everybody works together on this, and we have been really very pleased with the response that the private healthcare organisations have given to us at every stage of the plan.

**Q97 Lord Crickhowell:** One final question. It occurs to me, following the earlier question on ethical issues, that there may be some quite difficult ethical issues here, consultants who work in both private and public. I declare an interest, as one who has life membership of AXA/PPP, I can see pressures developing in between private patients and those without such care. Are these issues being considered and addressed, and if so how?

*Professor Davies:* They are being addressed. They are being addressed in the local discussions with an honest debate about what will and will not be sensible to keep going during a pandemic. There are discussions nationally in the committee that we have, which we do put these things on the table, because there are obvious issues about non-urgent procedures, for example, and whether those will continue to be done during a pandemic or not. The expectation is that a lot of people are ill with flu, then demand will go down very significantly, and equally, many of the staff who work within the private sector as you say also work in the public sector, and they will be needed to provide the essential healthcare that is

necessary to keep the whole country and the whole emergency system moving. I think both parties are very conscious of that, and as I say, I can only say I have been very encouraged by the nature of the discussions and the debates that I have heard, and I think the same would go for the insurers as well, because obviously they have concerns; they have slightly different anxieties, but we have had discussions with a range of those at the same time.

**Chairman:** Time is moving on, but I wonder if we could manage at least one more question, and I will ask Lord Methuen to pick up the issue of the Flu Line.

**Q98 Lord Methuen:** You have indicated that the Flu Line will go live in May. Who will staff the 7,500 call centres, and how are you making sure that the systems behind the call centre will actually take the load? So you need to do a real test with 7,500 people, to make sure it does not collapse.

*Professor Davies:* The first thing to say about the Flu Line, it is all about delivering antivirals to the right people at the right time. It has three arms, one of which will be via web-based access, so computer-based access for people who can use that. Another will be automated telephony, so as is used in many call centres these days, you get an automated voice, and they ask you questions, and you press buttons 1, 2 or 3. The third arm of the Flu Line will be the real people in call centres, and there will be transferability between those last two. We are, as you have heard already, doing a lot of work on the infrastructure supporting that and procurement of call centre staff.

*Mr Taylor:* Essentially we are looking at two main sources. Firstly the public sector, because the public sector has a large number of call centres, whether that is in Transport, Inland Revenue and potentially Work and Pensions, and therefore discussions have started with departments about the potential of being able to use some of the capacity within the public sector. But in order to get the full number of seats that we are seeking, that will need to be supplemented by the private sector as well, so again initial discussions have now started around looking at the potential of using some areas of the private sector who may well find that at the time of a pandemic, their own business needs are less and therefore actually would be able to see this as an opportunity for something. On the other question you asked about loading, built into the contract with British Telecom is the requirement that they must run regular dress rehearsals that would then link into our call centre links. So actually, the fact is that in total the expectation is that at any one time we would be expecting at least 20,000 people to be able to access one of those three channels to Flu Line, and that is really what we need to be testing in order to actually

17 March 2009

Professor Lindsey Davies CBE, Mr Bruce Taylor,  
Ms Janet Meacham CBE and Dr Becky Kirby

make sure that we have confidence that it could work through those three channels with the sorts of volumes we would expect at the peak, also recognising that if you can manage that, then in a lot of the instances during a pandemic, you will not be operating anywhere near that level, but actually you will have the confidence of being able to upgrade.

**Q99 Lord Jenkin of Roding:** It is the next question on the list, it follows very closely from Lord Methuen's question. How long do you imagine it will take if you have a patient who rings up, or a patient's friend who rings up and says, "I think I have got flu", or, "She has got flu", how long is the process of questioning, triage, decision, before they can get a number and go off to the collection point?

*Mr Taylor:* We have done a lot of work around that, both from the point of view of the initial clinical algorithm that we worked through with the clinicians, the questions in the order that they need to be asked, and now with British Telecom in developing the scripts to be used. I have to put two caveats to it in terms of the fact that clearly it will depend on the individual patient's circumstances, because there are some questions they will need to be asked if they answer yes to some questions which lead them in a way, but at the moment the view is that the process for getting to that point of being confirmed for antivirals is around eight minutes. What we are doing now though is actually putting that into public testing, because what we want to do is take people through that process in order to actually see how they react to that, the questions that are needed to be asked, because what you are doing is you are doing some introductory questions, then the assessment, then telling them about what we need to do in order to get access to the antiviral, so there are a number of elements we need to be testing with the public—

**Q100 Lord Jenkin of Roding:** One makes the comparison with NHS Direct which my wife has had occasion to use, and, of course, it is far longer for

that, but obviously different, I understand that, but I am genuinely astonished that you think in many cases it could be done in as little as eight minutes.

*Mr Taylor:* As I say, certainly we will test with the public to see their reaction to the nature of the questions, but having taken it through on that basis, that has been the understanding.

**Q101 Lord Jenkin of Roding:** There will be a lot of them without English as their first language, which will be an added difficulty.

*Mr Taylor:* Yes, and certainly with that, what we are doing is looking at the web in order to actually provide some additional languages that will be available through the web access, so what we have done is work with NHS Direct to identify, in addition to Welsh, the other languages that are accessed most through their own services currently, things like Turkish, Portuguese and Polish, and have those available on the web as well. But I think the other thing to flag is we do recognise there will be some people who will not be able to use the Flu Line, simply because there are certain issues, like other languages, which have not been able to be catered for, and therefore need to be using local healthcare services.

**Q102 Lord May of Oxford:** You will be able to do it through the web alternatively?

*Mr Taylor:* Yes.

**Chairman:** Perhaps as we conjure with the prospects and opportunities of the eight minute diagnosis, gosh, that is a thought, I think we should draw to a close now and say thank you very much in for participating in our robust discussion. It is robust because we think what you are doing is very, very important, and we have a sense of some of the importance of that. So again, many thanks, and we look forward to seeing the Minister as she recovers. Thank you very much. I just remind you, if there are points that you can expand on in writing in relation to the discussions we have been having, that would be very helpful.

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**Letter from Professor Lindsey Davies CBE, FRCP, FFPH, National Director of Pandemic Influenza Preparedness, Department of Health**

**DEPARTMENT OF HEALTH REVIEW OF NHS ORGANISATIONS' SELF-ASSESSMENTS OF PANDEMIC INFLUENZA PLANS**

At the committee hearing on pandemic influenza preparedness on 17 March, I agreed to provide a report on our analysis of NHS organisations' self-assessments of pandemic influenza plans. This letter updates the committee on progress.

On the 17th the committee asked for my initial reflections on the analysis, by the end of April. Not surprisingly, it is taking some time to complete this analysis and the last of the series of meetings, arranged with Strategic Health Authorities to discuss and validate the results, will only be completed on 30 April. Therefore, an initial

analysis and report based on the data and our discussions will not be complete until mid May. There are few areas of the NHS not affected by pandemic influenza, and considerable public interest in planning, we are therefore intending to publish the overall results of the self-assessments and expect to make these public in mid June. Prior to this the report will need to be cleared by the Department's Executive Board, which cannot be done until early June.

I do regret that I am unable to supply the committee with this report at an earlier stage but I hope you will understand how important it is to ensure the final report is comprehensive and complete. I am however happy to share my own reflections on the assessments with the committee, as suggested, once the meetings have been completed with SHA's and will, of course, make the more detailed results available in June. I am already aware that there has been 100 per cent response from NHS organisations and I remain confident that the report will confirm our early impression that a very high level of preparedness has been achieved.

7 April 2009

#### PAPER A: QUESTIONS NOT ADDRESSED AT EVIDENCE SESSION

**Question No 15.** *How many PCTs have already identified antiviral collection points? Are they spread equitably throughout each area and are steps taken to ensure that they are accessible?*

As part of their general preparedness work, all PCTs have been identifying the number and location of collection points that would be appropriate to their local health economy. Information received by the Department in February 2009 indicates that, in England, the NHS currently plans to have 3,321 Collection Points in place across 138 PCTs. Information is still pending from 10 PCTs and the department is currently looking into this).

PCTs have nominated a mix of NHS and non-NHS sites that meet the requirements for collection points. Some examples include: leisure centres, schools, non-acute NHS facilities, town halls, libraries, partner agency facilities, PCT premises and pharmacies.

This work was informed by a Collection Points modelling tool, with which the Department of Health provided PCTs in August 2008. This was developed as an illustrative modelling tool to provide PCTs with guidelines for approximate numbers of collection points at national and local levels to cover the population. This model encompasses the whole of England, both demographically and geographically.

The modelling tool is based on a number of assumptions that include:

- the population of England across 148 PCTs—with a demographic profile across age groups;
- a clinical attack rate of 50 per cent, with 22 per cent of cases occurring during the peak week (the reasonable worst-case scenario);
- the type of area, eg rural or urban, and accessibility;
- opening for 16 or 24 hours;
- the hours per shift and efficiency levels; and
- the time required for the process of allocation.

Minimum requirements for antiviral collection points are specified in detail in the Pandemic influenza "*How to*" guide for primary care trusts on local arrangements for antiviral collection points including details of technical and operational considerations.

The Department's validation of PCT self-assessments<sup>12</sup> will include checking that all PCTs have identified their collection points and carried out the risk assessments.

**Question 17.** *During the recent snowstorm, health care staff who could not travel to work were asked to go to their nearest hospital to help. Could you tell us how effective this was and an idea of how many did do that?*

In line with most employers, trusts asked their employees, including health care staff, who could not travel to their normal place of work to try to get to their nearest hospital to help.

We understand that many healthcare staff made great efforts to get to their normal place of work and did indeed either manage to get to their usual workplaces or went to their nearest hospitals. We know this because, during the recent snowstorm, the NHS managed to continue to provide the usual high standard of services we have all come to expect with no major difficulties being reported. This was particularly impressive given the normal winter pressures under which trusts were working at the time.

<sup>12</sup> This process was detailed in answer their Lordships' first question to panellists at the evidence session on 17 March 2009.

Decisions about attending alternative, local, hospitals during adverse weather conditions are local, operational decisions and they are not made centrally. For this reason, we do not hold information on the numbers involved so cannot provide information on the precise numbers.

Once again, we were indebted to health care staff for their commitment to providing high quality care during the challenging weather conditions. I am sure everyone involved in either using or supporting the NHS would like to place on record their appreciation of the efforts made by all NHS staff. The continued deduction of NHS staff to get to work, where possible, and ensure services could be maintained, is remarkable.

*Question 18. How will the UK coordinate its pandemic response with the World Health Organisation and other European bodies such as the Health Security Committee, the European Centre for Disease Prevention and Control and DG SANCO (Directorate General for Health and Consumer Affairs)?*

We already have close links with a very large number of international bodies that would be involved in a pandemic response and regularly co-operate with them on other health emergencies. The HPA has a well-established and key role in international and national surveillance and intelligence gathering. It is the nominated lead body for implementing International Health Regulations in the United Kingdom.

The precise roles of DG SANCO and some other EU organisations during a pandemic response remain fluid and have not yet been finalised. We are actively promoting further clarification on this, through our membership of the Health Security Committee. Communications with EU and other global partners are frequently tested in real life situations such as including the polonium incident in London. Representatives from EU and international organisations, including WHO, participate in a number of our advisory committees for pandemic flu.

#### EXERCISES

A number of EU wide exercises have been held to test out how EU member states communicate both clinically and operationally between governments, during incidents. The first of these, exercise New Watchman in 2005, was based on a suspected smallpox outbreak.

The UK participated in Exercise Common Ground in November 2005, the only major EU exercise to test pandemic influenza preparedness in EU Member States, to date. This was a two-day, command-post exercise across all 25 EU Member States, and included, the EC, European Centre for Disease Control (ECDC), the 25 Member States, European Economic Area (EEA) States, Switzerland, European Agency for the Evaluation of Medicinal Products (EMA), European Vaccine Manufacturers (EVM), pharmaceutical companies and the World Health Organisation (WHO). The aim was to test Member States' national pandemic flu plans. It tested all EU Member States' Emergency Operations Centres and included representatives from European vaccine and anti-viral manufacturers.

It was followed by a conference hosted by DG SANCO where member states agreed priorities for emergency preparedness and response between them. DQ: we should say whether we considered it a success and why?

Lastly, an EU-wide pandemic influenza command post exercise, Exercise Tor, is planned for 18–19 November 2009. The aim will be to examine the capability of departments and institutions at Member State and Commission level to work together and share information during a severe influenza pandemic. Special emphasis will be put on cross-sectoral coordination; it will build on some of the lessons learnt from Exercises New Watchman and Common Ground. The specific objectives will be to:

- to test pandemic preparedness plans and interoperability between the various national plans;
- to test continued operations in key societal sectors with limited manpower (Business Continuity issues); the sectors to be tested during the exercise will be reviewed during the first planning meeting;
- to explore the role and functionality of all appropriate and currently available communication systems;
- to test communication at national, EU, and international level;
- to explore the coordination of measures;
- to explore the coordination of public and media messages;
- to test interoperability of social distancing measures with cross border implications; and
- to test the development, availability and use of vaccines and antivirals.

## ROLES AND RESPONSIBILITIES

The World Health Organisation is the United Nations' specialist agency for health and has the lead role in providing rapid assistance for human disease emergencies. Through its Global Influenza Programme, it seeks to improve pandemic influenza preparedness and responses by coordinating international surveillance, investigation and response. It also provides information, technical standard-setting documents, a checklist for national plans and field assistance to member states on request.

The European Union (EU) Directorate for Health and Consumer protection has a responsibility for facilitating coordination and collaboration between member states in the prevention and control of communicable diseases. Several Directorates have pandemic influenza policy interests. A Council Directive on Community measures for the control of Avian Influenza is in place to contain and eradicate viruses in captive bird populations in order to protect animal and human health. Through the Health Security Committee (HSC), member states are working to coordinate information and risk management measures and to improve planned responses to an influenza pandemic.

The HSC is a non-statutory committee of senior health security experts from EU Member States and is chaired by the European Commission. It delivers opinions, identifies actions and decisions that might be taken at political level, and endorses guidelines and/or recommendations and considers scientific assessments in relation to EU health security issues.

The European Centre for Disease Prevention & Control is an EU agency whose role is to identify, assess and communicate current and emerging threats from communicable diseases; including providing scientific expertise. Key tasks include epidemiological surveillance, co-ordinating early warning and response, providing technical assistance and communications.

### EU HEALTH INFORMAL MEETING SEPTEMBER 2008

The Health Informal meeting of EU Ministers in Angers from 8–9 September 2008, under the French Presidency, took a critical look at influenza planning across the EU. It found that there was some variation in preparedness among Member States in the public health sector but largely in the non-health sectors, which could complicate the inter-operability of their pandemic plans DQ: *can we say how the UK compared? Can we say we are one of the leading countries in the EU on pan flu planning?*

## PAPER B: THE ROLE OF ANTIVIRALS IN THE TREATMENT AND PROPHYLAXIS OF PANDEMIC INFLUENZA

### *Summary*

1. This paper summarises the information currently available on scientific and clinical aspects of the use of antivirals for treatment and prophylaxis of pandemic influenza, and the practical and operational aspects that also need to be taken into consideration before embarking on a prophylaxis strategy.

### *Background*

#### Antivirals and influenza

2. Antiviral drugs may be used to treat a viral infection or to prevent infection from a virus (prophylaxis). They work by preventing viral release from infected cells and subsequent infection of adjacent cells (eg oseltamivir and zanamivir) or by blocking viral replication in the body (eg the adamantanes), hence lessening symptoms and the likelihood of complications.<sup>13</sup>

3. Unlike current vaccines, which must be based on a strain closely related to the pandemic strain to provide useful protection, antivirals may have universal activity against influenza A and B strains (though with some degree of variation depending on the specific virus). However, the degree of effectiveness of antivirals against a pandemic influenza strain cannot be known with certainty beforehand, and may change during the course of the pandemic because of the emergence of resistant strains.

4. Three antivirals are licensed in the UK for the treatment and prophylaxis of (seasonal) influenza:

- oseltamivir (Tamiflu®) and zanamivir (Relenza®) which target the neuraminidases on the surface of the virus and are known as neuraminidase inhibitors; and
- amantadine (Lysovir® and Symmetrel®) which targets the M2 proteins on the surface of the virus.

<sup>13</sup> NICE technology appraisal No 168 (2009) Amantadine, oseltamivir and zanamivir for the treatment of influenza. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_077276](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_077276)

5. Oseltamivir and zanamivir are generally well tolerated and experience so far is that serious side effects are rare although nausea and vomiting are relatively common. On the other hand, amantadine is associated with a range of side effects and drug interactions.
6. Oseltamivir may have additional benefits over zanamivir by being more systemically available against a wider spread of infection in the body; it is easier to use and can be given to younger children (one year and over). However, zanamivir has fewer side effects, a higher bioavailability in the lungs and theoretically less potential for viruses to develop resistance to it than oseltamivir.<sup>14</sup> In contrast to zanamivir and oseltamivir, amantadine and other M2 inhibitors have disadvantages including more serious side effects, and with amantadine, the high likelihood of emergence of transmissible antiviral resistant strains and the lack of demonstrated prevention of complications.<sup>15</sup>
7. The effectiveness of antivirals against a new pandemic influenza strain cannot be known until the pandemic strain has emerged.<sup>16</sup> In the pre-pandemic period, it is only possible to extrapolate the potential effectiveness and optimal dosage schedules on the basis of experience in managing seasonal influenza and human cases of avian influenza.
8. The evidence on the effectiveness of oseltamivir and zanamivir for the treatment and prevention of seasonal influenza has been reviewed by a number of committees including the Department's Scientific Advisory Group (SAG), its successor, the Scientific Pandemic Influenza Advisory Committee (SPI),<sup>17</sup> as well as the National Institute for Clinical Excellence (NICE) in developing their guidance on the use of antivirals for the treatment and prevention of seasonal flu.<sup>18</sup> These reviews interpreted the available data as supporting the effectiveness of oseltamivir and zanamivir in alleviating and reducing the duration of symptoms.
9. Both oseltamivir and zanamivir are licensed for prophylaxis based on clinical trial data submitted to the regulatory authorities.

