



Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009

Covering the period 24 April 2009 – 31 August 2009

(excluding vaccine policy issues)

16 April 2010

Health Protection Agency 2010



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Contents

Executive Summary	5
Résumé exécutif	7
Abbreviations and acronyms	9
1.0 Purpose and outline of report	10
2.0 Review methodology	11
• EU-wide web based survey	
• Interviews with the Commission (DG SANCO) and EU Agencies	
• Confidentiality and Comparisons	
3.0 Review Limitations	14
4.0 Terminology	16
5.0 Pandemic Background	17
• Global Situation	
○ Epidemiology	
○ Strategies and Statements	
○ Vaccines and anti-virals	
• European Situation	
○ Strategies and Statements	
○ Vaccines and anti-virals	
6.0 General Pandemic Preparedness and Response	21
• Preparedness	
• Containment Strategy	
7.0 Pandemic Preparedness and Interoperability	24
• Consultation	
• Interoperability	
• Planning	
8.0 Business Continuity Planning	27
• Impact on services	
• Mutual aid	
9.0 EU-wide Communications Systems	30
• Early Warning and Response System (EWRS)	
• Health Emergency and Diseases Information System (HEDIS)	

	<ul style="list-style-type: none">• Medisys• Arkadin• Other communications tools	
10.0	Coordination between National, EU and International Agencies	37
	<ul style="list-style-type: none">• DG SANCO<ul style="list-style-type: none">○ Meetings and audio-conferences○ HSC/EWRS audio-conferences○ Coordination○ Information Sharing• European Centre for Disease Prevention & Control (ECDC)• European Medicines Agency (EMA)• World Health Organisation (WHO)• Reporting	
11.0	Coordination of Public Health and Control Measures	45
	<ul style="list-style-type: none">• Transport and travel• Schools• Mass gatherings• Personal countermeasures• Influenza diagnosis	
12.0	Coordination of Public and Media Messages	51
	<ul style="list-style-type: none">• Health messages to the public• Health messages to health professionals• Media relations and perception• HSC Communicators' Network (HSC COMNET)	
13.0	Anti-viral Medicines	57
	<ul style="list-style-type: none">• Access to anti-viral medicines• Guidance on effective use• Susceptibility testing	
14.0	Appendices	62
	<ul style="list-style-type: none">1.0 Protocol Document2.0 EU-wide Pandemic (H1N1) 2009 Survey Questionnaire3.0 Interview topics – EMA4.0 Interview topics – the Commission (DG SANCO)5.0 Interview topics – ECDC6.0 Health Council Decisions from Extra-ordinary Meeting 30 April 20097.0 Graphs of Case Numbers8.0 European Union Case Definition9.0 EWRS Comparison Graphs – access statistics10.0 Affected Areas Definition – from ECDC	
15.0	References	96

Executive Summary

Introduction

An outbreak of novel influenza was notified to the European Commission and Member States on 24 April 2009 having been identified earlier in Mexico and the United States of America. This prompted the EC, EU Agencies and MS to initiate a response and the implementation of pandemic influenza plans. The disease spread rapidly across the EU and globally, and on 11 June 2009 was declared a pandemic when WHO raised the pandemic influenza alert from level 5 to Level 6.

This report is the result of an EC-commissioned review led by the HPA as a contractor through its framework contract, of the response to Pandemic (H1N1) 2009 in Europe by MS, EU Agencies and the EC covering the period 24 April to 31 August 2009. The report is structured around seven objectives and includes presentation of the data, analysis and observations in seven key areas.

Aim

The aim of the review is to examine the response at MS and EC level to the first four months of the pandemic (H1N1) 2009 from 24 April to 31 August 2009.

Objectives

The objectives for the review commissioned by the EC are:

1. Review pandemic response plans and interoperability between national response plans
2. Examine the effectiveness of business continuity plans (where implemented)
3. Evaluate the robustness and efficiency of communications systems utilised during the response at national and EU level
4. Assess the effectiveness of communications within and between national, EU and international participants
5. Examine the coordination of public health and control measures at national level and across the EU
6. Evaluate the response to media-quests at national level and coordination of public and media messages across the EU
7. Analyse the availability and use of vaccines and anti-viral medicines

Methodology

The review was conducted primarily using a web-based survey for completion by all participating MS. There were 22 responses. Interviews were held with ECDC, EMA, and DG SANCO personnel. Data and information collected from these sources were analysed according to objective, and the results are contained in the body of the report. See further Section 2.0 Review Methodology.

Limitations

The report has a number of limitations despite the readiness of its availability; it cannot be considered a formal external evaluation exercise since its framework was developed for another purpose and the time frame did not allow developing in-depth findings and observations.

Nevertheless, the Member States (21 Member States replied) survey response provide a realistic contribution in particular in developing ideas for improving the crisis response. Most of the observations referring to the Member States and to the World Health Organisation should not be transformed into definitive actions unless they have conducted their own review process and the consistency of the findings is considered. See further Section 3.0 Review Limitations



In spite of these limiting factors, the report brings forward a substantial number of useful observations which are a mixture of issues needing follow up at national or EU level.

Résumé exécutif

Introduction

Une épidémie de grippe inédite et préalablement identifiée au Mexique et aux Etats-Unis fut signalée à la Commission européenne et aux Etats membres le 24 avril 2009. La Commission européenne, les agences de l'Union européenne et les Etats membres se virent amenés à déclencher une réponse et la mise en œuvre de plans visant à combattre cette pandémie grippale. La maladie, s'étant rapidement répandue au niveau de l'Union européenne et du reste du monde, obtint le statut de pandémie le 11 juin 2009, date à laquelle l'OMS décida de faire passer le niveau d'alerte de la pandémie grippale du niveau 5 au niveau 6a.

Le présent rapport est le résultat d'un exercice commissionné par la Commission Européenne et menée par la HPA . Il porte sur la réponse à la pandémie de grippe H1N1 de 2009 constatée en Europe de la part des Etats membres, des agences de l'Union européenne et de la Commission européenne pendant la période allant du 24 avril au 31 août 2009. Il s'articule autour de sept objectifs et inclut une présentation des données ainsi que des analyses et des observations dans sept domaines clé.

