# The 2009 Influenza Pandemic

An independent review of the UK response to the 2009 influenza pandemic

Dame Deirdre Hine, DBE FFPH FRCP

July 2010







## **H1N1 CASE ESTIMATES AND TIMELINE**

APRIL 2009	MAY 2009	JUNE 2009	JULY 2009	AUGUST 2009	SEPTEMBER 2009	OCTOBER 2009	NOVEMBER 2009	DECEMBER 2009	JANUARY 2010	FEBRUARY 2010	MARCH 2010
<b>23 April:</b> Cases of H1N1 virus are confirmed in Mexico and the USA	1 May: First case of human-to-human transmission in the UK is confirmed	11 June: WHO raises its pandemic alert level to 6, the highest level	<b>2 July:</b> Treatment phase begins	13 August: Andy Burnham announces the identification of priority groups: pregnant women, front-line health	10 September: The four health departments release critical care strategies to cope with the expected increases	21 October: Vaccination programme begins: front-line healthcare workers and their patients who fall into at-risk	<b>19 November:</b> Phase two of vaccination programme begins: children over 6 months and under 5 years	<b>10 December:</b> Total UK deaths: 283	<b>7 January:</b> Total UK deaths: 308	4 February: Total UK deaths: 411	18 March: Total UK deaths: 457 342 in England
24 April: WHO announces an outbreak of numan cases of H1N1 confirmed n Mexico and the USA	14 May: First laboratory-confirmed case reported in Northern Ireland	13 June: Total number of UK cases reaches 1,000	6 July: Total UK deaths: 10	and social care workers, and everyone in at-risk groups (those who are at higher risk of serious illness or death should they develop influenza) aged	in demand during the second wave of the pandemic	categories  29 October: Total UK deaths: 137				11 February: National Pandemic Flu Service is stood down	69 in Scotland 28 in Wales 18 in Northern Ireland
				over 6 months					160,000		
7 April: he first two UK cases of H1N1 re confirmed in a couple from cotland	<b>15 May:</b> Press release confirms agreements to secure up to 90m doses of pre-pandemic vaccine	<b>15 June:</b> First UK death attributed to H1N1	23 July: National Pandemic Flu Service goes live in England	21 August: Total UK deaths: 60							APRIL 2010
VHO raises its alert level to Phase 4 FCO advises against all but essential travel to Mexico	FCO ceases to advise against all but essential travel to Mexico								140,000		1 April: Antiviral medicines no lon available from national sto
<b>28 April:</b> Michael McGimpsey makes a statement about the outbreak to	29 May: First laboratory-confirmed case reported in Wales. Cases now								120,000		England are closed  The Swine Flu Information is terminated
he Northern Ireland Assembly NHO raises alert level from 4 to 5	confirmed across the UK										Treatment of people with symptoms returns to busi as usual
9 April: ordon Brown announces that he stockpile of antivirals will be creased from 33.5m to 50m									100,000 SH		
valan Johnson informs the House of Commons of five confirmed ases in the UK and promises an dvisory booklet drop									CAL CAS		
dwina Hart provides an update In the situation to the Welsh ssembly Government icola Sturgeon updates the									O00,088 CIN		
Scottish Parliament on the putbreak and the two confirmed cases in Scotland  First case confirmed in England; First UK school closure									60,000 ES		
30 April: H1N1 information campaign is olled out on TV, radio and in print media and a booklet is prepared									40,000		
or household delivery										Estimate range Mid estimate	
									20,000	numbers provide	d to calculate case es a range within which r of cases may fall

APRIL 2009	MAY 2009	JUNE 2009	JULY 2009
23 April: Cases of H1N1 virus are confirmed in Mexico and the USA	1 May: First case of human-to-human transmission in the UK is confirmed	11 June: WHO raises its pandemic alert level to 6, the highest level	2 July: Treatment phase begins
<b>24 April:</b> WHO announces an outbreak of human cases of H1N1 confirmed in Mexico and the USA	<b>14 May:</b> First laboratory-confirmed case reported in Northern Ireland	13 June: Total number of UK cases reaches 1,000	6 July: Total UK deaths: 10
27 April: The first two UK cases of H1N1 are confirmed in a couple from Scotland	15 May: Press release confirms agreements to secure up to 90m doses of pre-pandemic vaccine	<b>15 June:</b> First UK death attributed to H1N1	23 July: National Pandemic Flu Service goes live in England
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<b>28 April:</b> Michael McGimpsey makes a statement about the outbreak to the Northern Ireland Assembly	29 May: First laboratory-confirmed case reported in Wales. Cases now confirmed across the UK		
WHO raises alert level from 4 to 5			
29 April: Gordon Brown announces that the stockpile of antivirals will be increased from 33.5m to 50m			
Alan Johnson informs the House			

Alan Johnson informs the House of Commons of five confirmed cases in the UK and promises an advisory booklet drop

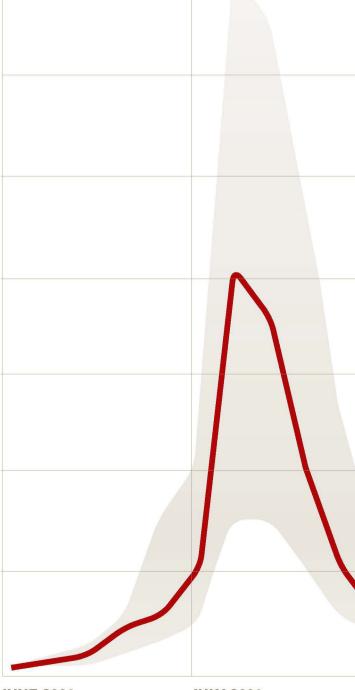
Edwina Hart provides an update on the situation to the Welsh Assembly Government

Nicola Sturgeon updates the Scottish Parliament on the outbreak and the two confirmed cases in Scotland

First case confirmed in England; first UK school closure

### 30 April:

H1N1 information campaign is rolled out on TV, radio and in print media and a booklet is prepared for household delivery



**JUNE 2009** 

**JULY 2009** 

### **AUGUST 2009 SEPTEMBER 2009** OCTOBER 2009 **NOVEMBER 2009** 13 August: 10 September: 21 October: 19 November: The four health departments Andy Burnham announces the Vaccination programme begins: Phase two of vaccination programme identification of priority groups: pregnant women, front-line health release critical care strategies to front-line healthcare workers and begins: children over 6 months and cope with the expected increases their patients who fall into at-risk under 5 years and social care workers, and in demand during the second categories everyone in at-risk groups (those who are at higher risk of serious wave of the pandemic 29 October: Total UK deaths: 137 illness or death should they develop influenza) aged over 6 months 21 August: Total UK deaths: 60 **AUGUST 2009 SEPTEMBER 2009 OCTOBER 2009 NOVEMBER 2009**

DECEMBED 2000	IANIIADV 2010	EEDDIIADV 2010	MADCH 2010
10 December: Total UK deaths: 283	7 January: Total UK deaths: 308	FEBRUARY 2010  4 February: Total UK deaths: 411  11 February: National Pandemic Flu Service is stood down	MARCH 2010  18 March: Total UK deaths: 457 342 in England 69 in Scotland 28 in Wales 18 in Northern Ireland
			APRIL 2010
	140,000		1 April: Antiviral medicines no longer available from national stockpiles Antiviral collection points in
	100,000		England are closed  The Swine Flu Information Line is terminated
	120,000		Treatment of people with flu-like symptoms returns to business as usual
	100,000 S S S S S S S S S S S S S S S S S		
	estimated clinical cases		
	60,000 ESTIMATE		
	40,000	Estimate range <sup>1</sup>	
		Mid estimate	
	20,000	numbers provide	d to calculate case es a range within which r of cases may fall
DECEMBER 2009			Source: HPA

**DECEMBER 2009** 

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## Foreword to the review of the UK response to the 2009 influenza pandemic

**Dear Ministers** 

I am pleased to present my report on the review of the response of the UK governments to the H1N1 influenza pandemic of 2009.

This review is one of many being conducted at every level from global to local. It has examined the strategic response in the UK, including the way in which this was planned and implemented across the four nations in the first serious health emergency since the advent of devolution. It does not focus on the operational responses to the pandemic in each of the four countries. I have sought to produce a report that identifies the lessons to be learned rather than one that second guesses the decisions made during the response. I am very aware of my responsibility to use hindsight sparingly.

The report is the product of three months of rigorous and searching analysis of the documentation and the reported experience of some of those who were involved in the response and others who were close observers. The Review Team received over 700 documents and I met almost 100 individuals in my interviews.

The majority of the evidence revealed as a result of this process leads me to judge that, overall, the UK response was highly satisfactory. The planning for a pandemic was well developed, the personnel involved were fully prepared, the scientific advice provided was expert, communication was excellent, the NHS and public health services right across the UK and their suppliers responded splendidly and the public response was calm and collaborative. I also found the vast majority of the reporting of the outbreak to have been highly responsible.

That said, it must also be acknowledged that the H1N1 'swine flu' pandemic virus was milder in its general impact than the H5N1 'bird flu' expected and planned for. Despite this, the relatively few deaths that occurred, including those of otherwise healthy children and pregnant women, were particularly tragic and poignant.

The pandemic and the response it generated have provided confirmation of the value of planning and preparedness and have demonstrated that the four UK governments can work together effectively and successfully to meet such an emergency. But the danger of another, more severe, pandemic has not gone away and the governments of the UK must avoid complacency and use this opportunity to learn lessons and make improvements for a future in which

resources will be tight. I have therefore sought to identify improvements that could be made so that future pandemic planning can be fine-tuned to address the characteristics of any outbreak. I have also recommended ways in which a UK-wide strategic response to a pandemic could be combined with more local operational flexibility.

I wish to express my gratitude to all who responded to the call for evidence, to all those who gave up their time to meet me and discuss their views and experiences and most of all to the team who supported me. Their competence, rigour and commitment are of the highest order and they were expertly and wisely led by Tim Baxter. I am also grateful for the generous guidance of Simon Webb. Any errors or omissions in this report are solely mine.

Deidre J. Hie

Dame Deirdre Hine, DBE FFPH FRCP

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### **Executive summary**

### Introduction

- 1. The UK government and devolved administrations have been preparing for an influenza pandemic for some years a pandemic that might kill many thousands of people and have a severe impact across the UK. Their wide-ranging preparations included substantial stockpiles of drugs and plans to purchase up to 132 million doses of vaccine, sufficient to protect the whole of the UK population. I found that those preparations were soundly based in terms of value for money, reflecting the inherently low cost of vaccination in relation to the value of lives saved.
- 2. However, the H1N1 pandemic which emerged in 2009 turned out to be a relatively mild illness for most of those affected, though it must not be forgotten that for some people its effects were very serious. Sadly, 457 people are known to have died during the pandemic in the UK as of 18 March 2010. In accordance with common practice, a review was established to learn lessons from the UK response to the pandemic, and in March 2010 I was asked to be its independent chair.
- 3. The four nations' health ministers, on behalf of the UK government and devolved administrations, requested that I review the strategic decisions made and the way in which all four nations and government departments worked together to develop a UK-wide strategy to manage the domestic consequences of the pandemic. My terms of reference are at Annex A.
- 4. My review took place between March and July 2010. During that period I received over 700 documents from the key organisations involved in the strategic response and interviewed almost 100 individuals, both inside and outside government. A list of those I interviewed is at Annex B.
- 5. Overall, from the discussions and meetings I have held, I consider this response to have been proportionate and effective. There is much good practice on which to build and the recommendations presented here are a recognition that we should always aim to improve systems and the way in which services are planned and delivered. Although I was not asked to review the operational side of the response, I heard nothing but praise and admiration from those interviewed for the health service and health protection staff right across the UK who led the response to the pandemic. Their dedication and professionalism in both tackling the pandemic and in ensuring that health services continued to run smoothly

- despite the additional pressures of the pandemic must be acknowledged and congratulated.
- 6. In Chapter 2 of this report I set out a timeline for the course of the outbreak.

### **Chapter 3: The central government response**

- 7. The UK's current central government crisis management arrangements have been in place since 2002, and have been tested in various crises and exercises and refined through those experiences. The pre-pandemic planning, set out in *Pandemic flu: A national framework for responding to an influenza pandemic*, <sup>1</sup> ensured that many decisions had already been made in principle prior to the pandemic and that key personnel had already had the opportunity to work together. Key issues, approaches and decisions were outlined in the National Framework to ensure that the UK was able to make decisions rapidly when required.
- 8. During the H1N1 pandemic, central government's crisis management arrangements effectively supported and facilitated decision-making in an atmosphere of considerable uncertainty and pressure. The Cabinet Office played a key role in driving decision-making, balancing views and ensuring strong co-ordination. The willingness of the devolved administrations and the Department of Health (DH) to work closely together within a common UK framework was fundamental to the overall success of the response.
- 9. Given the context of uncertainty inherent in the unpredictability of the influenza virus, there is a tendency, in an emergency situation and in the absence of information, to assume the worst-case scenario and resource the response accordingly. There is, however, an alternative approach, which is to take a view on the most likely outcome, while monitoring events closely and changing tack as necessary. Ministers should be invited to make a conscious choice as to which approach to adopt.

<sup>1</sup> www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandGuidance/DH 080734

**RECOMMENDATION 1:** Ministers should determine early in a pandemic how they will ensure that the response is proportionate to the perceived level of risk and how this will guide decision-making. This approach should be reflected in the revised pandemic-specific Concept of Operations by summer 2011.

10. The H1N1 pandemic was the first UK-wide crisis in a devolved policy area, and therefore there could have been inconsistencies and disagreements between the four UK nations during the response. The machinery of central government adapted to this situation by setting up a four nations health group, at both ministerial and official levels, to facilitate the agreement of a common approach to health issues. I heard that this worked well and ensured effective co-ordinated decision-making. This approach should therefore be adopted as a model for future emergencies and codified in the next iteration of the Central Government Arrangements for Responding to an Emergency – Concept of Operations (CONOPS).

**RECOMMENDATION 2:** The Cabinet Office should enshrine the position of the four nations mechanism for certain types of emergencies in a revised Concept of Operations by summer 2011. The mechanism should then be included in the exercise programme for emergencies in a devolved matter.

11. A UK-wide co-ordinated response to H1N1 pandemic influenza was well received and allowed the four governments of the UK to move together at key points of the response. This approach was made easier by the existing relationships between the UK government and the devolved administrations and by the new relationships built through the four nations health officials and ministerial meetings. There is a need to build on these relationships and to strengthen interaction between the four health departments more widely to support this.

**RECOMMENDATION 3:** The four health ministers should meet to discuss emergency preparedness (and a range of other issues) at least once a year. Officials should aim to meet face to face more regularly.

12. Although the four health departments worked well together during the response, the impact of geography on these relationships should not be overlooked. Telephone conferencing ensured that, in a fast-moving crisis, regular meetings could be held with all four health departments present. I heard, however, that more face-to-face meetings would have helped to build relationships, and could have eased some of the more difficult discussions. In any crisis in a devolved matter, particularly a pandemic, it is unlikely that all key officials or ministers will be able to be at the same venue. Therefore, as face-to-face meetings were not possible, video-conferencing might have helped all four nations to engage with each other more effectively than telephone conferencing.

**RECOMMENDATION 4:** The Cabinet Office should review the technological support available for emergency ministerial and official meetings, to ensure that those joining in meetings remotely can be engaged as fully as possible in the discussion.

13. The response needed for the H1N1 pandemic was both intense and long-running. The first ministerial crisis response meeting was held on 27 April 2009 and four nations meetings were still taking place in February 2010. Although pressures varied over time, this tested the resilience arrangements for key roles and put significant pressure on certain individuals. I heard that in some cases this was not sufficiently considered in business continuity arrangements.

**RECOMMENDATION 5:** Departments should consider how best to increase the resilience arrangements for key roles in an ongoing crisis response, including those in charge of the response and committee members, and revise their resilience arrangements accordingly.

14. Several parts of the National Framework dealing with wider non-health aspects were not fully tested by this pandemic. However, the management of additional deaths has been highlighted as an area which needs further work to ensure that the UK is prepared for a more severe pandemic.

### **RECOMMENDATION 6:** By December 2010:

- (i) Ministers should decide the levels of deaths for which planning is appropriate as part of the process of revising *Pandemic flu: A national framework for responding to an influenza pandemic.*
- (ii) The Home Office, working with others including the Ministry of Justice, the Department of Health, the Cabinet Office, Communities and Local Government and the devolved administrations, should ensure that plans are in place to deal with those levels of deaths during a pandemic, linking with other elements of mass fatality management and specifying clear responsibilities for the collection, transportation, storage and burial or cremation of bodies.

### Chapter 4: Scientific advice

15. Scientific advice received by officials and ministers was exceptionally important in this response. There were high levels of uncertainty regarding the nature of the virus, which meant that ministers were heavily reliant on scientific advice for an understanding of the potential threat of the pandemic. For their part, scientists on the Scientific Advisory Group for Emergencies (SAGE) and its secretariat worked very hard to respond effectively. Ministers and officials were keen to understand the likely outcomes as early as possible and this led to unrealistic expectations of modelling, which could not be reliable in the early phases when there was insufficient data. Once better data was available, modelling became extremely accurate. In order to further enhance scientific advice in future pandemics, ministers and key officials should be briefed on the strengths and weaknesses of the likely available information; officials should consider whether it would be possible to derive more robust information earlier to support decision-making; and the balance of contribution in SAGE should be reviewed to ensure that it benefits from the expertise of key disciplines.

**RECOMMENDATION 7:** The Government Office for Science, working with lead government departments, should enable key ministers and senior officials to understand the strengths and limitations of likely available scientific advice as part of their general induction. This training should then be reinforced at the outbreak of any emergency.

**RECOMMENDATION 8:** The four Chief Medical Officers should jointly commission further work to support key decision-making early in a pandemic by January 2011. This should consider the practicalities of developing methods to measure the severity of a pandemic in its early stages. In particular, further exploration of population-based surveillance, such as serology, should be considered.

**RECOMMENDATION 9:** The Government Chief Scientific Adviser and the Department of Health should ensure that there is an appropriate balance of contribution in the Scientific Advisory Group for Emergencies for future pandemic outbreaks.

16. I heard that the devolved administrations did not always feel fully involved and engaged with the process of reaching a scientific consensus (although I would note that the possibility of embedding senior staff in London during a response to address this issue was, and is, open to them). SAGE's processes need to be redefined to ensure that there is adequate opportunity for appropriate Chief Medical Officers and/or Chief Scientific Advisers from all four UK nations to feed into the advice submitted to ministers. As part of this, the process through which the four health ministers receive scientific advice from SAGE should be clarified.

RECOMMENDATION 10: The Cabinet Office, with the Government Chief Scientific Adviser (GCSA) and the four Chief Medical Officers (CMOs), should devise a process through which UK government ministers and the devolved administrations are presented with a unified, rounded statement of scientific advice. This process should engage CMOs (or CSAs for other emergencies) and should be included in a revised Concept of Operations by summer 2011.

17. The use and release of planning assumptions has been brought to my attention. There was some unease about how reasonable the 'reasonable worst-case' scenarios were. Also, the public release of planning assumptions, although necessary for emergency planners and those in public health organisations, caused confusion as they were immediately taken to be predictions rather than planning figures. There is recognition from many interviewees that these should be dealt with differently in the future.

**RECOMMENDATION 11:** The Government Chief Scientific Adviser and UK health departments should convene a working group to review the calculation of planning scenarios and how they are used in public. This should report by April 2011.

18. There was frustration that advice from the Joint Committee on Vaccination and Immunisation (JCVI) was channelled through SAGE before presentation to ministers. I consider the SAGE challenge function to be a critical one, but in future the JCVI may need to advise ministers on vaccination more rapidly.

**RECOMMENDATION 12:** The Joint Committee on Vaccination and Immunisation should report directly to the central emergency meetings in a future pandemic, although the Scientific Advisory Group for Emergencies should be used at the appropriate time to provide its challenge function. This should be clarified in a revised *COBR Response Guide for Pandemic Influenza* by summer 2011.

19. I heard that the behavioural scientists in the Behaviour and Communication sub-group of the Scientific Pandemic Influenza Advisory Committee (SPI-B&C) were not used as effectively as they might have been. There should be a concerted effort to build relationships between SPI-B&C and DH policy and communications teams so that SPI-B&C's expertise can be used in planning for vaccine uptake and other policy issues where a behavioural approach can pay dividends.

**RECOMMENDATION 13:** The Department of Health should build relationships between the Behaviour and Communication sub-group of the Scientific Pandemic Influenza Advisory Committee (SPI-B&C) and the Department of Health's policy and communications teams so that the SPI-B&C's expertise can be used in addition to in-house resources in planning for vaccine uptake and other relevant policy areas.

20. The transparency of scientific advice should be maximised to build confidence and trust. Factual SAGE papers such as forecasts and estimates of the progress of the pandemic should be made publicly available. This would reduce the news value and impact of isolated publications, such as the planning assumptions, and keep the science separate from the policy debate it supports. In addition, the Government Chief Scientific Adviser (GCSA) should look into identifying respected scientists outside SAGE who could receive technical briefings which would allow them to comment authoritatively on government strategy.

**RECOMMENDATION 14:** Any future Scientific Advisory Group for Emergencies should adhere as closely as possible to the established principles of scientific advice to government and should release its descriptive papers and forecasts (as distinct from any policy advice) at regular intervals. This should be clarified in a revised Concept of Operations by summer 2011.

**RECOMMENDATION 15:** The Government Chief Scientific Adviser should provide expert technical briefings to respected scientists not directly involved with the Scientific Advisory Group for Emergencies. This would enable a wider group of experts to comment in an informed manner on the government's approach.

### **Chapter 5: The containment phase**

- 21. While recognising that it would not be possible to prevent a pandemic from reaching and spreading within the UK, the National Framework sets out a variety of measures that could be taken to slow its initial spread and to learn more about the virus. In many respects, the measures taken during the 2009 H1N1 pandemic followed those that were planned, while other actions were necessarily shaped in response to the emerging circumstances.
- 22. I recognise the hard work of health services and health protection staff across the UK in delivering this part of the response. Many contributors to this Review believe that the steps taken during this period had some impact in slowing the initial spread, although this cannot be demonstrated definitively. However, the phase did allow scientists to gather valuable epidemiological data which was used to advise ministers about the nature of the H1N1 virus when they were considering policy options such as the prioritisation of groups for vaccination.

- 23. The containment phase of the response lasted for longer and consumed more resources than had been anticipated by those responsible for its implementation. There is an opportunity cost in carrying out tasks, such as meeting direct flights from Mexico, using skilled staff who then cannot be doing other work of more benefit in tackling the outbreak.
- 24. Although flexibility was built into the pre-pandemic plans, the adoption and maintenance of a common approach to tackling the virus in its early stages, coupled with the unexpected pattern of spread, created practical difficulties in tailoring countermeasures to fit local circumstances. This experience should now be used to inform planning for future pandemics and to ensure that the right balance is struck between central strategic co-ordination, subsidiarity and local flexibility.

**RECOMMENDATION 16:** The Department of Health, working with others through the revision of the National Framework, should explore a more flexible, evidence-based approach to triggering actions during a pandemic than the current WHO phases and UK alert levels. In particular, this work should ensure that clear guidance is set out to enable the rapid adjustment of the prophylaxis policy as more is learned about the nature of the virus. Work to revise the National Framework should be concluded no later than March 2011.

**RECOMMENDATION 17:** The Department of Health, working with others through the revision of the National Framework, should ensure that there is an appropriate balance between local flexibility and UK-wide public confidence in the response. A national strategic approach can and should be compatible with increased subsidiarity and therefore increased variation according to circumstances; triggers agreed and understood on a UK-wide level could be applied flexibly in different geographical areas on the basis of local circumstances. This should be set out in the revised National Framework and published no later than March 2011.

### **Chapter 6: Treatment**

- 25. The UK was well prepared to provide antiviral treatment for an influenza pandemic adequately and rapidly. Sufficient antiviral stocks had been procured and adequate plans were in place to ensure that they could be accessed and distributed effectively to the population. The decision to adopt a different antiviral strategy in each country was entirely comprehensible given the context in which it was made. Appropriate and proportionate measures had to be put in place to ensure that approaches were responsive to the needs of each individual nation at the time. This aim was achieved by implementing strategies that were responsive not just to scientific evidence but also to operational and presentational concerns. The production of an ethical framework to assist planners. strategic policy-makers and healthcare professionals with the ethical dimensions of decisions they would face before, during and after an influenza pandemic - drawn up by an independent body, the Committee on Ethical Aspects of Pandemic Influenza (CEAPI) - was a vitally important step, given the potential pressures on critical care which would therefore have necessitated prioritisation decisions.
- 26. As highlighted throughout this report, flexible and clear plans are essential to the smooth running of a response to an emergency. The National Framework originally set out that the National Pandemic Flu Service (NPFS) would be used across the UK. However, during the H1N1 pandemic this was not needed, and the plan was adapted so that only England used the service. This flexibility should be worked into future planning.

**RECOMMENDATION 18:** The Department of Health and the devolved administrations should agree triggers responsive to the capacity of primary care in the activation and stand-down of the National Pandemic Flu Service at both national and regional levels. These triggers should be set out in the revised National Framework and published no later than March 2011.

27. I have heard from many interviewees in England that the NPFS sufficiently reduced primary care pressure at a time when it was most required. The NPFS was a highly innovative scheme and therefore should be evaluated to incorporate lessons learned into future planning.

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**RECOMMENDATION 19:** The Department of Health should commission an independent evaluation of the National Pandemic Flu Service, covering value for money, risk analysis and any potential for wider application.

28. An expert clinical group, the Swine Flu Critical Care Clinical Group, was established to provide advice on surging critical care capacity in the health services. The group included medical, nursing, pharmaceutical and managerial representatives drawn from across the UK, and I heard that its advice was well received by all four nations. The group has highlighted several areas of focus for any future critical care planning to respond to an influenza pandemic, which should be considered and implemented as appropriate.

**RECOMMENDATION 20:** The four health departments should reflect on the proposals identified by the Swine Flu Critical Care Clinical Group and incorporate them, as appropriate, into the revised National Framework no later than March 2011.

### **Chapter 7: Vaccine**

- 29. Vaccination is widely used in the UK to offer protection against seasonal influenza strains. Vaccination was a key part of the mitigation strategy in the National Framework, as a pandemic-specific vaccine was likely to give long-lasting protection to those who received it. The 2009 H1N1 pandemic was the first where the UK had a specific vaccine available for use while the virus was still causing disease in the nation. This in itself has been a significant achievement for manufacturers, regulators and policy-makers, and reflects in no small part the exceptional level of preparedness the UK has attained.
- 30. DH followed good procurement practice when setting up advance-purchase agreements. There was significant flexibility in the amount the UK could purchase, ranging from 30 million doses to 132 million doses enough to vaccinate the whole UK population with two doses. There was, however, less flexibility once contracts had been signed, with Baxter Healthcare agreeing to a break clause but GSK not being willing to do so. Now that it has been shown that for certain pandemics a

one-dose strategy will suffice, it is important to build as much flexibility as possible into such agreements. I strongly believe that advance-purchase agreements are a valuable tool in the preparedness strategy.

**RECOMMENDATION 21:** The Department of Health should negotiate advance-purchase agreements that allow flexibility over the eventual quantities purchased.

31. To help ministers make decisions about the level of vaccine coverage needed in future pandemics, the JCVI should consider and advise on appropriate vaccination strategies during the planning stage, taking into account behavioural and economic analyses. This advice will allow ministers to see the full range of options when next deciding on levels of coverage.

**RECOMMENDATION 22:** The Joint Committee on Vaccination and Immunisation should be asked to advise on vaccination strategies across a range of scenarios, including severe and less severe pandemic viruses. This advice should incorporate the views of behavioural scientists and economic analysis, and be published in the revised National Framework no later than March 2011.

32. Health professionals in all four nations worked hard to deliver the vaccination programme to those in priority groups. Undertaking negotiations with GPs during the pandemic to ensure that the vaccine could be administered by them was a time-consuming and complex task. In future, this could be done better by negotiating prior to the pandemic, as is done with vaccine procurement, to allow detailed negotiations to take place without the constraints of simultaneously responding to a pandemic.

**RECOMMENDATION 23:** The four health ministers should commission officials to put in place arrangements to ensure the rapid implementation of a vaccination programme during a pandemic. For example, a sleeping contract with GPs and/or other willing providers could be negotiated.

### **Chapter 8: Communications**

- 33. There is strong evidence that the government's communication strategy was successful in building public awareness of pandemic influenza and in supporting critical elements of the response. The strength and reach of the public communications campaigns, and the availability of advice and guidance, were unprecedented.
- 34. There was in general a high level of public awareness and understanding of pandemic influenza. This is important because it facilitates and supports an effective response by promoting preventative strategies such as good hand hygiene and reducing the risks of panic. I would wish to see this built on in the future.

**RECOMMENDATION 24:** The Department of Health and the devolved administrations should explore what more can be done to raise levels of public awareness and understanding about the key characteristics of a pandemic and the core response measures.

35. Although communications materials were in general good, certain terms used during the pandemic were unclear and caused confusion. Given the critical importance of the public clearly understanding the advice being given by government, some of the terminology should be revisited. In particular, 'containment' was used to describe a strategy which was not intended to contain the disease but to slow the spread. 'Reasonable worst case' was also confusing as it was used for a scenario in which each parameter was a reasonable worst case, but when combined they resulted in an increasingly unlikely scenario.

**RECOMMENDATION 25:** The four UK health departments should review their use of language during pandemics to ensure that it accurately conveys the aims of the response efforts and the levels of risk. In particular, the use of the terms 'containment' and 'reasonable worst case' should be reconsidered as they are easily misunderstood. The National Framework and communications strategies should be amended to reflect such revisions by no later than March 2011.

36. The four health departments should seek to build on their success, further explore the potential of digital media and social networking, and look to publish as much information as possible, using independent partners such as the Science Media Centre to engage the wider independent scientific community and the media.