#### UK Pandemic Influenza Preparedness Programme: defence in depth

10. It is impossible to forecast the precise characteristics, spread and impact of a new influenza strain. It follows that the effectiveness of individual countermeasures can also not be assured in advance. For this reason, antivirals form just one part of the "defence in depth" approach that the Government has adopted to prepare for a pandemic, which includes:

- Good respiratory & hand hygiene: to reduce the spread of the pandemic.
- Public health measures: encouraging patients to stay at home when ill, and consideration of school closures.
- Vaccines: Pre-pandemic vaccine may reduce infection if there is immunological cross-reactivity between the pandemic virus and the H5N1 strains used in the production of available vaccines. However, in light of the uncertainty about this, to date the Government has only purchased sufficient pre-pandemic vaccine for front-line health care workers. This is a rapidly evolving scientific area and the Government, and its scientific advisors, keep the question of pre-pandemic vaccination under close review.  
Once available, a pandemic-specific vaccine will reduce infection. However, such a vaccine is unlikely to be available until four to six months after the start of the pandemic and it will take some months further to produce sufficient stocks to meet requirements.
- Antivirals: may reduce the severity, duration of symptoms and prevent transmission.
- Antibiotics: to treat and prevent the secondary bacterial infections that may be a significant cause of complications and death.

11. This approach is based on rigorous assessment of the available scientific information and advice. The Department continues to seek independent scientific advice from SPI. Details of how the Department obtains its scientific advice and the membership of SPI are set out in Appendix 1. SPI advice is publicly available on the Department of Health's website.

<sup>14</sup> Varghese JN, *et al* Drug design against a shifting target: a structural basis for resistance to inhibitors in a variant of influenza virus neuraminidase. *Structure* 1998;6:735-46 and Moscona A Neuraminidase inhibitors for influenza. *N Engl J Med*, 2005;353:1363-73.

<sup>15</sup> Monto AS (2003) The role of antivirals in the control of influenza. *Vaccine* vol 21(16) 1769-1800.

<sup>16</sup> Department of Health. Use of antiviral drugs in an influenza pandemic—scientific evidence base. 2007. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_077276](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_077276)

<sup>17</sup> SPI meeting paper SPI/01/08. Request for advice on stockpiling neuraminidase inhibitors. 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/minutes.htm#04apr08>

<sup>18</sup> NICE technology appraisal No 168 (2009) Amantadine, oseltamivir and zanamivir for the treatment of influenza. Available at: <http://www.nice.org.uk/nicemedia/pdf/TA168fullguidance.pdf> and NICE technology appraisal No 158 (2008) Oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza. Available at: <http://www.nice.org.uk/nicemedia/pdf/TA158Guidance.pdf>

12. The scientific evidence base for the use of antivirals in an influenza pandemic was published by the Department of Health in 2007.<sup>19</sup>

#### UK stockpile of antivirals for use in a pandemic

13. We are currently increasing the UK's stockpile of antivirals to have sufficient to treat up to 50 per cent of the population, our reasonable worst case of the number of people likely to show symptoms.

14. Due to the unknown characteristics of the pandemic virus, no guarantee can be given that any one antiviral will be more effective than another in any sub-group of the population. As indicated above, both oseltamivir and zanamivir have slightly different profiles of contra-indications and warnings. In addition, the mode of delivery of the drugs must be considered. Zanamivir is a dry powder, which is inhaled through the mouth using a Diskhaler. This device precludes certain groups from taking this drug, including young children under the age of five.

15. The likelihood of a pandemic virus being, or becoming resistant to an antiviral cannot be quantified, although it is possible for resistance to develop to any antiviral. During a pandemic, it will be necessary to monitor the susceptibility of pandemic viruses to antivirals so that the emergence of resistance can be identified as quickly as possible and decisions made on whether to switch to another antiviral.

16. In the light of these considerations and in line with the recommendations of the Royal Society<sup>20</sup> and the advice of the SPI,<sup>21</sup> the extended stockpile now includes zanamivir as well as oseltamivir.

#### *Use of the pandemic antiviral stockpile*

17. The UK stockpile is intended principally for treatment. We recognise the importance of ensuring that we achieve the greatest possible benefit in terms of our "defence in depth" approach. The Government has therefore indicated that it will keep under review the case for extending our antiviral policy to include prophylaxis.

#### Antivirals for treatment

18. There is an international consensus that stockpiling antivirals to treat pandemic influenza should play a key part in mitigating the impact of a pandemic and could reduce the severity of the disease and the number of cases, hospitalisations and deaths. Antivirals, combined with antibiotics for the treatment of bacterial complications, therefore form a key part of our defence in depth approach.

19. Although the main purpose of antiviral treatment is to reduce the severity of the disease, treating all clinical cases with antivirals might also decrease the overall attack rate in a pandemic.<sup>22</sup> Some models suggest a relative reduction of up to one third. This suggests, for example that treating all cases in a pandemic influenza outbreak, for which the attack rate would be 50 per cent in the absence of treatment, would require enough antiviral courses for approximately 35 per cent of the population.<sup>23</sup> However, there is considerable uncertainty over the extent of the reduction that is possible, as this will depend on many factors, including the timing of treatment, the proportion of cases that are symptomatic and the duration of the infectious period.

20. In line with advice from SPI,<sup>24</sup> oseltamivir will be used as the main treatment antiviral. Zanamivir will be used by those who are unable to take oseltamivir (ie due to contraindications) and will also act as a strategic reserve should resistance to oseltamivir emerge during a pandemic or should the attack rate be higher than anticipated.

<sup>19</sup> Department of Health. Use of antiviral drugs in an influenza pandemic—scientific evidence base. 2007. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_077276](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_077276)

<sup>20</sup> The Royal Society & The Academy of Medical Sciences. Pandemic influenza: science to policy. Policy document 36/06. November 2006.

<sup>21</sup> SPI Statement 2008/01. Statement providing scientific advice on stockpiling neuraminidase inhibitors. 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/statements.htm>

<sup>22</sup> Gani *et al.* Potential impact of antiviral drug use during influenza pandemic. EID. 2005;11(9):1355-1362 and Ferguson NM *et al.* Strategies for mitigating an influenza pandemic. Nature. 2006;442(7101):448-452.

<sup>23</sup> Scientific Pandemic Influenza Advisory Committee's modelling summary. 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/modelling.htm>

<sup>24</sup> Scientific Pandemic Influenza Advisory Committee Statement 2008/02. Statement providing scientific advice on usage options of stockpiled neuraminidase inhibitors 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/statements.htm>

*Operational issues*

21. In order to minimise the impact of the illness and maximise individual health benefits, patients should take an antiviral medicine as soon as possible within the first 48 hours after the onset of symptoms.<sup>25</sup> Therefore, rapid antiviral provision is an important planning aim in the National Framework for responding to an influenza pandemic.

22. The Department has recognised that this is a key challenge and has therefore directed substantial effort and resource to putting in place the arrangements for the National Pandemic Flu Line Service, backed up with stock management and distribution arrangements, collection points and communications. Full details of this have already been provided to the Committee.<sup>26</sup>

**Antivirals for Prophylaxis**

23. Antivirals may be given for prophylaxis either before exposure to the pandemic virus (pre-exposure) or soon after exposure (post-exposure). Pre-exposure prophylaxis refers to the use of antiviral drugs for a long period, beginning in advance of any exposure to influenza and continuing for the duration of the likely risk of exposure. Post-exposure antiviral prophylaxis is normally a short course of antiviral drugs (10 days duration) given to those who have been in contact with an infected person with the intention that this will act either as true prophylaxis or as a form of “early treatment” if the contact has already been infected. Such “early” treatment may still allow the development of a natural antibody response to influenza, providing longer term protection. In addition to the individual effect of post-exposure prophylaxis (preventing the recipient getting influenza) there is an additional population effect brought about by the recipients being less likely to become infectious cases themselves.

24. Evidence indicates that both the neuraminidase inhibitors (ie oseltamivir and zanamivir) work well in prophylaxis against susceptible seasonal influenza viruses<sup>27</sup> and that prophylaxis does not substantially increase the probability of resistance occurring in an individual.<sup>28</sup>

25. The Department acknowledges that the scientific evidence supports the use of prophylaxis in limiting the overall clinical attack rate, thus limiting the spread of the disease. However, the decision whether or not to implement a prophylaxis strategy needs to take into account the impact of the associated operational issues. These differ according to the various settings in which prophylaxis might be used.

26. There are a number of different situations in which prophylaxis might be considered including:

- in advance of a pandemic, as part of the management of avian influenza outbreaks;
- at the very outset of a pandemic in its source country, to attempt to contain the virus where it first emerges;
- for contacts of early cases in the UK;
- pre-exposure prophylaxis for essential workers; and
- wider household post-exposure prophylaxis,

**Post- exposure prophylaxis for avian influenza outbreaks**

27. Avian influenza is recognised as a potential source of the next pandemic influenza.

28. We have already had experience of dealing with seven avian influenza outbreaks in the UK; in two of these incidents human infections were identified, treated and appropriate controls put in place. The protocols for managing avian influenza outbreaks include, where appropriate, prophylaxis with antivirals for those who had been determined to have significant contact with the sick individuals or the source of the infection (assumed to be birds). Each local health protection unit of the HPA has a local stock of antivirals for this purpose, which could be rapidly augmented by neighbouring units. Further details have already been provided to the Committee.<sup>29</sup>

<sup>25</sup> Department of Health. Use of antiviral drugs in an influenza pandemic—scientific evidence base. 2007. Available at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_077276](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_077276)

<sup>26</sup> Follow-up papers from the Department of Health, under cover of a letter dated 11 December 2008.

<sup>27</sup> NICE technology appraisal No 158 (2008) Oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza. Available at: <http://www.nice.org.uk/nicemedia/pdf/TA158Guidance.pdf>

<sup>28</sup> Cabinet Office. Overarching Government Strategy to Respond to Pandemic Influenza. Analysis of the scientific evidence base. Available at: <http://www.cabinetoffice.gov.uk/ukresilience/pandemicflu/evidence.aspx>

<sup>29</sup> House of Lords Science and Technology Committee Hearing on Pandemic Influenza 25 November 2008: Follow-up papers from the Department of Health, Paper B: Early Containment Planning, pages 5–7.

### Prophylaxis for attempt at rapid containment in source country of pandemic

29. Modelling has suggested that a combination of targeted post-exposure prophylaxis and social distancing measures could in theory contain an emerging pandemic in the first affected country (assuming a rural rather than an urban population) and that a stockpile of three million courses should be sufficient for a reasonable chance of success. Whilst this modelling is well established and respected internationally, the practical application of such an approach (as outlined in the *WHO interim protocol: Rapid operations to contain the initial emergence of pandemic influenza*)<sup>30</sup> including timely receipt and distribution of antivirals in a containment zone would pose considerable challenges in many countries and remains untested.

30. A pandemic virus could first emerge anywhere in the world—including the UK. Two of the three pandemics of the last century emerged in China (1957 and 1968), whilst the origin of the 1918 pandemic is unknown.<sup>31</sup> The most likely geographic origin of the earlier pandemics since the 18th century were China and central (Asian) Russia. This region therefore may represent the most likely source of the pandemic.

31. However, in the event of sustained human-to-human transmission of an avian influenza outbreak in the UK,<sup>32</sup> we would need to implement the WHO rapid containment protocol using our existing incident and emergency response framework. The logistical issues of getting antivirals from WHO that many countries face in their planning can be discounted in the UK because we have sufficient stockpiles already. In addition, PCTs are developing plans for antiviral receiving and forward distribution. The rapid containment protocol includes widespread prophylaxis, establishment of containment and buffer zones and restrictions on movement. Depending on the nature of the virus, vaccination may also be offered, if available.

### Antiviral prophylaxis for early cases in the UK

32. Uncontained, a flu outbreak would be expected to spread to all major UK centres of population within one to two weeks. Because of the probable multiple importations of pandemic flu, and the concentration of the population in cities, attempts at containment by targeted antiviral prophylaxis and practical social distance measures are very unlikely to succeed at reducing the spread and extent of the pandemic.<sup>33</sup> In addition, as noted earlier the mass provision of antivirals to the population may simply postpone the outbreak by the length of period for which prophylaxis is provided.<sup>34</sup>

33. This approach would require large supplies of antivirals, even if the population identified were relatively limited. This would rapidly deplete our stockpile for treatment, and could not be sustained for as long as it would take a specific vaccine to be developed (likely to be four to six months before the first supplies of pandemic specific vaccine are available).

34. WHO advice suggests mass prophylaxis in school-attending children might reduce their burden of disease and theoretically limit the spread of the virus. However, it is extremely unlikely that antiviral prophylaxis could significantly delay the progress of a pandemic.<sup>35</sup> Therefore, the WHO does not recommend the mass prophylaxis of children to control a pandemic.

35. WHO notes that there exists modelling that supports a socially targeted prophylaxis policy, best use is made of drugs by targeting classmates rather than the entire population of a school. However, this would require an antiviral stockpile of up to 102 per cent of the population.<sup>36</sup>

### Targeted antiviral prophylaxis for contacts of the First Few 100 cases

36. How and when the first cases of pandemic influenza will be initially detected in the UK is unknown. However, knowledge of early cases in the UK would provide key epidemiological, clinical and virological data needed to attempt to predict the future course of the UK pandemic. This is supported by the World Health Organization's (WHO) Guidance for global surveillance during an influenza pandemic (WHO, in preparation), which recommends that countries undertake a comprehensive assessment of a minimum of 100 confirmed cases at the outset of each country's pandemic.

<sup>30</sup> *WHO interim protocol: Rapid operations to contain the initial emergence of pandemic influenza*. Geneva, World Health Organization 2007 [http://www.who.int/csr/disease/avian\\_influenza/guidelines/draftprotocol/en/index.html](http://www.who.int/csr/disease/avian_influenza/guidelines/draftprotocol/en/index.html)

<sup>31</sup> Hampson, A, Surveillance for pandemic influenza. *J Infect Dis*. 1997; 176 (Suppl 1):S8-13.

<sup>32</sup> NB it is possible that such transmission could be of a low pathogenic virus, with relatively mild symptoms, rather than a highly pathogenic virus.

<sup>33</sup> Ferguson NM *et al*. Strategies for mitigating an influenza pandemic. *Nature*. 2006; 442 (7101): 448–452.

<sup>34</sup> Longini IM, Halloran ME, Nizam A, Yang, Y. Containing pandemic influenza with antiviral agents. *Am J Epidemiol*. 2004;159(7):623–33.

<sup>35</sup> *WHO guidelines on the use of vaccines and antivirals during an influenza pandemic*. World Health Organisation (2004).

<sup>36</sup> Ferguson NM *et al*. Strategies for mitigating an influenza pandemic. *Nature*. 2006; 442 (7101): 448–452.

37. The HPA is developing plans for comprehensive assessment of the first few 100 (FF100) cases in the UK and their contacts. As part of this, consideration is being given to providing targeted post-exposure prophylaxis to the close contacts of confirmed cases. This would provide valuable information to allow an initial clinical assessment of the effect of antivirals, which would in turn inform the way the antiviral stockpile is subsequently deployed.

#### Pre-exposure prophylaxis for essential workers

38. Some countries are considering the use of pre-exposure prophylaxis during a pandemic for essential workers in healthcare or critical national industries. Prophylaxis of essential workers may lead to a possible two thirds reduction in both peak and total clinical attack rates for the groups receiving prophylaxis.<sup>37</sup>

39. However, there are a number of disadvantages:

- Pre-exposure prophylaxis requires very large stocks of antivirals. For example, a quarter of the 50 per cent national stockpile would be needed to provide on-going pre-exposure prophylaxis for front line NHS workers alone.
- It is likely that once pre-exposure prophylaxis ceases, the recipients' underlying susceptibility to influenza is unaltered, ie it is far less likely that the recipient will have developed protective antibodies. Unlike those treated with antivirals, those who receive prophylaxis for the duration of a first wave and do not develop clinical or sub-clinical infection would not be immune at the start of a second wave.<sup>38</sup>
- Unless it can be sustained until individuals are vaccinated, pre-exposure prophylaxis will merely delay a pandemic until the supply of drug is exhausted.
- If the purpose is to protect people before vaccines become available, prophylaxis would be needed from the onset of a pandemic, probably wherever in the world it begins rather than from the first UK cases, for an extremely long time. It could take a year or more to obtain sufficient vaccine doses for the entire population.
- Oseltamivir is only licensed for use for six weeks and zanamivir is only licensed for four weeks. There are likely to be compliance and tolerance issues associated with long treatment courses.

40. For these reasons, pre-exposure prophylaxis does not currently form part of the UK's defence in depth approach.

#### Post-exposure household antiviral prophylaxis

41. The Department's independent expert advisers have considered this issue at length at the meetings of the SPI sub group on Clinical Counter Measures (SPI-CC) in November 2008 and January 2009.

42. In addition, there are two published papers on the use of antivirals for post-exposure household prophylaxis.<sup>38</sup> These are based on analysis of four clinical trials<sup>39</sup> and are well respected within the science community. The modelling shows that antiviral prophylaxis of the household contacts of infected cases given within 24 hours of symptoms appearing in index cases, could have a greater impact on a pandemic than a simple treatment policy, reducing cases and hence deaths.

43. Modelling endorsed through the Scientific Pandemic Influenza Advisory Committee's modelling sub-group indicates that combining treatment of all cases and post-exposure prophylaxis of household contacts with antivirals, and the use of other countermeasures (ie antibiotics, pre-pandemic vaccination, masks, social distancing) could be sufficient to reduce the pandemic in the UK to localised outbreaks of seasonal influenza proportions, for a 25 per cent to 35 per cent raw (ie without intervention) clinical attack rate. Even for higher attack rates, or if one component is ineffective, the combined intervention could significantly limit the impact of a pandemic.

<sup>37</sup> Scientific Pandemic Influenza Advisory Committee's modelling summary. 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/modelling.htm>

<sup>38</sup> Longini IM, Halloran ME, Nizam A, Yang, Y. Containing pandemic influenza with antiviral agents. *Am J Epidemiol.* 2004;159(7):623–33 and Ferguson NM *et al.* Strategies for mitigating an influenza pandemic. *Nature.* 2006;442(7101):448–452.

<sup>39</sup> Summarised in: Halloran ME, Hayden FG, Yang Y, Longini IM Jr, and Monto AS. Antiviral effects on influenza viral transmission and pathogenicity: observations from household-based trials. *Am J Epidemiol.* 2007 Jan 15;165(2):212–21 and Yang Y, Longini IM Jr and Halloran ME. Design and evaluation of prophylactic interventions using infectious disease incidence data from close contact groups. *Journal of the Royal Statistical Society: Series C (Applied Statistics).* 55(3):317–30.

*Impact of a prophylaxis strategy on the development of resistance or reduced susceptibility*

44. The Department has also sought the advice of SPI on clinical and scientific issues regarding the use of a multi-drug stockpile for household post-exposure prophylaxis and in particular the question of the development of resistance or reduced susceptibility.