Objet

L'objet de cette revue est d'examiner la réponse des états membres et de la Commission européenne pendant les quatre premiers mois de la pandémie H1N1 de 2009, sur la période allant du 24 avril au 31 août 2009.

Objectifs

Les objectifs de l'exercice fournis par la Commission européenne sont les suivants :

1. Examiner les plans de réponse à la pandémie et l'interopérabilité entre les plans de réponse nationaux.
2. Examiner l'efficacité des plans de continuité d'activité (le cas échéant).
3. Considérer la robustesse et l'efficacité des systèmes de communication utilisés lors de la réponse, et ce, au niveau national comme au niveau de l'Union européenne.
4. Revoir l'efficacité des communications entre les participants au niveau national, international et de l'Union européenne, ainsi que celle de leurs communications internes.
5. Examiner la coordination des mesures de contrôle et de santé publique au niveau national et dans l'ensemble de l'Union européenne.
6. Considérer la réponse à la médiatisation au niveau national ainsi que la coordination des messages publics et médiatiques dans l'ensemble de l'Union européenne.
7. Analyser la disponibilité et l'utilisation des vaccins et des médicaments antiviraux.

Méthodologie

La revue a principalement pris la forme d'une enquête en ligne à remplir par tous les Etats membres participants. Vingt-deux réponses en furent obtenues. Des entretiens furent menés auprès du personnel du CEPCM, de l'EMEA, et de la DG SANCO. Les données et renseignements recueillis auprès de ces sources furent analysés conformément à l'objectif et les résultats en sont présentés dans le corps du rapport. Voir Section 2.0 Méthodologie.

Limitations

Bien que finalisé et disponible, le rapport a néanmoins certaines limites. Il ne peut être considéré comme un exercice formel d'évaluation externe étant donné que son



cadre fut développé pour un objectif différent. De plus les délais serrés accompagnant la réalisation de l'enquête n'ont pas favorisé les possibilités d'exploration approfondie des conclusions et observations.

Néanmoins, les réponses fournies par les Etats Membres (21 Etats Membres ont répondu) fournissent des éléments concrets permettant notamment de développer de nouvelles idées pour améliorer la gestion de crise. La plus part des observations faisant référence aux Etats Membres et à l'Organisation Mondiale de la Santé ne devraient donner lieu à des actions définitives que si ces derniers ont procédé à leur propre procédure d'évaluation dont les conclusions seraient en adéquation avec les observations du présent rapport. Voir Section 3.0 Limitations de l'évaluation.

Abbreviations and Acronyms

Acronym	Explanation
A(H1N1) or H1N1	2009 Pandemic Influenza Strain
C3	DG SANCO Health Threats Unit
CDC	US Center for Disease Control
CHM	Commission on Human Medicines
CHMP	Committee for Medicinal Products for Human Use
DGs	Directorate Generals of the European Commission
DG SANCO or SANCO	Directorate General for Health & Consumers
EC	European Commission
ECDC	European Centre for Disease Prevention & Control
ECMO	Extracorporeal membrane oxygenation
EFTA	European Free Trade Association
EMA	European Medicines Agency
EMT	Emergency Management Team
EPIS	Epidemic Intelligence Information System
EU	European Union
EWRS	Early Warning & Response System (on communicable disease)
FAO	United Nations Food & Agriculture Organisation
FDA	US Food & Drug Administration
FOPG	Friends of the Presidency Group on Pandemic Preparedness
GHSAG	Global Health Security Advisory Group
GHSI	Global Health Security Initiative (G7 countries, Mexico, European Commission and WHO)
GOARN	Global Outbreak and Response Network
GP	General Practitioner
HPA	Health Protection Agency (UK)
HEDIS	Health Emergency & Diseases Information System
HEOF	DG SANCO Health Emergency Operation Facility
HSC	Health Security Committee
HSC COMNET	Health Security Committee Communicators' Network
IHR	International Health Regulations
ILI	Influenza-like illness
MediSYS	Web-based Medical Intelligence System
MS	Member State(s) - for the purposes of this report MS includes the EFTA countries as well as the EU27 who participated in the review.
NCA	National Competent Authority (Medicines)
OIE	World Organisation for Animal Health
SMS	Short Message Service (Text Messaging)
SEE States	South East European States
SOP	Standard Operating Procedure
SSiaP	ECDC Pandemic Surveillance & Studies in a Pandemic Working Group
TESSy	ECDC European (Health) Surveillance System
WHO Euro	World Health Organisation European Region
WHO HQ	World Health Organisation Headquarters, Geneva
WTO	World Trade Organisation

1.0 Purpose and outline of report

- 1.1 Following the beginning of the outbreak of Pandemic H1N1 influenza in Europe on 24 April 2009, the Commission (DG SANCO) cancelled the planned EU-wide pandemic influenza exercise scheduled for 2009. In its place they requested an independent review of the EU-wide response to the current outbreak of Pandemic (H1N1) 2009 covering the period 24 April to 31 August 2009.
- 1.2 The aim of this report is to examine the response at MS and Commission level to the first four months of the Pandemic (H1N1) 2009 crisis.
- 1.3 There are seven objectives examined as part of the review:
- Examine pandemic preparedness plans and interoperability between national plans
 - Examine the effectiveness of business continuity plans (where implemented)
 - Examine the robustness and efficiency of communications systems utilised during the response
 - Assess the effectiveness of communications within and between national, EU and international participants
 - Examine the coordination of public health and control measures across the EU
 - Examine the coordination of public and media messages across the EU
 - Analyse the availability and use of vaccines and anti-viral medicines
- 1.4 The purpose of the review is:
- To identify lessons from the first four months of the crisis, including the containment phase and early weeks of mitigation
 - To inform the ongoing response to the current pandemic and future public health crises within the EU.
- 1.5 The report will present the data, analysis and observations in seven key areas:
- Interoperability of MS pandemic flu plans
 - Business continuity
 - Communications tools
 - Communication and liaison between MS and agencies
 - Public health and control measures
 - Media and public messaging
 - Vaccines and anti-viral medicines
- 1.6 While this report focuses on aspects of the EU-wide response during the current influenza pandemic, the principle observations could be applied to other events that may occur in the future.