**RECOMMENDATION 26:** The four UK health departments should consider new ways of proactively engaging with both journalists and the public. These could include disseminating transcripts of media briefings, using podcasts and making more use of social networking and digital technology to reach specific sections of the public. The National Framework and communications strategies should be amended to reflect any changes no later than March 2011.

37. The government's media briefings succeeded in keeping the media informed and engaged, helping reporting to remain largely accurate and removing space in which more speculative and alarmist stories could develop. They provide a model for future communications in a long-running crisis, as does the government's openness with journalists.

**RECOMMENDATION 27:** The Cabinet Office should ensure that the communications approach (weekly briefings, Q&A sessions, regular releases of facts and figures) adopted by the Department of Health and the devolved administrations is used, where appropriate, as a model of best practice for future emergency situations.

38. During the H1N1 pandemic, there was a need for rapid, clear and authoritative clinical advice. Interviewees suggested that, in the future, an advice line or secure internet site could help facilitate getting the advice quickly from the centre to front-line clinicians.

**RECOMMENDATION 28:** The Department of Health and the devolved administrations should discuss with professional health bodies how best to create sources of direct clinical advice for health professionals during a pandemic. This may be most appropriately hosted by one or more of the professional bodies.

## Chapter 1: Pandemic influenza and UK preparedness

### Influenza

- 1.1 Pandemic flu: A national framework for responding to an influenza pandemic, published in 2007, provides a basic introduction to influenza pandemics.¹ In summary, the National Framework explains that influenza is an acute infectious viral illness that spreads rapidly from person to person when in close contact. It is characterised by the sudden onset of fever, chills, headache, muscle pain, severe prostration and usually cough with or without a sore throat or other respiratory symptoms. The acute symptoms generally last for about a week, although full recovery may take longer. In most years, seasonal influenza occurs in the UK predominantly during a six- to eight-week period in winter and affects some 5% to 15% of the population.
- 1.2 Although there are three broad types of influenza virus (A, B and C), it is influenza A viruses that cause most winter epidemics (and pandemics). They change (or mutate) very rapidly, which is what keeps them in circulation, and have widely differing effects on those infected. This is why around half of people infected by seasonal influenza will experience no symptoms and most of the other half will suffer at worst a short, unpleasant illness. However, at the other extreme, the very young, older people and those with underlying medical conditions such as heart or chest disease are at risk of serious illness. Without interventions, those in high-risk groups can suffer significant ill health, and a small percentage of those affected die.
- 1.3 By contrast, pandemic influenza occurs when an influenza A virus subtype emerges or re-emerges which is:
  - markedly different from recently circulating strains;
  - able to infect people;
  - readily transmissible from person to person;
  - capable of causing illness in a high proportion of those infected; and

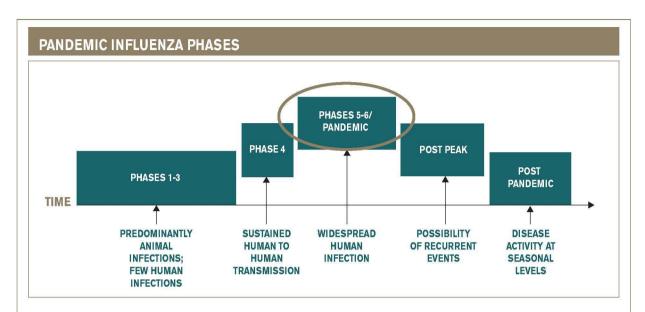
Paragraphs 1.1 to 1.5 summarise pages 16 to 19 of *Pandemic flu: A national framework for responding to an influenza pandemic* 

- able to spread widely because few if any people have natural or acquired immunity to it.
- 1.4 It is generally agreed that there were three pandemics in the 20th century:
  - the 'Spanish flu' outbreak of 1918–19, which is estimated to have caused between 20 million and 40 million deaths worldwide. This pandemic is thought to have had an overall case fatality rate of around 2% of affected persons;
  - the 'Asian flu' of 1957; and
  - the 'Hong Kong flu' of 1968–69.
- 1.5 The latter two pandemics together are thought to have caused between 1 million and 4 million deaths.

### Preparing for a pandemic

### International preparedness

- Given that a flu pandemic is a global health emergency, the role of the World Health Organization (WHO) in preparing for, and responding to, an outbreak is critical. WHO is a potential target for criticism, as its action or inaction can have significant impacts. Following the emergence of a new avian influenza virus (H5N1) in late 2003, WHO raised concerns about the likelihood of another pandemic, which led to active preparations for a pandemic across many countries. Within the European Union (EU), for example, there has been much preparedness activity since 2005, and all member states of the EU as well as the European Commission itself have produced pandemic influenza plans.
- 1.7 WHO has adopted six phases in the evolution of a pandemic (see box):



In nature, influenza viruses circulate continuously among animals, especially birds. Even though such viruses might theoretically develop into pandemic viruses, in **Phase 1** no viruses circulating among animals have been reported to cause infections in humans.

In **Phase 2** an animal influenza virus circulating among domesticated or wild animals is known to have caused infection in humans, and is therefore considered a potential pandemic threat.

In **Phase 3**, an animal or human-animal influenza reassortant virus has caused sporadic cases or small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks. Limited human-to-human transmission may occur under some circumstances, for example, when there is close contact between an infected person and an unprotected caregiver. However, limited transmission under such restricted circumstances does not indicate that the virus has gained the level of transmissibility among humans necessary to cause a pandemic.

**Phase 4** is characterized by verified human-to-human transmission of an animal or human-animal influenza reassortant virus able to cause "community-level outbreaks." The ability to cause sustained disease outbreaks in a community marks a significant upwards shift in the risk for a pandemic. Any country that suspects or has verified such an event should urgently consult with WHO so that the situation can be jointly assessed and a decision made by the affected country if implementation of a rapid pandemic containment operation is warranted. Phase 4 indicates a significant increase in risk of a pandemic but does not necessarily mean that a pandemic is a forgone conclusion.

**Phase 5** is characterized by human-to-human spread of the virus into at least two countries in one WHO region. While most countries will not be affected at this stage, the declaration of Phase 5 is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short.

**Phase 6**, the pandemic phase, is characterized by community level outbreaks in at least one other country in a different WHO region in addition to the criteria defined in **Phase 5**. Designation of this phase will indicate that a global pandemic is under way.

- 1.8 Within the UK, four further alert levels have been identified within WHO Phase 6:
  - 1 Virus/cases only outside the UK
  - 2 Virus isolated in the UK
  - 3 Outbreak(s) in the UK
  - 4 Widespread activity across the UK
- 1.9 The importance of the WHO alert levels is that they trigger particular public health actions, such as the option to purchase vaccines. I discuss this further below.
- 1.10 I should add that the above WHO phases were in fact introduced in April 2009, although I was told they had been under preparation for some time. With one exception, I have not heard that the changes in the pandemic phase descriptions in themselves caused problems for the response. What was more problematic was the degree to which plans were closely linked to WHO pandemic phases, however they were described.

### **National preparedness**

### **The National Framework**

- 1.11 The UK has been preparing for an influenza pandemic for some years. The possibility of the emergence of an avian virus such as H5N1 has been of particular concern. In 2002 the English Chief Medical Officer (CMO) published *Getting Ahead of the Curve: A strategy for combating infectious diseases*, which identified a new pandemic as a particular disease threat.
- 1.12 A new Ministerial Committee on Pandemic Influenza Planning (MISC32) met for the first time in December 2005 'to guide the preparations for a potential influenza pandemic and related international activity'. The committee was supported at official level by the cross-departmental Pandemic Flu Implementation Group. The devolved administrations, while not official members, were fully involved in both ministerial and official-level groups.<sup>2</sup>

New Cabinet committee arrangements for pandemic preparedness following the May 2010 general election have yet to be determined

- 1.13 The Department of Health and the Cabinet Office jointly published Pandemic Flu: A national framework for responding to a pandemic in November 2007. This formed the basis for the 2009 pandemic response. The National Framework represented a refinement of earlier plans, the last of which was published in October 2005. Key features of the National Framework include:
  - plans for a national pandemic flu service to enable symptomatic people to stay at home and have their symptoms assessed and antivirals authorised:
  - sleeping contracts with vaccine manufacturers to purchase enough vaccine to immunise up to 100% of the population, to be triggered by WHO declaring a pandemic;
  - a stockpile of antivirals sufficient to treat up to 50% of the population;
     and
  - clear policies on maintaining open borders and allowing mass gatherings to continue.
- 1.14 The National Framework was informed by a number of exercises to test preparedness, the largest of which was a UK-wide exercise called Winter Willow, held in January and February 2007 and involving over 5,000 people from government, industry and the third sector. This exercise identified a number of lessons, some of which remained issues during the 2009 response, including the distribution of antivirals and the management of excess deaths.
- 1.15 The National Framework covered not only the UK but also the UK's 14 overseas territories. The 14 overseas territories are a government-wide responsibility and the UK has given a firm commitment to assist them in emergencies. While most powers, including provision of healthcare, are devolved to the territories, the UK retains responsibility for good governance, defence and external relations, and for assisting them in the event of an emergency such as a pandemic. In the event of a severe pandemic, the UK is likely to be required to take both operational and legislative action in relation to the territories.
- 1.16 The scale of the preparations reflected the fact that an influenza pandemic was identified as a key risk facing the UK; indeed, in 2008 it was rated as the top risk facing the country in the first publicly available National Risk Register.

### Value for money

- 1.17 Underpinning the procurement of the stockpiles of countermeasures such as vaccines and antivirals was an economic case, which included a robust assessment of the value for money of public expenditure. The outline business case, which set out the overall value for money of the programme, was supported by a series of full business cases that set out a more specific assessment of each of the components of the programme.
- 1.18 As value for money is part of my terms of reference, I asked for an economic review of the business cases. The conclusion of that review was that, overall, the methodology used for assessing the value for money of the government's response was robust. Built on scientific assumptions, the economic case used standard appraisal techniques to produce a strong argument that the proposed countermeasures in the outline business case offered good value for money.
- 1.19 Building on these assumptions, the economic case valued the expected benefits of preventing fatalities, hospitalisations and less severe cases of flu using various countermeasures. The appraisal used well-established monetary values (e.g. £1.6 million for saving a life) and estimates of the health costs and lost productivity averted. These benefits were compared with the costs of various countermeasures to produce benefit-cost ratios for the policy options available.
- 1.20 The benefits in the outline business case generally substantially outweighed these costs, indicating that the pandemic flu preparedness programme offered significant value for money, higher than many other types of government policy. This conclusion was, however, dependent on a number of important assumptions, particularly about the number of fatalities prevented in a severe outbreak. Based on what we now know about the relatively mild nature of this outbreak, the actual benefits were lower. This raises two questions. Were the costs of the 2009 response value for money? And should the government resource the same approach again?

- 1.21 In answer to the first point, it is impossible to know for sure by how much morbidity and mortality were reduced by the countermeasures. The important issue here is that ministers were in a position of decision-making under uncertainty and given the potentially significant risk of huge social and economic costs, there was a strong value-formoney argument underlying the employment of the countermeasures.
- 1.22 As for the second question, given the possibility of a more severe outbreak in the future, the value-for-money case for maintaining substantial preparedness remains sound. It is worth noting, though, that the economic analysis is dependent on the projections on the epidemiology of future outbreaks and how far ministers are prepared to take risks in the public health sphere (a point I discuss further in Chapter 3).
- 1.23 The strength of the value-for-money case does not in itself tell us if the procurement programme was well managed or if the prices paid for its various elements were optimal. However, I heard that the Office of Government Commerce did review the management of the preparedness programme and that there were full public procurements for the countermeasures.

#### The devolved dimension

- 1.24 Each of the devolved administrations has developed its own pandemic preparedness plan, fully consistent with the UK-wide National Framework, to reflect its own particular circumstances
- 1.25 In Scotland, the Scottish Government Resilience Division has responsibility for co-ordinating the response to a pandemic. Planning is overseen by the Cabinet Sub-committee on Civil Contingencies. The Scottish Emergencies Co-ordinating Committee takes forward multi-agency planning, supported by a sub-group on pandemic influenza that brings together directorates from across the Scottish government and responder organisations.

- 1.26 The Cabinet Sub-committee on Civil Contingencies leads the response to a pandemic at a ministerial level, supported by the Scottish Emergencies Co-ordinating Committee. The Scottish Executive Emergency Room acts as a focal point for the co-ordination of government response activity.
- 1.27 In Wales, the Wales Resilience Forum provides the national multiagency overview for pandemic preparedness, with four local resilience fora addressing local multi-agency requirements. The Health and Social Services Directorate has responsibility for health and social care preparedness, with the CMO leading on public health and the use of medical countermeasures. The Welsh response arrangements for a pandemic build on arrangements for managing any national emergency. These arrangements are set out in the Pan-Wales Response Plan, which outlines the response structure, including establishing an Emergency Co-ordination Centre Wales and a Health Response Team.
- 1.28 In Northern Ireland, the Department of Health, Social Services and Public Safety is the lead department for pandemic preparedness and response. The Public Health Agency, which came into existence in April 2009, is responsible for health protection, including emergency preparedness. The Health and Social Care Board is responsible for finance, commissioning and performance management and service improvement for health and social care services, and works closely with the Public Health Agency in areas such as health protection. Finally, there are six provider trusts which are responsible for having robust emergency preparedness plans in place. The Business Services Organisation has responsibility for procurement and stockpiling of non-pharmaceutical products.
- 1.29 It is important to note that these major organisational changes in Northern Ireland came into place on 1 April 2009, just weeks before the outbreak of the pandemic.

- 1.30 The UK has been commended by WHO for the robustness of its preparations for a pandemic.<sup>3</sup> This point was reinforced by the evidence of our interviewees, who repeatedly praised the preparedness of the UK and the thoroughness of its planning.
- 1.31 No plan, however, survives intact its first contact with the enemy and the only predictable characteristic of the flu virus is its unpredictability. The National Framework noted that 'Although an influenza virus with potential to cause a pandemic could develop anywhere, it is most likely to emerge from South East Asia, the Middle East or Africa'. In the event, the first cases emerged in Mexico. Preparations were made to combat the potential emergence of an avian H5N1 virus as a plausible source of the new pandemic, but again this did not prove to be the case. Both assumptions were and remain very reasonable planning assumptions which turned out to be false. The point of mentioning them here is to highlight that any response has to be highly flexible to deal with changing threats.

### The Review

- 1.32 The 2009 H1N1 outbreak was striking in many ways. It was not thank goodness as serious as feared. As noted above, it emerged from a surprising quarter. It had an unusual disease profile. The political context was also new this was the first health crisis in a devolved UK. All these points make it very important to learn lessons about what could be managed better in the event of a future, possibly much more serious, pandemic.
- 1.33 I therefore welcomed the invitation in March this year from the UK health ministers to chair this review of the UK response to the pandemic. My terms of reference are at Annex A, along with the names of the Review Team. The list of contributors to the Review is contained at Annex B. In Annex C I have summarised the overall costs of both preparedness and the response.

<sup>3</sup> For example, 'The UK is still in the vanguard of countries worldwide in preparing for a pandemic, and is also one of the leading global players in addressing the cross-sectoral issues in their planning.' (Dr David Heymann, Previous Assistant Director-General for Health Security and Environment, Representative of the Director-General for Polio Eradication, WHO, November 2007)

1.34 In Chapter 2 I summarise the course of the outbreak and the steps taken at the UK level to combat it, turning in Chapters 3 to 8 to a more detailed exploration of the main themes of the response. In each I reflect on the planning assumptions that were made, what adaptations were made to the plan to address the H1N1 pandemic, and the lessons that can be applied to future planning.

26

## **Chapter 2: Timeline**

Above I described the preparations the UK had made for a pandemic. In this chapter I outline the course of the 2009 outbreak and the steps the UK government and devolved administrations took to respond to it.

### **Outbreak: April 2009**

23 April. Human cases of new swine influenza A/H1N1 virus were

confirmed in Mexico and the USA.

24 April. The World Health Organization (WHO) announced an

outbreak of H1N1 virus in Mexico and the USA.

27 April. WHO raised its alert level to Phase 4 (see paragraph 1.7).

The first two confirmed UK cases of pandemic influenza were reported in a couple who had returned to Scotland from Mexico. Ministers met for the first time in the UK's Civil Contingencies Committee (CCC), under the chairmanship of the then Secretary of State for Health, the Rt Hon. Alan

Johnson MP.

At that stage the information emerging from Mexico was worrying: there had been a total of 149 deaths from 878 reported cases (of which only 18 deaths were as yet confirmed to be H1N1). The Foreign & Commonwealth Office

(FCO) advised against all but essential travel to Mexico.

29 April. The Prime Minister announced to the House of Commons that

the stockpile of antivirals would be increased from 33.5 million to 50 million (covering 80% of the population). The first case in England, that of a schoolchild in Devon, was announced.

The child's school became the first school to be closed.

That evening WHO announced it was raising its alert level

from 4 to 5 (see paragraph 1.7).

30 April.

There had been 91 confirmed cases in the USA, with one confirmed death, while in Mexico there were 730 suspected cases, 26 confirmed cases and 7 deaths. At this point the virus appeared to be mild and self-limiting outside Mexico; the current outbreak seemed likely to be less severe overall than the 1918–19 pandemic, although it had the potential to be worse than the pandemics of 1957 and 1968.

Ministers decided that there was no need, at that point, to advise the public against attending mass gatherings, to restrict domestic transport or to recommend mass closures of schools. Individual schools would take decisions in consultation with the Health Protection Agency (HPA) and the health protection services in devolved countries. Proposals to extend the sickness certification period to 14 days during a pandemic in order to reduce the strain on GPs were agreed in principle, but it was decided that there was no need to implement them at the current time.

That day the H1N1/swine flu information campaign was rolled out on television, radio and in print media, with a booklet in preparation for household delivery. The Swine Flu Information Line was put into operation.

### Containment: May-June 2009

For roughly two months after the emergence of the virus in the UK there was a general policy of containment. This included:

- swabs taken for laboratory testing from individuals suspected of having contracted H1N1;
- antiviral treatment of cases meeting the agreed case definition without waiting for diagnostic confirmation;
- contact tracing, and prophylaxis of close contacts with antivirals;
- closure of schools based on expert advice from relevant health protection organisations;

- self-isolation of cases in the community; and
- detailed investigation of cases and contacts.

The purpose of containment was to slow the spread of the virus for as long as possible and to allow more information to be gained about the virus, including its severity, its transmissibility and those groups at greatest risk.

- 1 May. The first UK case of human-to-human transmission (transmission from someone who had been exposed to the virus outside the UK to someone who had not travelled abroad) was reported.
- 2 May. It was observed that UK cases thus far suggested a milder form of pandemic than the Hong Kong (1968) flu, although the virus could mutate.
- 4 May. 27 UK cases had been reported, including five new cases of human-to-human transmission at a South London school, which had been closed. Ministers decided that the Scientific Advisory Group for Emergencies (SAGE), which was to meet for the first time the next day, should be asked to advise on the government's forward strategy.
- 5 May. SAGE noted that more data from the USA and from clinicians dealing with pandemic flu in the UK was necessary to assess the seriousness of the virus. There was insufficient information to conclude that the virus would only result in mild, self-limiting illness.
- Ministers considered the possibility of purchasing vaccines in advance of the formal declaration of a pandemic (at which point the UK's sleeping contracts for vaccines (advance-purchase agreements) would be triggered). By purchasing an H1N1 vaccine before WHO declared a pandemic (prepandemic vaccine), the UK could build up vaccine stocks sooner and thereby get protection for high-risk groups in advance of any declaration. The purchase of vaccines would need to be in advance of certainty about the science. SAGE would advise further. The triggers for a future move from the current policy of containment to treatment were established.

#### These were:

- clear evidence of sustained community transmission of the virus;
- robust scientific evidence that the virus was no worse than seasonal flu; and/or
- the NHS and the HPA/other health protection organisations were being overwhelmed by the number of cases.
- 8 May. SAGE noted uncertainty about whether two doses of the vaccine were necessary or if a single one would be sufficient, and members recognised that even a vaccine with low efficacy could have a large impact on a pandemic. SAGE recommended that the government purchase H1N1 swine flu vaccine immediately, in advance of greater knowledge of the virus's characteristics.
- 11 May. Ministers decided to procure enough H1N1 vaccine for 45% of the population without waiting for Phase 6 (see paragraph 1.7) and the triggering of the advance-purchase agreements. If and when a pandemic was declared by the WHO, H1N1 vaccine could be purchased for the remainder of the population.
- 14 May. Northern Ireland reported its first laboratory-confirmed case of H1N1. On the same day, ministers decided that the Department of Health (DH) should provide antivirals and vaccines to the UK overseas territories on a cost-recovery basis.
- Agreements were signed for up to 90 million doses of vaccine. The aim was to have the first batches available from August 2009. On the same day, the FCO ceased to advise against all but essential travel to Mexico.
- 19 May. It appeared that the outbreak was a mild disease with a disproportionate number of younger age groups affected. However, data remained incomplete. SAGE's analysis suggested that the mortality rate was likely to be at the lower end of a range between 0.2 and 1.4%.

In discussions about the policy of containment, the HPA said that mass prophylaxis at schools where any pupils were affected should cease, due to significant numbers of children reporting side-effects from antiviral drugs and large numbers not completing the courses. The HPA stopped meeting flights from Mexico, as the outbreak there was no longer of concern.

- 21 May.
- SAGE had recommended that changing policy to more targeted prophylaxis in schools was scientifically robust. Given the onset of the half-term break in England and the possibility of a future spike in number of cases, ministers decided not to change the prophylaxis policy at this point.
- 27 May.
- There was no evidence as yet of widespread community transmission. In addition, people aged over 60 appeared to have a degree of immunity. The worst-case fatality rate was unlikely to exceed 1.5% during the summer, although this could worsen in the autumn.
- 29 May.
- Wales reported its first laboratory-confirmed H1N1 case. There were now confirmed cases across the UK.
- 5 June.
- A UK government reshuffle saw the Rt Hon. Alan Johnson MP moving to the Home Office, to be replaced at DH by the Rt Hon. Andy Burnham MP, who took over as Chair of CCC.
- 10 June.
- It was understood that WHO was on the point of declaring a pandemic. The main impact on the UK would be on vaccine production, as the vaccine manufacturers would move to fulfilling the advance-purchase agreements for pandemic-specific vaccine, meaning that the UK's recent orders for pre-pandemic vaccine would be suspended, and that any production of seasonal flu vaccine would cease.

Ministers agreed that the current containment phase should be moderated, as it was highly labour-intensive and therefore unsustainable. This meant moving away from laboratory testing of all cases, providing antiviral prophylaxis more sparingly, such as limiting prophylaxis in schools to those most at risk of having contracted the virus, and limiting contact tracing to contacts within households and schools only.

# Pandemic declared and the move towards the treatment strategy: June-July 2009

11 June. WHO raised its pandemic alert level from 5 to the highest

level, 6. This triggered the advance-purchase agreements for

vaccines.

15 June. The first death in the UK attributed to H1N1 occurred in

Scotland.

17 June. Cases around the world had reached almost 35,000 in 74

countries, with 163 deaths. Cases in the UK had almost doubled since the previous week to 1,582, with two main concentrations: the Heart of Birmingham Primary Care Trust and the Greater Glasgow area. Although much uncertainty about the data remained, SAGE advised that there was evidence to show sustained community transmission in the West Midlands and also the Clyde Estuary area of Scotland.

Now that WHO had declared the pandemic, a decision was required on activating the advance-purchase agreements. The options for procuring vaccines presented to ministers ranged from 132 million doses, sufficient vaccine to cover 100% of the population (assuming two doses per person and a certain amount of wastage), to no vaccines. Ministers agreed in principle to procure vaccine for 100% of the population, but to seek as much flexibility as possible in contracts with pharmaceutical producers.

DH's Joint Committee on Vaccination and Immunisation (JCVI) met and discussed the priority groups for vaccination. The committee advised that the following groups would be most at risk from H1N1 and should therefore be prioritised for vaccination:

- individuals aged between six months and 65 years in the current seasonal clinical at-risk groups;
- pregnant women in their second and third trimester;

- health and social care workers directly involved in patient care in line with the current seasonal flu vaccination programme; and
- all children aged from 3 to 16 years.

The JCVI agreed that they would want to consider this list again before final decisions were made about the vaccination programme.

18 June.

The four health ministers held a telephone conference to discuss the health-specific aspects of the pandemic response. This was an innovation which was later formalised into a regular meeting over the course of the following months, with health ministers regularly discussing and agreeing health policy issues.

24 June.

With the number of cases climbing steadily, local services in London, Birmingham and Glasgow were under considerable pressure. Ministers agreed that, in principle, once the response moved out of the containment phase, only those in high-risk groups should be treated with antivirals in order to prevent resistance to the antivirals emerging. Clinicians would retain the flexibility to respond to individual needs. The treatment phase should be adopted on a UK-wide basis.

26 June.

Contracts were signed with GlaxoSmithKline and Baxter Healthcare to provide a total of 132 million doses of H1N1 vaccine, sufficient for two doses of vaccine for the whole UK population.

2 July.

The strategy moved into the treatment phase. Cases would be identified through clinical diagnosis, not swabbing, and contacts would no longer be traced. While there was an agreed UK-wide strategy that anyone who had contracted H1N1 would be offered antivirals, GPs would use clinical discretion when prescribing antivirals to patients with coughs and colds, and to the worried well. At this point there were 6,929 laboratory-confirmed UK cases, and almost 1,000 additional clinically confirmed cases. Four deaths and 105 hospitalisations had been reported. The age profile was

different to that of seasonal flu, where the old and the very young made up the majority of admissions.

# The peak of the first wave: July 2009

- 6 July. SAGE endorsed the JCVI's advice of 17 June concerning the priority groups for vaccination and also agreed revised planning assumptions for discussion by ministers.
- 16 July. Ministers agreed that high-risk groups identified by SAGE, as well as front-line health and social care workers, would be vaccinated.

Ministers took the decision to publish the revised planning assumptions calculated by SAGE on 16 July. The key figures indicated that the clinical attack rate could be up to 30% of the population (19 million people), with a complication rate of up to 15% of cases (2.8 million), hospitalisation of up to 2% of cases (380,000) and a case fatality rate of 0.1–0.35% of clinical cases (up to 65,000 deaths).

23 July. A Scottish patient suffering from influenza A/H1N1 who had suffered a rare complication was transferred to Sweden to receive extracorporeal membrane oxygenation (ECMO). All five beds in the UK ECMO unit in Leicester were in use; therefore the transfer to Sweden was made as a result of pan-European arrangements for sharing these scarce facilities.

The National Pandemic Flu Service (NPFS) went live in England. Anyone who indicated relevant symptoms was given a unique reference number allowing them to pick up antivirals, while people in the clinical at-risk groups (including pregnant women) were advised to contact their GP.

The English Chief Medical Officer (CMO) announced plans for a confidential investigation of H1N1 deaths in England. Meanwhile, the four health ministers met face to face in Cardiff for the first formal four nations health group meeting. This forum would continue meeting by telephone conference, escalating issues to the CCC as necessary.

29 July.

By late July yields were lower than those seen with previous virus strains. Ministers were informed of any production problems and took steps to ensure the security of vaccine supply in the UK by purchasing 30 million doses of additional Pandemrix vaccine from GlaxoSmithKline to make up any possible shortfall, bringing the total Pandemrix purchased to 90 million doses. In the event, this volume of vaccine was not required and DH reached agreement with GlaxoSmithKline on 6 April 2010 to only take deliveries of just under 35 million doses of Pandemrix.<sup>1</sup>

# **Preparing for vaccination: August to October 2009**

7 August.

The JCVI discussed the vaccines strategy and the priority groups once more. The committee advised that the following groups should be prioritised for vaccination, once the European Medicines Agency (EMA) had licensed the vaccine, on the grounds that they were at highest risk of severe illness and death:

- individuals aged between six months and 65 years in the current seasonal flu vaccine clinical at-risk groups;
- all pregnant women, subject to licensing considerations;
- household contacts of immunocompromised individuals; and
- people aged 65 or over in the current seasonal flu vaccine clinical at-risk groups.

The JCVI also supported the early use of the vaccine for frontline health and social care workers.

13 August.

Ministers were told that full licensing of the vaccines was likely by the end of September or early October, which meant that the earliest that vaccinations could begin was mid-October.

www.publications.parliament.uk/pa/cm200910/cmhansrd/cm100406/wmstext/100406m0002. htm#10040611000118

There were 13 million people within the priority groups, among whom it was hoped that 75% would accept the call for vaccination. This phase of vaccination could be complete by early December, and could be delivered at the same time as other immunisations such as the seasonal flu vaccine. Ministers endorsed a decision not to delay re-opening of schools after the summer break.

2 September. Ministers agreed further revised planning assumptions. The key changes to the assumptions published in July were the reduction in the hospitalisation rate from 2% to 1% and a reduction in the upper case fatality rate from 0.35 to 0.1%. A second peak was unlikely to occur before mid to late-October. The revised assumptions were published the following day.

An expert clinical group, the Swine Flu Critical Care Clinical Group (SFCCG), was set up to advise on the critical care strategy, which aimed to double critical care capacity since even under the revised planning assumptions capacity could become very stretched.

10 September. The Critical Care strategy was published.

14 September. Agreement with the British Medical Association's (BMA's)
General Practitioners Committee on vaccinating at-risk groups was announced. GPs would receive £5.25 per dose as well as some lessening of the requirements for the Quality and Outcomes Framework in primary care to reflect the additional workload required because of the vaccination programme.

1 October. The four health ministers heard that the GlaxoSmithKline vaccine had been licensed for those over six months and for pregnant women. Ministers agreed to double existing ECMO capacity in line with broader policy on critical care capacity.