45. In planning for the most appropriate use of the antiviral stockpile, it is important to consider the potential for the emergence of antiviral resistance. The potential for a pandemic virus to be, or to become resistant to an antiviral cannot be predicted, although it is possible for resistance to develop to any antiviral.<sup>40, 41, 42</sup>

46. The Department has sought advice from SPI on the different scenarios in which resistance or reduced susceptibility to an antiviral may occur during a pandemic<sup>43</sup> including how best to use a mixed antiviral stockpile to minimise the likelihood of resistance or reduced susceptibility occurring during a policy of household post-exposure prophylaxis.

47. Based on the various scenarios and usage options, SPI noted that during a pandemic, the potential for resistance to oseltamivir to emerge is greater than for zanamivir due to more widespread use of oseltamivir. It recommended that oseltamivir should act as the main antiviral for treatment and prophylaxis (except where zanamivir was recommended)<sup>44</sup> until a trigger point of significant resistance/reduced susceptibility is reached or real-time modelling identifies that the remainder of the oseltamivir stockpile is only sufficient to treat and provide prophylaxis for those contraindicated for zanamivir. At this point the switch would be made to zanamivir as the main antiviral for treatment and prophylaxis.

**Other considerations**

48. Household post-exposure prophylaxis only becomes practical once the national stockpile is sufficient for 50 per cent of the population.<sup>45</sup> So far as we are aware, no other country is currently considering it.

49. Until now, the UK has only had a stockpile sufficient for 25 per cent of the population and the Department's priority has been to ensure rapid access arrangements are in place to ensure that all symptomatic patients will be able to receive drugs for treatment within the 48 hours of onset of symptoms.

50. In view of the advice from SPI based on clinical and scientific evidence, and the newly increased size of the national stockpile, the Department is actively examining the feasibility of introducing household post-exposure prophylaxis as part of the defence in depth strategy. This requires a rigorous cost-benefit analysis, taking into account the operational and practical implications alongside the scientific and modelling evidence.

*Conclusion*

51. This paper has outlined the careful consideration that the Department has given to the scientific and modelling evidence for a prophylaxis strategy. The Government seeks to ensure that all elements of the Pandemic Influenza Preparedness Programme are underpinned and guided by the best scientific evidence and robust planning for implementation.

52. The Department is actively considering how best to extend our defence in depth approach, taking into account all these considerations. It welcomes the Committee's interest in this topic.

<sup>40</sup> During the 2008–09 influenza season, 98 per cent of all influenza A(H1N1) viruses tested in Europe have been resistant to oseltamivir. However, all influenza A(H3N2) viruses have been sensitive to oseltamivir and zanamivir.

<sup>41</sup> Eichner M, Schwehm M, Duerr HP, Witschi M, Koch D, Brockmann SO, Vidondo B. Antiviral prophylaxis during pandemic influenza may increase drug resistance. *BMC Infect Dis.* 2009 Jan 20;9:4.

<sup>42</sup> Dharan NJ, Gubareva LV, Meyer JJ, Okomo-Adhiambo M, McClinton RC, Marshall, SA, St George K, Epperson S, Brammer L, Klimov AI, Bresee JS, Fry AM. Infections With Oseltamivir-Resistant Influenza A(H1N1) Virus in the United States. *JAMA.* 2009;301(10):1034–1041.

<sup>43</sup> Scientific Pandemic Influenza Advisory Committee meeting paper SPI/02/04 & SPI/CC01/02. Mixed antiviral stockpile usage pattern. 2008. Available at: <http://www.advisorybodies.doh.gov.uk/spi/minutes.htm#11nov08>

<sup>44</sup> Groups for whom zanamivir was recommended by Scientific Pandemic Influenza Advisory Committee: children (5–18 years) with renal insufficiency and patients on dialysis with creatinine clearance? 30ml/min as well as pregnant and lactating women.

<sup>45</sup> Ferguson NM *et al.* Strategies for mitigating an influenza pandemic. *Nature.* 2006; 442 (7101):448–452.

## APPENDIX 1

### SCIENTIFIC PANDEMIC INFLUENZA ADVISORY COMMITTEE (SPI)

The Scientific Pandemic Influenza Advisory Committee (SPI) was established in 2008 as an independent committee to advise the UK Government on scientific matters relating to the response to an influenza pandemic. This committee replaces the Scientific Advisory Group (SAG), set up in 2005, and includes a wider range of scientific disciplines including traditional infectious diseases-related sciences such as virology and immunology, and sciences such as risk management, behavioural sciences and diagnostics. This reflects the far-reaching implications of an influenza pandemic as well as the cross-government nature of this advisory group. The membership of SPI is set out below.

Besides providing advice on specific questions, SPI acts as an information and scientific challenge network for the government to ensure that it is informed of important developments in pandemic influenza related sciences, which could affect government policy.

Formal advice from SPI takes the form of a statement agreed by the full SPI committee. Statements provided to the Department can be found on the SPI website.<sup>46</sup>

The majority of SPI work takes place in sub-groups. There are two types of sub-groups. Standing sub-groups have been set up focussing on areas of science of continued interest to the SPI. Ad hoc sub-groups are established to tackle a particular question or piece of work that does not fall under the remit of any of the standing sub-groups and but does not require input from all sciences represented on the full SPI. There are currently three standing SPI sub-groups:

- behaviour and communications;
- clinical countermeasures; and
- modelling.

Sub-groups may include non SPI members for a particular project or tasks, co-opted on an *ad hoc* time-limited basis, to increase the range of expertise available.

Advice originating from sub-groups must be endorsed by SPI prior to publication.

### SPI MEMBERSHIP

*The membership of SPI as of 31 March 2009 is set out below.*

<i>Name</i>	<i>Professional role</i>
Professor Sir Gordon Duff (Chair)	Florey Professor of Molecular Medicine, University of Sheffield School of Medicine.
Professor Peter Aggett	Scientific Advisory Group on Nutrition representative. Professor of Human Nutrition, School of Medicine at the University of Southampton.
Professor Andy Alaszewski	Director and Professor of Health Studies Centre for Health Services Studies, University of Kent.
Dr Maureen Baker	General Practitioner, Honorary Secretary, RCGP.
Professor Sheila Bird	Principal Statistician, Medical Research Council Biostatistics Unit.
Dr Ian Brown	International Reference Laboratory for Avian Influenza.
Dr Ben Cooper	Mathematical Modeller, Health Protection Agency.
Professor Janet Derbyshire	Director Medical Research Council Clinical Trials Unit.
Mr Niall Dickson	Chief Executive King's Fund.
Professor John Edmunds	Infectious Disease Epidemiology Unit, London School of Hygiene and Tropical Medicine.
Dr Meirion Evans	Consultant epidemiologist, National Public Health Service for Wales.
Professor Neil Ferguson	Director, MRC Centre for Outbreak Analysis and Modelling, Imperial College.
Professor David Goldblatt	Head of the Immunobiology Unit, Institute of Child Health, University College London.

<sup>46</sup> Scientific Pandemic Influenza Advisory Committee website: <http://www.advisorybodies.doh.gov.uk/spi/index.htm>

<i>Name</i>	<i>Professional role</i>
Professor George Griffin	Chair of Advisory Committee on Dangerous Pathogens (ACDP). Head of the Dept of Cellular and Molecular Medicine and Infectious Diseases, St George's University of London.
Dr Peter Grove	Analyst, Department of Health.
Dr Paul Gully	Deputy Coordinator for the United Nations System Response to Avian and Human Influenza.
Professor Andrew Hall	Chair of Joint Committee on Vaccination and Immunisation. Professor of Epidemiology, London School of Hygiene and Tropical Medicine.
Dr Stephen Inglis	Director of the National Institute for Biological Standards Control (NIBSC).
Dr Steve Leach	Scientific Programme Head (Microbial Risk Assessment), Health Protection Agency.
Dr Simon Mardel	Consultant in Emergency Medicine, Leicester Royal Infirmary.
Professor Barry McCormick	Chief Economist and Director of Analysis, Department of Health.
Professor Susan Michie	Chair in Health Psychology, Department of Psychology, UCL.
Dr Jacqueline Morris	University Department of Geriatric Medicine Royal Free London.
Dr Kevin Moreton	MRC Infections and Immunity Section—Research Management Group.
Dr Simon Nadel	Consultant in Paediatric Intensive Care, Imperial College Healthcare NHS Trust.
Professor Angus Nicoll	Influenza co-ordination, European Centre for Disease Prevention and Control (ECDC), Stockholm.
Professor Karl Nicholson	Professor and Honorary Consultant in Infectious Diseases, University of Leicester.
Dr Babatunde Olowokure	Consultant Epidemiologist—Health Protection Agency Regional Surveillance Unit, West Midlands.
Professor Peter Openshaw	Professor of Experimental Medicine, Imperial College London; Director of the Centre for Respiratory Infections Research.
Professor Deenan Pillay	Liaison for Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI). Professor of Virology, UCL; Head of Research Department, Centre for Infections, Health Protection Agency.
Dr Bina Rawal	Therapeutic Area Expert in Virology, Roche Products Ltd.
Professor Robert Reed	Professor of Infectious Diseases, University of Sheffield.
Dr Jeremy Russell	Director of R&D, Smiths Medical International.
Dr Andrew Singer	Senior Scientific Officer, Centre of Ecology and Hydrology, Oxford.
Sir John Skehel	Retired as Director of the NIMR in 2006 Academy of Medical Sciences.
Professor Jonathan Van Tam	Professor of Health Protection, University of Nottingham.
Dr Alison Webster	Director of the Infectious Diseases Medicines Development Centre, GlaxoSmithKline.
Professor Lucy Yardley	Professor of Health Psychology, School of Psychology, University of Southampton.
Professor Maria Zambon	Deputy Director of Virology Reference Division, Health Protection Agency.

**Second supplementary evidence from the Rt Hon Alan Johnson MP, Secretary of State for Health,  
Department of Health**

RESPONSES TO THE COMMITTEE'S QUESTIONS OF 14 MAY

*How will antivirals be distributed during the current outbreak given the absence of the flu line and how has the mechanism for distribution been communicated to healthcare workers on the front line? What has caused the delay in setting up the flu line?*

A system for ordering and distributing antivirals is an essential element of the mitigation phase of the UK response to a flu pandemic.

The Flu Line will be ready in the autumn; it is a ground-breaking system and the first of its kind in the world. It will be able to assess people via either the internet or telephone, co-ordinate the distribution of antivirals and feed back to local health services. It will have the capacity to cope with the surges in demand that are likely if the virus becomes more widespread. It will have been thoroughly tested so that staff, patients and the public can have full confidence in its efficacy.

Because Flu Line is such an innovative system it has been very important to ensure that it is probed and tested sufficiently before it is used. A contract for the development of this system was signed with British Telecom in December 2008 and the Department is working to make the Flu Line operational as soon as possible.

If we need to move from the current containment phase to mitigation before the Flu Line is ready, we will have arrangements in place that enable those who develop the disease to get treatment as quickly and effectively as possible without unnecessarily exposing more people to the virus. In addition, local health services will be able to respond to people's everyday health needs, as well as concentrating their efforts on providing specialist support to those who develop this strain of flu and are severely affected, and those who have underlying complications that make them particularly vulnerable.

The interim service that we expect to have ready shortly will consist of a phone service that the public can access through a single 0800 number, and a supporting website application. That will mean that people can have their symptoms assessed either over the phone or online. Those symptoms will be checked against an algorithm—a list of the key symptoms and factors that determine whether the patient in question has been exposed to the infection. This is a system similar to NHS Direct, which is currently used by millions of people every year.

If it is established that someone has developed swine flu, they will be issued with an authorisation number that they will then need to access antivirals. Their go-between—or “flu friend”—will then take that authorisation number to their nearest collection point to obtain the antivirals. At current levels of activity there is no immediate requirement to activate the interim system but preparations are being put in place to be able to do so in the event of an upsurge in cases over summer or in autumn.

Currently we are in a containment stage. The NHS is working closely with HPA to ensure that antivirals are available prophylactically where needed. Communications with clinicians has been via CMO alerts. The Health Protection Agency (HPA) has provided an algorithm for use by GPs and other NHS staff receive regular communications via their designated flu leads and via routine communication channels such as the monthly pandemic flu news, an update circulated to various stakeholders.

The mechanism for antivirals distribution has been communicated in The National Flu Service Framework (guidance for SHAs and PCTs in England) which has been sent to all SHAs/PCTs and is additionally available on the “Pan Flu Forum”, an online tool available to relevant NHS staff and other stakeholders.

We also note some confusion that has arisen over the evidence given to the Committee by Mr Bruce Taylor, Deputy Director for Pandemic Influenza Preparedness, at the Evidence Session on 17 March 2009. The Rt Hon Andrew Lansley, MP mentioned in the topical debate on 14 May that the evidence at this time had stated that Flu Line would be ready by the end of May.

While Mr Taylor did state that Flu Line itself would be available at that time, he also noted that elements of the full “end-to-end” service, including the stock management system and storage and distribution system, would not be ready until the summer. He also emphasised the importance of extensive testing to the overall system to ensure confidence in the element of a response to a pandemic. The interim arrangements for antiviral distribution being finalised by the Department, described above, do build on the basic element of Flu Line that was scheduled to be available at the end of May.

*Have collection points been identified and tested, and how will they be staffed?*

As part of their general preparedness work, PCTs have been undertaking wider pandemic preparedness activities for the past 18 months. As a part of this activity, they have been identifying the number and location of antiviral collection points (ACP) that would be appropriate to their local health needs. The Department of Health provided a modelling tool in August 2008 to assist PCTs in planning the number of collection points locally required. This model encompasses the whole of England, both demographically and geographically (to allow for rural/urban differences).

PCTs have been using the existing list of previously identified antiviral collection points to identify appropriate locations to meet the needs of current circumstances.

PCTs have been asked to review their proposed network of ACPs to ensure that they could, as a contingency, be used for on-site assessment and authorisation as well as for issuing antivirals (should this be necessary as an interim measure pending the availability of the National Flu Service web and phone interface).

SHAs are reviewing PCT ACP plans this week (beginning 18 May) to ensure that they are robust, that there is clarity on the lead time for the establishment of the antiviral collection points, that a good spread of ACPs is available across the PCT geography and that sufficient ACPs will be up and running to meet the needs of the population. Guidance has been provided to PCTs and SHAs regarding the set up and operation of ACPs. Training materials are also in production for SHAs and PCTs.

*What is the policy on prophylaxis? In the current outbreak will the policy of prophylaxis be replaced by providing antivirals on the basis of symptoms only and, if so, when?*

Post-exposure prophylaxis means giving a short course of antiviral drugs (10 days duration) to those who live with an infected person. The intention is that this will act either as true prophylaxis or as a form of “early treatment” if the contact has already been infected.

In the containment phase we are providing antivirals for treatment for those who are symptomatic and as prophylaxis for those who have been in contact with confirmed cases—both household contacts and others who have been in contact with suspected cases. This is in order to contain the virus by reducing the occurrence of early outbreaks and delaying the establishment of the epidemic in the UK. This is in line with current scientific advice.

If the UK moved to a mitigation phase, where we had to deal with many more cases, household prophylaxis could be one of a range of strategic options adopted if the severity of the situation merited it. We will make decisions about prophylaxis based on the analysis of the situation as it develops, and taking into account our ability to implement a strategy based on prophylaxis.

We are currently exploring the scientific evidence, logistical implications and resource requirements of a household prophylaxis policy. For example, we must consider:

- whether we will be able to distribute antivirals efficiently enough on such a large scale;
- how best to prevent fraud when there is no clinical basis for receiving antivirals; and,
- the possibility that increased use will lead to a correspondingly increased risk of the virus developing resistance to the drugs.

The practical issues relating to a strategy of household prophylaxis would be substantial. So far as we are aware, no other country is currently considering it.

In the current containment phase, arrangements are being made for anti-viral drugs to be available to front line healthcare workers and social care workers. These will only be for those staff who come into close contact with individuals with swine flu while they are symptomatic—for post exposure prophylaxis.

*How is the risk of resistance to Tamiflu being addressed?*

The H1N1 virus currently circulating is sensitive to both Tamiflu and Relenza. However, genetic mutations of the virus leading to reduced susceptibility or resistance are a concern with any antiviral treatment. Accordingly, the Government has stockpiled both Tamiflu (23 million doses) and a strategic reserve of Relenza (10.5 million doses). Because initial treatment will be mainly with Tamiflu, it is probable that if the virus does develop resistance it will be to Tamiflu. In this situation, Relenza could be used in its stead.

An established network of HPA and NHS laboratories across the UK closely monitor changes in the nature of the influenza virus (including subtype, strain and susceptibility to antivirals) and any associated trends in bacterial infections (including susceptibility to antibiotics). This will continue to be reported weekly through the HPA CfI central databases to DH.

*Primary Care Trusts and GPs will be at the forefront of handling a pandemic. What support will they be given, and what support have they been given during the current outbreak? What steps have been taken to assess the effectiveness of that support?*

As with all other primary care services GP practices must expect to be under considerable pressure in the event of a flu pandemic. Most health and social care will need to be delivered in the community setting, with hospital capacity protected and preserved for those in most clinical need and likely to benefit. However, the National Flu Service has been designed to minimise pressure on GPs and primary care teams by allowing patients to

receive antiviral medication via a web or telephone based service together with a local network of ACPs. This is intended to allow GPs to concentrate their expertise on treating the patients that they normally see plus those with the complications of flu as opposed to—the potentially very large number of—patients who think that they might have flu.

Ian Dalton, the temporarily appointed National Director for NHS Pandemic Preparedness, has been brought in to further strengthen lines of communication with the NHS and to ensure robust implementation of NHS flu plans necessitated by a pandemic. Prof Lindsey Davies remains responsible for policy on national pandemic preparedness but obviously it will be important to ensure that decisions are implemented promptly and smoothly across the NHS during any pandemic. Ian Dalton's appointment is a prudent move that will build on the work of recent years to prepare the NHS for a potential pandemic.

To preserve GP capacity and enable practices to deliver care in the community setting, it is possible that non-essential activity will cease (but continuing to make essential care available for emergencies and patients with chronic or other illness), and GPs and those with higher clinical skills or experience will focus on those patients who may be at particular risk.

As part of the preparations the BMA and RCGP have produced guidance and assisted planning by GP practices. The Department continues to work with the NHS at a local level on arrangements for access to antivirals and are very conscious of the need to minimise the additional burden on GPs.