During the period of this review a second review – “Review of EU-wide Pandemic Vaccine Strategies” – was commissioned that specifically focuses on pandemic vaccine issues. The section on pandemic vaccines in this report is included for completeness, and any observations will be considered in the subsequent report.

2.0 Review Methodology

- 2.1 A protocol document was initially developed that outlined the aim, objectives and scope for the review (Refer Appendix 1.0). As all seven objectives had a broad scope, the protocol document also included a breakdown of the objectives to focus on specific parameters within each objective. Objective eight was undertaken in a separate review¹.
- 2.2 Data and information for the review were gained from the following principle sources:
- MS survey responses
 - Media reports and press releases from the Commission², EU agencies, and WHO³
 - Situation reports from the Commission, ECDC⁴ and WHO⁵
 - Interviews with the Commission (DG SANCO), ECDC and EMA
- 2.3 The four month timeframe for the review period was chosen to capture the first part of the Commission, MS and EU Agencies responses to the crisis. The period was originally set at three months, but at an review planning conference with MS, the Commission (DG SANCO) and EU agencies in Brussels on 22-24 September 2009 this was extended to four months at the request of delegates. This was due to some MS still being in the early stages of their response and by extending the review period it would allow inclusion of more information.

EU-wide web-based Survey

- 2.4 The main source of information for the report has been the EU-wide web-based survey that was developed for the EU27 and EFTA countries. A survey was deemed the best option available that allowed for contact with all MS within a relatively short timeframe.
- 2.5 The survey questions were designed to provide key information relating to each objective. The survey underwent extensive development and revision, including review at the September 2009 review conference in Brussels, and through audio-conferences attended by the Commission (DG SANCO), MS and EU agencies and held on 29 July 2009 and 26 October 2009. A copy of the survey is in Appendix 2.0.
- 2.6 The survey was available in English for completion by MS online from 27 October to 15 November 2009 (20 days). Twenty two countries responded to this survey as indicated below.
- Austria
 - Belgium
 - Bulgaria
 - Cyprus
 - Czech Republic
 - Estonia
 - Finland
 - France
 - Germany
 - Hungary
 - Latvia
 - Lithuania
 - Malta
 - Netherlands
 - Norway
 - Poland
 - Portugal
 - Romania
 - Slovakia
 - Spain
 - Sweden
 - United Kingdom

Two countries formally opted out of this review process:

- Denmark
- Ireland

Countries that did not take part in this survey:

- Greece
- Luxembourg
- Switzerland
- Iceland
- Slovenia
- Italy
- Liechtenstein

2.7 Participating MS were asked to complete the online version of the survey. Responses to the questions were in various formats including:

- Yes / no answers
- Multiple choice options
- Free text boxes
- Combination of free text and multiple choice options

2.8 Interpretation of the raw data was undertaken using two methods. The multiple choice options and yes / no answers were analysed and summary statistics and graphs of the data were produced. These were then examined for trends, common responses, or specific individual responses. These outputs are represented in the report as stand-alone graphs or as described in the text. As stated in the Review Limitations the time available for the process did not allow for a more thorough approach such as the Delphi-method.

2.9 Free text responses from the open ended survey questions were scrutinised differently. All responses for each question were collated then a simple thematic analysis was conducted to identify common themes in participant's responses, which were then grouped to derive the key issues. In some cases direct quotes are included in the report where they adequately illustrate an emergent theme derived from multiple responses to the open-ended questions.

Interviews with the Commission (DG SANCO) and EU Agencies

2.10 Information was collected by conducting a panel interview with EMA personnel who were involved in the response to the pandemic. The interview was held in London on 8 October 2009. An outline of the topics covered in the interview is contained in Appendix 3.0.

2.11 Interviews were also held with the Commission's DG SANCO Unit C3 personnel who were involved in the first four months of the response. A series of interviews were held in Luxembourg on 9 and 10 November 2009. Those interviewed represented preparedness, crisis management, communications, and scientific coordination. DG SANCO was the only EC service consulted as part of this review. An outline of the topics covered in the interviews is contained in Appendix 4.0.

2.12 Interviews were conducted with ECDC in Stockholm on 21 and 22 January 2010, and information was gathered from personnel involved in the pandemic crisis representing the following areas: communications, influenza coordination, vaccines, scientific and technical, crisis management, surveillance, and liaison. An outline of the topics covered in the interviews is

contained in Appendix 5.0. Supporting documents and presentations related to the response, vaccines, and publications were also provided by ECDC.

Confidentiality and Comparisons

- 2.13 In order to respect the confidentiality of the individual survey respondents and interviewees, the data presented in this report is not attributed but is described collectively. The review does not seek to compare MS, as agreed by delegates at the Barcelona review conference in February 2010.