7 October. It was announced that the Baxter Healthcare vaccine had been licensed by the EMA.

8 October. The JCVI reconfirmed its previous advice of 7 August concerning the priority groups for vaccination. Once all

those in the priority groups had been offered vaccination, it should be offered to the healthy population. The JCVI advised that a single dose of Pandemrix (the GlaxoSmithKline vaccine) should generally be sufficient for those aged 10 and above, although two doses would be required for the immunocompromised and those below 10 years would require two half-doses of vaccine. Two doses of Celvapan (the Baxter vaccine) would be required for all groups.

- 12 October.
- SAGE slightly updated the revised planning assumptions discussed in late September, but asked for further work to be done on the presentation of the change in planning assumptions. Members also discussed and agreed the JCVI recommendations.
- 14 October.
- The four health ministers agreed that the vaccination programme should start at the same time throughout the UK, while recognising that it would take a week for sufficient quantities to be distributed to all four countries.
- 21 October.
- The vaccination programme began. Increased numbers of cases were reported across the UK. Northern Ireland had experienced several deaths of children attending special schools for severe learning disability and so were treating these children as a priority group for vaccination. The CMOs were asked for advice on phase two of the vaccination programme, including which groups, if any, should next be regarded as priorities for vaccination.

# The second peak: October-November 2009

22 October.

Ministers agreed further revisions to the planning assumptions. The reasonable worst case for the clinical attack rate was reduced from 30% to 12%, and the reasonable worst case for further deaths from 19,000 to 1,000. The revised planning assumptions were published the same day by the English CMO, who was asked to highlight the ongoing severity of the pandemic and the need to avoid complacency.

- 28 October. The four health ministers discussed the CMOs' initial advice on phase two of the vaccination programme and noted that a variety of mechanisms to deliver the vaccine would be appropriate, including GPs, community pharmacies and occupational health services.
- 3 November. At a meeting of SAGE, modellers informed the committee that the published worst-case scenarios looked increasingly unlikely. There was a consensus that many more of the summer cases of H1N1 had been milder than previously estimated, leading to the development of immunity in many people who had mild or even no symptoms.
- 12 November. The four health ministers agreed that there should be a second phase of vaccination targeted initially at children under five years of age, as this group appeared to be suffering the greatest health burden. Poultry workers should be vaccinated at the same time. Carers and other possible priority groups would be considered later. Discussions should begin with the General Practitioners Committee of the BMA on arrangements for vaccinating children under five.
- 18 November. The four health ministers discussed advice from the JCVI (which had met the previous day). The JCVI had stated that there was no epidemiological basis for favouring one group over another for the phase two programme, but agreed that it was reasonable on operational grounds to start the next phase by making vaccine available, on request, to healthy children aged over six months and under five years. It was therefore decided that children under five should be the next priority group. It was agreed that this programme should be delivered by GPs. The case for vaccinating carers was noted, but ministers were concerned about defining the group appropriately.

The same day the CCC met for the last time during the pandemic response and endorsed the health ministers' views. Poultry workers and staff at the Veterinary Laboratories Agency were also added to the priority vaccination list, reflecting the risk of re-assortment with the H5N1 avian influenza virus.

- 19 November. Phase two of the vaccination programme was announced.
- 30 November. SAGE heard from its three groups of modellers: there was a consensus that the pandemic had now effectively peaked. SAGE agreed that the UK would not now reach the reasonable worst case set out in the most recent guidance for planners published on 22 October.

# Post second wave: December 2009 to April 2010

- 2 December. The four health ministers heard that there had been a gradual reduction of cases, but that intensive care admissions remained high. The first phase of the vaccination programme was on track to finish in mid- to late December, with uptake by staff of around 50%. Negotiations with the BMA's General Practitioners Committee on delivering the phase two vaccination programme were proving challenging; ministers decided to put a final offer to the BMA, with a fall-back option to pursue local agreements.
- 10 December. In the light of the failure to reach agreement with the BMA, local agreements were being reached with GP representatives on delivering the vaccination programme on similar terms to the phase one programme. The four health ministers agreed on a definition of carers and decided that if this vaccination was to go ahead it could be delivered through a variety of providers, including but not restricted to GPs.
- 23 December. DH wrote to Baxter Healthcare exercising the contractual break clause to cease supply of Celvapan from 28 February 2010.
- 8 January. The JCVI met and reconfirmed that there was no basis for recommending vaccination of further groups of people. The current programme of vaccinating those in priority groups, and children aged between six months and five years, should, however, be completed.
- 11 January. SAGE met for the last time in this pandemic response.

  Members heard that the UK had had an unusual pandemic profile, with a substantial summer peak in activity, and a smaller increase at the start of the traditional influenza season.

Comparable countries elsewhere in Europe had experienced a single peak beginning seven to ten weeks before the traditional influenza season. The committee agreed that the UK was well past the peak of the second wave of the pandemic, and that no third wave was expected.

- 14 January.
- The four health ministers agreed to suspend deliveries of the GlaxoSmithKline vaccine Pandemrix from 16 January and to enter into negotiations with the supplier over terminating the contract. A variety of options were considered for managing the pandemic flu vaccine stockpile, including donating or selling vaccines to pharmacies, private companies or other countries.
- 21 January.
- The four health ministers reflected on the JCVI's advice not to extend the vaccination programme beyond the current priority groups and asked the JCVI to provide more detailed advice as to whether to make the vaccine available to the general population.
- 4 February.

The four health ministers decided on the basis of further JCVI advice (of 3 February) to continue to vaccinate priority atrisk groups and front-line health and social care workers and pregnant women; and not to vaccinate healthy over-65s. The JCVI advised that there was no scientific justification to extend the vaccination programme to other healthy age groups of the population, although the vaccine could be offered as a travel vaccine. Ministers agreed this advice and decided to set up a strategic reserve of pandemic vaccine amounting to 15 million doses.

A written ministerial statement announced that the NPFS, which had been operating in England only, would be stood down as of 11 February. By the time it closed 2,732,582 assessments had been completed and 1,161,156 courses of antivirals collected.

- 18 March.
- 342 deaths in England related to H1N1 had been recorded, 69 in Scotland, 28 in Wales and 18 in Northern Ireland, giving a UK total of 457.
- 1 April.
- Antiviral medicines were no longer available from national stockpiles, and antiviral collection points in England were closed. The Swine Flu Information Line also ceased, and treatment of people with flu-like symptoms returned to business as usual, with people advised to contact their GP.

# Chapter 3: The central government response

- 3.1 Unlike most emergencies, an influenza pandemic requires significant central government co-ordination over an extended period. The Department of Health (DH) has overall responsibility for preparing for a pandemic and leading the response. Given the expected impact of a severe pandemic on life in the UK, other government departments will also have an important role to play in managing its impact across a wide range of policy sectors.
- 3.2 However, health policy and delivery in the UK are largely devolved responsibilities. The health systems in England, Northern Ireland, Scotland and Wales share core principles, but there are significant differences in the way in which services are delivered across the UK. They are also accountable to different political authorities.
- 3.3 In the case of pandemic influenza preparedness, the four nations of the UK deliberately sought to work within a UK-wide framework. This is not only because a UK response to a novel flu outbreak would be most effective in terms of managing risk and treating the disease for example through collective procurement of antivirals and vaccines but also because, given that infectious diseases do not respect borders, it makes little sense to try to adopt radically different policies across the UK.
- 3.4 In this chapter I explore how the pandemic was dealt with within central government, and how the four nations worked together to deliver tailored but consistent responses. I also focus in particular on one aspect of the pre-pandemic planning managing additional deaths which was, fortunately, not tested, but which could be critical to responding to a more severe pandemic.

# Central government's crisis management arrangements

3.5 The UK government's approach to responding to disruptive challenges is set out in *Responding to Emergencies: The UK central government response – concept of operations* (CONOPS).¹ This provides the generic arrangements, objectives and principles for responding to emergencies, whatever their nature.

www.cabinetoffice.gov.uk/ukresilience/response/ukgovernment.aspx

- 3.6 The response to most emergencies is led locally without central government involvement. Where central leadership is needed, it will fall to the lead government department. Under the 'lead department' principle, specific government departments are identified as being the lead on preparing for, and responding to, particular types of emergency. DH is designated as the lead department for an influenza pandemic.
- 3.7 While one department will be in the lead, other departments will remain responsible for issues that fall within their policy areas. For example, while DH will lead the response to a pandemic, the Foreign and Commonwealth Office will lead on travel advice.
- 3.8 If the situation is serious enough and requires input from other departments, a ministerial committee may meet to provide cross-government co-ordination and strategic leadership. At the time of the pandemic this committee was known as the Civil Contingencies Committee (CCC). It has since been renamed the National Security Council (Threats, Hazards, Resilience and Contingencies).
- 3.9 The committee, and the structures that support it (frequently referred to as COBRA in the media), are the UK government's dedicated crisis management mechanism. While the Home Secretary is the default chair, and the Prime Minister may chair in the most serious of crises, the committee is usually chaired by the lead minister for the type of emergency in question. In the event of an influenza pandemic, the committee would therefore normally be chaired by the Secretary of State for Health.
- 3.10 The committee brings together all the government departments that have a potential role to play in the response. As it is a UK government Cabinet committee, the devolved administrations attend by invitation but are not formal members. Other organisations with a key role may also be invited to attend.

- 3.11 The committee is supported by an official-level committee, known as the Civil Contingencies Committee (Officials) CCC(O) at the time of the pandemic. This is chaired by the Cabinet Office. It provides cross-government co-ordination and prepares advice for ministerial-level meetings.
- 3.12 These arrangements have a long history, but were greatly enhanced following a series of major challenges in 2001, including foot-and-mouth disease, major flooding and widespread protests over fuel prices. The creation of the Civil Contingencies Secretariat within the Cabinet Office, the passage of the Civil Contingencies Act 2004 and the development of the Concept of Operations were important milestones in this process.

### The central response in practice

- 3.13 Human cases of a new influenza virus (H1N1) were confirmed in Mexico and the USA on 23 April 2009. The CCC(O) met for the first time on 26 April, triggered by initial reports of the severity of the disease. The CCC met at ministerial level for the first time on 27 April. The same day, the World Health Organization (WHO) moved its alert phase to 4, indicating sustained human-to-human transmission, and the first cases of H1N1 influenza in the UK were confirmed.
- 3.14 The initial information coming from Mexico suggested that the disease was spreading rapidly and had a high fatality rate. While there were questions around the quality of this data, the decision to call the CCC at this stage was made based on the potential of the new H1N1 strain to have a severe impact on the UK.
- 3.15 The National Framework suggests that the virus could take two to four weeks to reach the UK from its country of origin, but recognises that modern travel might shorten this period and that the virus's early development might not be documented in areas where surveillance is not well developed. The National Framework implies that the UK would probably not see cases until after WHO had moved to alert Phase 6 and declared a pandemic.<sup>2</sup> In practice, the first UK cases

The National Framework sets out four UK alert levels within WHO Phase 6, the point at which a pandemic is declared. UK alert level 1 refers to cases only outside the UK

were confirmed on the day WHO moved to Phase 4, only four days after the virus was first identified in Mexico and the USA. Thus the UK did not, as was hoped, have a number of weeks to prepare before the disease reached its shores and started to spread. Key decisions therefore needed to be made while the nature and implications of the disease were still far from certain.

- 3.16 The CCC met 24 times between 27 April and 18 November 2009. The regularity of meetings decreased as the pandemic progressed and it became more clearly a health issue, from daily for the first four days to monthly by August. The committee was chaired by the Secretary of State for Health, with Andy Burnham MP replacing Alan Johnson MP in this role from 10 June onwards.
- 3.17 Those represented at the CCC were relevant UK government departments, the devolved administrations, the Health Protection Agency (HPA), the Government Office for Science, the Association of Chief Police Officers and the Local Government Association. Over time, departments with a less central interest in the response were represented by officials rather than ministers. The devolved administrations' health ministers were represented at all meetings via a telephone link.
- 3.18 The Chief Medical Officer for England, as the UK government's principal medical advisor and the professional head of all medical staff in England, attended the CCC. His wide-ranging role during the pandemic included advising ministers on policies, interventions and measures to reduce the impact of the disease, providing strategic leadership to medical professionals, and acting as the government's spokesperson in England. The Chief Medical Officers in Scotland, Wales and Northern Ireland also generally attended the CCC by telephone and fulfilled a similar role for their ministers.
- 3.19 The HPA was represented at the CCC to provide advice on the epidemiological and health protection response. The HPA's role during the pandemic included implementing control measures at a local level, national surveillance of influenza, and supplying information to health professionals and the public.

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- 3.20 Throughout the pandemic response, scientific advice was fed into the CCC by the Scientific Advisory Group for Emergencies (SAGE), which first met on 5 May. The UK government's Chief Scientific Adviser, the co-chair of SAGE, attended the CCC. The provision of scientific advice to the CCC is discussed in Chapter 4.
- 3.21 The CCC was supported by meetings of the CCC(O), which met a total of 66 times between 26 April and 18 November and was chaired by the head of the Civil Contingencies Secretariat.
- 3.22 CCC meetings routinely included an update on the current situation, prognosis for the course of the pandemic and discussion of the key preparedness and response issues at the time. Much of the business was understandably focused on health-related issues. These included the nature of the initial 'containment' phase and the move into the subsequent 'treatment' phase alongside the procurement and use of medical countermeasures. The planning assumptions, and proposed changes to them, were also discussed at length.
- 3.23 The committee also considered a range of non-health policy issues that are the responsibility of other departments, including:
  - travel advice to the population;
  - restrictions on mass gatherings;
  - schools closures;
  - handling of additional deaths;
  - possible postponement of elections;
  - sickness certification;
  - international assistance; and
  - advice to Hajj pilgrims from the UK.

- 3.24 There was much useful work done on these issues, and on issues such as the potential need for emergency legislation. This work was not tested during the 2009 pandemic, but will have undoubtedly helped increase preparedness in these areas in the event of a more serious pandemic. I discuss one particular area, the handling of additional deaths, below.
- 3.25 As the pandemic progressed it became clear that the response would be almost exclusively a health one and that it would not require the wider-ranging measures that a more severe pandemic might. By June, more and more time was being spent in the CCC(O) and the CCC on detailed health-specific issues. To help ensure that these largely operational issues were progressed quickly, the four health ministers started to have informal telephone conversations, supported by their chief medical officers (CMOs).
- 3.26 In July ministers agreed to establish a four nations health group, supported by the Cabinet Office, which would discuss operational health issues across the four home nations, escalating issues to the CCC for discussion as necessary. The group was formally recognised as being a sub-group of the CCC, and met, by telephone, 23 times during the pandemic. It was supported by a parallel officials group.
- 3.27 The four nations health groups represented a move to a more explicitly health departments-led model of response once it became clear that other departments represented at the wider CCC meetings had a more limited role to play in the response.

#### **Observations**

#### Planning and uncertainty

3.28 The UK's preparations for responding to an influenza pandemic had been praised by WHO as being among the best in the world. The UK's wider central government crisis management arrangements are tried and tested and have been refined through experience over many years. They have been widely praised and are considered to be world class. The UK centre was therefore well placed going into the pandemic.

- 3.29 However, those faced with leading the central response had to do so from the outset with considerable uncertainty over the nature of the pandemic. The National Framework's planning assumptions spoke of between 55,500 and 750,000 fatalities, and initial information coming from Mexico suggested a high mortality rate. Scientific analysis that would help clarify the severity of the disease would take time to establish, and a range of unpredictable variables, such as the possibility of a mutation of the virus, the development of resistance to antivirals and a significantly more virulent second wave, had to be considered.
- 3.30 The National Framework, and pandemic preparations generally, were impressive. The level of pre-planning meant that the key issues, approaches and necessary decisions were already well sketched out. A wide range of decisions had already been made prior to the pandemic and needed only to be reconsidered and confirmed in the light of circumstances. This included decisions concerning potentially complex issues such as entry and exit screening, mass gatherings and travel restrictions. Key personnel who would lead the response both gained in-depth understanding of the issues and, importantly, were able to build strong working relationships through the planning process. This level of pre-planning was key both to facilitating a rapid response and to reducing pressure on the central decision-making process.
- 3.31 The National Framework provides a strong basis to guide decision-making but needs to be adapted to the circumstances, as was recognised. I heard, for example, that it was developed primarily with avian influenza in mind and was based on the assumption of a severe pandemic. It did not consider sufficiently the possibility that a pandemic might be far less severe than the one it envisioned. The importance of this, not just for decision-making but in setting the tone and direction of the response, should not be underestimated.
- 3.32 Thus I heard that, at times, it had felt as if the response was being tailored to fit what was in the plan, rather than the nature of the virus itself. In other words, there was neither sufficient flexibility over response options nor scalability to tailor the response more closely to the emerging pandemic.

- 3.33 The planned linkage of decision-making to WHO phases proved of little use in practice, given the speed at which the latter changed and their lack of relevance to the UK's experience of the disease. The response rapidly moved away from this approach to take its lead from developments in the UK.
- 3.34 The key decisions that had to be made, such as the movement from 'containment' to 'treatment', the procurement of vaccine and the use of antivirals and vaccine, are explored in detail in subsequent chapters. All are characterised by the absence of unambiguous scientific advice and significant levels of uncertainty. That clear decisions were made in such challenging circumstances is a testament to the effectiveness of the central response machinery.
- 3.35 The spread of pandemic influenza within the UK was far from uniform. Some areas were 'hot-spots' while others were largely unaffected. Some 'hot-spots' saw pandemic-level activity before WHO officially announced a pandemic. Northern Ireland and Wales were affected later, and had a significantly milder disease profile than England and Scotland during the first wave of infection. These developments were unexpected, and the National Framework talks consistently of taking a UK-wide approach to the response. While recognising the devolution settlement, it does not suggest that the response may, for example, be varied within England to reflect differing experiences across the country.
- 3.36 The central government CONOPS enshrines subsidiarity as a fundamental principle of crisis management. That said, I heard that greater local flexibility in responding to the disease may have been desirable. Possible examples I heard included more focused attempts to reinforce primary care in the most affected areas as an alternative to the National Pandemic Flu Service (NPFS) and greater flexibility in the local implementation of containment measures by the HPA. This has to be balanced against the unpredictability of the future spread of the disease and the need for an equitable and consistent response that maintains public confidence.

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- 3.37 I recognise that greater local flexibility could lead to accusations of a 'postcode lottery' if it affected, for example, access to antiviral drugs. This in itself should not rule out such an approach. Indeed, such an approach existed at a national level during the pandemic, given that in England there was not the same level of clinical gatekeeping over access to antivirals as elsewhere once the NPFS was activated with a 'treat all' policy.
- 3.38 The pros and cons of the balance between central control and local flexibility will depend on the circumstances and priorities of any given incident. I discuss and make detailed recommendations on the issue of flexibility of planning in Chapter 5. However, it is important to recognise that there are characteristics of a pandemic which cannot be known in advance and which will take some time to identify clearly. These include its severity, speed and geographical spread.
- 3.39 Planning can be made more flexible, and triggers for moving from one stage of a response to another can be defined in advance to some extent. However, there is still likely to be a period when there is considerable uncertainty over the impact of the disease and its likely development. Improvements to evidence-gathering and the development of scientific advice may help, but decisions will still probably need to be taken at a time when the facts are not fully known.
- 3.40 Against this background, there are two main approaches that are likely to be available to ministers:
  - to assume that the outbreak could potentially be at the high end of planning scenarios in the National Framework (see Chapter 4) and redirect resources to meet that level until evidence emerges that the pandemic is less serious. This will give the best prospect of handling the outbreak, but may involve substantial costs and unnecessary diversion of staff which will affect healthcare elsewhere; or

- to make a series of calculated judgements, based on the available evidence of the likely scale and severity of the outbreak, and resource the response accordingly. This will help to ensure that the response is proportionate, and have lower resource costs in most cases, but will run the risk of the NHS being unable to cope if the outbreak increases in severity more quickly than the response can be adjusted.
- 3.41 To some extent this choice may properly reflect political judgements, in particular about public confidence, but it would be useful to acknowledge from the outset that it exists and to provide both advice and data, especially on the implications of diverting skilled staff and procurement, so that ministers can take the best view.

**RECOMMENDATION 1:** Ministers should determine early in a pandemic how they will ensure that the response is proportionate to the perceived level of risk and how this will guide decision-making. This approach should be reflected in the revised pandemic-specific Concept of Operations by summer 2011.

# Management of the central response

3.42 The central government response operated in line with the UK government's CONOPS. It is fair to say that the 2009 pandemic did not test those arrangements in the way that a more severe pandemic might have done. Some interviewees commented that it might have been possible to reduce the frequency of CCC meetings earlier, and that the pattern of CCC and CCC(O) meetings left little time in between for policy to be refined and actions taken forward. It was also suggested that having daily meetings in the absence of significant new information may have contributed to frustrations about the time taken to deliver clearer scientific advice. While the Cabinet Office might wish to reflect on the frequency of CCC meetings, the crucial issue is getting robust information to help decide whether to scale the response up and/or down. Overall, there was broad satisfaction with the operation of the CCC machinery.

- 3.43 The only significant innovation was the decision to set up a separate forum for the four nations to take forward operational health issues outside the main CCC meetings. It is important to understand that this was the first UK-wide emergency in which the subject matter was largely devolved, creating the risk of inconsistencies in the response between the four nations, and the risk of disagreement between the administrations.
- 3.44 I heard that the four nations worked very closely together, and that despite inevitable tensions there was a great willingness on all sides to resolve problems. Pre-pandemic preparations undoubtedly did a good deal to reduce possible sources of disagreement or tension and to build effective working relationships between both ministers and officials.
- 3.45 Interviewees told me that the Cabinet Office played a pivotal role in ensuring that the response was sensitive to the views of the devolved administrations and that their voices were always heard. The introduction of the four nations health meetings was identified as an important move in helping to speed up decision-making. It was also seen as facilitating a more equal dialogue between the four nations than the wider CCC meetings, at which the devolved administrations took part by telephone rather than being present in the room.
- 3.46 However, there are several areas where I feel improvements could be made.
  - The four nations meetings were an innovation and the concept should be further developed and clarified.
  - The Cabinet Office continued to play the co-ordination role well into 2010, at a point when the four health departments should have been in a position to manage the remaining issues themselves. This suggests that there remains a lingering lack of confidence in the relationships between the health departments.
  - The way in which the devolved administrations take part in meetings held in London is worth reviewing.
  - Resilience of key individuals was a concern.

- 3.47 I take these points in turn.
- 3.48 First, I consider the constitutional position of the four nations meetings within the overall emergency response structure. I understand that the devolved administrations cannot be formal members of the CCC, as it is a UK government committee. The creation of the four nations health group was a pragmatic response to handling what became a health emergency, and was warmly welcomed from ministers downwards. But its very utility, and potential application to other areas of devolved policy, means that its constitutional status within crisis management should be further clarified and spelt out in the CONOPS.<sup>3</sup>
- 3.49 As part of this process, it should be made clear whether the group should be considered part of the central co-ordination apparatus (that is, part of what was the CCC), or part of the lead department arrangements, given that it brings together the lead departments, primarily to discuss issues that fall within their remit rather than that of the wider response. The former would suggest that it may be appropriate for the Cabinet Office to co-ordinate meetings, the latter that this should be the responsibility of the four health departments.

**RECOMMENDATION 2:** The Cabinet Office should enshrine the position of the four nations mechanism for certain types of emergencies in a revised Concept of Operations by summer 2011. The mechanism should then be included in the exercise programme for emergencies in a devolved matter.

3.50 Second, from the discussions I have had I believe that there is a need to build relationships and understanding more widely between the health departments. There is a large agenda of issues that the UK health ministers can profitably address without trespassing on any country's right to manage its health service in the way that it thinks best. There needs to be greater awareness within DH of the implications of working in a devolved world, and a greater willingness within the devolved administrations to invest time and resources in influencing debate in London.

I discuss one aspect of this, the relationship between the devolved administrations and key expert resources, such as SAGE, further in Chapter 4

**RECOMMENDATION 3:** The four health ministers should meet to discuss emergency preparedness (and a range of other issues) at least once a year. Officials should aim to meet face to face more regularly.

3.51 Third, a number (though not all) of interviewees from outside England felt that taking part in meetings by telephone made it very difficult to engage meaningfully in discussions. For my part, I was surprised that video-conferencing was not used. I should make it clear that there was never a bar on devolved administration officials attending meetings in London, and I believe that the devolved administrations need to consider resourcing an embedded presence in London during the lifetime of an outbreak (I return to this point in Chapter 4). However, given that ministers and most officials will inevitably be engaging in discussions remotely, I believe there is sense in reviewing the technological support for ministerial and official-level crisis management meetings.

**RECOMMENDATION 4:** The Cabinet Office should review the technological support available for emergency ministerial and official meetings, to ensure that those joining in meetings remotely can be engaged as fully as possible in the discussion.

3.52 Finally, I explored the issue of personal resilience with a number of interviewees. The response placed a good deal of pressure on many of those playing an important role. To take one salient example, all four CMOs were under considerable pressure, and it would have been very difficult for relevant ministers if one or more CMOs had been unable to continue for any reason. The departments involved will want to assure themselves, as part of their business continuity planning, that the workloads and expectations placed on key individuals are reasonable and sustainable over the course of a long-running response.

**RECOMMENDATION 5:** Departments should consider how best to increase the resilience arrangements for key roles in an ongoing crisis response, including those in charge of the response and committee members, and revise their resilience arrangements accordingly.

# Wider pandemic preparedness: the management of additional deaths

- 3.53 I noted in paragraph 3.23 a number of wider, non-health issues that were part of pre-pandemic planning, but which in the event were untested by the 2009 pandemic. That said, there are important lessons to be learned for future preparedness from the 2009 experience. I will focus here on one area, the management of additional deaths.
- 3.54 The potential for additional deaths (beyond those expected in a normal winter) during an influenza pandemic presented challenges for planners. A large increase in the number of natural deaths in a potentially short period of time would place considerable pressure on local service providers. Local authorities, local resilience fora (LRFs) and other service providers (any private or public organisations involved in the management of deaths) were therefore required to develop plans for this eventuality.
- 3.55 Plans for single mass fatality events were in place in many areas, but a different approach is required during a long-term event such as a pandemic due to the different pressures they exert on responders and other stakeholders.

# Responsibilities for the management of additional deaths during a pandemic

3.56 In England and Wales, planning for the management of additional deaths during a pandemic is carried out at a local level by LRFs. The process involves category 1 responders, including the police, local authority emergency planners and NHS staff, coroners, registrars, funeral directors, and other stakeholders such as cremation and crematoria managers, with a number of central government departments/agencies acting as a source of guidance and expertise.

- 3.57 The Home Office is the lead government department for England and Wales on deaths management planning. The Ministry of Justice is responsible for coroners, cremation certificates and policy on burial and cremation. DH leads on death certification policy, and the General Register Office handles death registration by the bereaved family.
- 3.58 In Scotland, the work is led by the Pandemic Review Group, with the Scottish Emergencies Co-ordinating Committee's Sub-group for Pandemic Influenza acting as a wider network and including representatives of responder organisations. In Northern Ireland, the Pandemic Fatalities Management Sub-group, which sits within the Civil Contingencies Policy Branch under the Office of the First Minister and Deputy First Minister, leads on producing Northern Ireland's plans for the management of additional deaths during a pandemic.
- 3.59 Pre-pandemic planning, led by the Cabinet Office, identified gaps in LRF planning for the management of additional deaths during a pandemic. The provision of additional central guidance, and a National Pandemic Influenza Workshop on 19 May 2008, assisted LRFs in improving their plans for deaths management, but gaps remained. At the time the 2009 influenza pandemic began, most areas were still unprepared for the highest levels predicted, and few more were confident in the medium-case levels.

#### Evidence base and pre-pandemic guidance

3.60 The upper end of possible additional deaths per year from a pandemic was based on an analysis of 20th-century pandemics by a group of experts led by DH. Their work, which was summarised in the scientific evidence base, estimated that the worst-case scenario would result in 750,000 deaths from pandemic flu. This number was adopted by the National Framework as the upper planning assumption. *Planning for a Possible Influenza Pandemic: A framework for planners preparing to manage deaths* was released in May 2008 and was joined by a number of other sector-specific pieces of guidance.

#### **Experience during the 2009 pandemic influenza response**

- 3.61 In May 2009, the Home Office presented to colleagues a rapid assessment of deaths management preparation, which had been gathered from all English and Welsh regions. This revealed a number of issues to be addressed, including engaging with funeral directors, crematoria capacity, the potential impacts on doctors, coroners and registrars and a lack of burial space. Planning for the lower assumption of 55,000 deaths was showing progress, but there were still concerns in some areas. On the medium planning assumption of 210,000–315,000 excess deaths, the overall assessment was that capability gaps existed, and that they would increase as the plans moved towards the upper planning assumption of 750,000.
- 3.62 This was followed by a project to provide local planners with additional support and guidance to help local services and businesses plan for additional deaths. Additionally, central government drafted a series of relevant legislative measures that could be implemented during a pandemic, such as easements to the coronial process and the requirements for death certification. A second capacity assessment was conducted in August, and showed all regions having plans in place to manage the level of H1N1-related death up to 65,000, the 16 July reasonable worst-case planning assumption.
- 3.63 Work continues on deaths planning, and local planners are currently required to prepare by the end of 2010 for the medium-range planning assumption of 210,000–315,000 additional deaths.

#### Observations and recommendations

3.64 A number of interviewees expressed concern that insufficient progress had been made on planning for additional deaths, although there was agreement that much had been achieved in recent months. This is an area of planning that was not tested, but could be in future.

3.65 The worst case in the planning framework is for 750,000 additional deaths. Given pressures on resources, ministers will need to consider whether they wish to make any additional investment required to cope with the full worst-case scenario. I have no recommendation to make on what the correct figure might be for the worst-case scenario, although in Chapter 4 I have recommended that the Government Chief Scientific Adviser convene a working group to review the calculation of planning scenarios. However, I do believe that it would be unsatisfactory if the National Framework implied that government and local responders were prepared to cope with many more thousands of deaths than they were in fact equipped to handle.