Most flu sufferers can usually be cared for appropriately using a home care based approach. Although ceasing non-emergency activities can make some additional hospital beds available, it is not feasible to expand or staff additional hospital capacity to the extent necessary to meet the level of demand that a pandemic might generate. Therefore, our guidance on managing demand and capacity (surge) emphasises that most flu sufferers can be and will need to be cared for in a community setting.

Managing fluctuating demand and capacity for the NHS is part of normal working activity, especially during winter months. As part of a very widespread event such as pandemic, it may be necessary to consider the postponement of certain non-time critical procedures. The guidance takes a pan NHS approach, which aims to provide a framework to assist in such a “worst case scenario” situation. This is designed to assist the NHS, during any such event, to continue to provide the best patient care possible under pressure ensuring equity in assessment of patients. The guidance is supported by care protocols for both adults and paediatrics which have been developed with support from a number of experts from a range of colleges. These will shortly be available to the NHS. As part of surveillance a clinical information network will be established and these sites will contribute to the evaluation of the protocols.

The threat of a pandemic raises some very sensitive issues about how best to provide care for as many people as possible. We have published an ethical framework to assist clinicians during a pandemic. It includes information on how best to make decisions under pressure, and how to triage patients effectively, to ensure that the maximum number of patients get the care they need.

*What planning has been undertaken to ensure that there will be adequate intensive care provision in the event of a pandemic? What evidence is the Department relying on for the purpose of contingency planning?*

Planning assumptions for an influenza pandemic across Government are based on the “reasonable worst-case scenario” pandemic, which was developed based on advice from the Department of Health's Scientific Advisory Group (SAG)<sup>47</sup> and its modelling subgroup.

On 1 May 2009 the Department of Health published guidance for the NHS entitled *Pandemic flu: managing demand and capacity in healthcare organisations*. This includes advice from the Intensive Care Society on ways of increasing intensive care capacity, including suspending elective procedures requiring post operation critical care, withdrawing or reducing critical care outreach services, and increased use of agency staff for support.

However it also acknowledges that at the peak of a “reasonable worst-case scenario” pandemic intensive care capacity may well be inadequate even after these measures have been adopted. It therefore attempts to support staff by referring to the Department's ethical guidance agreed by our advisory committee, CEAPI. I would like to assure you that the Department has fully considered the difficult and sensitive issues surrounding surge capacity and patient prioritisation during a pandemic and I am confident that our position is in line with that of the Ethical Framework, which was published last year.

To further assist clinicians, we are currently developing clinical assessment tools specifically for an influenza pandemic. This work will engage Royal colleges and other stakeholders in agreeing a consistent approach to using the tools in primary and secondary care.

<sup>47</sup> Now called the Scientific Pandemic Influenza advisory group (SPI).

We need to think very carefully before proposing any legislation granting universal indemnity to healthcare workers in a pandemic. Although we fully understand the importance of supporting clinicians in what could be extremely difficult circumstances, we must also ensure that patients' rights are not infringed. Such rights include legal recourse for negligent care.

We feel that, although universal indemnity would not be appropriate, it would be helpful to reassure NHS staff that the extraordinary pressure they may face would be taken into account in any subsequent legal action and we are currently examining various proposals for doing so.

*What lessons have been learned from the swine flu pandemic? What has worked well and what has worked less well? The issue of "end-to-end" testing is critical. The swine flu represents an interesting live testing—a "real time pilot"—of some elements of the preparedness plan. Will the Department undertake an audit of each step of the preparedness strategy?*

We fully recognise the importance of identifying lessons learned from the current outbreak to inform future policy and this work has already begun internally at the Department. Ian Dalton will take forward work to identify lessons learned in the NHS. It is too early to be able to draw firm conclusions at this stage and we hope to have preliminary findings available by the autumn.

The system will be tested against requirements and design specifications to ensure a successful end-to-end delivery of the combined solution.

The test process will initially involve individual quality testing of the workstream solution before a combined integrated test phase which will cover functional, performance, accessibility, usability, penetration (security), user and operational acceptance testing.

Throughout the test process there will be input from stakeholders in government departments, medical advisors and business users to advise on the requirements and acceptance of the system.

The overall planned incremental approach to exercising is currently being reviewed in the light of the current swine flu. However, the current situation is providing an opportunity to test out the channels of communication and surveillance systems that are working well.

Guidance has been issued to PCTs on how to run an antiviral collection points (ACPs) and action cards, which will support the key players running ACPs, have also been issued. Following the SHA review of robustness of ACP plans, an operational test of a collection point is planned. Lessons from this will be reviewed by DH, incorporated in further guidance if necessary, and lessons shared with all PCTs.

A business continuity exercise (the Camden flu game) has already been produced and is available for organizations ranging from GP practices to regional wide organizations.

The possibility of testing out the response to surge across a whole system is being considered.

*What is the Department doing to ensure that the public understand that the pandemic is being handled effectively? What is the Department's communications strategy? Has it been tested? In particular, how effective has the "leaflet to every household" been in communicating the Department's messages?*

Conveying accurate, timely, consistent and credible advice and information to the public (including hard to reach groups), professions and business has always been a major strand of the Government's pandemic preparedness strategy.

Our communications have aimed to provide advice, information and campaign material to the widest possible audience, and use a diverse and comprehensive range of communications channels including: digital, print and broadcasting advertising campaigns, media relations, a national door drop leaflet and a national flu information line.

We have sought to make it clear that even in a full pandemic, business as usual means, wherever possible, going about your normal day-to-day business and that people should only stay at home if they have symptoms.

In response to the current outbreak there has been a mass public health campaign with print, TV and radio adverts to keep the public informed. The adverts warned the public about swine flu and reminded people to cover their noses and mouths with tissues when they cough and sneeze and then throw the tissue away and wash their hands. The message has been simple: CATCH IT. BIN IT. KILL IT. Members of the public who want further information can ring a single number, 0800 1 513 513, for regular recorded updates on the current situation.

A leaflet entitled “Important information about swine flu” was sent out between 5 and 19 May to cover the whole of the UK. It contained important information about this flu outbreak and preventative messages. The Swine Flu Information Line and the websites [www.nhs.uk](http://www.nhs.uk) and [www.directgov.uk](http://www.directgov.uk) continue to be regularly updated.

We have made information available in a range of other languages for people to order if English is not their first language. In addition, it is available in Braille, British Sign Language video, large print and on audio tape.

We have undertaken campaign tracking surveys to measure levels of awareness, understanding and attitudes among the general public during the course of the campaign activity. This research shows very high levels of awareness of swine flu and a good understanding of the actions that can be taken. It has also given us useful insights into the views of different groups of people and the extent that they regard swine flu as a threat. These insights will be used to inform any future public communication activity we undertake.

*28 May 2009*

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THURSDAY 2 JULY 2009

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Present	Sutherland of Houndwood, L (Chairman) Broers, L Colwyn, L Crickhowell, L Cunningham of Felling, L	Jenkin of Roding, L Haskel, L May of Oxford, L Neuberger, B Selborne, E Warner, L
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**Examination of Witnesses**

Witnesses: GILLIAN MERRON, a Member of the House of Commons, Minister of State for Public Health, PROFESSOR LINDSEY DAVIES CBE, National Director of Pandemic Influenza Preparedness, MR IAN DALTON, National Director for NHS Flu Resilience, Department of Health, PROFESSOR SIR GORDON DUFF, Chairman, Scientific Pandemic Influenza Advisory Committee and DR BECKY KIRBY, Head of Human Health, Civil Contingencies Secretariat, Cabinet Office, examined.

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**Q103 Chairman:** Minister, may I, on behalf of the Committee, welcome and congratulate you on your, I suppose, recent appointment, rather than new appointment, it must now be. We are delighted to see you here. As you know, we have had significant interest in the matter in front of us today and we have returned to it over the last few months. As it turned out of course, there was an outbreak of flu which was significant. Whether in terms of the nature or the way in which it affects people is another matter, but the widespread occurrence has occasioned lots of questions. We have had very helpful responses from the Department of various kinds, but we thought that this was a good moment to ask further questions about progress in the outbreak and also how we are dealing with that. I wonder, would you like to introduce your team.

*Gillian Merron:* I would, Chairman, and could I also have your permission to make an opening statement to the Committee?

**Q104 Chairman:** Of course.

*Gillian Merron:* Thank you very much. First of all, could I thank you very much for your warm welcome and congratulations. I am delighted to have my still-new post and you will imagine that it is an interesting challenge for me to appear before you in my fourth week, but that probably makes me long-term! I am fully aware of the elements of the Committee and the work that you have done and I am very happy to be as helpful as I possibly can be today. I would like to thank the Committee for its work; I know it has generated a lot of interest and has made a major contribution and, for that, I am grateful. First of all, perhaps I could introduce my team who will assist me today: Dr Becky Kirby from the Cabinet Office; Mr Ian Dalton who is Director of Pandemic Influenza Resilience at the Department; Professor Lindsey Davies, Director of Pandemic Influenza at the Department; and Professor Sir Gordon Duff from

SAGE, and all of us are available of course this morning to you. What I would like to do is just briefly set out the current situation, as I see it, and the main thing that strikes me coming to this fairly fresh, as will strike you, is that we are not in a theoretical situation, we are very much living it day to day, and I hope that will give some real flavour perhaps to our discussions this morning. The current situation is that the number of cases of swine flu continues to rise daily and, as of this morning, there are 7,447 lab-confirmed cases and, as we know, a number of people have been admitted to hospital and, sadly, we have seen some deaths. The virus is generally mild in most people, although it is proving to be more severe in a small number of cases and the majority of those have got underlying health conditions. I would like to put on record that the Health Protection Agency, in conjunction with the National Health Service, has been doing an excellent job of work to seek to limit the spread of the virus, we continue to keep the situation under close surveillance and we have recently adapted our approach in order that we can respond more flexibly to local situations as we find ourselves with concentrations across the United Kingdom. In areas where we have got the local outbreaks and because we know more about the spread and the symptoms of swine flu, doctors are diagnosing cases without waiting for a lab test. We are finding this more flexible and it is enabling GPs to prescribe antivirals immediately, and of course time is of the essence. Swab tests are not necessary in all cases and the decision on the need for laboratory testing and swabbing to continue is based on local assessment of the situation. All confirmed cases will continue to be treated with antivirals and there will be a more targeted use of antiviral prophylactics. The HPA will continue to perform risk assessments at each school, looking at each individual situation and not automatically recommending closure, but deciding whether there are special circumstances that

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

merit it and that it is a valuable thing to do. The Committee will know that we have been preparing for the possibility of a pandemic for a number of years and this is a major test for us. NHS organisations do have plans in place and I am glad to say, although not complacent, I think we should take pride, and those in the National Health Service should take pride, that the World Health Organisation recognises the UK as one of the best-prepared countries in the world. Our preparations include the procurement of a stockpile of antivirals, face masks, respirators and antibiotics. We publish guidance on pandemic planning in key sectors in the testing and evaluation of health and resilience sector plans, and we have advance purchase agreements which will enable the United Kingdom to purchase up to 132 million doses of pandemic-specific vaccine sufficient for everybody in the UK when it becomes available. We continue to monitor the situation carefully and we take the advice of leading scientists. The Civil Contingencies Committee, of which of course I am a member now and previously was a member as a Foreign Office Minister, has been considering how we might need to adapt our response to reflect the increasing number of cases, and my right honourable friend the Secretary of State for Health will be making a statement today in the Commons on this very matter, and we have also offered to repeat this in the House of Lords. I hope that will be a helpful and general introduction to our discussions this morning.

**Q105 Chairman:** Yes, I think it touches on many of the matters that we would like to explore a little bit further. Just on one factual point, you mentioned 7,400 cases, so is that across the UK or is that in England?

*Gillian Merron:* It is.

**Q106 Chairman:** So it is the whole of the UK?

*Gillian Merron:* It is.

**Q107 Chairman:** I wonder if I can start with the fact that you have included in your outline that the number of cases is growing, although the effect in many instances was fairly mild, but does this move the Government at all from containment to mitigation as a main driver for the strategy, and is there a target either in terms of volume or date when you might make such a move?

*Gillian Merron:* The first point perhaps I should refer you to, Chairman, is the fact that the Secretary of State will be making a statement and I know you will understand that I cannot give you the highlights of that. However, I can answer the second part of the question. As I mentioned in my opening statement, we have got certain hotspot areas and what we are

seeing is widespread transmission in local communities and there we have tailored our response to meet those specific needs, which are rather different from the rest of the country, but there are certain areas that will influence a decision to move to treatment only, and perhaps I can just run through them: first of all, the consideration of the levels of widespread transmission, the extent of the situation; secondly, what is our understanding of the virus, so the scientific advice that we are receiving; thirdly and importantly, how best can we help the healthcare services to do their job of work, how can they provide for those who need care, so operational considerations; and then there is a further one, which is important of course to me as a Minister, public confidence as it is extremely important that we keep the public with us and they feel secure in our ability. It is that mix that will make our decision, and our containment strategy has been very much focused on slowing the spread of the outbreak for a number of reasons, including providing more time so that we can complete our planning and also have an in-depth investigation so that we can learn more, and indeed it was producing that kind of information.

**Q108 Chairman:** The information, where is it collated and who works it through, so to speak?

*Professor Davies:* The information at the moment in the place we are currently in is collated by the Health Protection Agency from all the swabs and samples that get taken, and they also keep records of confirmed cases and analyse those. It is then considered and used on our behalf by the Scientific Advisory Group, SAGE.

**Q109 Chairman:** I wonder if I could take this just a little bit further. If there is a shift, what are the implications in terms of the surveillance and in the use of interventions? For example, GPs are making their diagnoses, and you have suggested this, rather than necessarily waiting for laboratory confirmation.  
*Gillian Merron:* It is true of course that with the change there would be the requirement that surveillance changes with that, that is true, so, rather than trying to find every case so that we can stop the flu spreading further, then where we would be is that the purpose will change and that will be to monitor the impact of the epidemic and to look at any changes, either ones in respect of the characteristics clinically or the virological characteristics, so the information also that we are seeking to collect, as I say, is very much to inform the science and also to inform our practice. Perhaps one point worth putting on record is that, when we have talked about containment, we have never said that it would work for ever, and I think that is an important point to put out there, which is obvious, but worth stating. I was

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

noting that during the debate, the Secretary of State on 15 May said, "It is unlikely we can prevent a more widespread outbreak indefinitely", so a feeling for me is that containment has worked for a period, is working for a period, and it is allowing us to look at the situation and to learn from it, but we have never said it would be for ever.

**Q110 Lord Cunningham of Felling:** Minister, good morning and congratulations.  
*Gillian Merron:* Thank you.

**Q111 Lord Cunningham of Felling:** How does the Department interface with general practitioners on the kind of issue you have just been describing?  
*Gillian Merron:* Well, we work very closely with them, and I notice that we have had a response to your Committee from the Royal College who have given their views. Probably Mr Dalton would be the person who, I know, has worked most closely, so perhaps I could bring him in on this, but, if I could put it this way, without GPs, it cannot work. We rely on them very much in terms of their advice and also their assessment of individuals. What we are keen about, and I want to put this on record, is that they are able to do the job and in the movement of a phase we are going to have to support them more.

**Q112 Lord Cunningham of Felling:** My question really, and perhaps I did not put it as clearly as I should have done, so I apologise, is more along the lines of: are you satisfied, bearing in mind you have only been in post for four weeks, that the arrangements for communication between the Department and the general practitioners across the piece here is robust enough to make sure that the strategy for containment will be properly delivered?  
*Gillian Merron:* I am satisfied and I am sure we can always do better, which is why Mr Dalton's work with GPs is very important. What I am very satisfied about is the lines of communication and the way in which we are working very closely with GPs. If there are points on which we can improve, I would be delighted for us to do so, but perhaps Mr Dalton could give us some information on the details.

*Mr Dalton:* There are a couple of points. Firstly, I have been in post, I think, for coming up to two months now and obviously the contacts with general practitioners go back a long way before that. My sense, coming into this, is that senior general practitioner leaders have been involved in creating the strategy that we are now delivering for some considerable time and I am sure that, if necessary, Professor Davies, who has been in this for longer than I, can comment. More latterly though, we have been engaged very, very closely with bodies, such as the RCGP, the Royal College of General

Practitioners, not quite on a daily basis, but, to give an example, I was talking to the President just yesterday about how things were working in general practice and the messages that we need to give out to the service so that GPs can be enabled to do their job. It is certainly one of the key points of our strategy, to make sure that general practice gets clear and consistent messages and that the NHS, particularly local primary care trusts who are in the front line of this, offer general practice the support they need to ensure that they can continue to function. My sense generally is that there is a two-way flow of information and we are getting a very regular feed really helpfully from the Royal College of General Practitioners where they have an open communication with all their members which is fed to us on a several-times-a-week basis, completely unexpurgated and obviously from individual general practitioners saying what they think about the way things are going. In general, my sense would be that the messages are good and clear, but what is coming from that is that we just need to keep on that all the time because there are individual examples where people do not think that has been the case, and it is our job then to feed that back out on a continual basis to the NHS down the chain of command through to the strategic health authorities and primary care trusts to make sure that the messages are continually kept on being a management priority. I guess that is probably all I need to say at this stage.

*Gillian Merron:* And of course the Chief Medical Officer gives regular written updates to GPs as and when required.

**Chairman:** This is very helpful, I think. We have been watching these regular communications as well and this is one of the reasons that we sought a response from the Royal College. It is interesting, however, it does show that a number of general practitioners are in some real difficulty, given the fact that there are many questions they are asking on which they do not know what the Government's view is.

**Q113 Lord Colwyn:** If I can just follow up on that, I am not sure that the advice to GPs is consistent. The ones I have talked to are finding that they are having to contact the HPA, the Health Protection Agency, about individual cases to find out, "What do I do in this situation?" Is access to the HPA 100 per cent? Can they get through very easily to get this advice?

*Professor Davies:* They do have access and in each region there is a flu response centre which has been set up exactly for that purpose. It is true that, when times have been very busy and particularly in the early stages of the centres being set up, some GPs have found it difficult to contact them, but my understanding is that we addressed that really quickly and the NHS came in and provided extra

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

resources to support and they are now finding life, I think, a lot easier, but yes, it is a fair comment, that at the beginning of this in one or two places it was hard. They do have clear information which is available on the HPA website and available also from the DoH if they wish it, but actually many of them use the RCGP, Royal College of General Practitioners, website which, we make sure, always has the right information on it and is giving a fair and very direct view and very practical advice, so we have worked with the Royal College and in fact with the BMA to develop guidance with them for GPs, but a lot of the time they put it out rather than us because they are a very classical source.