3.0 Review Limitations

- 3.1 As might be expected from a review of this size and complexity, there have been some limitations and constraints. Despite the readiness of its availability; it cannot be considered a formal external evaluation exercise since its framework was developed for another purpose (EU-wide pandemic influenza simulation exercise) and the time frame did not allow developing in-depth findings and observations.
- 3.2 The objectives were developed during the second month of the crisis without knowing future events and how applicable the objectives would be. The review cannot therefore be considered a thorough assessment of all relevant aspects of the response to the pandemic.
- 3.3 The broad scope of the objectives meant the survey was lengthy and some questions were removed from the original version of the survey at the request of MS. This had an impact on gathering sufficient detailed information in some areas.
- 3.4 The survey was only available in English which may have had an impact on the responses given by some MS. Interpretation of the questions varied across MS.
- 3.5 There was a relatively short timeframe for the consultation, approval and completion process of the questionnaire. The ability to delve further into the detail was constrained by this timeframe.
- 3.6 The short timescale for completion of the survey had an impact. There was limited access at the time of the questionnaire distribution to the appropriate people, many of whom were still responding to the pandemic and preparing vaccine strategies and programmes.
- 3.7 The large workload from the response to the pandemic meant that in many MS, the Commission and EU Agencies, the review was conducted against a background of fatigue.
- 3.8 It was not possible or feasible for the review team to visit every MS to gather information, and the team had to rely on one contact point for each MS.
- 3.9 Each MS completed the survey as they saw fit, and therefore responses could be regarded as inconsistent. Whilst 22 MS submitted surveys, not all surveys were complete, meaning that analysis of answers to some questions were based on less than the maximum possible 22.
- 3.10 When considering the responses to survey questions, some data received was incomplete or ambiguous. This data was therefore not included in the review. This predominantly occurred in the free text answers.
- 3.11 The operational challenges faced by health care sectors (such as those relating to increased pressure on intensive care units) were not part of this review. It is however noted that these areas are considered critical and may therefore benefit from future reviews.
- 3.12 It should be noted that the report does not address the issue of efficacy data for anti-viral medicines.

- 3.13 Despite the limitations, the Member States (21 Member States replied) survey response provide a realistic contribution in particular in developing ideas for improving the crisis response. Most of the observations referring to the Member States and to the World Health Organisation should not be transformed into definitive actions unless they have conducted their own review process and the consistency of the findings is considered

4.0 Terminology

- 4.1 Throughout the report various descriptive terms have been used, and they are explained below.
- 4.2 For the purposes of this report, the abbreviation MS refers to those countries from the EU27 and EFTA that participated in the review and survey. The term “participating MS” is also used in this context.
- 4.3 Throughout this report the terms ‘containment’ and ‘mitigation’ have been used to describe the various stages in the response to the pandemic. These terms are used in the following context and meaning:
- Containment:
Intensive case finding and delaying strategy
 - Mitigation:
Case management strategy
- 4.4 These terms were used during the Brussels pandemic review conference (September 2009) in the development of the questionnaire and agreed by MS and EU Agency delegates. The triggers for change from containment to mitigation were generally considered to be the evidence of local, or community, transmission.
- 4.5 The term “pandemic influenza” used in this document is the definition published by WHO:
“An influenza pandemic can be defined as a global epidemic of influenza and it occurs when a new influenza virus (i.e. an influenza virus subtype that is not circulating widely in human beings) emerges and starts spreading in a similar way to normal influenza - through coughing and sneezing.”

5.0 Pandemic Background

- 5.1 The following is a brief summary provided as a reminder of some of the key milestones, situation reports and activity undertaken at a global and European level during the period of the development of the pandemic from 24 April to 31 August 2009.
- 5.2 This section gives the context and provides a backdrop for the review. It is intended as a reminder of activities and decisions that took place during the review period (first four months of the pandemic). This is not an exhaustive list, nor does it indicate priority or importance.

Global Situation

Epidemiology

- 5.3 On 23 April 2009, the US CDC confirmed seven cases of swine influenza A(H1N1) in humans that had been identified in California and Texas. It was suspected that transmission was from human to human.⁶ On the same day Mexico reported 120 confirmed cases of respiratory illness due to influenza and 20 deaths.⁷
- 5.4 On 27 April, similar cases were being reported in the US, Mexico, Canada, and Spain⁸ as well as in New Zealand, the UK and Israel.⁹
- 5.5 As at 29 April 2009, nine countries globally had reported 148 cases.¹⁰
- 5.6 By 6 May, Mexico had reported 942 laboratory confirmed cases, including 29 deaths and the USA reported 642 laboratory confirmed cases including two deaths.¹¹ On the 7 May 2009 WHO reported that 24 countries were involved in the outbreak with 2371 reported cases.¹² Just over a week later WHO reported outbreaks in 40 countries with 8829 cases including 74 deaths worldwide.¹³
- 5.7 By 29 May outbreaks were reported in 53 countries with almost a doubling of cases to 15510 and 99 reported deaths.¹⁴
- 5.8 By 10 June 74 countries worldwide had reported 27737 cases and 141 deaths.¹⁵ Meanwhile the Southern Hemisphere countries were in the middle of their main influenza season (April to September) and by the end of August were reporting that H1N1 was the predominant strain of influenza.¹⁶
- 5.9 By 16 July WHO had decided to discontinue the reporting of global tables of cases by country and moved to reporting newly affected countries only.¹⁷
- 5.10 By the end of July 2009 global cases had reached 162380 with 1154 deaths.¹⁸
- 5.11 By the end of the month of August 48 of the 53 member states in the WHO European region had reported laboratory confirmed cases of pandemic (H1N1) 2009 virus infection.¹⁹

Strategies and Statements

- 5.12 On 27 April WHO raised its pandemic alert from Level 3 to 4.²⁰ At this point WHO did not recommend any trade or travel restrictions, and changed its approach from one of containment to mitigation.²¹ The pandemic alert was raised again from Level 4 to 5 on 29 April 2009.²²
- 5.13 FAO, WHO, WTO and OIE issued a joint statement on 30 April stating that well cooked pork and pork products were safe to eat.²³
- 5.14 On 2 May WHO published a guidance document on hand-washing as a means of minimising virus spread.²⁴
- 5.15 It was at this stage that Brazil reported that it believed the majority of its cases had been imported from Europe by returning travellers.²⁵
- 5.16 On 11 June WHO raised its pandemic alert from Level 5 to 6. This act officially confirmed the global pandemic.²⁶
- 5.17 At the end of the July WHO issued a statement on the increased risk of severe or fatal pandemic influenza illness in pregnant women.²⁷
- 5.18 The Global Health Security Initiative (in which the Commission participates) held informal meetings twice, first during the World Health Assembly in May and then, at the invitation of Mexico, in Cancun at a ministerial meeting on 2 and 3 July 2009 on Pandemic (H1N1) 2009. This network has been useful for sharing information between members on public health measures planned or taken.²⁸