#### **RECOMMENDATION 6:** By December 2010:

- (i) Ministers should decide the levels of deaths for which planning is appropriate as part of the process of revising *Pandemic flu: A national framework for responding to an influenza pandemic.*
- (ii) The Home Office, working with others including the Ministry of Justice, the Department of Health, the Cabinet Office, Communities and Local Government and the devolved administrations, should ensure that plans are in place to deal with those levels of deaths during a pandemic, linking with other elements of mass fatality management and specifying clear responsibilities for the collection, transportation, storage and burial or cremation of bodies.

#### Conclusion

- 3.66 The government's central response mechanisms proved effective in supporting and facilitating decision-making in an atmosphere of considerable uncertainty and pressure. The Cabinet Office played a key role in driving decision-making, balancing views and ensuring strong co-ordination.
- 3.67 The willingness of the devolved administrations and DH to work closely together to ensure a consistent UK response was fundamental to the overall success of the response. The opportunity to build on, and strengthen, the close working relationships and understanding that developed between health leads in the four nations during the response should not be missed.
- 3.68 This response was very much a health emergency, but there was much good work done across the range of government business, which should prove essential in the event of a more serious pandemic.
- 3.69 In one area, the management of additional deaths, more work is needed to ensure that the UK is as prepared as it could be for a more severe pandemic (or indeed another emergency that caused large numbers of additional deaths over a considerable period of time).

# **Chapter 4: Scientific advice**

- 4.1 There is a long-standing tradition of governments seeking scientific and medical advice and guidance in order to guide policy. If the situation is serious enough and requires input from other departments, a ministerial committee may meet to provide cross-government co-ordination and strategic leadership. At the time of the pandemic this committee was known as the Civil Contingencies Committee (CCC). It has since been renamed the National Security Council (Threats, Hazards, Resilience and Contingencies) (NSC(THRC)).
- 4.2 The role of the Scientific Advisory Group for Emergencies (SAGE) is to bring together scientific and technical experts to ensure co-ordinated and consistent scientific advice to underpin the central government response. The chair of SAGE, usually the Government Chief Scientific Adviser (GCSA), also sits on the CCC/NSC(THRC). The membership of SAGE varies with the nature of the emergency.
- 4.3 Experience of previous emergencies shows that there can be a variety of different purposes and types of external scientific advice provided, and that clarity over what is required is helpful in producing the best outcome. The most common purposes have been to:
  - provide scientific analysis of an event, to help government understand the nature, scope and relative scale of the issues (often accompanied by an informal tutorial on the underlying science);
  - comment on or validate current policy or proposals emerging from within government, which can range from private informal commentary through to formal endorsement (which can help public confidence in a decision); and
  - generate policy options for responding to or recovering from an event, usually with advice on relative merits or sometimes a recommendation on which policy to adopt. This can be a standing role or a special commission when ministers are uneasy about the current policy or the options provided internally within government, such as during the foot-and-mouth epidemic in 2001.

- 4.4 The type of advice can also vary. There might be:
  - advice based on actual research or scientific evaluation of the basic data or other evidence, such as hard science, usually delivered by a focused team;
  - advice based more on the experience and previous research of the members, usually where data is sparse or uncertain; here valid views can come from a range of backgrounds;
  - unified advice based on collective consideration by the experts involved (usually encouraged in Responding to Emergencies: The UK central government response – concept of operations (CONOPS) for responding to emergencies to help ministers towards rapid decisions, albeit with space for dissent to be recorded); or
  - a variety of views so that ministers can see a range, such as where choices are finely balanced.
- 4.5 Some of the difficulties that led to the revised guidance issued by the government after the Bovine Spongiform Encephalopathy/Creutzfeldt-Jakob Disease (BSE/CJD) controversy and the recent Principles of Scientific Advice to Government<sup>1</sup> arose from lack of mutual understanding of the purpose and types of advice being provided. Being clear about this point is likely to lead to better outcomes; below I explore how far this was achieved on this occasion.

# **Existing guidance**

4.6 The recommended mechanism for provision of scientific advice in the event of an influenza pandemic is detailed in both *Pandemic Flu:* A national framework for responding to an influenza pandemic (the National Framework) (www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_080734) and the UK government's COBR Response Guide for Pandemic Influenza.

<sup>1</sup> Issued by the Department for Business, Innovation and Skills in March 2010

- 4.7 The National Framework provides details of how scientific evidence is assessed before pandemics, and provides guidance on who will be the primary source of critical information at the various trigger points encountered during the pandemic response.
- 4.8 The COBR Response Guide states the following:

'DH [the Department of Health] will lead on presenting scientific issues to meetings of CCC and CCC(O) [the Civil Contingencies Committee (Officials)] and should consider convening SAGE.

'The Government's Chief Scientific Adviser will be a member of CCC and CCC(O), and will confirm the scientific validity of the advice given and will likely sit on SAGE or chair the committee.

'The Chief Medical Officer will convene the UK National Influenza Pandemic Committee to provide independent advice and peer review on proposed response measures, taking into account real-time advice from DH's Joint Committee on Vaccination and Immunisation (JCVI). DH's Chief Scientific Adviser will convene their Science Advisory Group [SAG] (including representatives from the devolved administrations) to provide independent scientific advice and peer review in the development of response measures. The Government's Chief Scientific Adviser may become the Chair of the SAG subject to issues under discussion and availability.

'The Government's Chief Scientific Adviser is ultimately responsible for resolving, with the CMO and DH's Chief Scientific Adviser where possible, any conflicts of view in the scientific community, including external commentators, so that a single source of co-ordinated advice can be presented to Ministers' (Emphasis added)

4.9 Below I explore how far this was followed in practice.

# Providers of scientific advice: the SPI, SAGE, the JCVI and PICO

- 4.10 In 2005, as part of the UK's pandemic influenza preparation, DH established a Scientific Advisory Group on Pandemic Influenza to advise on the scientific evidence base for health-related pandemic influenza policies. In 2008 these arrangements were enhanced by extending the membership to include a wider range of scientific disciplines and by recruiting an independent chair. The group was henceforth known as the Scientific Pandemic Influenza Advisory Committee (SPI).
- 4.11 The scientific disciplines represented in the new advisory arrangements extended to a wider range of scientific disciplines, including traditional infectious diseases-related sciences such as virology and immunology as well as sciences such as risk management, behavioural sciences and diagnostics.
- 4.12 When information began emerging from Mexico about H1N1, consultation took place between the GCSA and the Chief Scientist at DH. It was agreed that SAGE should be activated, drawing its membership from the SPI and other independent experts, and operating under the co-chairmanship of the GCSA and the SPI chair.
- 4.13 I heard that this was the first time that the SAGE machinery had been used in an emergency response. It was inevitable that there would be some teething problems and lessons to be learned during operations.
- 4.14 The memberships of SAGE, the SPI and SPI sub-groups are at Annex D.

# The Scientific Advisory Group for Emergencies

- 4.15 SAGE first met on 5 May 2009 and the final meeting was on 11 January 2010. There were 22 meetings in total, and DH performed the secretariat role.
- 4.16 Meetings covered the progress of the pandemic, with updates from the Health Protection Agency (HPA) on case numbers, surveillance, epidemiology and severity throughout England, and with similar

updates from the devolved administrations. One major role of DH representatives at SAGE was to update the committee on the thinking of ministers and the CCC. DH also provided updates on the National Pandemic Flu Service and vaccine development, licensing and procurement. Data on the international situation was provided principally by DH, the HPA, and the European Centre for Disease Prevention and Control.

- 4.17 During the pandemic, specific advice was requested of SAGE by the CCC and the CCC(O). This included forecasting numbers of cases and deaths, identifying priority groups for vaccination and updating planning assumptions. SAGE therefore provided the range of advice set out in paragraph 4.4 above.
- 4.18 During the pandemic, SAGE was supported by the existing SPI sub-group on Modelling (SPI-M, which became the Modelling and Operational sub-group (SPI-M-O) during the pandemic). Two further sub-groups of the SPI also provided advice during the outbreak: Behaviour and Communication (SPI-B&C) and Clinical Countermeasures (SPI-CC).

# The SPI Modelling sub-group

- 4.19 The remit of the SPI-M is to advise the SPI on all matters relating to the modelling of anticipated aspects of an influenza pandemic and the potential implications for policy decisions. During the pandemic, a reduced membership version of the SPI-M, called the SPI-M-O, was formed according to pre-existing plans. The SPI-M-O reported to SAGE on analysis and forecasts, but also directly responded to particular requests from government departments, in particular DH and the Cabinet Office, continuing its non-response period role.
- 4.20 The SPI-M-O provided, broadly, two types of report to SAGE. The first type of report was the SPI-M-O interpretive statement. This was generally a brief one-page document featuring the sub-group's interpretation of the current information and how such data informed real-time modelling of the pandemic. The second type of report was the SPI-M-O consensus statement on the epidemiology of influenza A(H1N1). This gave information on key parameters (case fatality rate, clinical attack rate, hospitalisations) and the implications of

these numbers for purposes of planning assumptions. Consensus statements were based on emerging epidemiology, as reported through the various surveillance schemes outlined in Chapter 6 and Annex E.

- 4.21 The SPI-M was particularly engaged in revising planning assumptions. Essentially, planning assumptions are descriptions of the types and scales of challenges that organisations should be prepared to respond to and recover from. As such, they are a key part of pre-pandemic planning. They are not necessarily a prediction of how a pandemic may develop.
- 4.22 In September 2008, the SPI-M had produced an updated modelling summary focused on information that would directly influence policy in the event of a pandemic. This included advice on figures to be used in planning relating to clinical attack rates, complication rates, peak illness rates, absence rates, hospitalisation rates and case fatality rates.
- 4.23 On 29 June 2009, SAGE urgently requested that the SPI-M-O provide figures to be used in revised planning assumptions. Updated planning assumptions were released to planners three times through the pandemic (16 July, 3 September and 22 October). These were also made available on the DH website.

# The SPI Behaviour and Communication sub-group

- 4.24 The remit of the SPI-B&C is to advise the SPI on the behavioural and communication science matters relating to the health response to an influenza pandemic. During the pandemic, it was intended that the SPI-B&C would supply this advice to SAGE.
- 4.25 The SPI-B&C provided SAGE with seven briefings between May 2009 and February 2010 on a range of topics, including aspects of vaccination and principles of effective communication.

#### The SPI Clinical Countermeasures sub-group

4.26 During the pandemic, the role of the SPI-CC was to provide advice to SAGE on science and technical matters relating to clinical countermeasures, such as antivirals and antibiotics. In the event, the group met three times. On 15 June, the SPI-CC met to discuss use of antivirals later than 48 hours after onset of symptoms. On 9 July, there was a joint meeting of SAGE, the JCVI and the SPI-CC to discuss issues relating to the vaccination strategy for H1N1. On 11 September, the SPI-CC met to discuss aspects of the management of severely ill patients.

#### The Joint Committee on Vaccination and Immunisation

4.27 The JCVI is a standing advisory committee with statutory responsibilities 'to advise the Secretary of State for Health and Welsh Ministers on matters relating to the provision of vaccination and immunisation services, being facilities for the prevention of illness'. The committee may also provide advice to Scottish and Northern Irish ministers. During the pandemic, JCVI advice on vaccines was, unusually, not given directly to ministers (although the JCVI secretariat did relay the committee's advice at four nations health group meetings), but was routed via SAGE for endorsement. The JCVI chair sat on SAGE during discussions about vaccination.

# The Pandemic Influenza Clinical and Operational Advisory Group

4.28 The work of SAGE and its sub-groups was complemented by the work of the Pandemic Influenza Clinical and Operational Advisory Group's Clinical Sub-group (PICO-CSG). This subgroup of PICO was set up in May 2009 to ensure that UK health ministers and government were provided with expert clinical advice and recommendations to support the health and social care response to an influenza pandemic in the UK. PICO-CSG included representatives of a wide range of branches of medicine whose practitioners might be implicated in the pandemic response, as well as representatives of the nursing profession, and met 18 times during

www.dh.gov.uk/ab/JCVI/DH 094787

the pandemic. The clinical information collected by the Influenza Clinical Information Network (FLU-CIN) was reported to both SAGE and PICO-CSG.

#### **Observations**

4.29 In the Review's discussions a number of issues were raised, which we explore below. However, I would like to stress at the outset, that I heard much praise for the sterling work of the scientists on SAGE and the secretariat. SAGE members were not remunerated for their work, and devoted much time and effort to this role. The secretariat worked extremely hard to provide high-quality papers and support to the committee. (I discuss the implications of this in paragraphs 4.62–4.65, below.) Interviewees have argued that the UK was very fortunate to have the calibre of advice available that it did, and I agree.

#### The balance of advice on SAGE

- 4.30 The use of modelling during an epidemic in order to influence policy was first employed during the foot-and-mouth epidemic in 2001. The use of modelling was a key factor in the decision then to introduce contiguous culling. Modelling was used heavily in developing planning assumptions for pandemic influenza.
- 4.31 The CCC was told at its first pandemic-related meeting on 27 April that modelling capability would be low due to the lack of available data. However, it is clear that modelling the pandemic was seen as a priority. SAGE (and ultimately the SPI-M) was asked to produce forecasts at early stages of the pandemic, and the CCC regularly requested advice on the progression of the pandemic, which involved frequent use of the SPI-M-O.
- 4.32 Information from Mexico was available relatively early following the emergence of H1N1. Some interviewees have commented that the data was of variable quality. In general, the early stages of what was to become the pandemic were characterised by uncertainty regarding various key parameters. Definitive scientific advice was therefore not always available. In a rapidly evolving situation, scientific decisions

may be based on high levels of uncertainty, and this lack of certainty clearly frustrated ministers and policy officials at times. However, interviewees also expressed to me understanding of the problems facing the scientists.

- 4.33 Hard, quantitative science such as modelling had been recognised as a key issue in planning and within the National Framework. Much of this had been based on the fear of an H5N1 (avian) influenza pandemic, which may cause severe illness in many. Modelling also provides easily understandable figures, and because of its mathematical and academic nature may seem scientifically very robust. In light of this, it is understandable that ministers and officials set a great deal of store by modelling.
- 4.34 However, in the context of a less severe pandemic, modelling did not provide early answers. The major difficulty with producing accurate models was the lack of a 'denominator' a relatively accurate idea of the total number of cases. Two factors caused this: the first was the relative mildness of the disease, which meant that many who were infected were asymptomatic and were not picked up during surveillance, and the second was the immunity to H1N1 variants present in large numbers of the population. This made calculating the clinical attack rates and the case fatality rates extremely difficult, which in turn made modelling more challenging than would have been expected in the event of a more severe pandemic. It is fair to say that this was an unexpected development.
- 4.35 However, from the end of the first wave, once sufficient data was available, the modelling provided very accurate figures relating to the second wave. Such forecasts were updated frequently to take account of the new information emerging as the pandemic progressed. These figures were never used publicly, as the focus was still on planning assumptions.
- 4.36 Early and emerging data should always be of some use, but its employment should be carefully managed. This is not to reject the use of models, but to understand its limitations: modellers are not 'court astrologers'. Time spent at SAGE and the CCC to discuss modelling produced using emerging data may have been better spent on other issues.

- 4.37 Interestingly, the use of modelling in informing disease control policy was the subject of a report in 2003 commissioned by Defra<sup>3</sup> in the context of the 2001 foot-and-mouth outbreak. It states that 'The fact that a stochastic model predicts a range of possible "futures", reflecting the unpredictability of real life, means that it must be used with care as a decision support tool. Decision-makers must not rely on the model to make a decision for them but be prepared to use it as part of a process in which other factors, such as the "riskiness" of a policy, are weighed.'
- 4.38 There have been suggestions that ministers would have appreciated the opportunity to explore the thinking of the scientists in more detail. However, this would be unwieldy within CCC meetings, and better undertaken in less formal 'tutorials' between meetings.
- 4.39 Ministers and senior officials should receive training on the strengths and limitations of scientific advice as part of their induction. It may also be helpful if a briefing is prepared during the early stages of a pandemic explaining for the benefit of the CCC and senior officials the limitations of science, and particularly of modelling. This could include what can and cannot be expected of SAGE and the SPI-M, depending on what sort of data may be expected to be available under different scenarios.

**RECOMMENDATION 7:** The Government Office for Science, working with lead government departments, should enable key ministers and senior officials to understand the strengths and limitations of likely available scientific advice as part of their general induction. This training should then be reinforced at the outbreak of any emergency.

4.40 Some interviewees have suggested that a serology programme based on a large, statistically significant section of the population, including those who had not presented with influenza-like illness, would have been beneficial in providing more timely data to inform modelling. There is indeed a wider point that research into more effective early surveillance could pay considerable dividends through facilitating earlier decisions on scaling responses up or down, and thereby avoiding precautionary expenditure.

Review of the use of models in informing disease control policy development and adjustment, a report for Defra by Nick Taylor

**RECOMMENDATION 8:** The four Chief Medical Officers should jointly commission further work to support key decision-making early in a pandemic by January 2011. This should consider the practicalities of developing methods to measure the severity of a pandemic in its early stages. In particular, further exploration of population-based surveillance, such as serology, should be considered.

4.41 I have reflected at length on whether SAGE should contain a broader range of scientific disciplines to help it tackle a future pandemic outbreak. I have concluded that SAGE had a good range of expertise, although the emphasis on modelling as discussed earlier reduced the opportunity for a full contribution by other disciplines.

**RECOMMENDATION 9:** The Government Chief Scientific Adviser and the Department of Health should ensure that there is an appropriate balance of contribution in the Scientific Advisory Group for Emergencies for future pandemic outbreaks.

# The respective roles of the Government Chief Scientific Adviser and Chief Medical Officers

- 4.42 While SAGE was obviously seen by ministers as the major source of scientific advice, it should also be acknowledged that there were other sources of advice available to ministers. Health departments also looked to their Chief Medical Officers (CMOs) and public health agencies to provide advice.
- 4.43 Guidance (see paragraph 4.8 above) suggests that the GCSA should be the final arbiter on the presentation of disputed scientific advice to the CCC. However, a number of interviewees (though not all) expressed concern that this did not always take place, and that the SAGE advice focused on the academic scientific viewpoint the modelling activity to the exclusion of views from those involved in operational epidemiology, such as people dealing directly with clinical cases, who arguably were better able to understand the virulence of the epidemic. On this view, there was therefore a lack of public health challenge to the numbers being provided by modellers, and

- ministers were not presented with sufficiently rounded information that brought together the perspectives of both the modellers and the public health experts.
- 4.44 Several interviewees have suggested that a certain lack of interaction between SAGE and the CMO (England) affected the balance of information being provided to the CCC, notwithstanding that other DH officials were present at SAGE. A symptom of this was the situation in the CCC where the GCSA apprised ministers of the views of SAGE while the CMO (England) was then asked to provide a public health perspective. This led to the CCC being used to iron out differences between, as it were, the modellers and the epidemiologists. This is an inappropriate use of the CCC, which should be using advice as a start point in defining the practical measures to be taken.
- 4.45 I recognise the pressures under which key officials were working. However, there is a strong argument for creating a process which ensures that the perspectives of different branches of science are brought together, and that differences are resolved, if possible, before advice is submitted to ministers. One suggestion has been to install a senior public health expert possibly one of the CMOs or a deputy CMO as co-chair of SAGE, to ensure that ministers do receive a rounded scientific view, although it was widely acknowledged that the existing co-chairing arrangements worked well. The key point is to create a process which would ensure that the views of all CMOs are fully engaged in advance of cross-government crisis management meetings. I turn to this below.

#### The relationship of SAGE to the devolved administrations

4.46 While the interactions between SAGE and DH are relatively clear, I did hear concerns that the relationship between SAGE and departments in the devolved administrations is less so. There appears to have been some confusion about the remit and role of SAGE in this context: the representation on SAGE of the devolved administrations, and the links between SAGE and the Chief Scientific Advisers (CSAs) or equivalents in Scotland, Wales and Northern Ireland. Devolved administrations expressed a wish to be reassured that their officials had had an opportunity to scrutinise relevant scientific advice

in advance of it being presented by SAGE to the CCC, despite the fact that the devolved administrations did have representatives on SAGE.

- 4.47 I explored this point in detail during my discussions. The key concern appears to be that devolved ministers wish to be reassured that their CMOs or other key advisers are engaged in the process of reviewing scientific advice before it is presented to the CCC in other words, to know that when advice is presented to the CCC their perspective has been taken into account. This is an issue that goes wider than pandemic influenza, as there will doubtless be other emergency situations where devolved ministers will wish to be reassured about the process of producing scientific advice.
- 4.48 The influenza pandemic represented the first occasion on which an essentially devolved matter (health) was tested in an emergency response. The opportunity should now be taken, through four nations consultation, to firm up arrangements and identify and correct areas that did not work well. For their part, devolved administrations need to reflect on the resources they need to invest in bodies such as SAGE, including considering locating senior personnel in London for the duration of a response, so that they are best able to brief their ministers effectively on the scientific debate.
- 4.49 As the pandemic progressed, key decisions were more frequently taken at meetings of the four nations health group. It is not explicitly laid out in any guidance how scientific advice should inform this group and, as a result, it is not clear how this group obtained and used scientific advice. This was regarded by all sides as unsatisfactory.

RECOMMENDATION 10: The Cabinet Office, with the Government Chief Scientific Adviser (GCSA) and the four Chief Medical Officers (CMOs), should devise a process through which UK government ministers and the devolved administrations are presented with a unified, rounded statement of scientific advice. This process should engage CMOs (or CSAs for other emergencies) and should be included in a revised Concept of Operations by summer 2011.

## Planning assumptions and the concept of the 'reasonable worstcase scenario'

- 4.50 I discussed the release of planning assumptions and the use of a reasonable worst-case scenario with a number of interviewees. Some have stated that creating planning assumptions based on using the most pessimistic case for all parameters is inappropriate because the likelihood of the eventuality being planned for becomes vanishingly small.
- 4.51 I asked a number of interviewees whether they felt that the term 'reasonable worst-case scenario' was unhelpful, given that it implies a reasonably likely event, rather than one that is extremely unlikely. There was general agreement that the term was unhelpful.
- 4.52 When planning assumptions were released, the CMO (England) took great care in his media briefings to explain that numbers represented reasonable worst-case estimates against which to plan, and not predictions, and a number of journalists did report the figures responsibly. However, this was not always the case, and the impression emerged that the government was 'predicting' 65,000 deaths. This figure was then revised down significantly in the subsequent revisions.
- 4.53 I have heard from several interviewees that the uncertainty inherent in such analysis was not easily understood by, or communicated to, the public.
- 4.54 While the use of the planning assumptions and the caveats were discussed at SAGE and the CCC, no one appears to have argued persuasively for the use of alternative scenarios, although we did hear of doubts from key individuals as to the usefulness of the planning assumptions. The Review is not in a position to make any definitive recommendations on the methodology for calculating worst-case scenarios that should be adopted in future. However, it is clear that there was unease about the approach adopted. There is recognition from those involved that this should be handled differently in future.

4.55 There is a separate issue to be considered about how such planning scenarios are communicated, where the SPI-B&C, health departments' communications specialists and indeed health journalists have much to contribute.

**RECOMMENDATION 11:** The Government Chief Scientific Adviser and UK health departments should convene a working group to review the calculation of planning scenarios and how they are used in public. This should report by April 2011.

#### Advice on vaccination

4.56 SAGE provided advice to the CCC on vaccination, but in effect relied on the JCVI as the statutory body to provide it. I have heard differing views on using SAGE as an extra step before advice on vaccination was presented to ministers. Several interviewees were sceptical about the usefulness of providing an additional hurdle for JCVI advice to clear before being presented to ministers. Others felt that SAGE provided a useful challenge function for JCVI advice. The SAGE challenge function is a critical one, but it should not delay ministers from receiving timely advice on vaccination. In more serious pandemics it will be essential that JCVI advice is available to ministers on a timely basis. This may require the JCVI to meet outside its normal meeting schedule.

**RECOMMENDATION 12:** The Joint Committee on Vaccination and Immunisation should report directly to the central emergency meetings in a future pandemic, although the Scientific Advisory Group for Emergencies should be used at the appropriate time to provide its challenge function. This should be clarified in a revised *COBR Response Guide for Pandemic Influenza* by summer 2011.

4.57 There was general agreement that the SPI-B&C's advice was rarely incorporated into actual advice provided by DH. This was attributed not to a lack of willingness but rather to the pressure DH communications was under to produce communication materials, as well as a lack of continuity in personnel. Advice on maximising vaccination uptake was a particular area where the SPI-B&C's advice

could be profitably sought in future. For their part, the SPI-B&C should in future be mindful of the need to provide rapid advice on specific issues as requested, as the SPI-M-O did throughout the pandemic.

**RECOMMENDATION 13:** The Department of Health should build relationships between the Behaviour and Communication sub-group of the Scientific Pandemic Influenza Advisory Committee (SPI-B&C) and the Department of Health's policy and communications teams so that the SPI-B&C's expertise can be used in addition to in-house resources in planning for vaccine uptake and other relevant policy areas.

#### **Transparency and openness**

- 4.58 The majority of scientific advisory committees regularly communicate their deliberations publicly. Summaries of meetings, minutes and in some cases papers are made available. The Code of Practice for Scientific Advisory Committees states that 'Scientific advisory committees should publish minutes of their meetings.' SAGE is unique as an advisory committee in that it only meets during an emergency. Its workings also differ from most committees. Papers must be turned over rapidly by a temporary secretariat. The committee must meet frequently, and is often asked to give extremely rapid advice on complex issues. Time constraints mean that SAGE membership must in part be decided by the discretion of the GCSA, rather than a more open, competitive process.
- 4.59 I heard much praise for the openness and transparency of the government's approach during the outbreak, but also an enthusiasm for it to go further. I debated this point with scientists both inside and outside SAGE, with officials and with a number of journalists. There was general support for as much openness as possible, but also recognition of the risks. There were concerns raised that releasing SAGE documents would require careful and time-consuming handling, and might put undue pressure on ministers when drawing on scientific advice.

- 4.60 I think it is important to separate, as the Freedom of Information Act does, factual background upon which policy deliberations are based from policy advice itself. It seems to me that there are elements of SAGE's deliberations, most notably the regular updates from the SPI-M on the course of the outbreak (see paragraph 4.20 above), which could usefully be made publicly available once they had been approved by SAGE and submitted to ministers. These would then be a regular source of information to the public which by their very regularity would reduce the newsworthiness of any particular set of figures. Undoubtedly the published figures would vary as the outbreak developed, but this in itself would serve to underline the uncertainty of the science.
- 4.61 One suggestion that I explored was the idea of releasing SAGE papers to a wider group of scientists than that engaged in SAGE, who would be bound by confidentiality but who would have greater freedom to speak to the media. It was put to me that such a group would be able to comment authoritatively on the overall government strategy and give the media greater assurance about the approach being taken, as well as being able to challenge this if necessary and reduce the chance of group-think clouding views. Although sharing actual papers would be very problematic, the same outcome could be achieved by the GCSA giving periodic briefing to scientists.

**RECOMMENDATION 14:** Any future Scientific Advisory Group for Emergencies should adhere as closely as possible to the established principles of scientific advice to government and should release its descriptive papers and forecasts (as distinct from any policy advice) at regular intervals. This should be clarified in a revised Concept of Operations by summer 2011.

**RECOMMENDATION 15:** The Government Chief Scientific Adviser should provide expert technical briefings to respected scientists not directly involved with the Scientific Advisory Group for Emergencies. This would enable a wider group of experts to comment in an informed manner on the government's approach.

#### Resilience

- 4.62 A great deal was asked of SAGE and the SPI sub-groups during the pandemic. Meetings were frequent, and many members contributed papers and other information to the respective groups. Committee members in general had other commitments, and many were under pressure in their day jobs during the period of the pandemic. Members of these groups were not remunerated for the time they gave up to attend meetings during the pandemic.
- 4.63 Certain resilience mechanisms were already in place and worked well. The co-chairing of SAGE was widely seen as effective. SAGE's membership did contain some overlapping expertise, important when certain members were absent.
- 4.64 The secretariat provided to SAGE has been widely praised. Some interviewees have recommended that more resources should be made available to this function in future, as certain key individuals were under considerable pressure. Departments should work to ensure resilience around those individuals with scarce skills.
- 4.65 All interviewees praised the hard work and the amount of time given by those involved in providing scientific advice.

#### Research

- 4.66 Prior to the pandemic, DH's Pandemic Influenza Preparedness Programme had developed a prioritised list of research areas for departmental funding and communication to other funders. In the light of the emergence of H1N1, these priorities were reviewed by scientists from the SPI and the JCVI and considered by SAGE on 9 June. SAGE identified high-priority areas for research, which were commissioned and managed by the National Institute for Health Research Evaluation, Trials and Studies Co-ordinating Centre.
- 4.67 The commissioning and funding of research was done effectively. An open call was issued immediately following the SAGE meeting on 9 June; by 14 August, 14 proposals had been funded with full peer review. I heard that there was a framework in place to obtain ethics approval rapidly. The National Institute for Health Research

had existing networks in place that allowed hospitals to obtain ethics clearance in order to carry out clinical trials. Relevant research was also funded by other bodies, namely the Wellcome Trust and the Medical Research Council.