**Q114 Lord Colwyn:** I think GPs are only taking swabs on patients who, they feel, are at risk, and apparently the swabs arrive in a package with the Tamiflu, but they are not necessarily using the Tamiflu as well as swabbing.

*Professor Davies:* Again, I think there was some confusion about that to start with, but I hope it is now absolutely clear what they are supposed to be doing, that they can now authorise the Tamiflu straightaway without waiting for swabs to be taken and the results to come back, but having the two things in the pack does make it easier for just one fit for the patient, so we are trying to make it easier all round, but yes, there have been some bumps along the way and we hope they are now sorted out.

*Lord May of Oxford:* Perhaps I could begin by adding my congratulations and appreciation which is all the more warm given that your predecessor managed consistently to avoid us!

*Chairman:* If you want to say “No comment”, it is understood!

**Q115 Lord May of Oxford:** I would like to focus on one particular aspect of the introductory question which touches on many of the subsequent ones, which is the definition of the movement from containment to surveillance. I think the Department of Health did a super job in adopting targeted local prophylaxis initially and I also recognise that now it is fairly established that, now it is on the rising curve, it is sensible to move away from that, but I am a little unclear as to exactly what is meant by “mitigation”. It is interesting, there was a paper in *Science* just the other day which is from a big consortium, the World Health Organisation, and it is particularly interesting that it is disproportionately Brits. This is a subject, population-level epidemiology, where we are world leaders and the senior author, Neil Ferguson, was a professor at Imperial. My understanding is that the feeling which emerges from this is that, as you move into the sort of mitigation strategy, you want to identify particular categories of people at risk and

give them Tamiflu and you want to use Tamiflu within a family maybe, but you want not necessarily to give it simply to everyone who asks, given that this appears to be no worse than ordinary seasonal flu and could thereby be speeding up the possibility of resistance. I am just curious, and I understand that there may even be some controversy between the Chief Medical Officer and more informed people and not for the first time.

*Gillian Merron:* It might be worth asking Sir Gordon to say something about the discussions in SAGE as that might enlighten us a little and be helpful.

*Professor Sir Gordon Duff:* SAGE has provided advice to the CCC on several occasions now on matters relating to antiviral strategy and antiviral use, including the groups who might be at high risk of severe illness with this particular influenza and the kind of scientific triggers that might underlie a shift of policy. There are several topics which have been discussed at length and in fact, Lord May, I think you have covered most of them in your question, but some of the things which have been taken into account would, for example, be the relatively mild nature of this illness in the majority, perhaps the great majority, of people, the possibility of avoiding over-treatment and the possibility of encouraging the emergence of an antiviral-resistant virus. All of those things have been deliberated at length and advice has been given.

**Q116 Lord May of Oxford:** Do you think it is being communicated effectively to GPs? It is early days.

*Professor Sir Gordon Duff:* That is certainly one of the things that SAGE is interested in doing, in making sure that the communications are clear and the messages are clear. We have a sub-group, the Scientific Pandemic Influenza Advisory Committee (Behaviour and Communications Sub-Group), and this group is working closely with DoH Comms to ensure that, whatever the messages are, they are optimally transmitted.

**Q117 Lord Warner:** I have a question on the interface between primary care trusts and GPs, which you have already mentioned, and presumably that interface becomes even more important as the number of cases increases significantly. On the Department's own evidence in the work that Mark Britnell has led on world-class commissioning amongst primary care trusts, I am seeking how best to put this, their performance on business planning in communications and forward planning was variable, which is the nicest way to put it, so what concerns does the Department have, out of these 150 PCTs, of how many might be weaker brethren at a time of a flu pandemic and might need more supervision?

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

*Gillian Merron:* Perhaps I could make a few opening comments which the Chairman also linked with some of the earlier questions about concerns about GPs, perhaps just a very general point. It is, in my view, working well generally, although I am sure there are always more things we can do, but we are making it very clear that this is a top priority for PCTs and, if GPs think they are not getting the advice, and I would go back to some earlier questions, they obviously should be contacting the PCT lead director. We are likely to go on to speak later, I believe, about what we are requiring of the local NHS, how they will report that and how they are testing that, so I am happy to answer that now or perhaps we might discover that more fully later.

**Q118 Chairman:** I am keen to get on as we have a big agenda of questions.

*Gillian Merron:* But Lord Warner is quite right, that this is the point where it matters and this is where it happens.

**Q119 Lord Jenkin of Roding:** Just very briefly for information, how many flu response centres are there, and are they all being run by the HPA?

*Professor Davies:* There is one in each region and they are run by the HPA with the support of the NHS.

**Q120 Lord Jenkin of Roding:** So they are spread around the country?

*Professor Davies:* Yes, there are 10 around the country, I think, and maybe two in one of the regions.

*Mr Dalton:* The basic arrangement is that there is one, I believe, in each region and the resources some weeks ago of the HPA looked like they might come under pressure with the number of cases that were projected to have grown, and clearly we have seen that growth, so very, very early certainly in my tenure in this job, I think, it was almost literally the first thing that I was asked to do. We were asked to communicate to the NHS the need to identify staff to go into these newly established flu response centres to help keep the HPA's ability to manage and contain the pandemic, so that is what we have done and those flu response centres have continued to operate to date.

**Q121 Lord Jenkin of Roding:** That is still mostly swabs and identification? Is that right?

*Mr Dalton:* Yes, there is also a point though around acting as a point of contact for primary care, individual practitioners, contact tracing, the full aspects of managing the containment phase, that these are effectively a local resource under the aegis of the Health Protection Agency with the NHS in support to front-line containment in each region.

**Q122 Lord Jenkin of Roding:** It seems to me it is an enormously important part of the whole machinery, which, Chairman, I am not aware that we have had a lot of information about before, so I think this is very helpful.

*Mr Dalton:* Certainly they are proving their worth.

*Lord Haskel:* May I add my congratulations.

**Q123 Chairman:** I think we can take them as read!

*Gillian Merron:* We can, but I am enjoying it! I do not get many moments like this!

**Q124 Lord Haskel:** You spoke of the NHS's plans. As I understand it, the NHS organisations did a self-assessment of these plans and the Department did an analysis of this. What were the results of this assessment and has this report on the analysis been published?

*Gillian Merron:* The simple answer is no, but perhaps, Chairman, you will allow me to explain why. Obviously, we are in a very different place, we are now in the middle of a pandemic, so the reason the answer is no is that of course recent events have superseded what is a full review of the audit because the pandemic plans are under way, so events have overtaken us, I think, would be my simple way of explaining it. Also, for me, we would be not right to divert efforts to complete an analysis, it would not be a good use of resources, but what we have got is a programme of testing which has been taken forward, and I hope perhaps the Committee might be interested in that, and the results basically will replace the audit. If I could just explain, the strategic objectives of that programme are to revalidate the NHS flu plans, they are to determine any additional skills that NHS staff might need and to determine any gaps that there are and to inform the short-term planning in advance of the winter, so this is very much work in action, so the arrangements will include the increase in critical care capacity to support front-line staff managing pressures through training exercises and guidance and it will include the use of countermeasures, for example, face masks and vaccinations, so that is the reason it was a no which was, I hope the Committee will agree, for a good reason, but I am sure you will want to discuss more about the testing programme.

**Q125 Lord Haskel:** You spoke about public confidence and, if you told the public what was going on, do you think they would have more confidence in what the Department was doing?

*Gillian Merron:* What would not be in the interests of public confidence, I believe, would be unvalidated data, data that was out of date or data which took us to a place which did not represent reality. We are obviously very open and I think that we would do

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

well to keep our resources to doing what we are doing and saying what we are doing, but I think out-of-date or unvalidated data is not going to help openness and transparency at all.

**Q126 Lord Crickhowell:** As one supplementary on this, if my memory is right, when we took evidence on this some time ago, we were concerned that the self-assessment programme was running behind what we had originally understood was its timetable and we pressed on it. I understand your point about publication, but what I am really pressing on is that you say everything has been overtaken by events, but would I be wrong in my instinct from your reply that what you actually found was that the self-assessment programme was showing some worrying results? Was the general picture all right without publishing the details or are you actually not revealing quite what the story really is?

*Gillian Merron:* No, we did not have calls for alarm, so perhaps I can reassure the Committee in that respect. This was a case of events having overtaken us and our needing to respond to events, but perhaps I can ask Professor Davies to give more detail.

*Professor Davies:* Yes, I am happy to, and certainly there was no cause for alarm. I have seen the results of the self-assessments and the general picture was really very, very encouraging. All the organisations had sent in their self-assessments, which was itself brilliant because what it meant was they had looked very critically at what they were doing and had learnt from that. What we were in the process of doing was going back to them to see what progress had been made and to see if the self-assessments were actually valid and comparable with others before we put them into the public domain, so that is the process we were undertaking, but we did not get that completed and we have moved on now to the new process which the Minister has been describing.

**Q127 Baroness Neuberger:** Good morning, Minister. I will not congratulate you, under instruction, but I think it is great!

*Gillian Merron:* Thank you.

**Q128 Baroness Neuberger:** You have answered part of the question I was going to ask or, at least, I think you said some of it will happen in a statement later today, but perhaps you could tell us a bit about how the NHS has been preparing for a significant increase in demand and particularly what you are doing in terms of staff surge, staff training and the sort of prioritisation of care.

*Gillian Merron:* Well, first of all, what we are doing is planning for “a reasonable worst-case scenario wave in the autumn”, and I think that is important. What is that expression—“Plan for the worst and hope for

the best”, I think, is where we are and the Committee will know that we have been preparing for a pandemic for a number of years and all the NHS organisations have got plans in place and they are being tested day to day. I am also deeply conscious that they are not just being tested day to day, but actually we are looking ahead to it getting worse, and I would like to give some information to the Committee about how we plan to deal with that, as Baroness Neuberger has asked. First of all, on 1 May we issued guidance to the NHS on managing demand and capacity in a pandemic. Now, that includes increasing ways of making available capacity in intensive care, so, for example, and this will be a matter for local judgment, suspending elective procedures and also using agency staff. All the NHS organisations are being encouraged to test out their plans as was set out in the 09/10 operating framework and they are, importantly, currently reviewing and testing the resilience of those plans in advance of autumn and winter. The kind of arrangements to increase critical care capacity, apart from, as I say, making decisions about elective procedures, are also training, the possibility of retraining, guidance on the use of countermeasures and also how NHS organisations can deploy their staff flexibly within the competencies, and that of course is overriding, and hospital staff who are familiar with the care of elective patients perhaps in a recovery area could be redeployed if that were necessary, and then there are practical things of course about, which I am sure we will go on to talk about, vaccinations and bringing into use other practical places as places of vaccination other than the ones one might expect, so people are testing it at the moment and preparing and that is very important.

**Q129 Baroness Neuberger:** In May, the Secretary of State, who was Alan Johnson at the time, said that the possibility of testing across the whole system as opposed to individual bits of the system was being considered in a letter to us. Has that actually happened or has the Department taken a decision about when it will happen, if it is going to happen?

*Mr Dalton:* We have got a three-phase programme running, the first phase of which is well under way and has been going for some weeks now, which is looking at, and I am sure we will talk about this later, the ability of every primary care trust in the land to stand up antiviral collection points as part of the National Pandemic Flu Service, and we are in a good place, I think, on that. The second part, which we have been talking about for a while and which will be reinforced in a letter from myself to every NHS chief executive in the country which is going out later today, will stress the governance responsibilities of

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

every board in an SHA, a primary care trust, an NHS trust or an NHS foundation trust, because the issues apply commonly across all forms of NHS organisations, to run a rigorous programme of self-test and self-assurance in the period between now and September on the assumption that any peak of the attack wave is likely to come after that and, therefore, the way I see it is that we have been working on this for a lengthy period and we are pushing hard for the line now and expecting every single organisation to rise to the challenge. The third element of that is the one the Secretary of State was referring to, which we are still working up the details on, but which would see whole-system, what I would describe as, “stress tests” to take place in the period hopefully during September, and we are still working on the logistics and the detail of that, but the idea would be to push the system hard on the usual contingency planning basis of preparing for the worst and seeing how the various bits of the system, primary care, ambulances, hospitals and mental health services, actually interact in practice. Of course, that will itself build on some work that did take place under Exercise Winter Willow in the past, so it is not as if we are starting with a blank sheet of paper, but the sense would be that we will do the national exercises and we will take from the Department of Health a very, very strong management line on this stuff because this is not the sort of normal business where we are in devolution mode, but this is a strong mode. However, I would really want to stress the importance of the boards in this because my main effort is directed at NHS boards; we have governance structures and this is as much a matter for the boards as the general quality of care or the financial governance of the organisations and it needs to be right up there at the very top of the board agendas, as it is.

**Q130 Baroness Neuberger:** I am a former Chair of an NHS Trust—

*Mr Dalton:* I am well aware of that.

**Q131 Baroness Neuberger:**—so I take the point about the boards, but I am a bit surprised about your timing. If the assumption is that, if there is going to be a huge increase, it will be at the beginning of the school term, that actually is September or, in some cases now, even the very end of August, so would the stress tests not need to be ideally right at the end of August before that happens?

*Mr Dalton:* We are trying to get it as early as possible, but not so early that we have not given the boards enough time to really push their own internal plans to a point at which they have complete confidence around things, such as the internal actions they will take to move up to potentially doubling critical care facilities under a severe attack phase. I think there is

a judgment to be made and, to be honest, I am not trying to obfuscate here, I am just saying that we are still working on that and it is a matter of regular dialogue between me and the 10 strategic health authority lead directors.

**Q132 Chairman:** Minister, if I may recap just a little bit to set the context, clearly we are where we are, but our discussions began before the current outbreak and they were based on our previous report, and one of the things that we have stressed throughout is the need for advance testing of the system and I think we are simply disappointed, which is one word for it, that at this stage this is the level that we have reached because, having been at this game for a few years around this committee table, we rather thought that some of those would have been done, marked up and available now. However, we are where we are and we do not want to disrupt currently what is going on and there are priorities, but that is the situation as we see it.

*Gillian Merron:* I appreciate the comments of the Committee, but just one point I would want to emphasise that Mr Dalton made is that of course we are not starting from nothing because NHS planning has been informed by Exercise Winter Willow and that was a very big exercise, so I understand the point, but I hope that the Committee will bear that in mind too.

**Chairman:** There is clearly always a comment to be made on another comment, but I will restrain myself!

**Q133 Lord Crickhowell:** Minister, can I preface my question by declaring a kind of interest, that my younger daughter is pregnant. She tells me that, having visited the excellent maternity unit at the Hereford Hospital where her last baby was delivered and talked to the midwife who delivered that baby and her local GP practice, they are not receiving, or have not received, clear guidance about what advice to give to pregnant women and the parents of younger children. We have had reference already to the RCGP paper and you will, therefore, have noted that it says that concerns were also raised about prescribing Tamiflu to pregnant women, to women who are breastfeeding and to children under the age of one year, so my first question is: what specific advice with regard to the swine flu outbreak is being given to pregnant women and to parents of younger children?

*Gillian Merron:* Very specifically, Chairman, perhaps I can just advise about the Cabinet Office first of all. They are holding teleconferences with regional resilience teams to make sure that the messages are got through locally, that is to local authorities as well as school authorities and obviously healthcare workers, and it is an area that we need to apply

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

ourselves to very closely. I am sorry to hear your comments of the individual case, but perhaps I could just make a few comments about the information we have made available. On our swine flu area of the NHS Choices website, there is a very specific pregnancy and children section, we have also published recommendations on the use of antivirals linked to the maternity guidance on the Department of Health's website and we are working closely with the College of Obstetrics and Gynaecology to produce a leaflet for patients and for professionals, so that is in terms of advice. We work very closely with midwives to develop our response, and of course again we can always do more and maybe the Committee would have specific recommendations for us, and in practical terms we have a stockpile of 10.5 million doses of Relenza, which is the recommended antiviral for treating pregnant women and that is to limit symptoms and to reduce the chances of complications arising because we of course know from SAGE that pregnant women, amongst others, are some of the most at risk should they contract swine flu. We have also published dosage advice in respect of prescribing antivirals for children over one and we have made arrangements for a solution to be manufactured for administering Tamiflu for the under-ones because of course women who are pregnant are going to be interested in that when they have had their children and where they go from there.

**Q134 Lord Crickhowell:** That sounds all very well, despite the rather specific evidence I have had, but going back to this general advice, when the pamphlet which we all received came out which told us fairly obvious things about washing our hands, using tissues and so on, the immediate comment made by my daughter then was that it had absolutely nothing to say about pregnant women. There are a great many pregnant women around who are deeply concerned and we have actually had deaths of babies, and I find it quite extraordinary that general guidance has not gone out already. Indeed, going back to the GP paper, we read there the concern of family doctors who have also been in contact, seeking the latest recommendations on the protection of pregnant healthcare workers who might come into contact with possible swine flu patients. It appears that guidance on this issue is not very clear. It does seem to me extraordinary that in this central area of public concern very little guidance appears to have got to the public.

*Gillian Merron:* As I say, I do not doubt the description of the circumstances which have been described. However, I have outlined to the Committee where the information is available and on the very specific point about the swine flu leaflet, no,

it did not make that reference, but at the time the at-risk groups had not been identified by SAGE, and there is probably a more general point which I am sure we will talk about when we talk about communications, that it was absolutely intended to be extremely generic, it went into every household, and its singular message was "Stop the spread". One small thing I would take issue with is clearly we all have our anecdotes of sitting on the Underground and being sneezed over and there is much work to be done still with the general population about explaining how one does stop the spread, so actually I would say that it is not as obvious as we might like to think. I am also advised that the Royal College had a major launch of guidance last autumn to doctors and individuals in this area, so again I am not saying there is not more we could do, and I am very happy to hear how it should be, but certainly the information is there and we work closely with the people concerned and the generic leaflet was indeed intended to be generic.

**Q135 Chairman:** I see the point of a generic leaflet out very quickly because all of us might be affected and it is good that that was done, but clearly I think the concerns that we are raising have to do with whether specific sectors of the population who might be thought to be at risk might have, and I declare an interest, I am one of the elderly—

*Gillian Merron:* You look well, so do not worry!

**Chairman:** —specific advice. In a sense, we are hoping that that is not just under consideration, but in progress.

**Q136 Lord Crickhowell:** Well, I have made my point, but I hope that more general advice will be out very soon. One supplementary, which is particularly relevant as far as pregnant women are concerned, but actually has wider application, is: what studies have been done about possible problems of allergic reactions to flu injections and Tamiflu? My wife, as it happens, cannot have the ordinary flu injection because of allergic reaction. I understand that a child in a Dulwich school who had a very mild attack of swine flu had a violent reaction to a Tamiflu injection and was then very seriously ill, so there clearly is a problem and I wonder what analysis has been done of it and what advice is being given, particularly relevant, I think, for pregnant women, but I think it has a wider application as well?