Vaccines and anti-virals

- 5.19 WHO carried out a survey in May 2009 among influenza vaccine manufacturers on their planned seasonal and pandemic production with a view to developing recommendations on the distribution and use of pandemic influenza vaccine.²⁹
- 5.20 During August 2009 WHO issued a briefing note on the safety of pandemic vaccine and the proposed manufacturing process.³⁰ It also published recommendations on the use of anti-virals in the management of pandemic influenza cases.³¹
- 5.21 Significantly during the course of August WHO had been notified of 12 cases of Oseltamivir-resistant virus globally, despite many millions of courses having been given. Only one resistant case had so far been identified in Europe (Denmark). No instances of onward transmission of drug-resistant virus had been documented at this stage.³²

European Situation

- 5.22 On 24 April 2009 ECDC posted an analysis of the influenza situation in Europe on its website, stating that seasonal influenza activity remained at baseline levels for Europe where the 2008-09 winter season was coming to an end.³³ Later the same day ECDC issued a threat assessment update which was communicated to MS via EWRS. This assessment considered the implication for Europe of the identification of human cases of swine influenza A. ECDC conclusions at 24 April reported that further vigilance was required

in Europe, due to early indications of human to human transmission of the virus.³⁴

- 5.23 On 28 April the first laboratory confirmed cases were announced in the EU with one case in Spain and two cases in the United Kingdom (Scotland).³⁵
- 5.24 By 2 May there were 49 confirmed and 14 probable cases reported in the EU and EFTA countries all but one of these presenting with mild symptoms.³⁶
- 5.25 The first known pandemic influenza death outside the Americas and in the EU was confirmed in Scotland (UK) on 14 June in a patient with underlying health conditions.³⁷
- 5.26 By the 19 June 30 of the 53 member states of the WHO European region reported a total of 3308 cases including one death. Reported cases rose by 83% in this one week alone.³⁸
- 5.27 By 3 July Malta had reported its first two cases of pandemic H1N1 influenza. This was the last MS to be affected by the virus.^{39 40}
- 5.28 On 20 July 2009 ECDC published a third pandemic risk assessment which indicated 20 – 30% of the population were expected to be affected during the second wave of the pandemic. Attack rates were expected to be highest in children and young adults; hospitalisation rate 1 – 2%; case fatality rate 0.1 – 0.2%.⁴¹
- 5.29 By 25 July the EU and EFTA countries' case count had risen to 20463.⁴²
- 5.30 On 27 August EU and EFTA cases had reached 44651 with 94 deaths.⁴³
- 5.31 The ECDC surveillance bulletin of 28 August 2009 stated that what appears to have been an unusual summer peak of influenza activity is on the decline with no countries reporting increasing trends other than Romania and Bulgaria.⁴⁴

Strategies and Statements

- 5.32 A HSC / EWRS joint meeting was held on 25 April, and discussion included the worldwide situation, case definitions, and updates from MS on measures. This was followed by the first HSC COMNET meeting.⁴⁵
- 5.33 On 23 April the European Commission (DG SANCO) raised its level of alert to 'red' and launched its Health Emergency Operation Facility.⁴⁶
- 5.34 On 30 April 2009, the Ministers of Health adopted Council conclusions on influenza A/H1N1 Infection.⁴⁷ See Appendix 6.0
- 5.35 The EU adopted a common case definition on 1 May for the novel flu virus.⁴⁸
- 5.36 On 4 May 2009, advice for the general public on personal protective measures was agreed and made available to Member States in all the official EU languages⁴⁹
- 5.37 On 18 May 2009 agreement on advice to persons planning to travel to or returning from affected areas was reached. On the same day guidelines on

case management and treatments and advice on medical countermeasures for health professionals was issued.⁵⁰

- 5.38 On 6 June ECDC published mitigation and delaying strategies for the use by European countries.⁵¹
- 5.39 The Swedish Presidency hosted an expert meeting titled 'Influenza Preparedness and Response – Lessons Learned and Next Steps' held in Jönköping on 2–3 July.⁵³
- 5.40 The Health Ministers met informally on 6 and 7 July 2009 to discuss preparedness and response to Pandemic (H1N1) 2009, focusing on a Commission information note on vaccination policy and the outcome of the meeting of technical experts organised by the Swedish Presidency on 4 and 5 July 2009.⁵⁴
- 5.41 A joint HSC / EWRS meeting on 20 July reviewed national measures concerning containment and mitigation following the technical meeting in Jönköping held under the Swedish Presidency on 2-3 July.⁵⁵
- 5.42 On 13 August the ECDC SSiaP published its work on the challenges involved in surveillance.⁵⁶ On the same day the Health Security Committee and the Early Warning and Response System (EWRS) contact points made statements on school closures and travel advice.^{57 58}

Vaccines and anti-virals

- 5.43 On 8 May EMA issued guidance on the use of anti-virals.⁵⁹
- 5.44 On 8 and 9 June the Council discussed vaccines and vaccination strategies against Pandemic (H1N1) 2009 and gave the HSC a mandate to work on these two issues.⁶⁰
- 5.45 Following the declaration of an influenza pandemic by WHO on 11 June, EMA initiated its pandemic crisis management plan to enable quicker assessment of influenza anti-virals and vaccines as well as safety monitoring. By 12 June EMA reported advanced discussions with vaccine manufacturers.⁶¹
- 5.46 At the 21st joint HSC meeting on 18 June, the European and global situations were reviewed, the implications for recommendations regarding anti-virals and marketing authorisation were analysed, and the extension of the shelf-life of Oseltamivir was clarified.⁶²
- 5.48 During the informal Health Council on 6 July and based on a broad consensus on pursuing joint procurement of vaccine against the pandemic (H1N1) 2009 influenza virus, in particular for Member States which had not yet placed orders, the Swedish Presidency asked the Commission to set up a mechanism to help with joint procurement of vaccines for interested Member States.⁶³
- 5.49 A statement on 'Vaccination strategies: target and priority groups' was agreed by the Health Security Committee and the EWRS contact points on 25 August 2009.⁶⁴
Refer to Appendix 7.0 for a graphical representation of the evolution of case numbers in MS.