4.68 By any standards, the research response was an excellent achievement.

#### Conclusions

- 4.69 The efforts of all those involved in the scientific response were praised by the people I interviewed. I can only echo these sentiments.
- 4.70 There were excessive expectations of modelling during early phases when only very limited data was available. Modelling became extremely accurate once better data was available. There is a need to balance such projections with those from operational epidemiology, and a process is required for allowing CMOs and the GCSA to balance the tension between different sources of advice in order to provide a clear view to ministers. This will probably require clarification of SAGE's remit and procedures.
- 4.71 SAGE's processes need to be redefined to ensure that there is adequate opportunity for all CMOs (or CSAs, depending on the emergency) to feed into the advice that is submitted to ministers.
- 4.72 For their part, devolved administrations need to ensure that they are resourcing their response adequately. They should consider embedding senior trusted individuals in London during the pandemic to ensure that the voice of the devolved administrations is heard.
- 4.73 Use of the phrase 'reasonable worst case' should be reconsidered in future. It suggests that the outcome is relatively likely, whereas this is usually quite the opposite.
- 4.74 The GCSA should convene a working group to review the calculation and presentation of worst-case scenarios.

- 4.75 The JCVI should report directly to the central emergency meetings in a future pandemic, although SAGE should be used at the appropriate time to provide its challenge function.
- 4.76 There should be a concerted effort to build relationships between the SPI-B&C and DH policy and communications so that the SPI-B&C's expertise can be used in planning for vaccine uptake and other policy issues where a behavioural approach can pay dividends.
- 4.77 The way in which scientific advice is drawn on by the four nations health group should be defined.
- 4.78 The transparency of scientific advice should be maximised to build confidence and trust. Factual SAGE papers such as forecasts and estimates of the progress of the pandemic should be made publicly available. This would reduce the news value and impact of isolated publications, such as the planning assumptions, and keep the science separate from the policy debate it supports. In addition, the GCSA should look into providing technical briefings for respected individuals outside of SAGE who could comment authoritatively on the government strategy.
- 4.79 More resilience could be embedded into the SAGE structure, which may become more important if a severe pandemic results in members and representatives from the secretariat being unable to attend. Deputies for all members should be considered, particularly in areas where there is no overlap between members (such as behavioural science).

# **Chapter 5: The containment phase**

- 5.1 From 27 April 2009, when the first cases of H1N1 (swine flu) were detected in the UK, until 2 July 2009, the UK implemented a series of measures that were intended to slow the spread and gather data to build a clearer understanding of the virus. This period was referred to as the 'containment phase' of the response.
- 5.2 This chapter examines the pre-pandemic plans for containment and the steps taken during the initial phase of the 2009 H1N1 pandemic influenza response, including areas in which those actions matched or differed from pre-pandemic plans. It concludes by drawing on the experience of the 2009 pandemic to present observations and recommendations for future pandemics.

# **Pre-pandemic planning**

- 5.3 The National Framework sets out a wide range of 'options for mitigating the impact' of pandemic flu in the UK. It states that 'The demands and uncertainties associated with an influenza pandemic require flexible plans based on a combination of strategies to develop an effective and sustainable response. Medical or pharmaceutical countermeasures, combined with public health and personal infection control initiatives, and the possible application of measures to reduce social mixing, form the basis of the UK's mitigation strategy.'
- 5.4 The recommendations set out in the National Framework are underpinned by the scientific evidence base. They emphasise the importance of maintaining flexibility to respond to the nature of the pandemic as it emerges.
- 5.5 The key elements of the planned response during the early stages of an outbreak, set out in the National Framework, are set out below.

#### School closures

- 5.6 The National Framework recognises the likelihood that children could be among the groups worst affected by a flu pandemic owing to their lack of residual immunity from previous exposure to a similar virus and the fact that the flu virus spreads rapidly among those in close contact, including in schools. Children also act as 'super spreaders', as they shed more virus than adults and are less likely to follow rigorous hand and respiratory hygiene measures.
- 5.7 The scientific evidence underpinning the National Framework indicates that there is mixed evidence for the impact of school closures on the course of an influenza pandemic. The effectiveness of such a policy would be influenced by the movements of children in the wider community when schools are closed and their exposure to infection in other settings. Therefore, the National Framework states that plans should be prepared on the basis that some school and childcare closures will be likely; that decisions on whether to advise schools and childcare settings to close can only be made in the light of emerging information as a pandemic develops; and that schools and childcare settings will be advised to close only if it is anticipated that this will produce significant health benefits.

#### International travel, border restrictions and screening

- These aspects of pre-pandemic planning were informed both by the available scientific evidence on the efficacy of such measures and by the practical implications for economic, commercial and social activity of restricting international travel. Scientific evidence indicates that no practical level of travel restriction would prevent the arrival of a pandemic in the UK altogether, and that highly disruptive screening and restriction measures would only serve to delay a pandemic's arrival by a matter of weeks, even if they were over 90% effective.
- 5.9 Weighing the 'possible health benefits that may accrue from international travel restrictions or border closures' against the 'practicality, proportionality and potential effectiveness of imposing them,' the National Framework concludes that 'the Government will keep under review the evidence on the benefits and disadvantages of various approaches'.

5.10 The National Framework does, however, recommend the strengthening of port health vigilance and capacity to ensure that the UK is able to implement any such measures that might be issued by the World Health Organization (WHO), the European Union or other governments.

#### **Domestic travel**

- 5.11 As with international travel, the scientific evidence that informed pre-pandemic planning indicated that the benefits of seeking to restrict internal travel within the UK would be very limited relative to the disruption it would cause. Accordingly, the National Framework states that 'the Government is unlikely to impose any restrictions on internal travel unless it becomes necessary to do so as the pandemic develops for public health reasons, in which case it is likely to be on an advisory basis'.
- 5.12 Supporting messages about minimising non-essential travel, good personal hygiene and staggered journeys would act as personal precautionary measures without disrupting business as usual.

# Mass gatherings

5.13 Recognising that there was little scientific evidence to support the widespread cancellation of large public gatherings as a measure to combat the spread of influenza, the planning assumption set out in the National Framework is that 'the Government is unlikely to recommend a blanket ban on public gatherings. However, informed judgements by the event organiser and/or governing body in conjunction with the regulatory authority may become necessary at the time. If international events are due to be held in the UK with participants from affected areas, the Government may recommend postponement.'

# Prophylactic use of antiviral medicines

5.14 The National Framework recognises the potential for antiviral medicines to be used as a limited measure in the early stages of a pandemic. The underpinning scientific evidence states that

'Although the use of antivirals for limited post-exposure prophylaxis in the very early stages of a pandemic is unlikely to delay the pandemic's arrival in the UK by more than 1-2 weeks (and possibly for much less than this)... by adopting such an approach, valuable epidemiological data will be obtained about the effect of antivirals on household transmission.'

5.15 The National Framework suggests that in place of a generalised strategy of prophylactic medication, a more limited 'household prophylaxis' approach, which would involve treating symptomatic patients and their immediate contacts, may be effective in mitigating the spread of the virus in combination with other measures such as school closures. It notes that any approach involving prophylactic use of antiviral stocks would need to take account of the competing demands of prophylactic and treatment use on those limited stocks during a pandemic.

#### Pre-pandemic surveillance mechanisms

- 5.16 In the UK, influenza activity is monitored throughout the year, with particular focus on the winter season between October and May. There are a number of systems in place that operate throughout the winter flu season which are internationally respected and are used to inform policy and planning. These systems collate data from a variety of sources across the UK in order to:
  - detect as rapidly as possible a rise in influenza activity (such as QSurveillance activity; the Royal College of General Practitioners (RCGP) weekly returns/influenza-like illness (ILI) calls to NHS Direct in England and Wales; NHS 24 in Scotland; and/or the Sentinel Practice Network in Northern Ireland);
  - monitor and characterise the nature of influenza activity (such as calls to NHS Direct in England and Wales; calls to NHS 24 in Scotland; and/or the Sentinel Practice Network and out of hours service in Northern Ireland);
  - isolate and characterise the circulating virus (using the national laboratory reporting scheme);

- quantify the burden of the disease (such as RCGP weekly returns in England and Wales);
- provide a baseline of influenza activity (such as QSurveillance activity; RCGP weekly returns; ILI calls to NHS Direct; and the Pandemic Influenza Primary Care Reporting (PIPeR) system in Scotland); and
- report on influenza activity to inform public health policy and guidance.
- 5.17 Information from these surveillance systems is compiled into a weekly influenza report by the Health Protection Agency (HPA) in order to demonstrate the overall level of influenza activity and the burden of the disease for health professionals. Health Protection Scotland (HPS) provided data to the HPA every week for the UK report provided by the English Chief Medical Officer. HPS also maintained and published Scottish H1N1 data weekly on its open website. Further details of UK influenza surveillance mechanisms are given at Annex E.

# **Experience during the 2009 pandemic**

# The decision to adopt a 'containment' approach

5.18 Although the actions taken in the UK during the early stages of the pandemic were labelled 'containment', in reality it was clear from a very early stage that 'rapid containment' as defined by WHO would not be possible since the virus had already spread widely from its point of origin by the time it was first identified. More accurately, these measures could be described as attempts to slow the spread and buy time in order to find out more about the virus through detailed analysis of the first few hundred cases, including its severity, the risk groups and transmissibility. The information gained would assist in the development of the response strategy and facilitate the production of a pandemic-specific vaccine.

- 5.19 The path on which the UK embarked during the early days of the 2009 pandemic influenza outbreak was heavily influenced by the worrying information emerging from Mexico, which indicated the possibility of a severe illness with a high fatality rate. The steps taken following the activation of the Civil Contingencies Committee (CCC) on 27 April should be viewed in that context, recognising the very real need at the time to reassure the public that all necessary steps were being taken to protect against an unknown and potentially dangerous virus.
- 5.20 The approach adopted by the CCC during the containment phase included the following key components:
  - identifying and tracing close contacts of probable and confirmed cases, including those arriving from Mexico, and gathering and recording epidemiological data through swabbing and laboratory testing;
  - initially meeting all direct flights from Mexico in order to ease public concerns, and maintaining a presence in airports during the hours that flights were arriving;
  - giving post-exposure prophylaxis to all close contacts of probable and confirmed cases of H1N1 pandemic influenza;
  - advising on the closure of schools in the event of a probable or confirmed case in a school setting;
  - making information about pandemic influenza available at all ports of entry; and
  - putting in place enhanced surveillance arrangements.
- 5.21 A range of other measures to which the National Framework refers were considered at the outset but were deemed by ministers not to be required, although the situation was kept under review throughout the response. Thus borders were not closed, nor were restrictions placed on international or domestic travel as any possible health benefits of doing so were agreed by ministers to be far outweighed by the adverse impacts and risks involved. Similarly, the UK position that public mass gatherings should continue during a pandemic was confirmed by ministers at the beginning of the outbreak.

- 5.22 The measures adopted during the containment phase were therefore an amalgam of measures explicitly set out in the National Framework (such as the policies on school closures and mass gatherings) with adjustments in certain respects in response to the circumstances at the time (including the policies on prophylaxis, contact tracing and meeting flights from Mexico).
- 5.23 The public health measures taken during the containment phase were led by the relevant health protection authorities in each part of the UK working, where appropriate, with local health bodies and school authorities. Potential cases were identified on the basis of recent travel to affected countries or contact with known or suspected cases within the UK. Suspected cases were assessed, specimens were taken for laboratory testing, and isolation at home was advised (unless their clinical condition warranted hospitalisation). Contacts of cases were traced and offered antiviral treatment as a prophylactic measure. Schools with a confirmed case of pandemic influenza were advised by health protection authorities to close for seven days, the first such closure being that of Paignton College on 29 April 2009. In the school setting, the identification of close contacts was problematic; in many cases, prophylaxis was offered to the whole year group of an infected pupil, or to the whole school. The policy of advising schools with confirmed cases to close continued throughout the containment phase. These closures were generally for one week.
- 5.24 On 6 May, ministers agreed that the containment phase should continue until one or more of the following 'triggers' were met:
  - a. clear evidence of sustained community transmission;
  - robust scientific evidence that the disease was no worse than a seasonal flu; and/or
  - c. the number of confirmed cases was overwhelming operational and NHS resources.

#### Surveillance during the containment phase

- 5.25 The following additional surveillance mechanisms were used during the early stages of the response.
  - The First Few Hundred (FF100) project enhanced the surveillance of cases and close contacts. Epidemiological analysis of information was used to determine the virological and clinical characteristics of the virus, as well as its potential spread and impact, and to provide information on susceptible groups and risk factors. All of this contributed to vaccine deployment decisions.
  - Hospital surveillance of confirmed cases was used to identify and quantify risk factors for severe disease and to assist the detection of emerging changes in the epidemiology of the virus.
- 5.26 During the containment phase, surveillance information was based on collection and analysis of data from confirmed cases of H1N1 gathered through laboratory testing and contact tracing. The focus was on characterising the clinical, epidemiological and virological features of the new disease.

### Adjustments to the containment approach

- 5.27 The UK maintained its initial approach to containment until 19 May 2009, at which point ministers agreed to end the practice of meeting all direct flights from Mexico. A further change was agreed by ministers on 10 June on the basis of evidence from the HPA that the measures were becoming increasingly resource-intensive and of diminishing value as the virus spread more widely. These changes involved:
  - a more limited approach to the use of antiviral prophylaxis, based on a local risk assessment and limited to contacts considered most at risk of contracting the virus;
  - the use of clinical diagnosis (instead of laboratory testing) where there
    was a high probability that cases were positive; and

- school closure decisions continuing to be taken on the basis of local risk assessment, with antiviral prophylaxis in schools limited to contacts considered most at risk of contracting the virus.
- 5.28 The decision to move out of the containment phase and into the treatment phase was made by ministers on 2 July. This meant that thereafter cases would be identified through clinical diagnosis, not swabbing, and contacts would no longer be traced.

#### **Observations and recommendations**

#### The efforts of staff who contributed to the response

- 5.29 It is clear from both the written and oral evidence presented to the Review Team that the containment measures implemented during the early stages of the pandemic required a considerable effort from a great many people.
- The containment phase on which the UK embarked at the end of 5.30 April 2009 was not explicitly planned for - ministers responded to the threat as it emerged, based on the information available at the time, using the National Framework as a guide and taking decisions about specific courses of action. Implementation of the containment approach therefore necessitated the rapid introduction of new and untested delivery mechanisms. In England, the HPA led the response and put in place a new operational model based on co-operation between the HPA and NHS staff through regional Flu Response Centres. The establishment of these centres was not part of the prepandemic plans but was completed swiftly during May in all English regions. Staff in some of the Flu Response Centres were under considerable pressure throughout the containment phase. HPA also put in place a centralised 'flightdesk' service based in the North East which eventually took on responsibility for contact tracing on flights with probable or confirmed cases of pandemic influenza on behalf of Scotland, Wales, Northern Ireland and the English regions.

- 5.31 The Scottish response was led by HPS working in partnership with NHS services, and services in those areas of Scotland most significantly affected were similarly stretched during the containment phase. Although Northern Ireland and Wales had fewer confirmed cases during the early months of the pandemic, follow-up of suspected cases by their respective authorities and arrangements for prophylaxis of contacts was labour-intensive, and services were stretched.
- 5.32 Health protection staff and front-line healthcare services responded quickly to establish new ways of working in order to implement the containment policy, adjusting the approach as necessary to reflect the different circumstances and healthcare arrangements in each nation.
- 5.33 The Review recognises and applauds the dedication and professionalism of all those whose efforts enabled the implementation of the containment phase. The approaches taken in each of the home nations during this period provide a range of experience on which future pandemic planning can build.

## Links between plans and WHO pandemic phases/UK alert levels

5.34 Pre-pandemic plans assumed that certain characteristics of the pandemic would coincide with WHO pandemic phases and UK alert levels, and that corresponding considerations would need to be made and actions taken at each stage. In the event there was no easy fit between WHO phases and the UK experience of the pandemic, rendering some planned actions inappropriate. For example, the Foreign and Commonwealth Office (FCO) had planned to raise its travel advice automatically when WHO phases were announced, but from an early stage it was clear that the planned changes would have been disproportionate to the risks facing travellers. Accordingly, when on 29 April 2009 WHO announced the move to Phase 5, FCO did not automatically implement the planned changes to its travel advice for affected areas, but instead instituted a more pragmatic approach based on the advice of a wide range of experts and the information available at the time.

5.35 The experience of 2009 tested a number of the assumptions on which the UK's pre-pandemic plans had been based. The assumptions that WHO and UK alert levels would serve as triggers for the introduction of specific actions was challenged by the emergence in the UK of a virus that was quicker to arrive, more sporadic in its spread and generally milder in its effects than anticipated.

#### Prophylactic use of antiviral drugs

- 5.36 The widespread use of antivirals as a preventative measure during the early stages of a pandemic had been considered in pre-pandemic planning, but plans for doing so had not been formalised when the 2009 influenza pandemic arrived. Antiviral prophylaxis was the subject of considerable discussion among ministers and officials at the outset and throughout the containment phase.
- 5.37 At the start of the outbreak, when information from Mexico pointed towards a severe and highly virulent illness, the balance of risk and benefit supported the adoption of widespread prophylactic treatment. As more was learned about the virus, and patterns emerged to indicate that in most cases those who were infected experienced only mild symptoms or none at all, the balance of risk and benefit changed, and some experts concluded that the widespread prophylactic use of antivirals, particularly in schools, was no longer appropriate. As early as 19 May, the HPA advised that the policy of antiviral prophylaxis in schools should be adjusted to cover only the closest contacts of suspected or confirmed cases, rather than all possible contacts (which in some cases had meant entire school populations). This was in part a reflection of the evidence that otherwise healthy children had experienced side-effects and of the risk of drug resistance created by high levels of non-compliance with treatment courses. A decision to scale back the use of antiviral prophylaxis was not finally made by ministers until 10 June.

# Continuation of the containment phase and proportionality of the response

- 5.38 The National Framework was designed to prepare the UK for a variety of pandemic scenarios up to and including a reasonable worst case in which the clinical attack rate reached 50% and the case fatality rate reached 2.5%. In late April, the limited information coming from Mexico gave cause for considerable concern, but as the pandemic progressed it gradually became clear that a scenario approaching that scale was unlikely. A number of contributors to this Review have noted that it was difficult to switch from the plan we had predicated on a worse pandemic than that which emerged to a more proportionate response.
- Considerable resources were required during the containment 5.39 phase to maintain a programme of measures that included the laboratory testing of suspected cases, the tracing of contacts and the provision of prophylactic treatment. The Review Team has heard from numerous perspectives that the containment phase was successful in demonstrating a strong, co-ordinated response that maintained public confidence at a worrying and uncertain time, and that it may have helped to slow the initial spread of the virus. But a number of contributors to the Review have also commented that the containment measures remained in place for longer than may have been beneficial. As the pandemic developed and more cases emerged, some experts argued that the measures on which the UK embarked in April had become less appropriate and impractical to maintain. The virus continued to spread in an uneven manner across the UK, with some areas developing 'hot-spots' that placed extreme pressure on frontline health services while others remained largely unaffected. In most cases, but not all, the virus proved to be less severe than the early indications from Mexico had suggested it would be.
- 5.40 Some contributors to the Review have suggested that a containment approach of the type adopted in 2009 is not appropriate at all once the infection has spread beyond its initial geographical focus, given the inevitability that the virus would continue to spread within the community.

- 5.41 Some contributors have commented that, paradoxically, the continuation until July of the containment phase is likely to have been possible only because of the relatively mild nature of the virus; in a more severe pandemic, public health professionals would probably have been overwhelmed more quickly, and resources would have been deployed to treat cases instead of implementing containment measures.
- 5.42 Triggers to move away from containment were agreed at the 6 May CCC meeting. But the Review Team has heard from various perspectives that the concept of 'sustained community transmission' was problematic and was not clearly enough defined or understood. The need for demonstrable scientific evidence that sustained community transmission was occurring placed considerable additional strain on those who were responsible for gathering that information. Some observers have also commented that the very fact that evidence of sustained community transmission was sought in order for ministers to authorise the relaxation of containment measures indicates that ministers were taking detailed operational decisions that might have been more appropriately left to others who were closer to the front line.
- 5.43 This highlights a broader question raised by some contributors to the Review regarding the nature of decision-making during the pandemic and the level at which decisions were taken. In areas with high concentrations of H1N1 cases, public health practitioners reported feeling that, at times, what appeared to them to be the most appropriate course of action to manage outbreaks in their areas was at odds with the national containment policy. Conversely, in areas where the virus was not spreading widely, a move away from the containment approach may have seemed premature.
- 5.44 The National Framework emphasises the importance of flexibility in the response to a pandemic. Some contributors to this Review felt that the adoption of a single UK-wide approach, in which a containment phase was followed by a treatment phase, was a hindrance to flexibility and unhelpful in managing local circumstances. The virus progressed at a different pace and in different ways from locality to locality, so the most appropriate response in each locality was likely to vary. It is important to recognise that the policy for 'hot-spots' was modified in June; the change of policy did not cause problems, but some people commented that this move could have been made earlier.

5.45 An important point to note here is the opportunity cost of adopting a single UK-wide approach: a uniform response across the board can lead to the unnecessary use of resources and a more expensive response than a more tailored, localised strategy.

#### The balance between public confidence and public health measures

- 5.46 The need to reassure the public and maintain confidence is an important factor in decision-making during a pandemic response. Some of the measures adopted during the containment phase, for which there was a limited case on scientific grounds, were of higher value in assuaging public concern. For example, during the early weeks of the response, HPA staff met planes arriving directly from Mexico in order to provide reassurance to travellers and the public in general.
- 5.47 Such measures were not explicitly planned for in advance of the pandemic, were of no real public health benefit, and their implementation placed further burdens on health protection staff.

# **Terminology**

5.48 The label 'containment', although frequently used by ministers and officials during the response, was not strictly accurate. While the Review has not heard evidence to suggest that this misnomer created significant problems, many people have observed that such a term had the potential to raise unrealistic expectations about what could be achieved. Nobody involved in the response argued that the H1N1 virus could be prevented from spreading.

**RECOMMENDATION 16:** The Department of Health, working with others through the revision of the National Framework, should explore a more flexible, evidence-based approach to triggering actions during a pandemic than the current WHO phases and UK alert levels. In particular, this work should ensure that clear guidance is set out to enable the rapid adjustment of the prophylaxis policy as more is learned about the nature of the virus. Work to revise the National Framework should be concluded no later than March 2011.

**RECOMMENDATION 17:** The Department of Health, working with others through the revision of the National Framework, should ensure that there is an appropriate balance between local flexibility and UK-wide public confidence in the response. A national strategic approach can and should be compatible with increased subsidiarity and therefore increased variation according to circumstances; triggers agreed and understood on a UK-wide level could be applied flexibly in different geographical areas on the basis of local circumstances. This should be set out in the revised National Framework and published no later than March 2011.

#### Conclusions

- 5.49 While recognising that it would not be possible to prevent a pandemic from reaching and spreading within the UK, the National Framework sets out a variety of measures that could be taken to slow the initial spread of a pandemic and to learn more about the virus. In many respects, the measures taken during the 2009 H1N1 pandemic followed those that were planned, while other actions were necessarily shaped in response to the emerging circumstances.
- 5.50 Valuable information about the nature of the H1N1 virus was obtained during the early months of the outbreak. Many contributors to this Review believe that the steps taken during this period had some impact in slowing the initial spread, although this cannot be demonstrated definitively.
- 5.51 The containment phase of the response lasted for longer and consumed more resources than had been anticipated by those responsible for its implementation. Although flexibility was built into the pre-pandemic plans, the adoption and maintenance of a common approach to tackling the virus in its early stages, coupled with the unexpected pattern of spread, created practical difficulties in tailoring countermeasures to fit local circumstances. This experience should now be used to inform planning for future pandemics and to ensure that the right balance is struck between central strategic co-ordination, subsidiarity and local flexibility.

# **Chapter 6: Treatment**

- 6.1 This chapter summarises the approaches adopted to treat patients who contracted the pandemic H1N1 virus in the UK, with particular focus on antiviral treatment strategy and distribution of antiviral medicines, as well as the provision of critical care. It analyses the approaches identified in pre-pandemic plans and how these were implemented in the response to the H1N1 pandemic, including the reasons behind any decisions to diverge from pre-agreed treatment strategies. In doing so, it identifies lessons learned for future planning and evaluates whether the decisions taken about treatment strategy were reasonable within the context in which they were made.
- 6.2 By the end of June 2009, sustained community transmission of the virus was being seen in some 'hot-spot' areas of the UK. At the same time, the use of antivirals for widespread prophylaxis and contact tracing was placing considerable strain on front-line health services, and it was becoming clear that this strategy could not be continued indefinitely. This meant that the four health ministers had to re-evaluate the treatment approach towards the H1N1 virus in order to ensure the long-term resilience of the health service.

# Pre-pandemic planning

- 6.3 The use of antiviral medicines to treat seasonal influenza has been shown to reduce the length of symptoms (by around a day) and severity, provided that they are taken within the first 48 hours of onset of symptoms. Although it was impossible to predict the effect that antivirals would have on pandemic flu due to the unknown characteristics of the virus, it was reasonable to assume a similar effect.
- 6.4 It was anticipated that the prompt use of antivirals would benefit individual patients, as well as having a public health benefit by reducing infectivity in patients and therefore lowering the overall clinical attack rate (CAR). By reducing the effects of illness, they would also reduce the economic impact of a pandemic. The National Framework therefore advocated making antiviral medicines available initially to all symptomatic patients.

- Originally, UK antiviral stockpiles provided sufficient coverage for patients in the event of a 25% CAR. Further plans to increase the antiviral stockpile to cover 50% of the population, in line with the National Framework's reasonable worst-case CAR, were announced in November 2007. This decision was taken as a result of lessons learned from Exercise Winter Willow, which demonstrated that the stockpile should be increased to cover a CAR higher than 25% or circumstances where a strain requiring higher dosage levels emerged.
- 6.6 Pre-pandemic planning also recognised that prioritisation of antiviral treatment could be required in the event of a virulent pandemic to protect against the emergence of antiviral resistance. In order to provide further protection in this area, and based upon advice from the Scientific Pandemic Influenza Advisory Committee (SPI), two forms of antivirals were procured: oseltamivir (commonly known as Tamiflu®) and zanamivir (also known as Relenza®).
- 6.7 It was recognised in pre-pandemic planning that face-to-face assessment of each patient at the peak of a severe pandemic would not be feasible and that the introduction of call centres, staffed by call centre workers using a clinical algorithm, could reduce the pressure on primary care. To this end, a contract was signed in December 2008 between NHS Direct, on behalf of the four health departments, and BT plc for the development of a system and web application, known as the National Pandemic Flu Service, to provide patient assessment by telephone and enable distribution of antivirals.
- 6.8 Initial assessment would focus on confirming that the caller had signs and symptoms of influenza, had no indicators of complications, was aged three or over and had been symptomatic for less than 48 hours and that antiviral treatment was not otherwise contraindicated. Should an assessment be successfully completed, callers would be referred to their GP or sent to collect antivirals at a designated centre as appropriate.

# What happened in practice

- On 29 April 2009, the Prime Minister announced in a statement to the House of Commons that the antiviral stockpile was to be increased to provide coverage for 80% of the population. Similar statements were made in the devolved administrations. An antiviral stockpile providing 80% coverage allowed for a CAR of 50%, as well as the use of antivirals for prophylaxis during the early stages of the outbreak. It was recognised that the full stockpile was unlikely to be required for the H1N1 pandemic.
- 6.10 The DH outline business case includes the option to increase the antiviral stockpile to 80%, and presents a value-for-money argument. The Review Team was told that the decision to act on that option was taken following discussions at ministerial level. However, the Review Team has thus far been unable to find a clear record of when the decision to increase the stockpile was taken.
- 6.11 Early surveillance indicated that a number of underlying medical conditions can increase risk of a severe reaction to pandemic influenza. Antiviral at-risk groups were identified at the Scientific Advisory Group for Emergencies (SAGE) on 22 June 2009 and were based on the seasonal flu definition used by the Joint Committee on Vaccination and Immunisation (JCVI) that 'members of an at-risk group are defined as those who are at higher risk of serious illness or death should they develop influenza'. Further detail on antiviral at-risk groups is included at Annex F.
- 6.12 The decision to move to the treatment phase was made by the four health ministers on 1 July 2009 and announced publicly the following day. This meant that cases would be identified through clinical diagnosis rather than swabbing, and contacts would no longer be traced. It was agreed that, at least initially in the treatment phase, patient assessment would be carried out by clinicans supported locally as necessary.

#### Treat all versus at risk

- 6.13 When moving away from the containment phase and into the treatment phase, a key decision had to be made about whether to treat all those with symptoms of H1N1 infection with antivirals, or whether to provide treatment only for those most at risk of developing a severe illness or complications. While scientific evidence in this area at the time was finely balanced, there was a consensus that:
  - antivirals were of most value if given in the first 48 hours after the onset of symptoms;
  - antivirals were of particular benefit to those who were seriously ill;
  - it was not possible to predict with complete accuracy those who would become seriously ill at the onset of illness; and
  - antiviral drugs had a very good safety profile.
- 6.14 The potential for these strategies to increase the level of antiviral resistance was taken into account at ministerial level when discussing possible treatment approaches. Antiviral resistance was also discussed in greater detail by SPI-M, who considered the implications of resistance to oseltamivir (Tamiflu®) during the pandemic and determined the level required to initiate a policy shift towards the use of the secondary stockpile, zanamivir (Relenza®) only, if required.
- Operational Advisory Group (PICO) (PICO-CSG) acted as a source of guidance on issues concerning clinical management. As well as preparing guidance for the four health departments on clinical management of adults, children and pregnant women, PICO-CSG provided advice on a number of specific clinical management issues. These included the use of antiviral prophylaxis in the treatment phase: while the widespread use of antiviral prophylaxis ceased once the UK moved into the treatment phase, such prophylaxis can be of significant benefit to a very small number of individuals who are at high risk of serious illness or complications from influenza and the guidance provided by PICO-CSG helped to promote a consistent clinical approach to this issue.