*Gillian Merron:* Before I pass to Sir Gordon, can I just reiterate my point that we are actually working with the Royal College to produce a very specific leaflet, and I do feel it is important that we give the right information to people that is tailored to them so that we do not frighten people unnecessarily, but that they have the facts before them, and we will ensure that the

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

leaflet is available, but leaflets are not the only way anymore, I am glad to say, but I will pass to Sir Gordon on that matter.

*Professor Sir Gordon Duff:* Perhaps I may just talk about Tamiflu first as it is, I think, a different question when we get to vaccines. The use of Tamiflu in the world has really been rather large year on year, especially in countries like Japan which has had SARS and quite severe seasonal influenzas, and the overall profile of safety is extremely good. There are very few reports of suspected serious adverse reactions. There have been suggestions of neuropsychiatric reaction in some younger people mainly from Japan, but the evidence, as it stands at the moment, does not support a causal relationship with taking Tamiflu, so it is, I think you could say, a safe drug, given that there is no such thing as a drug that carries no risk, and that this is a very good one. We did, through the HPA, try to get an early idea of how young people and children were reacting to taking Tamiflu at around the time of the first outbreaks in schools and there was a higher than expected reported rate of feeling sick, but, as I recall, I do not think that was associated with vomiting which would clearly be more serious. The product characteristic summary for the drug does say that up to 10 per cent of people report nausea, particularly after the first few doses, but then that goes away.

*Lord Broers:* I just have a point about pamphlets. I am not an expert in this field, but I did chair this Committee's original inquiry into pandemics and of course we were looking at a different situation by far because we were considering the sort of morbidity rate of an H5N1 virus, so we were not considering a virus like this which develops into a fairly light flu at the moment at least. This of course has led the public into this idea that they should have flu parties which seems to be being widely talked about on the radio and nobody is taking a very strong leadership position on it. I just feel that, if there is going to be a pamphlet, some official strong position should be taken before everybody goes off and does something rather stupid.

**Q137 Lord May of Oxford:** Could I just say quickly to that that this is not the first thing, is it, and it has been preceded by imbecile middle-class mothers with good intentions having measles parties, and I know a child who was invited to one of them.

*Gillian Merron:* I can tell that this is a matter of strong opinion and rightly so, Chairman. Perhaps I could quote the Chief Medical Officer who gave a very clear line on swine flu parties, which I am sure the Committee would welcome, which was that "we would never recommend intentional exposure of anyone to swine flu", and he goes on to describe swine flu parties as "seriously flawed thinking", "the

fact that we do not know enough about the risk profile", "the fact is that in some parts of the world young, but previously healthy, adults have died" and "parents", and I think this is a strong point, "parents would never forgive themselves if they exposed a vulnerable child to serious illness", so I hope that is strong and we will continue to state that very point.

**Q138 Chairman:** I think the point is that there may be a need to push the message out even more firmly because certainly I have picked up—

*Gillian Merron:* I would share that view of concern; a very worrying development.

*Lord Broers:* It should go in any general pamphlet or supplementary one.

*Lord Jenkin of Roding:* I think it is important to say that this is not the same as chicken pox and you had the chicken pox parties some years ago because the effects of chicken pox on a pregnant woman were very serious indeed, so little girls went and had mild chicken pox as children.

*Lord May of Oxford:* It is generically a foolish idea.

**Q139 Lord Jenkin of Roding:** It is bonkers!

*Gillian Merron:* I have certainly got the message! I would not argue with you!

**Q140 Lord May of Oxford:** Vaccinations—I just precede this by saying that I had just moved to Princeton when there was the swine flu fiasco in the States in the mid-1970s, and the Secretary of State at that time, whose name, I am sure, Sir Gordon may know, wrote a wonderful little short book reflecting on lessons learned, one of which was where he said, "I'm a lawyer and I thought the science would give me the answer, but science is about asking the right questions", so I hope this is the right question we have signed up to. What is the influenza vaccination strategy and, in particular, when is the vaccine likely to be available? Would the plan be to give it to people particularly at risk, as with the usual seasonal flu vaccine, or would you actually give it to everyone, and when is it likely to be available?

*Gillian Merron:* On the plans for the implementation of a mass vaccination strategy, they are already set out in guidance which we published in November 2008, guidance for primary care trusts. What we have done in practical terms, and I mentioned Sir Michael's statement, is we have signed contracts to procure vaccine for 100 per cent of the UK population. The first deliveries are due in August and at least 60 million doses are scheduled to be delivered by the end of the year, and the question, which is a very important one, about the order of things, about who will get what first, this will be science-led, so maybe I am going to have to look to the scientists, so I will ensure that we ask the right questions.

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

**Q141 Lord May of Oxford:** Hopefully led by all the scientists!

*Gillian Merron:* The science will guide us very strongly about where we should start and the priority, and also perhaps I could highlight here that obviously the front-line health and social care workers are going to be one of those groups for practical reasons, for operational reasons. I would also inform the Committee that the Director of Immunisation at the Department wrote last month to immunisation co-ordinators in the NHS and HPA to notify them of the plans for procurement and to provide the advice that is necessary on storage, on some ideas and discussion about priority groups and data-collection and recording so that their preparations can be under way, and, very importantly, we are working on a very comprehensive approach to communicate to the public so that they understand what vaccination is and what the arrangements will be. I mentioned earlier in an answer to Baroness Neuberger how we would seek to implement this, not just using GPs, but others and the possibility of course of GPs, and there may be GPs around the table, who may like to come back in to assist, but also other staff to be trained and perhaps moved off duties that are less urgent, and the use of wider locations other than GP surgeries and healthcare centres. Also, of course we will have to bear in mind that people may need to be vaccinated against both swine flu and also seasonal flu as it is very important, I think, for the public to know that we have not forgotten about seasonal flu.

**Q142 Lord May of Oxford:** As a quick follow-up to Lord Crickhowell's question to Sir Gordon, the real problem with swine flu vaccine in the States in the 1970s was that it did more harm than good.

*Professor Sir Gordon Duff:* I think it was discontinued because of two reasons. It was discontinued in youngsters because of what is called "reactogenicity" which caused severe painful local reactions and people were beginning to perceive that it seemed like quite a mild illness anyway; (this is the 1976 Fort Dix outbreak). The other reason for loss of enthusiasm for the programme was an apparent detection of an increased rate of Guillain-Barré syndrome and other neurological complications. I believe that subsequent wider analysis against background rates of those things during an influenza outbreak do not really back up that observation, that deduction. The other thing, I believe, which is important is that that was 33 years ago and there is no doubt that the quality of vaccine manufacture has increased considerably since then and, although there are no certainties that anything is going to be 100 per cent safe, I think that this, on a benefit:risk assessment would be thought to be a favourable strategy.

*Chairman:* I note that the statement is going to be repeated at 12.30 today, so we must make progress to make sure that we are there to comment on it!

**Q143 Lord Jenkin of Roding:** I would like to come to the question of the Flu Line and the distributional system for antivirals at the moment. When Professor Davies and your predecessor met us before Christmas, it was made clear to us that this was an enormously important part of the planning for a major outbreak. There would be up to 7,000 staff who manned the Flu Line and we were told that the average time for assessment might be as short as eight minutes, a code number would be given and a "flu friend" would then be despatched to a collection point from where the Tamiflu would then be collected and delivered to the patient. We were told that it was all going to be up and running last month and then Lord Darzi, repeating the statement again, I had a subsequent question, made it clear that this is not going to happen until the autumn. Well, I have tried to get hold of BT to say, "What has been the problem?" and, I have to say, they clammed up and would not tell me anything, so the first question I have is: what is the hold-up on the Flu Line? The second question would then be: how many of the people to be appointed to man the Flu Line have been appointed and trained? The third question is: when are we going to know where all the collection points are going to be? These seem to me to be three absolutely important, hugely important questions if we are going to have this system operating properly.

*Gillian Merron:* They are very reasonable questions and ones that we have also been asked in the Commons of course, so perhaps I can give you a few bits of information which, I hope, will be of reassurance. The first one is that there has been an interim flu service, the National Pandemic Flu Service, which has been developed and that can be mobilised in about a week. The full solution, the one that is being referred to, will be available in the autumn. Why the change in timing? Well, it is true indeed that the original Flu Line was on course to be delivered by the end of May, but, because we had the outbreak, this is perhaps another area where its development was actually put on hold because we felt it was important to get the interim solution up and running because we knew that could be done quicker because the outbreak was such that we felt we were going to need something quicker. The next point about why the change in timing is, I feel, the National Pandemic Flu Service was such a new approach that we would have been remiss not to have tested it sufficiently to make sure that it both would work, but that it was also value for money, and that involved the approval of both the Treasury and the Department of Health. In terms of where we are now, the assurance I

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

can give is that we are in the final stages of concluding agreements with private sector providers and also memoranda of understanding with public sector bodies, and it is actually going to be more than 7,000 people. We currently have identified that we will need around 3,000 agent seats which, for a 24-hour cover, will be around 9,000, and they can be available within seven days. I was very interested to read, Chairman, that training takes approximately four hours. A number have already been trained, but it is as speedy and as efficient as this. It is probably worth saying about the Flu Line that, when we talk about it, it is important that we all remember that it is actually a groundbreaking system and it will be the first of its kind in the world, which, I think, shows the importance of testing, and it will be able to assess people either through the Internet or telephone, it will be able to co-ordinate the distribution of antivirals and it will be able to feed back to local health services, so we have got quite a task there, but perhaps the thing for the Committee to be aware of is the fact that the interim Flu Line can be up and running within seven days, it can be operated and it can do the job that we need it to do.

**Q144 Lord Jenkin of Roding:** How is it accessed?

*Gillian Merron:* By the telephone or the Internet.

**Q145 Lord Jenkin of Roding:** But will the public be given the telephone number?

*Gillian Merron:* Yes, absolutely, and it will be an 0800 number.

**Q146 Lord Jenkin of Roding:** But, if it is going to be ready in a week, surely people need to be told.

*Gillian Merron:* Yes, but it has not been activated yet. Perhaps I might refer the Committee to the statements that will be made in the House.

**Q147 Lord Jenkin of Roding:** Yes, we will certainly see that, but, Minister, I have to say, what you have told us a few minutes ago is completely inconsistent with what we were told before. We were told that the contract with BT had been agreed last December and one was left with the impression that somehow BT were creating the difficulties of getting it up and running. You have now told us that actually the Department has put this on hold. I hope I am quoting your words right.

*Gillian Merron:* Well, perhaps I can clarify. The contract I was talking about was not one with BT, but those who would fill the seats, so that is what I was referring to. The commercial agreements with private sector providers was a reference not to BT, but to those, and perhaps I can give an example without naming commercial considerations, those who provide call centre solutions to various other things,

and of course a number of them have spare capacity because we are in a downturn, so we actually are benefiting from an unfortunate economic situation and that is one of the reasons that we know that we can staff up and we can train people suitably. I am sorry if there was a misunderstanding, but I was not talking about the contract with BT.

**Q148 Lord Jenkin of Roding:** Chairman, I wonder whether it might be right that we could ask the Minister to let us have a short supplementary paper about this because, I have to say, I find myself extremely confused.

*Gillian Merron:* I would be delighted to.

**Q149 Lord Jenkin of Roding:** If it is such an important part of the whole system, we must know what is going to happen.

*Gillian Merron:* It is, but, Chairman, perhaps my biggest reassurance, and I think it has been hard to get this over generally, is that the interim solution can happen, as and when the situation requires it, within seven days, so we are not sitting waiting for something which cannot appear until the autumn, and I think it is very important that the Committee is aware of that. I will be very happy to set out whatever the Committee wishes, but, if there are any further points now, Professor Davies, I am sure, can also add to the points that I have made.

**Q150 Chairman:** Well, thank you. That is an advance in my understanding of the position, that there is a fall-back system in place at seven days' notice.

*Gillian Merron:* Absolutely.

**Q151 Chairman:** What we have been looking for is what seemed to be suggested which was a date by which everything will happen, come what may, but you have given us a rather different picture and it is helpful to have that clarified.

*Gillian Merron:* Also, Chairman, it is very important, and we were talking earlier about support to GPs, this is about making sure that the National Health Service can deal with the situation before it, so it is crucial.

**Q152 Chairman:** And to make sure that NHS Direct is not so overwhelmed that it cannot deal with all its calls.

*Gillian Merron:* That is right.

**Q153 Earl of Selborne:** Minister, there appears to be some inconsistency at local level in procedures for surveillance, case investigation and case management. There are messages and guidance from different organisations and agencies from

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

departmental to Health Protection Agency to strategic health authority, and we have heard from the Royal College that there is conflicting advice indeed from different agencies. What steps will the Government take to ensure that the overall management of their response is effectively co-ordinated?

*Gillian Merron:* The first thing perhaps I could say is that we have built in flexibility to our approach, that is within the national framework, and I think that is important because local situations, as we have discussed, are rather different and we have to respond appropriately. The NHS and the HPA work closely and have worked closely throughout the outbreak and I think that this co-ordination has helped us to restrain the spread of the virus. The HPA, to give some suggestion about meetings, is represented at the meetings of the Civil Contingencies Committee which brings all together and two essential advisory groups, the Scientific Advisory Group for Emergencies and the Pandemic Influenza Clinical and Operational Advisory Group, in order that we can have a joined-up approach to planning. We have systems in place to make sure that guidance does reach front-line workers, so, for example, when our strategy changed in response to the West Midlands and London, NHS flu leads received a letter which set out outbreak management considerations, and that went out to GPs and other staff, so very specific to those areas. The Royal College of General Practitioners also, I understand, issues daily guidance and we have systems in place to ensure good practice to make sure that extra support can be provided, if needed, so I do feel we have mechanisms in place, some of which I have outlined, which ensure that we can be co-ordinated and that we can also, importantly, deal with any future changes. I would say my own experience of the COBRA meetings is that we also work very closely together of course with the devolved administrations, which is also crucial to obtaining a UK-wide response.

**Q154 Earl of Selborne:** I suspect it is not so much at the COBRA level as at the local level where there is a potential for confusion, and I am just wondering if you are satisfied that the potential for confusion is minimal?

*Gillian Merron:* I am and it would be foolish for any Minister to sit here and say it never happens. What I would say is that, if there are examples of specifics, I would be very interested to know them. If there is confusion, people should, in the first instance, go to their PCT, but operationally I would be interested to know, so I can never say “Never”, it would be foolish, but I can say that I do believe the systems are there, and perhaps Professor Davies could comment to add to that.

*Professor Davies:* Yes, I would agree with that. The situation on the ground, particularly in hotspots at the moment, is very difficult; there is an awful lot of flu out there, people are in distress and they have been working in that way for some time, but, to their huge credit, the relationships between organisations and individuals are strengthening as time goes on. They were good to start with and, as I say, they have had some bumpiness along the way, but that is now really very, very much better, it has strengthened and they are doing a grand job locally. What we are doing here to support that is to listen when we do hear of any examples and to make sure that we get messages right down the system as quickly as possible to whoever it is to sort the matter out. We are not sitting passively, we are very actively engaged in making sure that the thing does work properly and we are currently looking forward to thinking how that would work in future phases of the pandemic as well to ensure that people know in advance what their roles would be and how the various systems would fit together and, very importantly in that, how we would collect information and make sure that we get the right information at the right time, not over-burdening anybody, but having enough to give us a very clear picture of what is happening generally across the country, how we might need to adjust our strategy and what more we might need to do.

**Q155 Lord Broers:** My question relates to the distribution of antivirals and we have discussed this a lot, but, just to get the questions on the record, when will the antiviral collection points be operational at a local level, how many have been identified so far, how will the NHS and the public be informed about the collection points, how will patients be referred to them, who will provide the diagnosis, and will local pharmacies be involved in dispensing antivirals?

*Gillian Merron:* Strategic health authorities have already been reviewing and, where necessary, challenging PCTs in this very area to make sure that there are collection point plans locally, that premises have been adequately thought of and staffing teams and the supply chain that is referred to, so all of that work is going on and of course in the hotspot areas this is already happening, but this is about ensuring that across the UK it will be able to meet the needs of the population. Each strategic health authority has now confirmed that sufficient collection points within each PCT area can be stood up within seven days of any decision to mobilise the National Pandemic Flu Service, and they have already agreed with the PCTs the numbers and the distribution of collection points across the country, so we would anticipate several hundred collection points operational across England during peak activity periods which we anticipate in autumn and winter. Plans are being

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

finalised at national and also local level to communicate with GPs and service-users about what will be expected of them when the service is introduced. Operational decisions will dictate the exact nature of the message, but we will deliver those messages, as we always do, through national and local media briefings, targeted advertising, direct marketing and obviously communication to GPs through the usual channels. In respect of pharmacies, during the current outbreak there are some PCTs which have already given stocks of Tamiflu to select pharmacies to assist them and other pharmacies have been identified as collection points, so yes, where appropriate, indeed we are working very closely with pharmacies.

**Q156 Lord Broers:** But the procedure will be that people who suspect they may have swine flu must go to their GP first, presumably?

*Gillian Merron:* Not necessarily. That is the purpose of the Flu Line, not least of all because the first advice is to stay at home so as not to infect others. Not necessarily. Going back to our earlier discussion, we cannot overburden GPs and that is why the Flu Line becomes extremely important and why the interim arrangement is important.

**Q157 Lord May of Oxford:** It might be worth underlining that the Chief Medical Officer underlined something he called an algorithm that will lead you through the questions.

*Gillian Merron:* Yes, correct.

**Q158 Lord Broers:** That algorithm is sufficient to determine that you have swine flu and not some other sort of flu?

*Gillian Merron:* It has been developed with the Royal Colleges and, indeed, it is to give that kind of guidance.<sup>1</sup> It is exactly the kind of support we were talking about right at the beginning of this meeting to ensure that the local health service can operate and the GPs can do their job. There is a role for GPs, but it is not the case that everybody should present to a GP.

**Q159 Lord Broers:** I know a lot of people who will be persuaded they have got swine flu at the first sneeze regardless of what anybody else says, so they are going to rush straight off to a pharmacy, I would assume, if not one of these centres and pick up their Tamiflu and start eating it, are they not?

*Gillian Merron:* Some may, but the Flu Line also does refer people to go and see their GP if it picks up that is required. It does have that sensitivity.