6.0 General Pandemic Preparedness and Response

6.1 This section does not relate to a specific objective, but reports on general preparedness issues across MS. Information for this section is sourced from the EU-wide survey and interviews with ECDC, and DG SANCO.

Preparedness

6.2 General preparedness planning was adopted by the Commission in November 2005⁶⁵ to address threats and emergencies likely to affect public health in more than one MS. The goal of general preparedness planning is to assist Member States in developing response plans and factoring them into the EU structure.

6.3 Preparations and planning for pandemic influenza have been ongoing across the EU and MS since 2005, driven predominantly by the threat of avian influenza. The EU27, EFTA countries and the Commission have all produced pandemic influenza preparedness or response plans. Many of these are available in the public domain.

6.4 From the survey 11 MS reported revising their pandemic influenza plans in 2009, with only one MS saying that no revision had been undertaken of their plan. All but one MS reported testing their national or agency influenza plan at some stage with 11 MS reporting these were tested in 2006 or earlier. (Figure 1) Whilst the current pandemic may have thrown previous testing plans into doubt, it appears that in some MS revisions are undertaken much more frequently than actual testing of plans.

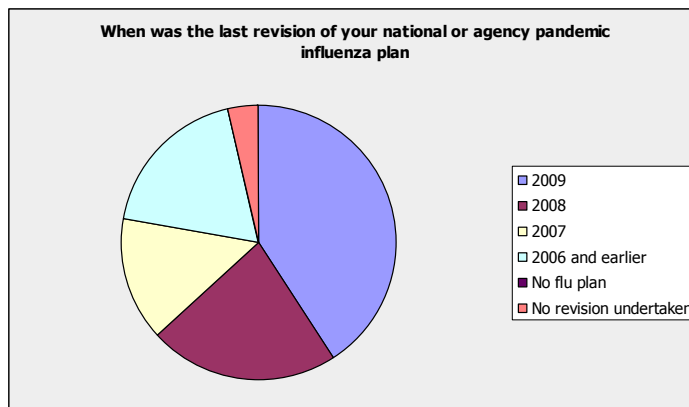


Figure 1: When was the last revision of your national or agency pandemic influenza plan? Source: EU-wide survey

6.5 Exercise Common Ground took place in 2005 and is the most recent EU-wide influenza exercise that MS and EU Agencies have participated in. Exercise Common Ground was led by the HPA and funded by the Commission, and Participants included the Commission, ECDC, WHO, 25 MS, EFTA countries and other EU Agencies. 2009 should have seen the second joint EU and MS pandemic influenza exercise (Exercise Tor) until it was cancelled following the outbreak of H1N1. Eleven MS report not having participated in any joint pandemic influenza exercise. Other than Exercise Common Ground, two other smaller joint influenza exercises were reported as having been undertaken, both of a regional nature.

- 6.6 All participating MS report that Health Ministries or similar were the lead authority for the response to pandemic influenza in their MS during the first four months. Through information contained in the survey, 12 MS report a number of health organisations and government departments all having various roles in the response to the pandemic. The effectiveness and efficiency of this combined responsibility are uncertain.
- 6.7 A number of pandemic response review activities had already been initiated or undertaken in 14 MS by 31 August 2009. (Figure 2) The most common review activity is an internal government review in eleven MS, closely followed by informal health personnel surveys in nine MS. Other options chosen include formal structured debriefing and a public enquiry. Seven MS indicated that by 31 August 2009 they had not yet initiated a review of any sort of the pandemic response.

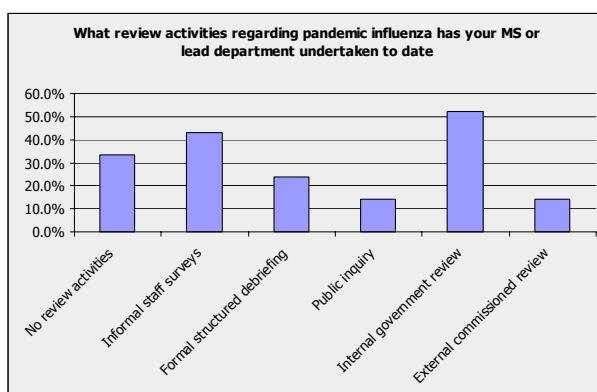


Figure 2: What review activities' regarding pandemic influenza has your MS or lead department undertaken to date? Source: EU-wide survey

Containment Strategy

- 6.8 The majority of participating MS used strategies of containment and mitigation (refer section 4.0 for definition) during the pandemic and as MS experienced the pandemic at different times and rates, the move from containment to mitigation varied across MS. (Figure 3) Predominantly this occurred during the summer months of July and August. Seven MS remained in the containment phase beyond 31 August 2009.

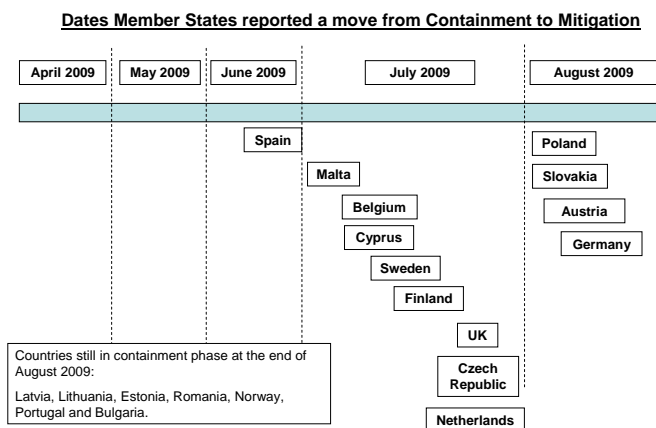


Figure 3: Dates Member States reported a move from Containment to Mitigation. Source: EU-wide survey

- 6.9 The issue of containment was discussed at a technical workshop in Jönköping under the Swedish presidency from 4 - 5 July 2009 which examined the experience to date in the most affected countries in Europe and internationally. The workshop recommended that countries in Europe proceed to mitigation alone, and focus on protecting the vulnerable and promoting personal measures. This recommendation was adopted by Ministers in the informal Health Council held 6 - 7 July 2009, and prepared the ground for MS declaring their change in strategy.
- 6.10 The move from containment to mitigation was triggered by several factors, with 14 participating MS reporting the number of cases reached was a factor. As case numbers varied greatly across countries in Europe there was no defined number of cases defined by the EU for European countries to reach before changing their response strategy, but rather the change tended to reflect internal MS policies and decisions. Sustained community transmission was also cited as one of the triggers by nine of the participating MS. Four MS reported being influenced by the actions of neighbouring European countries.