- 6.16 Opinion at SAGE was finely balanced between a 'treat-all' approach and an approach targeting the at-risk groups. However, the group advised that, on balance, a targeted approach was the sensible way forward, providing that there was scope for local flexibility to enable clinicians to respond to individual needs. It was its belief that while antivirals should be used for treatment of at-risk groups only, treatment of all cases and prophylaxis should not be ruled out in limited circumstances where it was judged to be clinically appropriate at local discretion.
- 6.17 On 24 June 2009, ministers agreed in principle to adopt SAGE advice whereby only those in at-risk groups would receive antivirals during the treatment phase, and that all treatment decisions would be subject to local clinical judgement.
- 6.18 However, the final treatment strategies adopted in each country were not solely guided by scientific advice, which is unsurprising given the lack of a clear consensus. On 2 July 2009, all four nations issued a guidance document<sup>1</sup> outlining a broad UK strategy for the move from containment to treatment which allowed for flexibility between nations. While there were some differences in emphasis between the four countries, there was a common agreement on the need for clinical discretion.
- 6.19 In England, a 'treat-all' approach was adopted, meaning all those with symptoms of 2009 pandemic influenza received antivirals based upon clinical diagnosis, irrespective of risk status. In the devolved administrations, GPs followed advice to prescribe antivirals to those in the groups most at risk of severe illness or complications, and any other individuals based on clinical discretion.

<sup>1</sup> www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 102094

#### Distribution

- 6.20 In England, by the middle of July 2009, GP consultation rates for influenza-like illness (ILI) were increasing rapidly, and anecdotal evidence suggested that primary care was becoming overwhelmed. Increased consultation rates were seen in all strategic health authorities, whereas previously 'hot-spot' areas such as London and the West Midlands had been experiencing the highest levels of activity. By the penultimate week in July 2009, pressure in some areas was equivalent to exceptional levels of seasonal flu circulating during winter months.
- 6.21 While ILI consultation rates in England highlighted the increased pressure on primary care, the number of consultations remained below the threshold for epidemic influenza activity. It must be remembered, however, that ILI consultation rates do not capture the pressure exerted upon GPs by the 'worried well', which a number of interviewees suggested was placing considerable strain on primary care. In addition, NHS Direct was coming under severe pressure on a regional and a national basis, leading to a degradation in its level of performance. On a national basis, calls relating to ILI were four times the normal winter average, with call rates far higher in 'hot-spot' areas such as the West Midlands. Performance suffered significantly, with less than 10% of calls answered in under 60 seconds and 50% of all callers hanging up before their call was answered.
- 6.22 By contrast, the pressure on primary care in the devolved administrations was less intense. In Scotland, while primary care services were not being significantly affected overall, they were experiencing some severe pressure in particular local areas and the Scottish Flu Response Centre (SFReC) was established within NHS 24 on 1 June 2009 to relieve this pressure. In Wales, the threshold for normal seasonal flu activity had yet to be breached, and Northern Ireland was experiencing increased levels of influenza activity, but well within the capacity of primary care to cope.

- 6.23 In order to ease the increased pressure on primary care, the National Pandemic Flu Service (NPFS) was launched in England only on 23 July 2009. Devolved administrations continued to carry out patient assessments and issue antivirals through clinicians. Although the devolved administrations did not find it necessary to use the NPFS when it was launched, there was always the option for them to opt in if required.
- 6.24 Development of the NPFS was not complete at the start of the outbreak, necessitating the development of an interim system. This system supported a 'treat-all' approach only, as the 'at-risk' algorithm was still being developed at the time. This interim system provided an online and telephone self-assessment service to enable large numbers of people to be assessed for pandemic flu and, if required, authorised to receive antiviral medicines. In order to distribute antivirals, over 2,000 antiviral collection points (ACPs) were established across England.
- 6.25 These services used a clinical algorithm to assess whether an individual was eligible for treatment with antiviral medicines. The algorithm and associated protocols were developed with advice from a very wide range of clinical experts, including a number of the Royal Colleges, and expert advisers from remote assessment services (NHS Direct). The algorithm was approved and kept under review by the PICO-CSG.
- 6.26 The NPFS operated in England until 11 February 2010, and over the course of the outbreak 2.7 million assessments were completed and 1.1 million courses of antiviral treatment were distributed. The overwhelming majority of these antivirals were collected within 48 hours, meaning that the service ensured that those requiring medicine were able to access it rapidly. While roughly one in four people were still advised to contact their GP, the NPFS succeeded in providing relief for primary care during the outbreak.
- 6.27 In the devolved administrations, GPs followed advice to prescribe antivirals to those in the groups most at risk of developing a severe illness or complication and any other individuals based on clinical discretion. This approach was similar to the one adopted for seasonal influenza and it minimised the potential effect on the antiviral stockpile, as well as reducing the risk of antiviral resistance developing.

- In Scotland, patients who thought they had flu accessed care by 6.28 contacting their GP or NHS 24. As mentioned above, NHS 24 also established the SFReC to reduce pressure on primary care. This service provided vital information, advice and reassurance to the public and health professionals about the H1N1 virus and how it might affect them. Patients who thought they had flu completed a telephone assessment and appropriate follow-through, including referral back to general practice to arrange the supply of antivirals from NHS board stocks as appropriate. The majority of cases accessed antivirals through the normal primary care route by taking the prescription to a community pharmacy. However, some boards with high numbers of cases set up additional collection points to relieve pressure.
- 6.29 In Wales, pre-existing primary care routes were the preferred vehicle for providing resilience, with telephony and web-based systems being viewed as contingency options. Public messaging sought to minimise non-essential burdens on primary care, advising people to contact their GP only if symptoms were causing concern or if they were in an at-risk group.
- In Northern Ireland, patients who thought that they might have 6.30 pandemic influenza were advised to contact their GP. If the clinician determined that they required antivirals, they followed the normal process and arranged for their prescription to be collected from their GP and taken to their local pharmacy to receive antivirals. Pressure on primary care was further decreased by effective public messaging and the introduction of a public helpline operated by the Public Health Agency.

#### Surveillance

6.31 The move away from containment had a significant effect on the surveillance mechanisms employed to monitor H1N1 activity. Laboratory confirmation of all cases was discontinued in favour of clinical diagnosis, which meant that surveillance information would focus primarily on the geographical spread, trend, intensity and impact of the virus. The discontinuation of routine laboratory testing also meant that, rather than providing an absolute number of confirmed cases, estimated ranges of cases were produced by the Health Protection Agency based on available surveillance information.

6.32 Safety and adverse reactions to antiviral medicines were monitored by the Medicines and Healthcare products Regulatory Agency, which developed a web-based reporting system for use by patients, the public and healthcare professionals wanting to report suspected adverse reactions to these antivirals.

#### **Observations**

#### **Antiviral procurement**

6.33 It is unfortunate that there is no clear audit trail behind the decision to purchase enough antivirals to cover 80% of the population.

### Antiviral strategy and distribution

- 6.34 I recognise the reasons why the four health departments made different decisions about their approach to antiviral treatment and distribution. These decisions reflected the scientific uncertainty at the time, the nature of the pressures each was facing, and the individual operational arrangements in place within each administration. I heard that effective central co-ordination of communications messages significantly reduced the risks associated with this divergence in strategy.
- 6.35 The different antiviral treatment strategies adopted reflected the need for scientific advice to inform decisions but not be used as the sole rationale, given that the advice was so finely balanced. Presentational and operational considerations also needed balancing against scientific ones, since maintaining public, professional and media confidence in the government's response was crucial to actually delivering the response itself.
- 6.36 It is important that future planning incorporates learning from the various responses employed to supplement primary care during the response to the pandemic in order to improve flexibility in this area. I have remarked upon the need for greater flexibility in operational responses in Chapter 5.

- 6.37 In the Review's dicussions, a number of interviewees made the point that the introduction of the NPFS was essential to relieve the pressure on primary care in England, which could have otherwise collapsed in some areas. Despite some initial reservations about the efficacy of a telephone-based triage system, most interviewees felt that it was successful in achieving the aim of reducing primary care pressure and ensuring rapid access to antiviral treatment.
- 6.38 I have heard from a range of English interviewees that the NPFS sufficiently reduced primary care pressure at a time when it was most required. Evidence also suggests that patients were able to access antiviral treatment rapidly, with 97% of those who collected antivirals authorised by the NPFS doing so within 48 hours. But its activation was not without some controversy.

**RECOMMENDATION 18:** The Department of Health and the devolved administrations should agree triggers responsive to the capacity of primary care in the activation and stand-down of the National Pandemic Flu Service at both national and regional levels. These triggers should be set out in the revised National Framework and published no later than March 2011.

6.39 As the NPFS was a highly innovative scheme, it is important that it is thoroughly evaluated to allow learning to be incorporated into future planning.

**RECOMMENDATION 19:** The Department of Health should commission an independent evaluation of the National Pandemic Flu Service, covering value for money, risk analysis and any potential for wider application.

#### Surveillance

6.40 It is worth noting that UK surveillance of influenza activity is internationally respected. The excellent work in this area during the outbreak provided a broad range of evidence upon which policy decisions could be based.

- 6.41 Different antiviral approaches, cessation of routine testing and inherent cultural differences meant that making comparisons between UK countries based on available surveillance data during the outbreak was difficult. For example, I heard that the lack of a single definition for a 'pandemic influenza-related death' prevented direct comparisons between countries.
- 6.42 I have explored the possibility of standardising UK surveillance in interviews during the review process. I recognise that differences in healthcare systems drive aspects of surveillance in each country and that there are, therefore, objective reasons why direct comparisons cannot be made across all areas.
- 6.43 However, it would still be beneficial for the four health ministers to commission further work in this area to provide standardised, high-level surveillance information across the UK to aid any future pandemic response. I am encouraged therefore by the news that the Department of Health has established a working group to review the data collection procedures instigated during the H1N1 (2009) influenza pandemic for the benefit of any future influenza pandemic.

#### Critical care

- 6.44 Pandemic planning had identified demand for critical care beds as a major challenge. In the event of a virus with a 50% CAR, demand might rise up to 110 beds required per 100,000 of the population per week at the peak, which would greatly exceed available capacity. Estimates also suggested that up to 25% of the symptomatic patients who would warrant admission to hospital if sufficient beds were available might require critical care. Under these worst-case planning assumptions, demand particularly for ventilation would exceed available resources rapidly as the pandemic developed, even where all possible local measures to supplement and expand capacity had been implemented.
- 6.45 The Department of Health had issued best practice guidance on increasing critical care capacity in 2005, which was then updated in 2007. The central message was that, during a pandemic, critical care capacity would need to be increased by 100%. It was clear, however, that in the event of the reasonable worst-case scenario, as envisaged

- in the National Framework, demand would still outstrip supply and doubling capacity would not be sufficient to provide the usual standards of care.
- 6.46 With capacity overwhelmed, prioritisation of all patients on an individual basis matched against available resources would become necessary. With this in mind, the Committee on Ethical Aspects of Pandemic Influenza (CEAPI), an independent body set up to advise on the ethical issues arising from an influenza pandemic, produced an ethical framework to assist planners, strategic policy-makers and healthcare professionals with ethical aspects of decisions they would face before, during and after an influenza pandemic. The ethical framework was not designed to address individual clinical decision-making, but was designed to assist healthcare professionals, who would also be guided by their own professional codes of practice, in developing policies on clinical issues. This framework was published in November 2007.

# **Experience during the 2009 pandemic influenza response**

- 6.47 On 1 May 2009, the four health departments issued guidance to the NHS recommending that, in the event of an influenza pandemic, organisations should prepare to double critical care capacity. This guidance reinforced the need to increase critical care capacity by the 100% originally identified in the previously published guidance.
- 6.48 As well as outlining ways to double capacity, these plans sought to outline methods by which healthcare organisations could make the best use of their staffing resources during a surge in demand. In addition, regulatory bodies such as the General Medical Council and the Nursing and Midwifery Council also issued guidance for healthcare staff during the pandemic. This guidance reminded healthcare professionals that they are accountable for their actions and must assure themselves that they are working safely within the scope of their training at all times.
- 6.49 Following the May guidance, health services across the UK worked hard and successfully to increase critical care capacity. By September 2009, ministers heard that arrangements were in place to double capacity, and a critical care strategy outlining the approach to doing

- so was published on 10 September. However, the revised planning assumptions indicated that there could still be demand during the peak weeks of the pandemic for critical care beds over and above this doubling of capacity.
- 6.50 An expert clinical group, the Swine Flu Critical Care Clinical Group (SFCCG), was established in early September 2009 to provide advice on surging critical care capacity and practical issues that may arise during the second wave of the pandemic. The group included medical, nursing, pharmaceutical and managerial representatives drawn from across the UK.
- 6.51 During the pandemic, roughly 10% of hospitalised H1N1 cases required critical care. This rate of admission to critical care, coupled with a CAR significantly below the reasonable worst-case planning assumption of 50%, meant that while critical care services were not significantly overwhelmed as envisaged in pre-pandemic planning, there was pressure on some services. Further detail on critical care admissions is included at Annex G.

# Extracorporeal membrane oxygenation

- 6.52 A particular issue which emerged during the outbreak was the role of extracorporeal membrane oxygenation (ECMO). ECMO is a technique for providing both cardiac and respiratory support to patients whose heart and lungs are very severely diseased or damaged. It is a highly specialised treatment which was still being medically trialled in the UK at the beginning of the pandemic; it is staff-intensive and requires a considerable degree of training for optimal results. Pre-pandemic, ECMO capacity in the UK amounted to five beds available at Glenfield Hospital in Leicester for adult, paediatric and neonatal care, and beds for paediatric and neonatal treatment in Glasgow (four beds), London (three beds) and Newcastle (two beds).
- 6.53 ECMO became the subject of much media interest when a patient was transferred from Scotland to Sweden to receive ECMO treatment. In addition, there were reports that ECMO was being used extensively in Australia to treat patients with H1N1. The SFCCG was therefore asked to advise on the provision of ECMO treatment for critically ill H1N1 patients.

On the recommendation of the SFCCCG, by mid-October 2009 6.54 Glenfield Hospital increased its ECMO capacity from five to eight beds. Further capacity of two beds each was also created at the Royal Brompton and Papworth hospitals, with Glenfield providing support to ensure that extra capacity was provided at a similar standard of care.

# **Committee on Ethical Aspects of Pandemic Influenza**

6.55 The CEAPI met in May, September and December 2009 and reviewed the government's handling of the ethical dimension of the pandemic. The committee declared that it was satisfied with the response.

### Observations and recommendations

- 6.56 Critical care surge planning, in particular the UK-wide co-ordination of ECMO care, was widely praised by interviewees. The excellent work in these areas was a result of the effective working relationships established during the response. It also demonstrated the capability of planners to respond to emerging pressures, as well as the value of high-quality clinical engagement in the form of the SFCCCG, which was an excellent example of cross-UK working.
- 6.57 However, while the increased capacity in these areas meant that there were adequate resources during this response, it must be remembered that H1N1 pandemic influenza was relatively mild. I heard that some intensive care units still came under pressure; that some children had to be treated in adult intensive care beds; and that the lack of isolation rooms in many accident and emergency departments impacted on their effective working and may also have led to increased admissions to general medical wards.
- 6.58 I also heard that the pandemic, while relatively mild, particularly affected certain groups, such as pregnant women, who then required very careful clinical management by obstetricians and critical care consultants. Tragically, despite this excellent care, a number of pregnant women died due to pandemic influenza.

- 6.59 These experiences reinforce the assumption in pre-pandemic plans that further measures will be needed to reduce demand on critical care services and increase the available supply of critical care beds in the event of a more virulent pandemic. Pre-pandemic modelling assumed that 25% of all hospitalised cases would require critical care, and while this was later revised down to 15%, the actual figure was closer to 10%.
- 6.60 Realistically, health services will not be able to provide vastly increased numbers of critical care beds and staff on a permanent basis, although the excellent work of the SFCCCG points to ways to use existing resources as effectively and efficiently as possible during a pandemic. The group has highlighted the following areas of focus for any future critical care planning to respond to an influenza pandemic:
  - Critical care networks should be revisited, and lessons learned about their utility should be incorporated into future planning.
  - Further engagement is needed between health departments, professional bodies and employers to further develop clinical advice and provide support to staff during a pandemic.
  - Lessons learned regarding bed management, triage and surge capacity should be incorporated into future planning and these processes should be well documented and rehearsed.
  - Further consideration should be given to assess the long-term capacity of ECMO treatment as part of a range of treatments for patients in severe respiratory failure.
- 6.61 There is therefore a continuing need to think through how best to put in place surge capacity, particularly in the case of paediatric intensive care.

**RECOMMENDATION 20:** The four health departments should reflect on the proposals identified by the Swine Flu Critical Care Clinical Group and incorporate them, as appropriate, into the revised National Framework no later than March 2011.

- 6.62 I would also highlight the importance of the CEAPI. The fact that the committee had consulted on and approved an ethical framework for the pandemic response well in advance was an important step, given the possible pressures on critical care and therefore the potential for prioritisation decisions to have to be made. It would have been very difficult to reach a consensus over the ethical issues concerned in the heat of a pandemic response.
- 6.63 I did hear the view that more prescriptive guidance on prioritisation decisions would have been welcomed by some clinicians, although I also heard the contrary view that no framework can remove the individual clinical responsibility for such decisions. I welcome the role of the CEAPI and would encourage the committee to reflect on the existing framework in the light of the response to consider what, if any, changes need to be made.

# Conclusions

- 6.64 The UK was well prepared to provide antiviral treatment for an influenza pandemic adequately and rapidly. Sufficient antiviral stocks had been procured and adequate plans were in place to ensure that they could be accessed and distributed effectively to the population.
- 6.65 The decision to adopt different antiviral strategies in each country was entirely comprehensible given the context in which it was made. Appropriate and proportionate measures had to be put in place to ensure that approaches were responsive to the needs of each individual nation at the time. This aim was achieved by implementing strategies which were responsive not just to scientific evidence but also to operational and presentational concerns.
- 6.66 The Department of Health should ensure that the NPFS, an innovative policy, is thoroughly and independently evaluated.

# **Chapter 7: Vaccine**

7.1 This chapter examines the role of vaccine in the response to pandemic flu in the UK. It highlights the pre-pandemic planning undertaken and the way in which vaccine procurement, prioritisation, delivery, administration and uptake was handled by the UK government during the response. It concludes by drawing on the experience of the 2009 pandemic to present observations and recommendations for future pandemics.

# Pre-pandemic planning

- 7.2 Vaccination is widely used in the UK to offer protection against seasonal influenza strains. These vaccines, offered in the UK to those in 'at-risk' groups, contain the three most likely strains to be circulating that season. Production of a pandemic-specific vaccine can only be started once the strain has been isolated, and from that point it takes around four to six months to produce.
- 7.3 Vaccination is one of a suite of countermeasures, including both pharmaceutical countermeasures and personal infection control initiatives, which are set out in the 2007 National Framework. These measures form the basis of a flexible mitigation strategy intended to protect the population from pandemic influenza. The National Framework sets out the issues surrounding pre-pandemic¹ and pandemic-specific² vaccines, but does not set out the amount that should be purchased.
- 7.4 As discussed in Chapter 1, there was a strong economic case for the procurement of vaccine against pandemic flu. The approach to doing this was through the establishment of advance-purchase agreements between the government and pharmaceutical companies for the procurement of vaccine to be developed and delivered in the event of a pandemic.

Pre-pandemic vaccine: procured prior to a pandemic and stockpiled, ready to be deployed before a pandemic occurs but when the risk of a pandemic is high. Pre-pandemic vaccine contains the virus strain experts believe is most likely to be similar to a future pandemic virus. If the pandemic virus matches closely with the vaccine strain, the vaccine would be expected to provide a good level of protection, while poorly matched strains would give far lower levels of protection

<sup>&</sup>lt;sup>2</sup> Pandemic-specific vaccine: procured once a pandemic is declared. Pandemic-specific vaccine is produced using the actual pandemic strain of influenza and therefore would give good protection once available

- 7.5 The UK government started discussing the potential for advancepurchase agreements for pandemic-specific vaccine after the European Agency for the Evaluation of Medicinal Products (EMEA)<sup>3</sup> published guidance in April 2004<sup>4</sup> which allowed vaccine manufacturers to gain an authorisation for a 'mock-up' vaccine ahead of a pandemic occurring. These advance-purchase agreements allow the UK to receive a proportion of the production capacity of a specific company once a Phase 6 pandemic has been declared by WHO. Without advance-purchase agreements there was a real and significant risk that the UK would not be able to secure sufficient vaccine in the event of a pandemic.
- 7.6 Agreeing a procurement deal for pandemic flu vaccine that delivers good value for money is complex. The scale of production required to deliver the quantities of vaccine needed, alongside the obvious technical requirements, limits the number of possible suppliers. The UK government went through a full tendering process in accordance with the procurement regulations for advance-purchase agreements that took into account a range of factors, such as the benefit of splitting the award between more than one supplier and cost. Through this tender process, the UK government was able to agree two advance-purchase agreement contracts for delivering vaccine in July 2007 (GlaxoSmithKline and Baxter Healthcare), maintaining a level of competition and reducing some of the risk in security of supply by having two differing technologies. However, initially there were no break clauses within the advance-purchase agreements, although a break clause was negotiated with Baxter Healthcare at the point of contract amendment in 2009 - immediately after the outbreak of the pandemic. This was not possible with GlaxoSmithKline.

Since 2005, this agency has been known as the European Medicines Agency (EMA)

Committee for Proprietary Medicinal Products, Guideline on Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application (CPMP/VEG/4717/03)

A mock-up vaccine mimics the future pandemic influenza vaccine in composition and manufacturing method. However, as the pandemic virus strain is unknown, the mock-up vaccine contains instead another flu strain that humans have not been exposed to in the past. This enables the company to test its vaccine in preparation for any flu pandemic that may occur in the future by carrying out studies that predict how people will react to the vaccine when the strain causing a pandemic is included

7.7 The advance-purchase agreements allowed the government considerable flexibility on the amount of vaccine to purchase once a pandemic had been declared, from 30 million doses up to 132 million doses, which is an amount sufficient for the whole population to receive two doses of vaccine. The 2007 National Framework and the advance-purchase agreements the UK government had in place with vaccine manufacturers therefore gave ministers both flexibility in the decisions they could make and the best chance of getting vaccine into the UK at the earliest point by having access to the first vaccine produced.

# **Experience during the 2009 pandemic**

# H1N1 pandemic flu - vaccine coverage

- 7.8 The decisions on when to procure vaccine and the quantity required were both important to the UK government's strategy for treatment during H1N1 pandemic flu. These decisions were difficult, as there were several key uncertainties which had to be taken into consideration:
  - Severity and infectivity of H1N1: even in June 2009, uncertainty remained about all aspects of the influenza outbreak, and although data was being collected and analysed, there was little confidence that severity or infectivity could be predicted.
  - Time before vaccine became available: production timescales and the product licence approval process for pandemic-specific vaccine take around four to six months, so vaccine was unlikely to be available until the end of the first wave at the earliest.
  - The size of the first wave of the swine flu pandemic in the UK: at the time the decision needed to be taken, the size of the first wave of infections was not known. It was possible that a substantial proportion of the population could still have been vulnerable to infection by the time the vaccine was available.
  - Vaccination programme: distinguishing those individuals who had already had H1N1 pandemic flu in the context of a large-scale vaccination campaign was likely to be impractical. Vaccination

if previously infected was unlikely to be harmful, and therefore, depending on the developing situation, offering vaccine to everyone could be appropriate.

- Number of doses required for immunity: the best scientific advice available at the time was that two doses of vaccine would be needed for protection. This advice was not changed to one dose being required until new data became available from the vaccine trials in October 2009.
- Vaccine uptake: without knowing the severity or infectivity of the H1N1 pandemic flu, it remained difficult for judgements to be made about the likely uptake rates both for the public and for health and social care workers.

# **Procurement timing**

- 7.9 The advance-purchase agreements already in place were set to be triggered at the declaration of WHO Phase 6. However, during April and May 2009 it was not clear when Phase 6 would be declared. Both GlaxoSmithKline and Baxter Healthcare were in a position to commence production of an H1N1 vaccine ahead of the pandemic declaration. The Scientific Advisory Group for Emergencies (SAGE) was asked a number of questions on 8 May concerning the risks and benefits of procuring H1N1 vaccine before the pandemic was formally declared. SAGE recommended that orders should be placed as early as possible for vaccine.
- 7.10 Ministers considered this advice alongside further information, including contractual issues from the Department of Health (DH) and devolved administrations, and agreed that DH, on behalf of all four nations, should commence negotiations with GlaxoSmithKline and Baxter Healthcare for the supply of a pre-pandemic H1N1 vaccine. This was a supplementary agreement to the advance-purchase agreements, which would be superseded by the advance-purchase agreement if and when a pandemic was declared. These negotiations were still ongoing when the pandemic was declared and so no pre-pandemic vaccine was purchased.

# Quantity of vaccine to procure

- 7.11 As the timing of procurement was being discussed, ministers also started to consider the quantity of vaccine to be purchased. The 2007 National Framework, while recognising that final decisions about the application of any control measures would need to be made 'as the exact nature or impact of the emerging strain of virus becomes evident', nonetheless made clear that the UK's strategy was to secure sufficient vaccine to protect the population as soon as it was available.
- 7.12 The then Secretary of State for Health, Alan Johnson, when announcing the advance-purchase agreements and the National Framework to the House of Commons in November 2007, stated, 'To make sure that the UK has access to a pandemic vaccine I have signed advanced supply agreements with GlaxoSmithKline and Baxter to deliver enough vaccine to cover the entire population'. However, from the context of the National Framework and advance-purchase contracts it appears that final vaccine procurement decisions had not been made prior to the 2009 pandemic flu outbreak.
- 7.13 Ministers were required to come to a decision on the level of coverage needed in order to procure vaccine in time to be useful to the population. Ministers agreed at the Civil Contingencies Committee (CCC) on 11 May 2009 to procure enough pre-pandemic vaccine for 45% of the population to have two doses. If and when a pandemic was declared, H1N1 vaccine for the remaining 55% of the population could be purchased under the advance-purchase agreement, subject to ministerial discussion at that time. However, on 14 May, the then Secretary of State for Health, Alan Johnson, announced to the House of Commons that 'it is our intention to acquire sufficient stocks to vaccinate the entire UK population'. Once the pandemic was declared on 11 June 2009, the CCC met again and was asked to confirm its previous decision to procure enough vaccine for 100% of the population or, alternatively, to review and select other procurement options. Following further discussion of the options, ministers reconfirmed their decision to procure sufficient vaccine for 100% of the population, and requested as much flexibility in the ordering process as possible.
- 7.14 Ministers therefore made the key initial decision on 11 May, and subsequently reviewed and confirmed it on 17 June.

# **Vaccine production**

7.15 Manufacturing a vaccine is a complex biological process. There can be difficulties associated with the low yield from certain strains of influenza, and the process of manufacturing itself can be problematic. All vaccine manufacturers had problems with low yield at the beginning of production, but Baxter Healthcare and GlaxoSmithKline altered their manufacturing processes to increase yield. The regulators had to approve any changes in production process. Ministers were informed of any production problems and took steps to ensure the security of vaccine supply in the UK by purchasing 30 million doses of additional Pandemrix vaccine from GlaxoSmithKline to make up any possible shortfall, bringing the total Pandemrix purchased to 90 million doses. In the event, this volume of vaccine was not required and DH reached agreement with GlaxoSmithKline on 6 April 2010 to only take deliveries of just under 35 million doses of Pandemrix.<sup>6</sup>

#### Vaccine donation

7.16 On 17 September 2009, the International Development Secretary, at that time Douglas Alexander, announced that the UK would provide up to £23 million to help the developing world tackle the H1N1 pandemic. The commitment was equivalent to 10% of the domestic supply of H1N1 vaccine. Several other countries, including the USA and France, announced similar donations at this time, enabling the United Nations to provide the poorest countries with vaccine and other pandemic response measures as required.

# Vaccine prioritisation

7.17 Although the UK ordered enough vaccine for 100% of the population, initial supplies of vaccine were very limited. The UK therefore had to decide which groups to prioritise. Given their clear remit in this area, the Joint Committee on Vaccination and Immunisation (JCVI) was asked to consider the best way of prioritising for the H1N1 influenza pandemic.

<sup>6</sup> www.publications.parliament.uk/pa/cm200910/cmhansrd/cm100406/wmstext/100406m0002. htm#10040611000118

- 7.18 The JCVI gave advice to ministers based on the best evidence of the spread and severity of H1N1, and reflected current good practice and expert opinion when considering H1N1 vaccination. They agreed that the primary objective of the vaccination programme should be to reduce morbidity and mortality from the infection. They met several times to discuss prioritisation, initially on 17 June 2009, and then twice more before the initial vaccination programme rolled out to ensure their advice was based on the most up-to-date evidence.

  On 8 October 2009, they confirmed their previous advice that groups should be prioritised as follows:
  - individuals aged between six months and up to 65 years in the current seasonal flu vaccine clinical at-risk groups;
  - all pregnant women;
  - household contacts of immunocompromised individuals; and
  - people aged 65 and over in the current seasonal flu vaccine clinical at-risk groups.<sup>7</sup>
- 7.19 They also supported the proposed early use of the vaccine in front-line health and social care workers, as they were at increased risk of infection themselves and of transmitting that infection to susceptible patients or people they were supporting. At this meeting the JCVI also advised that as the benefits of vaccination to healthy individuals over three years of age greatly outweighed any risks, the vaccine should be made available to anyone who requested it after the at-risk groups had been vaccinated. The JCVI also suggested that the main carers for elderly or disabled persons in particular should be encouraged to receive the vaccine once all the priority groups had been vaccinated
- 7.20 The UK government announced on 13 August 2009 that the first phase of vaccination would cover the JCVI-recommended prioritisation groups. Vaccination of front-line health and social care workers would begin at the same time as the first at-risk group. This initial phase started on 21 October 2009, as soon as the first supplies of vaccine were distributed to all four countries.