**Q160 Lord Warner:** I would just like to return to this issue of the weaker brethren amongst the PCTs, which we all know are there. There seems to be quite a heavy emphasis on self-assessment about readiness. I would like to know a bit more about what your failsafe systems are for the weaker brethren.

*Gillian Merron:* Can I just say I understand why Lord Warner particularly would ask these questions. Perhaps I could turn to Mr Dalton.

*Mr Dalton:* Thank you, Minister. Clearly it is the responsibility of boards to ensure their acts are together but that is not enough in this situation, so I think it would be wrong for us to give the impression, if that has been given, that this is all down to self-assessment. We have a clear chain of command through from the Department of Health to SHAs down to PCTs. When it comes to antiviral collection points, a point that has not yet been brought out in discussion is that while PCTs were asked to identify provisional antiviral collection points some time ago at the end of last year we are facing a different situation now than was potentially perceived to have been the case when that was first issued. If we had been facing a very rapidly expanding full national coverage pandemic where the whole national network of antiviral collection centres would need to be set up at once, which was the kind of scenario that was underlying the potential H5N1 attack when we were originally asked to look at this, that would have been a different scale of response that we might need at some stage going forward. One of the things we have done over the last two months is ask every single PCT to go back, look at their map and be clear where their antiviral collection points would be and to be clear and to guarantee to the satisfaction of the Strategic Health Authority concerned that they could be stood up within seven days. To give an example, just one picked at random, I happen to have a map in front of me of Bassetlaw PCT which shows that there would be an antiviral collection point in Bawtry, Retford, Worksop and at Tuxford Clinics and those would be stood up within a week. I think we have done a lot of work on this because it is critical, as was implicit in your question, that this works across every single PCT in the land and that is why we have been using more than just self-assessment, we have been using performance management lines to drive this as well. Certainly that is something I have been heavily engaged with over the last five or six weeks.

**Chairman:** Now we all want a local map!

<sup>1</sup> "The algorithm is designed to identify cases of swine flu. However the symptoms of seasonal flu are very similar and therefore there is likely to be some overlap with other circulating flu cases. As swine flu becomes more common, a higher proportion of influenza like illness will be swine flu."

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

**Q161 Lord Cunningham of Felling:** Has anyone done any secret shopping to find out whether what you see on the paper is what the public will actually get in practice?

*Mr Dalton:* Clearly antiviral collection points have not been stood up.

*Gillian Merron:* It is a good idea, we will send you out!

*Mr Dalton:* One example that has been undertaken that I am aware of, which I think is what is happening in a number of areas, is for instance in the three PCTs south of the River Tyne, they have undertaken a week live—

**Q162 Lord Cunningham of Felling:** I could easily do a bit of secret shopping for you there because that is where I live, but I did not particularly have that in mind.

*Gillian Merron:* You have got the job!

*Mr Dalton:* I was more prescient than I had imagined. The PCTs there did a live stand-up exercise running a week to test exactly how the logistics and the staffing and the other process that will be necessary when and if the mobilisation order comes through. I think PCTs, notwithstanding Lord Warner's points, have done a lot of work on this.

**Q163 Lord Broers:** I have got a supplementary here, and that is which public sector workers will receive antivirals for post-exposure prophylaxis? Have they now been supplied with these antivirals to administer when necessary?

*Gillian Merron:* That has not been decided as yet, but obviously the priority will be to protect those in order to keep the system working.

**Q164 Chairman:** Do not forget the lorry drivers then because unless somebody delivers them!

*Gillian Merron:* I would not dare, I used to be a trade union organiser for the National Union of Public Employees.

**Chairman:** Well-positioned.

**Q165 Lord Cunningham of Felling:** Minister, some doctors, consultants and GPs have expressed concerns about what I guess they say are ethical concerns, what they hear about the possible need to ration resources, to make judgments about who may be treated and who may not be treated, or maybe not just a case of drugs provision but provision in intensive care beds, for example. How do you respond to that?

*Gillian Merron:* The first point is that we do realise this does leave people operating in very difficult circumstances. The importance, I think, is that professionals are treated fairly and reasonably. We do understand the circumstances. The GMC has produced some very good practice guidelines for

doctors to use during a pandemic and, in addition, the Department has published possible strategies for how we deal with patients in a pandemic in guidance entitled *Managing Demand Capacity*. We have to balance the position of healthcare workers, which is very difficult, with their responsibility to make sure the patient's rights are not infringed. It is a delicate, sensitive balance that will have to be made. In general terms of indemnification, NHS organisations have indicated that normal entitlements will continue to apply during a pandemic whilst GPs are carrying out their normal duties. Any doctors who return to service or carrying out duties over and above will be given honorary contracts by an NHS body and will also be covered by NHS indemnity. Joint guidance for GPs on dealing with an influenza pandemic, prepared in agreement with the BMA and the Royal College, was issued in January 2009 and made it quite clear that a GP is responsible for their individual clinical decisions. The Committee on Ethical Aspects of Pandemic Influenza are developing a range of scenarios which can be used for guidance. I am also hoping that our continued work in this area will be able to guide people. I did want to ensure the Committee knew that we understand how sensitive this is and it is that balance.

**Q166 Lord Cunningham of Felling:** Can I ask an entirely different question. What, if any, thought has the Department given to how a serious development in the autumn might affect people and services in remote rural areas as opposed to highly populated areas?

*Gillian Merron:* Everything. All of our guidance takes account of that. We are fully aware that the initial hotspots, the West Midlands, for example, and London, are areas of dense population but that is why it is spread. Clearly there is much discussion on the whole. Linking back with the earlier question about antiviral distribution points, all of our preparations take account of the many different local factors, but I have to say that is the benefit of our working closely with local organisations and testing and ensuring, as we heard earlier, that their provisions will stand up to the test, but they are going to be different. They are going to be different in my constituency in Lincoln from what they are going to be in the more rural areas of the county or in the area that, of course, your Lordship is very familiar with. It is a very different project but that is why it has to be a local decision.

**Q167 Lord Warner:** Has the Government's communication strategy on pandemic flu been fully audited and are you satisfied that you are capable of reaching every section of the population? Can you give us any information about the results of the

2 July 2009

Gillian Merron, Professor Lindsey Davies CBE, Mr Ian Dalton,  
Professor Sir Gordon Duff and Dr Becky Kirby

campaign tracking survey completed by the Department of Health for the flu leaflet?

*Gillian Merron:* We are still doing the tracking research so we have not yet produced the findings, but we would be very happy to share them as and when. It is of course crucial that all sectors of the population, as we have heard in our discussions, get the right messages. We are evaluating all of our campaign activity and we publish summaries of that on our website. I believe I mentioned right at the beginning of the meeting the need to sustain and develop public confidence, and that is absolutely key in all that we do. We are looking at an exercise which will assess the distribution of the information leaflet that we spoke of earlier to households in England, Scotland and Wales, and we will be publishing some of this research and are happy that the Committee receives that. We are continuing with our research into attitudes and understanding from all sections of society. I think it is crucial that as we move on, it is not just an understanding of the virus but an understanding of the effectiveness of the communications and I believe that will also develop in time. I am just looking at something that has been handed to me, it says: "Hot news. Over 70 per cent think that the Government is very or fairly well-prepared for a swine flu pandemic". This was a sample size at the end of June of over 1,000 people. This is interesting: "Just under half of the respondents thought that too much fuss was being made about the risk of swine flu". That is pretty 50/50.

**Chairman:** I do not think we will hold a poll round the table on that!

**Q168 Lord Crickhowell:** Under the subject of the communications strategy, can I ask a question because there is one little thing that has been worrying me. You said that people who suffer from signs of flu understand that they should stay at home, but one of the difficulties is that nobody has got swine flu. I did test the system when my granddaughter unexpectedly came down with a temperature. I went on the website and went through this very interesting, thorough and lengthy set of questions that you have to answer which basically establishes that you have not got something else. You learn by answering the questions that you have not got meningitis, or whatever it is, but I am not sure that you learn that you have got swine flu or some other flu or a seasonal bug. At the end of the day, if people do not go to see their GPs, how are people going to know what they have got?

*Gillian Merron:* The Flu Line will take us to a better stage. The reference that is made there is obviously to alert you as to whether you might have it or not and

what you should do next if you are in the "might do" category. I hope I did not say that everybody understood they should stay at home. The message is out there, but I would not presume that everybody does understand that they should isolate themselves. We do need to remember that this is generally a mild disease, although it does have severe implications, and it is very important in our communications that we reassure and yet alert. I think that is the challenge about communications. How do we alert people to the seriousness without over-worrying them? How do we alert them to the need to protect themselves and carry out hygiene measures?

**Q169 Lord Crickhowell:** Am I right in thinking that the symptoms of swine flu are very, very similar to a wide range of other bugs that we all suffer from from time to time?

*Gillian Merron:* You are correct indeed.

**Q170 Chairman:** I think what you are illustrating very well, Minister, is that this is a multifaceted issue: there are medical issues, scientific issues and communications issues that are quite fundamental.

*Gillian Merron:* Yes.

**Chairman:** What we have been focusing on are the policy issues and the ways in which these are rolled out because that is clearly our remit. Thank you very much, you have been generous with your time and your openness, we appreciate that very much indeed. As I think you know, we hope to publish a follow-up report very soon. I did want to say if there is anything that has come out of the discussion that you would like to clarify in writing, if the officials could be in touch, that would be helpful. May I draw their attention particularly to the Royal College of General Practitioners' memorandum that came to you and to us very late indeed, but it will be part of the formal evidence and you may wish quickly to put down some markers, but that is a matter for you.

**Q171 Lord Jenkin of Roding:** My Lord Chairman, I hope we will get a short statement about updating this and the Flu Line because it needs to be absolutely clear.

*Gillian Merron:* You have my absolute assurance. Could I say thank you to the Committee. Your work greatly assists us and I welcome the opportunity to be able to go through what are very important areas. We want to get it right and do the best we can, and the Committee is part of that. Following today we will review all that we have talked about and provide any extra written information that would be helpful. If there any further matters I hope you will not hesitate at any time to let me know. Thank you.

**Chairman:** Thank you very much.

### Letter from Gillian Merron MP, Minister of State, Department of Health

As promised in my letter of 3 July, I am sending you the following:

- a paper on the National Pandemic Flu Service;
- a response to the Royal College of General Practitioners' submission and information on GP communications; and
- a note on the Flu Response Centres.

I have merged in to one paper the information I promised on GP communications and the response to the RCGP as the issues sat well together.

I hope these are of interest and I look forward to receiving the Committee's report in due course.

*10 July 2009*

## THE NATIONAL PANDEMIC FLU SERVICE

### DIFFERENCES BETWEEN INTERIM AND FULL-SOLUTION SERVICES

The interim National Pandemic Flu Service (NPFS), if it is mobilised, will provide a flu assessment and, where appropriate, authorise antiviral treatment to symptomatic individuals. The service will also provide patients with self-care advice and, where necessary, advise patients to seek further assessment from other health services (typically a GP). The interim NPFS will be available to the public via the internet or telephone. Telephone services will be available on a 0800 number and will be provided by dedicated call centre staff.

An enhanced National Pandemic Flu Service, based on the original "Flu Line" design, is still planned to be available in the autumn. The key differences between the interim service and the enhanced service are that the enhanced service will have:

- Increased functionality to provide greater verification of patients identity against a pre-existing database.
- Automated Interactive Voice Response telephony function, in addition to call centre handlers.
- Flu Line Professional—to allow authorised health care professionals to authorise an antiviral to a patient directly, without completing the full IT assessment process.
- Enhanced clinical algorithm including separate adult and paediatric pathways, with greater flexibility to alter the assessment process.

### TRANSITION FROM CURRENT ARRANGEMENTS TO NATIONAL PANDEMIC FLU SERVICE

To move from the initial treatment arrangements to a system where we can support antiviral distribution outside of the normal NHS procedures, plans are now being finalised at national and local level to communicate to the NHS and service users what will be expected of them if the service is introduced. The exact nature of the communications messages will be dependent on operational decisions about how the service is delivered, but communications are likely to include national media briefing and a range of targeted advertising and online information.

Communication to the NHS will be through existing DH channels, for instance we have already advised the NHS in guidance sent out on 2nd July of the need to ensure that local plans are in place in each PCT area for the introduction of the National Pandemic Flu Service.

### RESILIENCE

This system has undergone extensive testing, both to ensure that it will function correctly, and also to ensure that it can handle the expected volumes required to launch and operate the service.

Specific testing has included testing for security, performance, usability, accessibility, clinical safety and functional flow. A similar approach will be undertaken for the full solution before it is operationalised.

### STAFFING

We are currently in the final stages of concluding commercial agreements with private sector providers and Memoranda of Understanding with public sector bodies. We have currently identified sufficient call centre agents to make the service available. Given the unknown call centre capacity demands in a pandemic, a pool of providers from both the public and private sectors are being used to provide flexibility on a call-off basis. To minimise unused capacity and cost to the taxpayer, activation and training will not occur until needed.

Agent training to use the Flu service algorithm takes approximately four hours. It is intended to train contact centre agents within a defined mobilisation period only once the demand is reasonably certain and they are actually required. During the first few weeks of May 2009, approximately 300 public sector agents were trained but not authorised to start.

#### ANTIVIRAL COLLECTION POINTS

SHAs have been reviewing and, where necessary, challenging the antiviral collection point plans of each PCT in terms of premises, staffing, IT and the supply chain for antivirals. This will ensure that PCT plans are robust, that there is clarity on the lead-time for the establishment of the collection points, that a good spread is available across each PCT geographically and that sufficient collection points will be up and running to meet the needs of the population.

Each SHA has confirmed that sufficient collection points to cover the population in each PCT could be stood up within seven days of a decision to mobilise the National Pandemic Flu Service. SHAs have agreed with their PCTs the number and distribution of collection points across the country. It is anticipated that there will be up to several hundred collection points operational across England during the peak activity periods of swine flu cases anticipated over the autumn and winter.

#### REASONS FOR DELAY

The full National Pandemic Flu Service, formerly known as “Flu Line”, will be ready in the autumn. This system will be able to assess people via either the internet or telephone, co-ordinate the distribution of antivirals and feed back to local health services.

While the “Flu Line” itself was originally scheduled to be available by the end of May, it was also noted that elements of the full “end-to-end” service, including the collection point system and stock management system, would not be ready until the summer. The importance of extensive testing to the overall system was emphasised to ensure confidence in the element of a response to a widespread outbreak. With the swine flu outbreak, the original solution was put on hold so that an interim, scaled down solution could be developed and tested to be available more quickly if need. This interim still provides assessment via the internet or telephone and includes other functionality to support the service such as supporting antiviral collection points.

Department of Health

*July 2009*

#### COMMENTS ON THE RCGP EVIDENCE TO THE COMMITTEE AND INFORMATION ON GP COMMUNICATIONS

1. The Royal College of General Practitioners (RCGP) wrote to the Committee on 1 July setting out GPs’ views on the Government’s preparedness for pandemic flu. It is helpful to have such feedback and this note gives further information on the points raised. It also sets out the advice and information that has been sent to GPs to date.

2. PCTs and GPs are in the forefront of the response to the current outbreak of swine flu, and will continue to play a vital role in the event of a widespread outbreak. PCTs have a central role in supporting the GPs in their areas. Ian Dalton, National Director for NHS Flu Resilience has raised this issue with the Chief Executive of each SHA so that they understand how vital support for GPs is and that this works in every PCT. This message will have been cascaded to PCT Chief Executives via the normal management channels. This remains a key message from the Department and it was reiterated at the NHS Confederation Conference in June. Ian Dalton invited Dr Maureen Baker, Honorary Secretary of the RCGP, to his meeting with the SHA Flu Directors this month to brief them on her views on what every PCT should be doing.

#### OUTBREAK MANAGEMENT

3. Over recent weeks, there have been more widespread outbreaks of swine flu in some areas. Managing these has involved the introduction, in consultation with the Health Protection Agency (HPA), of local flexibilities to reduce pressures on GPs and others. For example, in the containment phase, GPs were undertaking the majority of swabbing and in some areas giving out Tamiflu in schools to large numbers of children, which was time consuming. As part of local outbreak management, the decision to reduce patient swabbing to suspected cases only and ensuring other staff such as primary care nurses could swab reduced pressure on GPs, as did allowing them to treat symptomatic patients on the basis of clinical judgement. The move away from widespread prophylaxis also helped relieve pressure on GPs.

4. The move to the treatment phase of the response on a UK-wide basis allows GPs to authorise Tamiflu on clinical diagnosis, without the need for swabs. This is supported by a regime of sample swabbing similar to that used during the normal flu season. This further reduces this element of work for GPs in all areas. To preserve GP capacity and enable practices to deliver care in the community setting, it is possible that non-essential activity will cease (but continuing to make essential care available for emergencies and patients with chronic or other illness), and GPs and those with higher clinical skills or experience will focus on those patients who may be at particular risk. As above, we have emphasised the importance of PCTs working to support GPs in their work at this time. As part of the preparations the BMA and RCGP have produced guidance and assisted planning by GP practices.

5. The next steps will provide the option of mobilising the National Pandemic Flu Service (see enclosed paper on National Pandemic Flu Service). This has been designed to minimise pressure on GPs and primary care teams by allowing patients to access antiviral medication through a web or telephone application, rather than contacting their GP. The medication will be collected by the person's "flu friend" via a local network of antiviral collection points. Most flu sufferers can be cared for appropriately using a home care based approach, so this system enables people to stay at home while they are infectious.

6. In its letter of 1 July, the RCGP mentioned that sessional GPs felt they had not been provided with adequate information from their Primary Care Organisations (PCOs) and that they liaised with the DH to suggest solutions. DH was grateful for their help.

#### COMMUNICATIONS

7. We understand that there will always be local variation in the experiences of GPs. Following some initial problems, all PCTs have been reminded of the importance of good communications with all their GPs, including those employed on a sessional basis. In areas where case numbers are significant, liaison with Local Medical Committees has taken place and has improved communications.

8. The Committee also asked about communications with GPs. The Department of Health and the HPA have issued information and advice to GPs throughout the swine flu outbreak.

9. The Department has systems in place to ensure that guidance reaches frontline healthcare workers. For example, when the strategy for the West Midlands and London was changed, NHS flu leads received a letter setting out outbreak management considerations, which was cascaded to GPs and other staff. A number of other organisations also provide GPs with information.