Observation 1.0

It is considered important that MS evidence the decision making process with respect to changing their pandemic response strategies, and that triggers identified for this change should be shared across MS, the Commission and EU Agencies.

7.0 Pandemic Preparedness Plans and Interoperability

7.1 The objective is to review pandemic preparedness plans and interoperability between national plans. This focuses specifically on the degree of interoperability between national plans and looks at areas of differences or examples of coordinated working practices. Information for this section is derived from the EU-wide survey and interviews held with ECDC and the Commission (DG SANCO).

Consultation

7.2 In the survey, seventeen MS report that consultation occurred between themselves and neighbouring European countries in the development of plans during the preparedness phase. This was not often a regular occurrence, however all but five participating MS undertook some form of consultation. (Figure 4) The outputs from these consultations were reported as beneficial with outcomes such as improving mutual understanding and better integration of national plans.

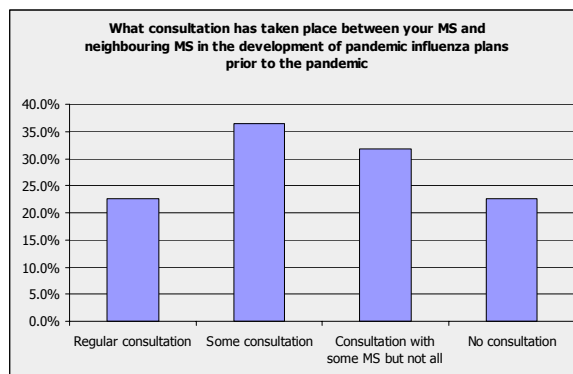


Figure 4: What consultation has taken place between your MS and neighbouring MS in the development of pandemic influenza plans prior to the pandemic? Source: EU-wide survey

Comments from MS regarding bilateral consultations include:

“Developed net of contacts, bettered our response and communications with these countries, heightened political awareness and given hints of possible point for improvements in the ongoing revision of our national pandemic plan”

“Operational and logistic issues from other MS were taken into consideration”

“By understanding the reasons and rationale taken by other MS on different decisions [and] issues to enable us to decide the best decision to take ourselves”

7.3 Participating neighbouring MS reported liaising on such issues as vaccines, influenza workshops, and visits with specialist teams both prior and during the crisis. Such cross-border meetings and visits are important in understanding best practice and identifying lessons from other European countries who may have already experienced similar problems. These visits and opportunities for learning and consultation should be continued, in order to reinforce lessons identified.

Interoperability

- 7.4 Sixteen of the participating MS indicated that they relied on recommendations, policy and guidelines from the Commission, EU Agencies and other organisations (WHO), as well as information from workshops, meetings and audio-conferences to inform their own plans. ECDC held workshops and assessment opportunities (e.g. self-assessment toolkit) for MS to evaluate and plan their preparedness. Four MS reported not liaising with other European countries or Agencies to develop influenza policy and guidance. For those MS that did not undertake formal liaison they need to keep informed about areas of best practice and operating procedures in other European countries to avoid operating in isolation.
- 7.5 In response to the survey, MS identified key processes that highlighted the interoperability across the EU of influenza planning. In some cases similar, but not joint, policies were developed following consultation. These included the vaccination issues of common procurement measures, and common vaccination strategies which were deemed beneficial. Commonality of EU documents and legislation was also considered very helpful.
- 7.6 The move from containment to mitigation across Europe may be attributed to the work of the Presidency, and European countries with support from ECDC, the EC and WHO which was coordinated through the meeting held in Jönköping during July 2009. The development of the case definition was also considered integral to interoperable working (Refer Appendix 8.0). ECDC considered agreement of the case definition to be important as it meant a data set was adopted early in the crisis and led to stability in reporting by European countries.
- 7.7 Coordination of the response was a key area that was reported to have benefitted from interoperable working across the EU. Information collection and sharing was considered key by MS completing the survey, and opportunities for this included HSC audio-conferences, ECDC daily reports, and the use of EWRS and HEDIS. Regular consultation and communication was highlighted by participating MS as beneficial. Information for travellers and the coordination of contact tracing, along with other containment measures was reported by participating MS as an important factor in interoperability across the EU. Key public health measures and the interoperability of communications about public health messaging were also important.

Observation 2.0

It is considered valuable that MS continue regional and EU-wide cooperation and consultation for pandemic preparedness, and share learning across the EU to enhance pandemic planning and the sharing of relevant practices.

Planning

- 7.8 Participating MS believe that additional preparedness guidelines would assist with improved planning and exercising of pandemic plans. Increased preparedness and planning beforehand resulted in an improved response such as avoiding the closure of borders.
- 7.9 Participating MS have different policies underpinning their planning assumptions, thereby not enabling EU-wide assumptions to be agreed.

However, consideration could be given to incorporating national planning assumptions into national influenza plans to enable enhanced impact preparedness for sectors other than health. This may be helped by improving EC inter-service coordination among DGs other than SANCO, particularly those with oversight for non-health sectors, and those with an external remit, such as RELEX.