<sup>7</sup> www.dh.gov.uk/ab/JCVI/DH 113328# 2

- 7.21 On 12 November 2009, the four health ministers met to discuss whether a second phase of vaccination should start. Given that the JCVI had advised that vaccine should be made available to anyone, but that due to operational supply issues there was still a need to undertake this on a phased basis, ministers considered that children should be vaccinated next. Children, especially young children, were more likely than other groups to be hospitalised if they became ill, had high rates of admission to critical care, and as a group had suffered some deaths. The JCVI was asked to advise as to whether the vaccine was safe for children under three. The JCVI met on 17 November and advised that children from six months could be vaccinated safely. They also endorsed the four nations' health ministers' decision to vaccinate children from between six months to five years in the next phase. This second phase was announced on 19 November.
- 7.22 On 8 January 2010, the JCVI met and considered the latest epidemiological evidence, which showed that H1N1 virus activity had decreased to a low level. They also looked at modelling that showed a third wave was unlikely, and at the progress already made on the vaccination programme. On the basis of this evidence, they advised that the vaccination of children between six months and five years should be completed, but that the programme should not be extended to other healthy groups where vaccination had not begun, including carers of the elderly and disabled.

#### Vaccine distribution

7.23 In order to get the vaccine out to the initial priority groups, a distribution strategy was adopted which ensured that all parts of the UK received vaccine as soon as possible and on an equitable basis during a period when vaccine supplies were limited. To ensure this was done in an effective manner, the UK government chose to use a similar system to that which is used for delivering child vaccines across the UK. This choice was closely aligned to a guiding principle of emergency response, continuity: 'The response to emergencies should be grounded within organisations' existing functions and their familiar ways of working.<sup>18</sup>

www.cabinetoffice.gov.uk/media/349120/conops-2010.pdf

7.24 Both GlaxoSmithKline and Baxter Healthcare had some difficulties in their production of the vaccine. The impact of this was that DH was unable to give devolved administrations and the NHS as much notice of available stock as they had wished. DH therefore had to wait until they received a vaccine delivery before being able to confirm that the vaccine was available to the devolved administrations and to the NHS. As all vaccine was initially being delivered to England, DH and the devolved administrations worked closely together to ensure the rapid and smooth distribution of vaccine across the UK.

#### Vaccine administration

- 7.25 For the initial phase of the H1N1 vaccination programme, both GP and primary care trust-based systems were considered as possible vaccine administration mechanisms. As the initial priority groups were already linked into the GP system, and therefore it would be straightforward to identify, contact and vaccinate eligible patients, it was agreed that a GP-based vaccination programme should be used. The first supplies of vaccine were distributed to acute trusts and other centres so that the vaccine could be offered early to the highest-risk patients and front-line healthcare workers.
- 7.26 Although GP negotiations were initiated as soon as an H1N1 pandemic looked likely, there was useful earlier groundwork completed in 2007 and 2008 which culminated in joint guidance issued by the British Medical Association (BMA) and the NHS setting out the key principles for payments to General Medical Services (GMS) practices during a flu pandemic.9 DH worked with the General Practitioners Committee (GPC) on an emergency Statement of Financial Entitlements (eSFE) that would protect practices' income in the event of their being unable to fulfil all their contractual commitments due to having to divert resources to treat patients with pandemic flu symptoms. The eSFE was not implemented during the H1N1 pandemic because negotiations were not completed in time. More importantly, the pandemic was not placing sufficient extra burden on practices to warrant income protection. If the point had been reached where the eSFE was needed, it was sufficiently developed to have been used.

www.nhsemployers.org/Aboutus/Publications/Documents/Pandemic%20influenza%20-%20 Principles%20of%20negotiations.pdf

- 7.27 Discussions about payment for administering vaccinations were held with the GPC of the BMA as soon as it became clear that there was likely to be a swine flu pandemic. At that time it was not known how much of the country's population would need to be vaccinated, nor how many doses of vaccine would be required. An initial deal for GPs to administer vaccine to individuals in phase one of the vaccination programme was announced on 14 September 2009, about six weeks before vaccines started to arrive at GP practices. The deal meant that GP surgeries received £5.25 per dose of vaccine given. The additional money came from health budgets and helped surgeries to contact patients, administer the vaccine and, if necessary, take on extra staff.
- 7.28 Phase two negotiations were not so successful, and a national deal was not possible to achieve. Primary care organisations across the four nations were therefore asked to negotiate deals locally, with clear directions on terms within which they could negotiate. Once arrangements were in place, vaccination of healthy children under five started in December 2009. Some interviewees felt that the length of time these negotiations took impacted on the speed with which the vaccine could start being given to children.

## Vaccine uptake

7.29 Seasonal flu uptake rates for health and social care workers are historically quite low, so for the H1N1 pandemic flu vaccine DH and the devolved administrations focused on raising uptake where possible to better protect the population. To use England as an example, uptake rates for vaccine for healthcare workers was higher for the H1N1 pandemic than for seasonal flu across every strategic health authority (SHA), and rose from 123,000 doses of seasonal flu vaccine administered in 2008/09 to over 400,000 doses of H1N1 pandemic vaccine administered in 2009/10. The North East SHA rose from 11.2% of health and social care workers vaccinated in the 2008/09 seasonal influenza season to 40.7% with the H1N1 pandemic vaccine. There were variable results across the country in each trust, but it seemed that where leadership teams were fully engaged, and staff given easy access to the vaccine (for example vaccination trolleys on wards), the uptake was higher.

# Observations and recommendations

# Pre-pandemic planning

- 7.30 In general, the fewer suppliers in a market, the less competitive it is. Since the EMEA agreed to 'mock-up' vaccine, DH ensured that the requirements for the advance-purchase contract were communicated to a wide range of suppliers; however, eventually only two companies who were judged capable of the conditions required were left in the tendering process. DH chose to split the award between the two suppliers in order to reduce some of the risk in security of supply and to maintain a level of competition. DH followed good procurement practice when setting up the advance-purchase agreements, and the Office of Government Commerce (OGC) examined the process without raising concerns. Agreeing two advance-purchase contracts reduced some of the risk in security of supply and maintained a level of competition, but I was not able to make a judgement as to whether the prices paid were optimal. I believe advance-purchase agreements are valuable. I support the approach taken and am pleased that DH is looking to widen the range of suppliers for the future.
- 7.31 However, when compared to more standard government procurement contracts, certain conditions to protect value for money, such as break clauses on supply, were more difficult to establish, although a break clause was agreed with Baxter Healthcare at the time the order was placed in 2009. Break clauses in British government contracts usually provide for supply to be terminated at will, but for the contractor's reasonable costs incurred to be paid. In this context, break clauses would allow the UK to retain the option to cancel further deliveries of vaccine at a particular point if it emerged that more vaccine was no longer needed. The lack of such a clause in the advance-purchase agreements for both contracts consequently exposed the Exchequer to some risk. Interviewees have noted that, in future, negotiations should attempt to include break clauses wherever possible to allow for further flexibility, especially as the potential for one-dose vaccine protection from a pandemic flu has now been demonstrated.

**RECOMMENDATION 21:** The Department of Health should negotiate advance-purchase agreements that allow flexibility over the eventual quantities purchased.

- 7.32 Some interviewees have suggested that, given the limited supply of vaccine available worldwide for pandemic flu, there is an argument for more international co-operation in the procurement of vaccine, and that the UK government should work with other EU countries when negotiating with global pharmaceutical companies who may have more market power. This suggestion has some attraction, as it could allow for more equitable access to vaccine across Europe, it could avoid countries engaging in a bidding war and driving up the price, and it could allow for fixed terms and price across Europe.
- 7.33 However, other interviewees strongly cautioned against such an approach. Aside from the contractual difficulties multi-national procurement would undoubtedly encounter, such as attempting to harmonise one set of contracts across the EU, it would be exceptionally difficult to design a distribution policy which would take into account the potentially significant differences in epidemiology across countries and differing national strategies on vaccination. EU-wide procurement would also be legally challenging. I heard that procurement negotiation at this level would not necessarily drive down prices, but could in fact give the UK a worse deal on pricing. I therefore consider full joint procurement with other EU countries unwarranted. However, the UK has excellent expertise in this area, and should look for ways to share this with those EU countries that have need for greater capacity.

#### Vaccine coverage – timing

7.34 Interviewees felt that procuring pre-pandemic vaccine could have helped the UK to receive vaccine at the earliest opportunity, and the decision to move forward with this option was based on the best available scientific advice. I agree that this was a sensible option to progress in the circumstances, and understand that it was no longer possible to progress it once WHO raised the alert level to Phase 6.

# Vaccine coverage - quantity

- 7.35 With the uncertainties regarding the virus at the beginning of the outbreak, timely, current and clear advice was important to give ministers the best foundation for making a decision about the amount of vaccine to procure.
- 7.36 Having considered the advice put before ministers at the two CCC meetings in May and June 2009, it seems that scientific and economic advice could have been more explicit and the process of decision-making less ambiguous.
- 7.37 In general, the level of economic evidence presented to ministers was satisfactory, and there was a relatively strong economic case for the various countermeasures proposed and implemented which underpinned the advice given. However, at times such as the vaccine coverage discussions, the presentation of economic advice to ministers could have been made clearer. In particular, the economic arguments were often embedded within papers and implicitly considered alongside the scientific, policy and delivery issues. It may have been helpful for ministers, having to make swift decisions, to have been presented the economic arguments more explicitly.
- 7.38 Scientific advice on the level of coverage (suggesting universal vaccination or, if not, 45% coverage) came from a meeting of the JCVI in October 2007 and was made in relation to pre-pandemic vaccine stockpiles rather than pandemic-specific vaccine. The JCVI was also advising with regard to an initial H5N1 pre-pandemic vaccine stockpile. Vaccine coverage was not explicitly discussed by SAGE or the JCVI again in light of specific evidence of the H1N1 pandemic. I have heard that further explicit discussion was unlikely to have changed the advice given, especially in light of the uncertainties at that time. However, I feel it is important that the time and context of advice is clearly stated in papers to allow ministers to understand the background to the advice.

- 7.39 Behavioural scientists from the Behaviour and Communication subgroup of the Scientific Pandemic Influenza Advisory Committee (SPI-B&C) could have advised on likely uptake rates; however, policy officials did not request this advice from them. Therefore, although uptake rates were discussed, this was not underpinned by any advice from scientists, who potentially could have been able to provide useful comments. In future, behavioural scientists could be involved in developing scenarios used to judge vaccine coverage.
- 7.40 The initial ministerial decision on 11 May 2009 came before officials had set out full options on the vaccine coverage. This meant that ministers, as well as choosing to procure vaccine as soon as possible, also made a decision at that meeting to procure vaccine for 100% of the population without the full advice being available to them.
- 7.41 I heard from a number of people closely involved in these decisions. Ministers in particular told me that, in the absence of greater clarity about the nature of the virus, its potential to mutate, and the likely impact on different groups, and given the availability of the advance-purchase agreement, the only decision they felt comfortable making was to purchase enough vaccine to cover 100% of the population. I did hear the contrary view, that a lesser amount of vaccine would almost certainly have sufficed, and more vaccine could have been purchased if necessary, but this ignores in my view the intense pressure to produce enough vaccine had the virus become severe.
- 7.42 I therefore entirely understand the position taken by ministers and do not criticise it.
- 7.43 However, in terms of good process, it would have been better if ministers had made these decisions in full possession of all the relevant facts. To help ministers make decisions about the level of vaccine coverage needed in future pandemics, the JCVI should consider and advise on appropriate vaccination strategies during the planning stage, taking into account behavioural and economic analysis. This advice will allow ministers to see the full range of options when next deciding on levels of coverage.

**RECOMMENDATION 22:** The Joint Committee on Vaccination and Immunisation should be asked to advise on vaccination strategies across a range of scenarios, including severe and less severe pandemic viruses. This advice should incorporate the views of behavioural scientists and economic analysis, and be published in the revised National Framework no later than March 2011.

7.44 I would make a further point on the criticism that this decision represented poor value for money. This argument relies heavily on hindsight, which I have endeavoured to avoid as far as possible. The point was put to me on more than one occasion that the essential consideration here was how much one is willing to pay for an insurance policy against the emergence of a very severe virus. I agree. It is important to emphasise that the business case for vaccination demonstrated that the programme offered very good value for money. The economic case was based upon sound scientific evidence of the potential prevalence and severity of a pandemic flu attack and the likely preventative benefits of vaccination. Using well-established valuations of lives saved and hospitalisation cases reduced, the valuefor-money case was strong. With hindsight, the low virulence of this particular virus strain weakened the value for money in this case; however, this should not detract from the fact that in the future, given the risk of a pandemic flu with a higher fatality rate, there will be strong economic arguments to deliver a similar vaccination programme.

# **Vaccine prioritisation**

7.45 The phasing of the vaccination programme has been endorsed by many interviewees. The UK government chose to vaccinate individuals in order to reduce morbidity and mortality rather than to reduce transmission, which was a less feasible objective at the stage at which vaccine became available. The phasing of the programme allowed those in most need of protection the chance to be vaccinated first, and made best use of the supply coming into the UK. The communications that went alongside ensured that the public were aware which groups were being vaccinated and the reasoning behind their selection. I would contrast the calm and orderly way in which vaccination proceeded in the UK with what happened in parts of some other countries such as the USA, where there were incidences of long queues of anxious

people seeking vaccination. In France, too, the setting up of separate vaccination centres operated by the Armed Forces was not perceived to have been successful.

#### Vaccine distribution

- 7.46 Interviewees, although noting the inherent difficulties in distributing a biological product such as a vaccine, felt that this system had worked extremely well, with the real-time tracking of each batch of vaccine singled out for particular praise. Although not needed in the UK, this level of tracking would have ensured that any recall of vaccine could have been completed extremely rapidly.
- 7.47 In passing, I feel it is important to highlight that the vaccine manufacturers succeeded in developing, manufacturing and supplying large volumes of vaccine in a remarkably short time.

#### Vaccine administration

7.48 The administration of vaccine was an important part of the vaccine strategy. Health professionals in all four nations undertook the task of vaccinating those in priority groups, and I congratulate them for their excellent work. Negotiations for vaccine administration by GPs were ultimately successful; however, I heard that undertaking them during a pandemic was time-consuming and complex. Ministers, officials and negotiators were involved throughout the negotiations, which took individuals away from other work they could have been progressing. The process of holding negotiations during a pandemic, although ultimately achieving agreement, did not reflect well on either the GPC or DH. I have also heard that capacity exists within the GP system to support an emergency response, and that in 2008 it was agreed, in principle, that GPs would dedicate capacity to any pandemic response provided that overall practice income was protected and costs reimbursed.

7.49 Many interviewees, including those internal and external to government, have suggested that, in future, a sleeping contract already in place with GPs or other willing providers such as community pharmacists would be helpful. A sleeping contract would allow difficult negotiations to be undertaken in a more reasonable timeframe than is possible during a pandemic and could set out: the costs of delivering a pandemic response, including a vaccination programme; the responsibilities of both the government and GPs; and a clear trigger for when the programme would be both stood up and stood down. I understand that preliminary discussions on such a sleeping contract are already taking place.

**RECOMMENDATION 23:** The four health ministers should commission officials to put in place arrangements to ensure the rapid implementation of a vaccination programme during a pandemic. For example, a sleeping contract with GPs and/or other willing providers could be negotiated.

# Vaccine uptake

- 7.50 The SPI-B&C group produced useful advice for the communication of the vaccination programme to ensure better uptake rates. Due to their low profile during the pandemic (discussed in more detail in Chapter 4), however, not all of their work was fully utilised. Despite this, I have heard that the uptake rates achieved were a success, and although each country had a different experience, it is important for future campaigns to build on the successes of this one.
- 7.51 I understand that good practice on vaccine uptake is already in the process of being shared within individual UK nations. I suggest that this is shared more widely across the UK. Also, in future pandemics behavioural scientists should be closely involved with the lead government department communications team, and have clear channels to pass advice to the devolved administrations.

- 7.52 Although publicly there was very little dissent by clinicians on the vaccine strategy the UK took, I heard that some UK health professionals expressed negative views on vaccination privately to friends, family and, in some cases, patients. It has been suggested that unfounded concerns over the safety of the vaccine may have led to this situation, which is likely to have impacted to some degree on the uptake rates for H1N1 vaccine. It is understandable that clinicians will have questions regarding novel vaccines, and that they will wish to be certain of the safety of a vaccine before recommending it to their patients or taking it themselves. There was extensive safety data available on the H5N1 'mock-up' vaccines which were the basis for the H1N1 vaccine. DH may wish to consider giving this data more prominence in a future pandemic, and clearly explaining its relevance to the novel vaccine to both clinicians and the public in order to balance media reporting on 'untested' vaccines.
- 7.53 DH and the devolved administrations were aware of the importance of clinicians having the right information so as to make informed decisions and to pass on the right information to patients. Considering the number of individuals vaccinated during the H1N1 pandemic, it seems that many clinicians were confident in recommending the vaccine to patients. In the future, this work should be built on.
- 7.54 The use of independent experts in relaying vaccine safety and testing information to both the public and to informed clinicians could have an important role to play in allaying concerns and therefore raising uptake. This will be reliant on the information that is made available to them being up to date. Recommendation 15 in Chapter 4 suggests the way in which independent experts could be kept informed of the current situation and scientific evidence. A more explicitly risk-focused approach to communication may also help. For example, explicit comparison of the risks associated with catching H1N1 versus those of vaccination may have helped both the public and clinicians make a more informed judgement.

#### Conclusions

- 7.55 The 2009 H1N1 pandemic was the first pandemic for which the UK had a specific vaccine available for use while the virus was still causing disease in the nation. This in itself has been a significant achievement for manufacturers, regulators and policy-makers, and reflects in no small part the exceptional level of preparedness the UK has attained.
- 7.56 There is much to be praised about the way in which vaccine was procured, distributed and administered to the UK population, and I have made recommendations that will build on the achievements of this response and enhance decision-making and administration in a future pandemic.
- 7.57 There are aspects of the process through which decisions about vaccine purchase were made that could be improved, and I have made recommendations accordingly.

# **Chapter 8: Communications**

- 8.1 Clear, consistent and co-ordinated messaging across the full range of communication channels, tailored to the needs of specific audiences, is crucial to maintaining the public trust, compliance and support essential to the effective management of a pandemic. Adoption of hand and respiratory hygiene advice, social distancing measures, effective and responsible use of antivirals, and uptake of vaccination, are all predicated on successful communication.
- 8.2 However, changing public attitudes towards government and a growing scepticism of institutions and of official information, coupled with greater ease of access to alternative sources of information, mean that the public are no longer passive recipients of official information and advice. Previous challenges, such as BSE and the foot-and-mouth epidemic, have highlighted the need for a more 'evidence-based, open and participative approach' 1 to communication.
- 8.3 The generic challenge of communicating clearly and consistently during a pandemic was made all the more complex by the variability of the H1N1 pandemic. The disease was widespread in some geographical areas but almost non-existent in others. The overall profile was of a mild illness, yet its severity for any one individual was impossible to predict.
- 8.4 The government and devolved administrations faced the challenge of giving clear information and advice while scientific knowledge was at an early stage of development and while there was uncertainty over the severity of the pandemic. They faced the risk of being accused of either underestimating the threat and failing to protect the public, or of over-reacting and 'crying wolf' at taxpayers' expense.
- 8.5 The devolved nature of health poses its own communication challenges. Ensuring consistency and clarity of messaging in the context of potentially differing approaches and experiences is key to a successful UK-wide response.
- 8.6 This chapter explores the government's communications activity during the pandemic and identifies lessons for the future.

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# **Pre-planning**

- 8.7 The 2007 National Framework emphasised the need for 'strong national direction of public information from the outset'. It recognised that 'timely advice and information will help prepare the population for the potential impact of a pandemic and will be critical to its subsequent management'.
- 8.8 During the pandemic, the key communications objective identified was 'to promote and reinforce individual and collective actions that reduce the spread of influenza and minimise its health and wider impact on the UK'.
- 8.9 The National Framework is clear about roles and responsibilities for communications. The Department of Health (DH) is the primary source of health-related messages during a pandemic, working closely with the Cabinet Office, the devolved administrations, other government departments and the Health Protection Agency (HPA) 'to deliver a nationally co-ordinated communication strategy'. The government's News Co-ordination Centre (NCC) would be mobilised to support DH to ensure co-ordination and consistent messaging across government.
- 8.10 A comprehensive communications strategy was in place prior to the pandemic, developed in close collaboration with the devolved administrations, which adopted their own tailored versions based upon it.
- 8.11 The government's planned approach followed that of the National Framework, with an escalating series of communications activity and messages linked to the World Health Organization (WHO) alert phases. For example, WHO Phase 4 would see leaflets containing information on pandemic flu sent to every household, the launch of a National Pandemic Flu Service information line and the commencement of radio and newspaper adverts. Messaging would focus on measures that individuals could take to minimise spread, such as respiratory and hand hygiene.
- 8.12 Development of the communications and messaging strategy was informed by a significant amount of audience research. Public opinion would be tracked throughout the pandemic to provide feedback that would support the tailoring of communications activity to best meet public concerns.

- 8.13 Throughout the pandemic, the relevant health department would lead communication with the NHS, with appropriate departmental leads communicating with appropriate NHS communities, and supplying a range of communications advice and resources for the use of local NHS communications leads.
- 8.14 The HPA would provide both advice and guidance to the public and to specific audiences, such as schools and employers. It would also provide information on the epidemiology of the disease, alongside regular updates on key indicators of its impacts, such as GP consultation rates. Health Protection Scotland, the Public Health Agency in Northern Ireland and the National Public Health Service in Wales would play a similar role.
- 8.15 The Cabinet Office would lead wider stakeholder communication with the resilience community, business and voluntary sectors. Other government departments would provide information, guidance and advice to stakeholders within their policy sectors.

# What happened in practice

- 8.16 Public information and advice was extensive and difficult to miss. The 'sneezing man' image and 'catch it, bin it, kill it' slogan produced a clear 'brand' which was recognisable throughout the pandemic. UK-wide media campaigns ran on television, on radio and in print. Posters were displayed in a wide range of settings by the NHS, businesses and the voluntary sector. Information and advice were accessible on a range of government websites. An information leaflet was delivered to every home in the UK. Advice could be seen online, on bus shelters, billboards and shopping trolleys. NHS Direct provided advice, as did the special Flu Information Line and the National Pandemic Flu Service (NPFS) in England. Similar over-the-phone information was available in Scotland, Northern Ireland and Wales.
- 8.17 Information was made available to the media through a variety of means over the course of the pandemic. Unlike the public information campaigns, media briefing operated on a devolved rather than a UK-wide basis.

- 8.18 All four nations adopted a 'single authoritative voice' to provide information to the media. In England, weekly media briefings were led by the Chief Medical Officer (CMO) between 2 July 2009 and 14 January 2010. In Scotland, the Deputy First Minister and Cabinet Secretary for Health and Wellbeing held media briefings in Edinburgh, supported by the CMO for Scotland, initially daily, from the end of April 2009 to early July 2009. In Northern Ireland, the Health Minister issued press releases on the progress of the pandemic. The CMO (Northern Ireland) gave radio and television interviews as required. He fronted weekly media briefings from 29 October until 23 December 2009. The CMO for Wales fronted public communications in Wales, with information circulated regularly to journalists by email and through press briefings.
- 8.19 The four health ministers regularly updated their respective parliaments and assemblies on the course of the pandemic and the response effort, answering questions and responding to concerns voiced by elected representatives.
- 8.20 In addition to the mainstream public information campaigns and media briefing, DH used a variety of means to target harder-to-reach communities and those with specific concerns. Tailored information and guidance was targeted at a range of audiences, including pregnant women and Hajj pilgrims.
- 8.21 The media briefings provided a summary of the current situation, new developments and key messages. They provided the latest facts and figures on the progress of the disease, including detailed breakdowns of GP consultation rates, hospitalisations and deaths. They included updates on the procurement, distribution and uptake of vaccine and, in England, usage of the NPFS.
- 8.22 In addition to publishing a range of guidance documents and advice on its website, the HPA and its devolved equivalents published weekly epidemiological updates containing key factual information about the course of the pandemic. Health Protection Scotland, the Public Health Agency in Northern Ireland and the National Public Health Service in Wales provided data to the HPA every week for the UK report and published their own weekly data on their websites.

8.23 The appointment in England of a National Director for NHS Flu Resilience and a National Director for Social Care Flu Resilience was important in providing a clear source for communications to the NHS and social care. DH communications leads worked very closely with strategic health authority communications leads to facilitate the effective cascading of information throughout the NHS. Communications to social care workers were primarily conducted by DH through directors of social services at a local level. Similar roles and arrangements were in place within the devolved administrations appropriate to their organisational structures.

## **Observations**

- 8.24 The communications strategy followed the National Framework, in that it was based on the presumption that a pandemic would most likely be caused by an H5N1 virus, with accordingly alarming worst-case planning assumptions, and was tied very closely to the WHO phases. DH and devolved administration communications leads mobilised very quickly to revise the strategy, messages and materials to fit the circumstances. Close working relationships and understanding built up during the planning phase played a crucial role in enabling this to be done so smoothly and efficiently.
- 8.25 I heard considerable praise for the government and devolved administrations' communications efforts during the pandemic. Particular praise was expressed for the efforts of the CMO for England. Public opinion tracking work on behalf of DH throughout the outbreak shows very high levels of public satisfaction with the amount of information available. In contrast, I heard that governments in several other major European countries were criticised for their communications efforts.
- 8.26 Some 2.7 million people in England used the NPFS as a result of the government's awareness campaign. The success of the service in reducing pressure on GPs represents a significant achievement from a communications perspective. Although it is difficult to assess the impact of communications on behaviour, the strength and ubiquity of the 'catch it, bin it, kill it' campaign may also have lasting benefits in raising awareness of good hand and respiratory hygiene.

- 8.27 I was told that communication of the story of the pandemic, and its likely course, was well handled and that the UK government and the devolved administrations were open and frank about the levels of uncertainty involved.
- 8.28 Public understanding of a pandemic, what it will be like and what will happen, facilitates and supports an effective response. The pandemic will have led to a substantial increase in public knowledge and awareness. While recognising that educating the public about pandemics during normal times can be challenging, given the absence of direct relevance to people's lives, it will be important to build on this greater understanding. The Science Media Centre could be a useful partner in this regard.

**RECOMMENDATION 24:** The Department of Health and the devolved administrations should explore what more can be done to raise levels of public awareness and understanding about the key characteristics of a pandemic and the core response measures.

8.29 Interviewees suggested that some of the terminology used during the pandemic was not widely understood by the public. Examples included 'planning assumptions', which was often taken to mean 'likely events', and 'pandemic', which was often assumed to refer to the severity of the disease. While efforts to raise public awareness may help to tackle this, I believe that a concerted effort is needed to adjust the language used to ensure that the message the public take away is the one that is intended.

**RECOMMENDATION 25:** The four UK health departments should review their use of language during pandemics to ensure that it accurately conveys the aims of the response efforts and the levels of risk. In particular, the use of the terms 'containment' and 'reasonable worst case' should be reconsidered as they are easily misunderstood. The National Framework and communications strategies should be amended to reflect such revisions by no later than March 2011.

# Public understanding: communicating risk and uncertainty

- 8.30 Many people journalists, officials and emergency planners alike had been waiting for a pandemic for a long time, based upon the expectations built up around H5N1. The scale of the government's planning assumptions did nothing to allay the widespread belief that a 'pandemic' meant a very severe disease, rather than referring, as it does, to the geographical nature of its spread. Given that the government had publicly identified an influenza pandemic as the number one threat to the UK in 2008, there was a widespread expectation that pandemic H1N1 would be 'the big one'. In the event, in terms of its severity, this was not the case, although these expectations coloured a great deal of thinking about the pandemic.
- 8.31 For a long time, there was considerable uncertainty about the pandemic's development and impact, and the government and the devolved administrations were in the challenging position of simultaneously asking the health services to prepare for the worst while trying to reassure the public and accurately communicate the level of risk.
- 8.32 The government was very open and frank about the levels of uncertainty. In communicating its planning assumptions, it attempted to make it very clear that these were not 'predictions' but the basis on which services were being asked to plan to ensure that they were prepared for the worst.
- 8.33 Discussions with journalists demonstrated that they took this message away clearly and believed that the public were comfortable with the idea of there being uncertainty over the development of the pandemic.
- 8.34 However, use of the planning assumptions, in the absence of any other figures that described the possible development of the pandemic, was not without its risks. The English CMO's citing of the 'reasonable worst-case' planning assumption of 65,000 fatalities on 16 July 2009 was widely reported in headlines in somewhat alarmist terms.

- 8.35 The communication of only the 'reasonable worst-case' planning assumptions meant that there was an obvious gap between what the government was saying and what was observable on the ground, namely that the disease was mild in most cases and that mortality levels were low. This gap could have risked damaging the government's credibility and undermining public trust in the response.
- 8.36 In Chapter 4, I have made recommendations on releasing more information, which would, I believe, increase the likelihood of a more accurate picture of the pandemic being communicated. I was impressed by the role of the Science Media Centre in helping to facilitate engagement between the media and independent expert scientists, and would highlight the important role that such organisations can play in creating a more informed debate that can help the government better communicate the level of risk and uncertainty.
- I would highlight that Cabinet Office guidance<sup>2</sup> on best practice in 8.37 communicating risk identifies the importance not just of openness but of transparency in the way in which assessments are made and decisions taken.
- 8.38 I reiterate my recommendation that publication of more scientific papers underpinning policy debates and, in particular, regular publication of best estimates of spread and fatalities are the best ways to shift attention towards the most robust information available, rather than focusing minds on very unlikely events.
- 8.39 The near-absence of public dissent from clinicians, politicians and commentators during the pandemic is, nevertheless, a testament both to the openness of communication about uncertainty and to the considerable pre-planning and prior debate on the response that took place.
- 8.40 While the government tracked public opinion and tailored its communications work accordingly, it could have been more proactive in identifying and challenging inaccurate information or advice and responding to concerns and misunderstandings. A more aggressive communications campaign that focused on dispelling concerns that

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- the vaccine was not safe and had been rushed into production without the usual rigorous testing and licensing may have helped uptake rates.
- 8.41 The regular media briefings, and those held off the record, did much to tackle such stories in the media, but stronger horizon-scanning of media reporting to identify emerging themes and issues of concern may have helped DH to more proactively challenge misunderstandings and public concerns.
- 8.42 The government made limited use of social networking. It used its existing presence on sites such as Facebook, Twitter and YouTube, primarily to direct people to its websites rather than to engage in discussion. Social networking sites were, however, monitored to identify issues of concern. This did help to identify the concerns that some pregnant women had about vaccination, which led to an updating of relevant material online and DH's Director of Immunisation holding webchats on the issue on the popular parenting sites Mumsnet and Netmums. The Secretary of State also took part in a webchat on Mumsnet which covered broader issues.