10. The Chief Medical Officer has issued advice and information through the Central Alerting System, which is cascaded to all GP practices, on a number of occasions. This system has been used to pass on top line messages and changes in policy and has covered the following areas:

- Advice that cases of the swine flu were being reported in the US and Mexico and that these cases are unusual and warrant further investigation. A copy of the Health Protection Agency algorithm for the management of returning travellers and visitors from countries affected by swine flu presenting with febrile respiratory illness: recognition, investigation and initial management (25 and 26 April).
- Advice to GPs on the steps to take to deal with enquiries about potential cases of swine flu. The alert gave information on the World Health Organisation alert levels, the details as known of the virus to date and who should be offered antivirals. It also gave information on the plans for the distribution of antivirals from the stockpile and links to information for patients (30 April 2009 and 1 May).
- Additional advice on household contacts asking GPs, when a case of swine flu is suspected, to liaise closely with the local health protection unit and stressing the importance of diagnosing and treating suspected cases and controlling further spread by treating close contacts (6 May).
- A note asking doctors for their help in detecting cases of swine flu in hospitals (16 June).
- Advice on the move to the treatment phase of the response including information on the epidemiology of the virus so far, some pointers as to what might happen next, the rationale for the public health and clinical response so far, information and guidance on steps that now need to be taken and an outline of further planning and policy decisions (2 July).

11. The Department has passed operational information, for example detailed advice on treatment, on to GPs through the usual channels, such as through the HPA website and the RCGP. In between issuing alerts, the Department has liaised closely with the RCGP to make sure correct and consistent advice is given to GPs from the DH, HPA and RCGP. On 16 June DH issued a clinical package of a set of tools for use in a pandemic situation by frontline healthcare professionals. The tools are designed to support and empower GPs and others and assist them to assess patients, authorise antivirals, refer those with severe illness or complications, and guide treatment of patients in hospital.

12. At a local level, it is for PCTs to advise GPs of the detail of the arrangements in their areas. Ian Dalton's letter of 2 July to NHS Chief Executives about the move to the treatment phase of the response includes advice to PCTs that they should "Continue to ensure that communications with and support to GPs (as patients' primary source of contact) are clear and help to maintain public confidence in our approach to managing the pandemic."

13. The HPA has issued detailed advice for health professionals including information on the following:

- Case investigation and management, including treatment.
- Prescribing.
- Clinical diagnostic criteria.
- Testing.
- Treatment.
- Decisions to admit patients to hospital.
- Flu response centres.
- Personal protective equipment.

14. Within each region, Flu response Centres (FRCs) had a responsibility to respond to enquiries from GPs and other health professionals. In addition, HPA provided guidance directly to GPs through PCTs. In each region the HPA maintained a regular dialogue with SHAs and PCTs—for example, in London, there were daily teleconferences involving the HPA Regional Director, the RDPH and a representative PCT Chief Executive.

15. In addition, the RCGP issues daily guidance to GPs that draws together information from all agencies. There are also systems in place to share good practice across the profession and extra support if needed. Lessons learned from the hotspot areas are being shared between SHAs.

#### OTHER ISSUES RAISED BY THE RCGP

16. Some concerns were raised about the problems in accessing FRCs. The FRCs have generally worked well, they have allowed the containment phase to continue and are a positive example of HPA/NHS joint working. The Department is aware that FRCs came under pressure from high numbers of both incoming and outgoing calls and that this pressure on the centres caused delays for GPs needing to make contact with them. The changes brought in by the move to local outbreak management, such as a reduced need for contact tracing, reduced these pressures. As we have now begun the treatment phase Flu Response Centres will slowly be phased out. The timing of this will be decided for each local area through consultation between the HPA and SHAs.

17. Some GPs asked why they were not able to prescribe Tamiflu and the RCGP rightly advised that, through discussion over the last few years, we have agreed an approach that lessens pressure on GPs and surgeries as much as possible.

18. The RCGP report that some Out of Hours (OOH) providers felt that their local PCOs did not value their help during the outbreak and that they had received poor, inconsistent communication. Good communication and planning with OOH services is a key lesson that has been shared by the hot spot areas with other SHAs so that it can be reinforced in other regions.

19. Some GPs expressed concerns about a lack of Personal Protective Equipment (PPE) such as eye protection, gowns and gloves and of guidance about their use. PCTs hold stocks of PPE for use in their local area as part of the national stockpile. There was also concern among pregnant GPs about whether to continue working. It will not be possible for pregnant women to avoid contact with swine flu in the community or in the family. PCTs should have infection control policies and occupational health policies in place and advice on use of antivirals for pregnant women and use of PPE is available on the DH and HPA websites.

20. There were also comments on public health information, with some doctors noting that many patients had received the Government's swine flu leaflet but had not actually read it, a problem that it is difficult for any organisation to solve. The Government fully recognises the importance of ensuring messages reach all sections of the population. The Swine Flu Information leaflet is available in audio CD, large print, easy-read, braille and a number of other languages. We continue to look at ways of making public information as accessible as possible.

21. There was an information campaign in May, including TV, press and radio advertising, to advise people about swine flu and the public about swine flu and the importance of good respiratory and hand hygiene. Going forward we will be running a respiratory hand hygiene campaign over the summer repeating the messages encouraging people to use tissues to “Catch it, Bin it, Kill it”. We plan to extend this into a new phase in the autumn to link in with planned vaccination campaigns. We continue to undertake more research and develop more insights into the needs of a range of specific groups and this will inform our wider communication strategy as it develops. Our immediate priority is to reach as wide a mass audience as possible with hygiene messages.

Department of Health

*July 2009*

## FLU RESPONSE CENTRES

### FLU RESPONSE CENTRES IN THE CONTAINMENT PHASE (UNTIL 2 JULY 2009)

1. The proposal to establish Flu Response Centres (FRCs) was agreed on 4 May and they “went live” between 12–27 May 2009 with the purpose of taking on much of the frontline response work initially undertaken by the Health Protection Agency’s (HPA) 26 Health Protection Units (HPUs). Their aim was to extend the intensive public health and public confidence response (the “containment phase”) to cover the first 2–3,000 confirmed cases of H1N1v infection in England.
2. There were 10 FRCs, one was established in each Strategic Health Authority region. Each FRC had a dedicated telephone number which was communicated to health professionals prior to the FRCs going live. The HPA commissioned a bespoke information system, Flu Zone, to support all aspects of call enquiries and case investigation and management. During the containment phase the FRCs took over 5,000 calls per day, provided antivirals to over 6,000 cases and 10,000 contacts and dealt with outbreaks in over 400 schools.
3. The FRCs were a joint HPA and Department of Health initiative. The centres themselves were established, equipped and managed by the HPA and were jointly staffed by HPA staff and seconded NHS staff, all under the clinical supervision of the HPA. In total around 900 NHS staff were seconded to provide support to the FRCs at different times with around 200 involved on any day. Around 360 HPA staff were involved at different times with around 60 working in FRCs on any day.
4. The FRCs dealt with a range of issues. General telephone enquiries were dealt with relatively quickly by referring them to NHS Direct. Calls relating to suspected cases required an assessment by the FRC staff in discussion with the reporting clinician to determine whether the patient met the agreed clinical criteria. If so, “swabbing” (the taking of clinical samples for laboratory testing) and antiviral treatment was arranged by the FRC.
5. For any patients who became probable (ie with appropriate symptoms and close contact with a confirmed case) or confirmed (by laboratory test) cases the FRC took the following action:
  - (i) a detailed enquiry to identify any close contacts needing antiviral prophylaxis;
  - (ii) assessment of contacts for symptoms. Any symptomatic contacts were then managed as possible cases and swabbing and treatment arranged; and
  - (iii) close contacts were those who had spent one hour or more at a distance of less than a metre whilst the case was symptomatic. This was often complex involving school contacts, work contacts, wider contacts, for example when the case had attended a social event such as a party. Where cases occurred in school children actions included liaison with the school, consideration of potential closure of the school and distribution of antiviral prophylaxis to many people in year groups or even the whole school. Where cases had been on flights whilst symptomatic follow up of other passengers on flights was undertaken.
6. This action was significantly resource intensive as situations often required a team of people to manage them.
7. The original intention in setting up FRCs was to provide capacity to deal with the first 2–3,000 cases provided these occurred over “a reasonable timescale”.

**OUTBREAK MANAGEMENT IN HOTSPOTS (FROM 19 JUNE 2009)**

8. The Outbreak Management strategy was announced on 19 June 2009 and implemented in “hotspots” where there was such widespread community transmission it was no longer realistic to try to stop the spread of the disease. In these areas, the following national guidelines were applied by the FRCs but with flexibility to meet local needs and according to clinical judgement:

- (i) No contact tracing.
- (ii) No prophylaxis save in rare cases subject to local clinical judgement.
- (iii) Limited swabbing of patients to that required for surveillance purposes.
- (iv) Treatment provided to both laboratory confirmed and clinically presumed cases.

**TREATMENT PHASE (FROM 2 JULY 2009)**

6. The Flu Response Centres will not have a significant role in diagnosing cases or providing treatment in this phase as this will be undertaken by NHS staff. Health Protection Agency staff and resources will be redirected to other necessary areas of work such as surveillance and management of outbreaks affecting vulnerable groups, such as in nurseries. During July, the HPA will continue to support the NHS to ensure a smooth handover.

Department of Health

*July 2009*

**Memorandum by the Royal College of General Practitioners**

**GPS' VIEWS ON THE GOVERNMENT'S PREPAREDNESS FOR PANDEMIC FLU**

**1. RCGP PANDEMIC PLANNING**

The College has been involved in preparing for an influenza pandemic for a number of years. Dr Maureen Baker, RCGP Pandemic Planning Lead, works closely with organisations including the Department of Health's (DH) pandemic team and the BMA's General Practitioners Committee (GPC) to ensure that pandemic planning is put in place.

The College has also formed an excellent working relationship with the recently appointed government “flu tsar”, Ian Dalton, who has been using RCGP Members' feedback on the situation to inform his discussions with SHA Leads in England.

A joint RCGP-HPA panel has also recently been formed and now meets via teleconference once or twice per week, depending on how the H1N1 outbreak has been developing. The panel has proved particularly effective as a means to discuss how the situation is operating on the ground and to examine what guidance is required for GPs.

In addition, Joint RCGP/BMA guidance was published in January 2009, to help GP practices prepare for an influenza pandemic. It was supported by the DH and offers advice on business continuity in general practice. The RCGP, BMA and DH met recently to discuss updating the document in light of recent developments.

At present, the College continues to watch the situation to ensure that the GP profession is as prepared as possible for a pandemic.

**2. UPDATING THE GP PROFESSION ON THE H1N1 OUTBREAK**

The RCGP responded rapidly to news that there had been an outbreak of A (H1N1) “swine flu” in Mexico, recognising the need to provide GPs with up-to-date information on a regular basis.

Dr Maureen Baker has been issuing regular messages to the profession, with a frequency of one-per day or one-per week based on necessity. Each provides an overview of how the outbreak is developing in the UK and worldwide, along with any information which can support GPs and practices in their pandemic planning—including algorithms from the HPA or advice from the DH on, for example, the procurement of face masks. Messages are intended for a UK-wide audience and offer information which is relevant to GPs in Northern Ireland, Scotland and Wales, as well as those in England.

The updates invite GPs to send their comments, queries and suggestions to the RCGP's dedicated flu mailbox. Feedback is then collated and sent to colleagues in the DH, the HPA, and to Ian Dalton. The College has found that this helps inform policy and that most issues are ultimately addressed—at least in part—by forwarding on these concerns/comments.

### 3. THEMES ARISING FROM GP FEEDBACK

The following offers an overview of the comments received in the RCGP's dedicated flu mailbox, highlighting GPs' views on the Government's preparedness for pandemic flu. It includes details on the mechanisms undertaken by the College to address concerns, often involving liaison with the DH and/or HPA.

#### (a) *Lack of Information and Conflicting Advice*

Locum GPs, GP trainees and sessional GPs felt they had not been provided with adequate information from their Primary Care Organisations (PCOs). The RCGP liaised with the DH on behalf of sessional GPs and suggested that one way to overcome this problem would be to enhance the Performers List and use it as a means of disseminating information.

Comments were also received highlighting the fact that national changes (such as amendments to the procedure for obtaining Tamiflu) were not cascaded down to PCTs/GPs. Family doctors also noted that conflicting advice was being provided by different agencies.

#### (b) *Variation in Support from PCTs*

Some GPs raised concerns about the lack of support provided by their PCTs, such as no action plan to help primary care respond to the outbreak. Others reported positive feedback, for example, Dr Fay Wilson (part of the Birmingham and District General practitioner Emergency Rooms group which led on the care of 47 confirmed cases of H1N1 flu in Birmingham) commented: "*We want to praise our local Health Protection Unit (HPU), local Trust, regional Health Protection Agency and PCT Public Health Lead who were all very flexible in helping us with our requests and making things happen quickly when we needed them.*"

#### (c) *Difficulties Accessing Flu Response Centres*

Concerns were raised about the severe problems in accessing flu response centres, in particular, the variability in opening times. Particular comments from GPs include:

*"There is variability in the timings when flu distribution centres are open eg in one PCT this is only open 9 to 6pm, another until 5pm". (Comment, 20/06/09)*

*"The Sheffield PCT flu helpline said sorry we can't help, please phone the swine flu helpline". (Comment, 18/06/09)*

#### (d) *Problems Relating to Swabbing*

The College is aware of both positive and negative experiences of GPs of arranging for swabs to be taken. In some cases there is excellent communication between HPUs, Public Health Departments and Out-Of-Hours services. However, the RCGP has also heard that in some instances it has taken several hours to arrange with the HPU how swabs will be taken, how Tamiflu will be supplied and how the swabs will be transported to the virology lab. It is quite clear that in some cases HPUs, Public Health Departments and GPs have not had access to the information that they need.

Family doctors who reported that they were not getting enough swabs were advised by the College to contact their PCT or local Health Protection Unit to arrange for more to be delivered.

#### (e) *Uncertainty around Prescribing Tamiflu*

Some GPs have asked the College why they are not able to prescribe Tamiflu—and a few even perceived that they are not "trusted" to do so. The RCGP response was "There is no question of any lack of trust in GPs and primary care. As a result of intense discussion over the last few years, the DH—together with the College and the BMA—want to avoid the pressure on GPs and surgeries which could occur if large numbers of people had to use surgeries to access antiviral medicines. The feeling is that this arrangement will allow GPs to do what they do best—to offer high quality expertise to those who really need it, such as the patients that they normally see and those who might have complications resulting from flu. It is also the case that the current arrangement avoids patient prescription costs and will hopefully be a more convenient way for patients to quickly obtain access to antiviral treatment".

Concerns were also raised about prescribing Tamiflu to pregnant women, women who are breast feeding and children under the age of one year. In the RCGP update 15 (issued on 22 May 2009) the College notified readers that the HPA had issued recommendations on the use of antiviral medicines among these groups.

(f) *Difficulties in Providing Out of Hours (OOH) Care*

Some OOH providers felt that their local PCOs did not value their help during the outbreak. They reported that they had received poor and inconsistent communication, including lengthy and verbose documents that were unworkable operationally. They also called for better resourcing. Lack of involvement in strategic planning was also cited, with OOH providers feeling that they were not seen as the “major player in the flu plan operationally in their area”.

Providers felt their workload is unsustainable and that there is a risk that non-flu patients will be missed—these issues were also raised by in-hours GPs.

(g) *Concerns about Protection for Healthcare Workers*

Many comments have been received about the lack of Personal Protective Equipment (PPE) such as eye protection, gowns and gloves. A lack of guidance on their use has also been noted. Some GPs stated that their PCTs have advised that PPE is not required or that they will not be providing such items.

In particular, GPs were unsure about where to obtain facemasks, how many they require, and whether these items would be free. In RCGP update 14 (sent on 19 May 2009) the College informed readers that “The DH has confirmed to us that PCTs have now been supplied with facemasks and will be able to provide these to GPs when required. (GPs in Wales, Northern Ireland and Scotland will need to check the situation with their PCOs).”

GPs have informed the College of their anxiety in relation to the risk their work poses to themselves and their families. Many have commented on the lack of advice about whether tamiflu could be used as a personal prophylaxis.

(h) *Apprehension among Pregnant Doctors Whether to Continue Working*

Concerned family doctors have also been in contact seeking the latest recommendations on the protection of pregnant healthcare workers that might come into contact with possible swine flu patients. It appears guidance on this issue is not very clear.

(i) *Uncertainty about Isolation Period Following Infection*

Family doctors have also informed the RCGP that they do not know when they should advise their patients to come out of isolation following an episode of H1N1 flu. In addition, there seems to be confusion around how long health workers need to stay off work following a presumed flu diagnosis.

(j) *Inadequate Public Health Communications*

GPs informed us that a lot of patients were asking about swine flu symptoms and turning up to the surgery even when they display symptoms of a fever or cold. Many had received the Government’s swine flu booklet but had not actually read it. Family doctors suggested a more comprehensive and systematic approach in order to reach the whole population, including patients who do not have a working knowledge of English.

(k) *Comment on NHS Direct*

The College has had one comment relating to NHS Direct, which it received on 04/05/09:

*“I have heard that when patients are calling NHS Direct they are being directed to contact their GP practices. From the information I understood, NHSDirect will be able to make arrangements to get swabs etc”.*

The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the “voice” of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 36,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

1 July 2009

**Memorandum by the Royal College of Physicians****SUBMISSION TO THE HOUSE OF LORDS SCIENCE AND TECHNOLOGY COMMITTEE ON THE STATE OF PREPAREDNESS FOR THE ANTICIPATED AUTUMN WAVE OF SWINE FLU**

The Royal College of Physicians has been working closely with the Department of Health in making preparations for an anticipated outbreak of pandemic influenza for some years. The first step was a conference in September 2006 in corporation with the British Thoracic Society entitled “Pandemic Influenza—how would your hospital cope?” The proceedings of this conference were put on to CD-Rom and sent to all hospital College Tutors throughout the country and is still available on the RCP website. <http://www.rcplondon.ac.uk/event/ArchiveEvent/0609pandemicflu.aspx>.

More recently, the College has produced guidelines in association with the specialist societies for hospitals on how each speciality service should be organised in an outbreak. <http://www.rcplondon.ac.uk/pubs/brochure.aspx?e=276>.

Although the flu virus anticipated (Avian Influenza H5N1) is not the one causing the current outbreak (Swine Flu H1N1) the plans are easily transferable. There are still things that need to be done but in general the College feels that the Department of Health has done an excellent job of preparing for the anticipated outbreak. We will continue to work with them to promote the highest standards for patients during this difficult time.

*July 2009*

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