# Briefing the media

- 8.43 I spoke to a range of journalists across the UK and heard widespread praise for the regular media briefings that took place. For their part, ministers and officials considered most media coverage to have been responsible and balanced.
- 8.44 Journalists told me that the levels of information released were unprecedented in a public health emergency, and the opportunity to question face to face the key figures leading the response was critical to both establishing an accurate picture of the outbreak over time and being able to contextualise new developments. The regularity of the briefings, and level of information being given, prevented an information vacuum emerging which may have been filled by speculation. The ability to raise emerging issues directly with key figures such as the CMOs played an important role in dispelling rumours and misunderstandings.

- 8.45 I heard, however, that much depended on journalists being able to physically attend the briefings, as information was not proactively sent to those not able to do so.
- 8.46 I also heard that greater direct real-time communication with sections of the public with particular concerns may also have played an important role in tackling rumours and misunderstanding.

**RECOMMENDATION 26:** The four UK health departments should consider new ways of proactively engaging with both journalists and the public. These could include disseminating transcripts of media briefings, using podcasts and making more use of social networking and digital technology to reach specific sections of the public. The National Framework and communications strategies should be amended to reflect any changes no later than March 2011.

8.47 There is a clear lesson that treating the media as being responsible, and taking the time to explain and contextualise information, encouraged responsible reporting.

**RECOMMENDATION 27:** The Cabinet Office should ensure that the communications approach (weekly briefings, Q&A sessions, regular releases of facts and figures) adopted by the Department of Health and the devolved administrations is used, where appropriate, as a model of best practice for future emergency situations.

8.48 Each of the four nations adopted a trusted 'single authoritative voice' to communicate key information. In England, Wales and Northern Ireland this person was the CMO. In Scotland it was the minister responsible for health. I heard that the use of a single trusted voice throughout the outbreak worked well and built on learning from previous emergencies. I also heard, conversely, that access to a wider range of expert voices may have helped to further boost the credibility of the government's response. The use of independent experts to, for example, comment on the safety of vaccines may have helped to provide further reassurance to those concerned about this. I have explored this in more detail in Chapter 4.

8.49 I was told that the four separate briefings by DH and the devolved administrations helped to reveal differences in the way the four nations collect health data. These differences made it difficult for the media to compare the pandemic's effects across borders and to develop a clear UK-wide understanding of its impact. This is discussed further in Chapter 6.

#### Communication with the NHS and social care

- 8.50 I heard, anecdotally, that the flow of information to front-line health workers could have been improved. Some heard key information first through the media rather than from the authorities, and others felt inundated with information and guidance. I heard that some freelance and locum staff did not receive any information but could have played a role in augmenting services if asked. While I did not explore this element of the response in detail, I would suggest that the four health departments ensure that a clear gateway system is in place to make sure that the information and documentation reaching staff is timely and co-ordinated, and takes account of the overall burden it places upon them.
- 8.51 It was also suggested by interviewees that a source of direct clinical advice for health professionals would have been welcomed, perhaps in the form of a phone number or secure internet site.

**RECOMMENDATION 28:** The Department of Health and the devolved administrations should discuss with professional health bodies how best to create sources of direct clinical advice for health professionals during a pandemic. This may be most appropriately hosted by one or more of the professional bodies.

8.52 I heard too that there was a risk that messages coming from the Cabinet Office to the local resilience community and from DH to the local health community perhaps were not always as consistent as they could have been. Closer collaboration between the two departments and at lower levels on this point should be embedded into the communications response.

#### **Devolution**

- 8.53 This was the first widespread ongoing emergency that took place in a devolved area. It brought with it the potential for inconsistency in communication between the four nations or for political point-scoring. I found no evidence of the latter and strongly support the decisions of all four UK health ministers to work closely together to ensure a consistent UK-wide response.
- 8.54 The one area in which policy diverged across the four nations was the distribution of antivirals. This raised some minor difficulties for communications leads in the devolved administrations, as the NPFS was available only in England but was advertised in UK-wide national media.
- 8.55 Greater divergence would have carried greater risks, but I heard that the four nations worked very closely together throughout the outbreak to share information and to ensure that their communications were consistent.

## Conclusions

- 8.56 There is ample evidence to suggest that the government's communications strategy was successful in building awareness of 2009 pandemic influenza and in supporting critical elements of the response. The strength and reach of the public communication campaigns, and availability of advice and guidance, were unprecedented.
- 8.57 DH and the devolved administrations' media briefings succeeded in keeping the media informed and engaged, helping reporting to remain largely accurate and removing space in which more speculative and alarmist stories could develop. They provide a model for future communications in a long-running crisis, as does the government's openness with journalists.

- 8.58 The four health departments should seek to build on their success, further explore the potential of digital media and social networking, and look to publish as much information as possible, using independent partners such as the Science Media Centre to engage the wider independent scientific community and the media.
- 8.59 A focus on providing a more accurate picture of the pandemic, and thus the levels of risk, through looking again at the communication of planning assumptions and greater transparency concerning scientific evidence will also be important in a future outbreak.

## Annex A

### Terms of reference

## Purpose of review

- To review the appropriateness and effectiveness of the UK strategy for responding domestically to the H1N1 pandemic, given the information and knowledge available at each stage; and
- To make recommendations to update and refine planning for any future influenza pandemic.

## Scope

The review will include consideration of:

- the strategic approach at each key phase, from first cases, through declaration of the pandemic, containment, mitigation, to stand down of the response;
- b) the major elements of the response, both health and non-health (eg antiviral policy, the vaccination programme, school closures and international travel) and the background and local context against which decisions were made;
- c) whether the decisions and actions at the UK level were reasonable and represented good value for money, on the basis of the information, knowledge and advice available at the time;
- d) cross-cutting issues affecting the strategic decisions, including surveillance and data gathering, communications, scientific advice; and
- e) cross-Government co-ordination and decision making.

The review will make recommendations to update and refine planning for any future influenza pandemic.

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## **Annex B**

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Mr Justin McCracken

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Mr Hywel Griffith (BBC Wales)

Mr Andrew Jack (Financial Times)

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Mr Sam Lister (Times)

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# **Annex C**

## Costs of preparedness and the response

Description	Preparedness (£m)	Response (£m)
Pharmaceuticals (including antivirals, vaccine and antibiotics)	506.32 <sup>1</sup>	505.42 <sup>2</sup>
Consumables (including face masks, respirators and other consumables)	113.1 <sup>3</sup>	2.34
Infrastructure (National Pandemic Flu Service development and maintenance costs, stock management, etc)	27.73	65.74 <sup>5</sup>
Communications	O <sub>e</sub>	15.72
Total	654.75	587.38

Includes costs of the Advance-Purchase Agreements for pandemic specific vaccine originally signed in July 2007. Also includes cost of stockpile of AVs held for a future pandemic.

Includes the cost of vaccines purchased for the UK. Also includes, for England only, the costs of antiviral stock deployed to the NHS for the H1N1 pandemic and of administering the vaccine. Costs for Scotland, Wales and Northern Ireland were available but not in a comparable format.

<sup>&</sup>lt;sup>3</sup> Includes cost of stockpile of consumables held for a future pandemic.

Includes, for England only, the costs of consumables deployed to the NHS for the H1N1 pandemic, and manufacturing costs for AV solution. Costs for Scotland, Wales and Northern Ireland were available but not in a comparable format.

Note that the NPFS was only activated in England. Figure includes additional costs for the Health Protection Agency (England only).

<sup>&</sup>lt;sup>6</sup> No costs have been attributed to communications work covered within departmental budgets.

# **Annex D**

## **Membership of scientific groups**

## **Membership of SAGE**

Member	Institution	Speciality
Professor John Beddington (Co-Chair)	Government Office for Science	Government Chief Scientific Adviser
Professor Sir Gordon Duff (Co-Chair)	University of Sheffield School of Medicine	Immunology and genetics
Sir Roy Anderson	Imperial College London	Epidemiology and mathematical modelling
Dr Meirion Evans	University of Cardiff/ National Public Health Service for Wales	Epidemiology and public health
Professor Neil Ferguson	Imperial College London	Mathematical modelling of infectious disease
Professor George Griffin	St George's University of London	Infectious disease
Professor Andrew Hall (when vaccine issues discussed)	London School of Hygiene and Tropical Medicine	Vaccination
Dr Stephen Inglis	National Institute of Biological Standards and Control	Virology
Professor Susan Michie	University College London	Health psychology
Professor Angus Nicoll	European Centre for Disease Prevention and Control	Public health
Professor Karl Nicholson	University of Leicester	Infectious disease
Professor Peter Openshaw	Imperial College London	Respiratory infection
Sir John Skehel	Former director of the National Institute for Medical Research	Influenza
Dr Peter Grove (ex-officio)	Department of Health	Mathematical modelling

## Representatives of HPA

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## SPI membership<sup>1</sup>

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More details on SPI can be found at http://www.dh.gov.uk/ab/SPI/index.htm

## **SPI Behaviour and Communication (SPI-B&C)**

#### Role

To advise SAGE on the behavioural and communication science matters relating to the response to an influenza pandemic.

### Membership

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Dr Maureen Baker\* Professor Lucy Yardley

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## **SPI Clinical Countermeasures (SPI-CC)**

#### Role

To provide advice to SAGE on science and technical matters related to clinical countermeasures (eg antivirals, antibiotics, etc.).

<sup>\*</sup>Not permanent members of the sub-group

## Membership

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Dr Peter Grove Dr Alison Webster

Professor Andy Hall Professor Sir Gordon Duff
Professor Peter Openshaw Professor David Goldblatt

Professor Deenan Pillay Dr Stephen Inglis

Dr Jeremy Russell Professor Maria Zambon

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## **SPI-Modelling**

#### Role

To advise SAGE on all matters relating to the modelling of anticipated aspects of an influenza pandemic and potential implications for policy decisions.

## **Membership**

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<sup>\*</sup>Not permanent members of the sub-group

# **Annex E**

# **UK** influenza surveillance systems<sup>1</sup>

Influenza surv	reillance systems: primary care			
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
RCGP Weekly Returns Service (England & Wales)	Provides estimates of incidence of clinical respiratory illness by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Weekly incidence and prevalence rates of influenza-like illness, pneumonia, acute bronchitis by age, sex, region, and comparison against defined thresholds.	Onset Spread Impact	Winter and as required
and RCGP swabbing scheme	Swabbing of patients with acute respiratory illness identifies and monitors changing phenotypic/genotypic characteristics of the pandemic strain, including antiviral resistance and pathogenicity markers (virology component)	Virus isolates and proportion by subtype and Respiratory Syncytial Virus (RSV)		Winter and as required
NHS Direct (England & Wales)	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Daily age group-specific trends and HPA Region- specific trends for 'swine flu', colds/flu, fever.	Onset Spread Impact	Winter and exception reporting

<sup>&</sup>lt;sup>1</sup> Source: Health Protection Agency.

Influenza sur	veillance systems: primary care			
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
Q-Surveillance (UK)	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Daily incidence and prevalence rates of influenza-like illness, Upper Respiratory Tract Infection (URTI), Lower Respiratory Tract Infection (LRTI) by age, sex, region, PCT and comparison against defined thresholds. Antiviral (AV) use.	Onset Spread Impact	Winter and exception reporting

Influenza surv	veillance systems: microbiological			
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
Datamart	Virological surveillance of acute respiratory viruses as tested in the full respiratory screen by HPA Regional Microbiological Network (RMN) laboratories on patients presenting with respiratory illness. It would indicate trends in respiratory virus activity and provide a measure against which to compare other influenza-illness-like (ILI) indicators if there is an upsurge in ILI activity. This will assist in providing a more complete picture of the contribution of the different pathogens (RSV, influenza A, influenza B, HPIV, adenovirus, HMPV, coronavirus and rhinovirus) to acute respiratory infections.	Provides data on the proportion of respiratory samples positive by week; trends in respiratory virus activity by age group and location.	Onset Spread Impact	Exception reporting and winter
HPA RMN/ Centre for Infectious Diseases (Cfl) spotter practice scheme (England)	Swabbing patients with acute respiratory illness identifies and monitors changing phenotypic/genotypic characteristics of the pandemic strain, including antiviral resistance and pathogenicity markers (virology component)	Weekly virus isolates and proportion by subtype and other respiratory viruses.	Spread Impact	Winter and as required

System	Public health parameters	Key Outputs	Surveillance objective	Reporting
National reference laboratory (England & Wales, Scotland, Northern Ireland)	Identifies and monitors changing phenotypic/ genotypic characteristics of the pandemic strain, including pathogenicity markers as follows:  1) Mutations conferring enhanced viral growth properties (e.g. enhanced attachment to cell surface, faster replication kinetics, etc)  2) Mutations associated with poor clinical outcome (e.g. enhanced evasion of host cellular immune response, etc)  Provides estimates of incidence by age group or other risk parameters (target interventions and refine countermeasures e.g. towards children)	Weekly age group- specific totals, regional totals by subtype.	Impact	
Monitoring of bacterial pneumonia and antimicrobial resistance (England, Wales and Scotland)	Monitoring of bacterial superinfection — bacterial type and resistance (refine antibiotic recommendations and limit the emergence of antimicrobial resistance).  The majority of samples are from England but, as monitoring takes place at the UK WHO National Influenza Centre, samples are received from across the UK.	Weekly totals, regional totals by pathogen for three key pathogens – H influenzae, S pneumoniae and S aureus. Percentage resistant to first-line antimicrobials.	Impact	
HPA Antiviral Resistance Monitoring and Viral Sequencing of Influenza	Identify and monitor changing phenotypic/ genotypic characteristics of the pandemic strain, including antiviral resistance and pathogenicity markers (determine antiviral resistance pattern to direct initial recommendations on use of antivirals, determine if likely to be higher level virulence, informing development of a specific pandemic vaccine).	Weekly number (and rates) of antiviral resistant strains, genetic/antigenic analysis.	Impact	Winter

Influenza surv	eillance systems: severity			
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
HPA Web- based Hospital Surveillance System	A web-based reporting system for laboratory-confirmed influenza hospitalisations designed to identify and quantify risk factors for severe disease and to assist in the detection of emerging changes in the disease epidemiology at a minimal burden on clinicians. This platform provides a robust and reliable mechanism for collecting basic data on hospitalised cases of laboratory-confirmed seasonal influenza.	Daily regional total inpatients, new admissions, and Intensive Treatment Unit (ITU) admissions by age group, number of cases with comorbidities by age group, deaths by age group.	Impact Spread	Exception reporting and winter (weekly)
Excess deaths from all causes by age group and region (mortality data are provided by GRO – General Register Office)	Provides an indicator on whether more deaths (due to all causes) are occurring in a particular age group than would be expected for that time of year. This is important for influenza surveillance, but also for other serious health events such as heat-wave monitoring, and surveillance during the Olympics.	Provides alerts on excess all-cause mortality by age group (and by region) and are based on the number of deaths occurring per week, adjusted for reporting delay. These alerts are non-specific to influenza and need to be interpreted with other surveillance indicators such as flu activity, temperature etc.	Impact	Exception reporting and winter (weekly)
Excess Mortality monitoring (England and Wales) – Office for National Statistics	Broad estimate of severity of the pandemic (determining the limits of public health actions that are justified).	Weekly estimation of national all-cause excess mortality.	Impact	Winter

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Influenza surveillance systems: interventions				
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
Influenza vaccine uptake	Provide timely measure of influenza vaccine uptake in target populations (clinical risk groups, health care workers etc).	Monthly influenza vaccine uptake by age and risk group for clinical risk groups at national, SHA and PCT level.  Monthly influenza vaccine uptake for health care workers at national, SHA and trust level.	Effectiveness	Winter – monthly
Vaccine effectiveness surveillance	Provide measure of the effectiveness of new influenza vaccine through the sentinel virological surveillance networks.	Interim and end of season measure of flu vaccine effectiveness	Effectiveness	

Influenza surv	veillance systems: outbreaks			
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
Medical Officers of Schools Association (MOSA) and HPA scheme (England only)	Give estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models).	Weekly report of significant incidents in this network of independent schools (incidence rates are calculated and relayed back to the schools).	Onset Spread	Winter
Outbreaks of respiratory illness	Outbreaks in institutional settings (schools, care homes, hospitals etc) are reported to the Respiratory Diseases Department, Cfl on an ad hoc basis.	Ad hoc reports of outbreaks	Onset Spread	Winter

Influenza sur	veillance systems: enhanced surveilla	ance		
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
First Few Hundred (FF100) project	Enhanced surveillance of cases due to novel influenza virus and their close contacts (or potentially other new respiratory viruses or public health-related incident). This includes collection of detailed demographic data, exposure, clinical, treatment and outcome data on cases and their close contacts.	Public health-based epidemiological analysis to determine key epidemiological, virological and clinical characteristics of a novel pandemic virus e.g. serial	Spread Impact Effectiveness	As required
		interval, effectiveness of antivirals.		

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Influenza surveillance systems: international				
System	Public health parameters	Key Outputs	Surveillance objective	Reporting
International surveillance	Monitors rumour and formal data sources to identify new and ongoing diseases, including influenza, of interest to England.	ILI rates by country, deaths by country, virological surveillance including dominant influenza strain.	Onset Impact	Winter and 'switched on' as required

Note: The HPA is also currently exploring whether flu-related absenteeism from a major employer in London could be used as a future indicator for influenza surveillance.

# Additional UK-wide surveillance systems: public health parameters, outputs, objectives, and reporting

System	Public health parameters	Key Outputs	Surveillance objective	Reporting
Northern Ireland Sentinel Practice Network	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)  Identifies and monitors changing phenotypic/genotypic characteristics of the pandemic strain, including antiviral resistance and pathogenicity markers (virology component)	Weekly incidence and prevalence rates of influenza-like illness, pneumonia, acute respiratory infection by age and sex. Work in defining thresholds underway. Virus isolates and proportion by subtype.	Onset Spread Impact	Winter
NHS 24 (Scotland)	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Daily age group-specific trends and HPA Region- specific trends for 'swine flu', colds/flu, fever.	Onset Spread Impact	Winter and exception reporting
Out of Hours Primary Care Surveillance (Northern Ireland)	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Daily age group-specific trends for flu/FLI.	Onset Spread Impact	Winter

System	Public health parameters	Key Outputs	Surveillance objective	Reporting
PIPeR/ PTI Scheme (Scotland)	The Pandemic Influenza Primary Care Reporting (PIPeR) system was designed to meet surveillance needs in the event of a pandemic of influenza developing. This system has three main components, two of which emulate existing systems for flu surveillance or vaccine monitoring. PIPeR was used over the course of the 2008/2009 season to generate influenza (and pneumococcal) vaccine uptake and provide trend data on clinical presentation with ILI and acute respiratory illness (ARI). In addition, PIPeR generates clinical trend data for ILI and ARI presentations by age and clinical risk groups whilst reporting on the laboratory investigation of presentations using multiplex Polymerase Chain Reaction (PCR) testing of respiratory samples.  Identifies and monitors changing phenotypic/ genotypic characteristics of the pandemic strain, including antiviral resistance and pathogenicity markers (virology component).	Daily and weekly incidence and prevalence rates of influenza-like illness, pneumonia, acute bronchitis by age, sex, Health Board, and comparison against defined thresholds. Rates by vaccination status. Virus isolates and proportion by subtype	Onset Spread Impact	Winter
Rapid surveillance of influenza in Wales using Audit+	Provides estimates of incidence by age group or other risk parameters (trigger for change in public health response mode, inform health service planning, target interventions and refine countermeasures e.g. towards children, input to real-time models)	Daily incidence and prevalence rates of influenza-like illness, URTI, LRTI by age, sex, region, and comparison against defined thresholds.	Onset Spread Impact	Winter

## Annex F

## Definition of an at-risk group, as agreed by the Scientific **Advisory Group for Emergencies (SAGE)**

"Members of an at-risk group are defined as those who are at higher risk of serious illness or death should they develop influenza."

List of at-risk groups who should receive antiviral treatment for clinically diagnosed swine flu:

- 1. people aged 6 months or over with:
  - chronic respiratory disease (including asthma that requires continuous) or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospitalisation)
  - chronic heart disease
  - chronic renal disease
  - chronic liver disease
  - chronic neurological disease
  - immunosuppression
  - diabetes mellitus.
- 2. people who have received any medical treatment for asthma in the last three years (in addition to those included above)
- 3. pregnant women
- 4. children under the age of 5 years
- 5. people over the age of 65 years.

## **Annex G**

# Hospitalisations and critical care admissions during the H1N1 pandemic

	Hospitalised Cases	ICU/HDU Admissions <sup>5</sup>
England <sup>1</sup>	25,785	2,326
Scotland <sup>2</sup>	1,531	187
Wales <sup>3</sup>	451	64
Northern Ireland <sup>4</sup>	580	50

<sup>&</sup>lt;sup>1</sup> From 17th July 2009 until 1st March 2010 (DH)

<sup>&</sup>lt;sup>2</sup> From 2nd July until 25th January 2010 (HPS)

<sup>&</sup>lt;sup>3</sup> From 24th May 2009 until 28th April 2010 (CDSC Wales)

<sup>&</sup>lt;sup>4</sup> From 20th August until 2nd April 2010 (CDSC NI)

<sup>&</sup>lt;sup>5</sup> ICU: intensive care unit; HDU: high dependency unit

## Annex H

## Glossary

Advance-purchase

agreement

An agreement in which the purchaser commits to purchase a product prior to its development.

Antivirals/

antiviral medicines

Types of medicines used to treat viral infections

such as influenza.

**Asymptomatic** 

Infected but not showing symptoms.

**Break clause** 

A clause which allows a contract to be

terminated early.

Clinical attack rate

(CAR)

The cumulative proportion of people infected

and showing symptoms over a specified period

of time.

Clinical diagnosis

The identification of a patient's illness from a physical examination of their signs and

symptoms.

Containment

Measures to limit the spread of infection from an

affected area(s).

Countermeasures

Interventions that attempt to prevent, control or

treat an illness or condition.

Critical care

Care of patients with life-threatening conditions.

**Epidemic** 

The widespread occurrence of significantly more cases of a disease in a community or population

than expected over a period of time.

Epidemiological models Mathematical simulations of the spread of a disease and the likely effectiveness of

countermeasures.

**Epidemiology** 

The study of patterns, causes and control of

disease in groups of people.

**Excess deaths** Deaths which exceed the expected number of

deaths for a particular season.

**Exercise Winter Willow** A government-led exercise to test the UK's

ability to manage the effects of an influenza

pandemic.

Extracorporeal membrane

oxygenation (ECMO)

A medical technique for providing both cardiac and respiratory support to patients whose heart and lungs are very severely

diseased or damaged.

Face mask/ surgical mask A disposable face mask that provides a physical

barrier but no filtration.

H1N1/
swine influenza A

A strain of the influenza virus, endemic in pigs.

H5N1/ avian influenza

Highly pathogenic avian influenza virus, endemic

in birds in South East Asia.

**Infectivity** The extent to which a given micro-organism

infects people (or animals), i.e. the ability of the organism to enter, survive and multiply in people

and cause disease.

Mathematical modelling

An abstract model that uses quantitative data

to describe the behaviour of a system.

Mitigation Actions taken to decrease or moderate the

severity or intensity of an event or process.

**Morbidity** The incidence of ill health.

**Mortality** The incidence of death.

National Risk Register Report released by the Cabinet Office as part

of the government's National Security Strategy.
It provides an assessment of significant potential

risks to the UK.

NHS 24 (Scotland) National Health Service telephone helpline

(Scotland).

NHS Direct National Health Service telephone helpline

(England).

NHS Direct Wales National Health Service telephone helpline

(Wales).

Outbreak Sudden appearance of, or increase in, cases

of a disease in a specific geographical area or population, e.g. in a village, town or closed

institution.

Pandemic Worldwide epidemic – an influenza pandemic

occurs when a new strain of influenza virus emerges which causes human illness and is able to spread rapidly within and between countries

because people have little or no immunity to it.

'Pandemic Flu:

A national framework for responding to an

influenza pandemic'

Joint Cabinet Office and Department of Health framework for dealing with a pandemic. Published in 2007 (also referred to as the National

Framework, The Framework, 2007 Framework).

Pandemicspecific vaccine A vaccine that is procured once a pandemic is announced, using the correct strain of influenza

for the outbreak.

**Pre-pandemic vaccine** A vaccine that is procured prior to a pandemic

and stockpiled ready to be used. It may therefore not be the correct strain of influenza that occurs

in a pandemic.

**Priority groups** Groups of individuals identified as needing to be

prioritised in terms of receiving vaccination.

**Prophylaxis** Administration of a medicine to prevent disease

or a process that can lead to disease – with respect to pandemic influenza, this usually refers to the administration of antiviral medicines to

healthy individuals to prevent influenza.

**QSurveillance system** A database, formed by the University of

Nottingham and Egton Medical Information Systems Ltd, containing primary care data from a nationally representative sample of practices.

Scientific evidence base

The scientific evidence upon which preparedness plans are developed.

Seasonal flu vaccine Annual vaccine for use against influenza viruses.

**Sleeping contract** A contract that is in place to be activated

only when needed. The advance-purchase

agreements are examples of sleeping contracts.

Statement of Financial Entitlements The Statement of Financial Entitlements relates to the payments to be made by primary care trusts to a contractor under a General Medical

Services contract.

**Surveillance** The continuing scrutiny of all aspects of the

occurrence and spread of disease pertinent to effective control in order to inform and direct

public health action.

**Symptomatic** Showing symptoms of disease or illness.

**Transmission** Any mechanism by which an infectious agent

is spread from a source or reservoir (including

another person) to a person.

**Virulence** The degree to which a micro-organism is able

to cause serious disease.

**Wave** The period during which an outbreak or epidemic

occurs either within a community or aggregated across a larger geographical area. The disease wave includes the time during which the disease occurrence increases, peaks and declines back

towards baseline.

## Annex I

## **Acronyms**

ACP Antiviral collection point

BIS Department for Business, Innovation and Skills

**BMA** British Medical Association

**BSE** Bovine spongiform encephalopathy

**CAR** Clinical attack rate

**CCC** Civil Contingencies Committee

**CCC(0)** Civil Contingencies Committee (Officials)

CCS Civil Contingencies Secretariat

**CEAPI** Committee on Ethical Aspects of Pandemic

Influenza

**CFR** Case fatality rate

**CHR** Clinical hospitalisation rate

CJD Creutzfeldt-Jakob disease

**CLG** Department of Communities and Local

Government

**CMO** Chief Medical Officer

**CO** Cabinet Office

COBR Cabinet Office Briefing Room (often referred

to as COBRA)

CONOPS The Central Government's Concept of

**Operations** 

CSA Chief Scientific Adviser

**Defra** Department for Environment, Food and Rural

**Affairs** 

**DH** Department of Health

**DHSSPSNI** Department of Health, Social Services and

Public Safety Northern Ireland

**DWP** Department for Work and Pensions

**ECDC** European Centre for Disease Prevention and

Control

**ECMO** Extracorporeal membrane oxygenation

**EMA** European Medicines Agency (previously

European Agency for the Evaluation of Medicinal

Products (EMEA))

**FCO** Foreign and Commonwealth Office

**FLU-CIN** Influenza Clinical Information Network

**FMD** Foot-and-mouth disease

GCSA UK Government Chief Scientific Adviser

GMC General Medical Council

**GPC** General Practitioners Committee

**HPA** Health Protection Agency

**HPS** Health Protection Scotland

ICU Intensive care unit (see also ITU)

ILI Influenza-like illness

ITU Intensive treatment unit (see also ICU)

**JCVI** Joint Committee on Vaccination and

**Immunisation** 

Local Resilience Forum/a LRF

MISC32 Ministerial Committee on Pandemic Influenza

**Planning** 

NCC News Co-ordination Centre

**NMC** Nursing and Midwifery Council

National Pandemic Flu Service **NPFS** 

NSC (THRC) National Security Council (Threats, Hazards,

Resilience and Contingencies)

PCT Primary care trust

**PICO** Pandemic Influenza Clinical and Operational

Advisory Group

PICO-CSG Clinical Sub-group of PICO

RCGP Royal College of General Practitioners

**RCM** Royal College of Midwives

**RCOG** Royal College of Obstetricians and

Gynaecologists

RHH Respiratory health and hand hygiene

SAC Scientific Advisory Committee

SAG Scientific Advisory Group

SAGE Scientific Advisory Group for Emergencies SECC Flu Scottish Emergencies Co-ordinating Committee's

Sub-group for Pandemic Influenza

SFCCCG Swine Flu Critical Care Clinical Group

**SFE** Statement of Financial Entitlements

SHA Strategic health authority

SPI Scientific Pandemic Influenza Advisory

Committee

SPI-B&C Behaviour and Communication sub-group

of SPI

**SPI-CC** Clinical Countermeasures sub-group of the SPI

**SPI-M** Modelling sub-group of the SPI

**SPI-M-O** Modelling and Operational sub-group of the SPI

**URN** Unique reference number

WAG Welsh Assembly Government

**WHO** World Health Organization

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