- 7.10 Planning for staff during a response needs to have increased prominence in pandemic influenza plans to avoid situations where staff are placed in inappropriate roles during the response. As well as planning for the physical response to flu, staffing issues could form part of plans to ensure optimal staff performance. In some cases participating MS and EU Agencies reported an overload in work by key staff, and in some cases key staff were not used to working in crisis situations. Staff on the frontline of the strategic response may be taken for granted and expected to work in unfamiliar situations. This may differ from staff on the frontline at an operational level who are often more used to working in crisis situations, such as in hospitals.

Observation 3.0

It is considered useful that as part of preparedness planning MS, the Commission and EU Agencies identify and review organisational capacity as well as the roles of key personnel within influenza pandemic plans. This is to ensure resilience of staff and the flexibility to appropriately manage a prolonged influenza crisis, regardless of severity.

- 7.11 Interviews with the Commission (DG SANCO) indicated that countermeasure stockpile information available from MS in July showed the levels of measures available, and revealed that some MS are better prepared than others in this area. It was identified that there may be potential for joint purchasing policies from some MS if they wanted it, and that it could be developed through common tenders, dependant on commercial and legal processes.
- 7.12 EU-wide information gathering may need to occur more frequently to highlight issues regarding any resource shortcomings and lack of preparedness. A stock-take of preparedness across European countries would assist with knowledge about generic health preparedness in the EU. This was planned to be undertaken in 2009 using indicators developed by ECDC and WHO Euro and agreed by the HSC.

Observation 4.0

It is considered valuable that MS and EU Agencies undertake a pandemic “lessons identified” review process and the outcomes, where appropriate, are shared across MS and the EU. Outputs of this process should be inputted into the development of pandemic plans at MS and EU level.

8.0 Business Continuity Planning

8.1 This objective focussed on business continuity plans (where implemented), and in particular the issues around the impact on services, managing concomitant incidents, mutual aid, and foreseeable degradation of systems. Information for this section was sourced from the EU-wide survey and interviews held with the Commission (DG SANCO), EMA and ECDC.

Impact on services

8.2 When asked which sectors of MS economies were significantly impacted by the pandemic during the first four months, unsurprisingly 20 MS reported that health sectors were most affected. (Figure 5) Specific areas included laboratory capacity, epidemiology, virology, primary care doctors and hospital staff. Within the hospital systems, infectious disease control and influenza centres, along with specialist wards were reported to be directly affected.

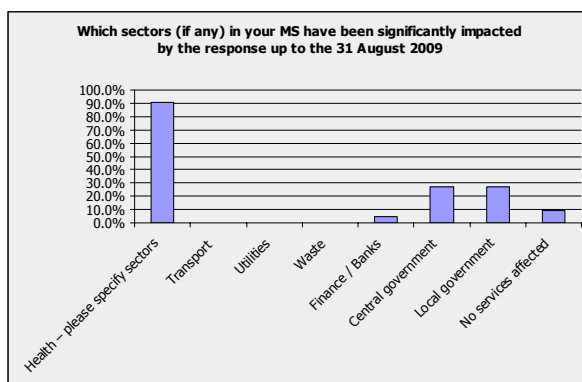


Figure 5: Which sectors (if any) in your MS have been significantly impacted by the response up to the 31 August 2009? Source: EU-wide survey

8.3 During the containment phase, primary health care services were reported as suffering the most increased pressure. Part of the overwhelming number of consultations and questions from the worried well, general public and travellers many have been generated by the predicted worst case scenario placing increased demands on these services. Health care staff, particularly those working in laboratories, contact tracing, and antiviral distribution were also under significant pressure, many of which were reported by participating MS as only having limited diagnostic skills available. Three MS also reported that the high interest of the media and public added to the pressure on primary health care staff.

8.4 Through the survey it became evident that sectors outside health were generally not affected by the pandemic. These unaffected sectors should be evaluated to identify gaps as they may be affected by future pandemics or large scale public health crises.

Observation 5.0

It is considered valuable that MS, the Commission and EU Agencies continue to evaluate pandemic preparedness for sectors and services identified as potentially at risk, (health and cross-sectoral), particularly as not all sectors experienced similar levels of pressure.

- 8.5 In response to the survey, one MS reported that suppliers of masks and gloves were impacted by the crisis. European countries need to ensure that business continuity of supply chain providers is checked and meets expected and published national standards. Participating MS reported that sectors outside of health were also impacted by the pandemic. These sectors included finance and banking as well as agriculture (pork related) and tourism.
- 8.6 Early in the crisis, it was reported that restrictions on the export of pork products had an impact on one MS.

Observation 6.0

It is considered useful that MS, the Commission and EU Agencies refine and publicise estimates of pandemic planning assumptions for a new pandemic as early as possible to enable other sectors to prepare, and ensure these are reviewed as the pandemic progresses.

- 8.7 In order to mitigate the impact on health services, participating MS reported a variety of steps that were implemented. This included providing guidance to the health care sector about issues such as reprioritising hospital beds and utilising the private sector for the management of influenza cases. Communication about health policies and service impact was also increased to the health sector. The number of influenza centres was also increased in many areas to cope with demand.
- 8.8 Participating MS also adapted response strategies and standard operating procedures as the crisis progressed, including the reduction of contact tracing and concentrating on vulnerable groups as the numbers affected increased.
- 8.9 During the mitigation phase of the crisis, participating MS reported an increase in pressure on primary care services that centred on primary care doctors working long hours and providing out of hours services, particularly as consultation rates increased in line with a strong demand for anti-viral prophylaxis. Changes to participating MS anti-viral policies also combined to increase the pressure on primary care services.
- 8.10 One MS reported that implementation of a 24 hour helpline for patients successfully reduced pressure on primary care doctors by diverting patients to collect anti-virals from collection points. This left primary care doctors and other healthcare workers to concentrate on their daily work and those with flu complications.
- 8.11 Participating MS have suggested that business continuity planning and associated issues need to be promoted as part of general infrastructure preparedness. (The operational challenges faced by health care sectors (such as those relating to increased pressure on intensive care units) were not part of this review. It is however noted that these areas are considered critical and may therefore benefit from future reviews).

Mutual aid

- 8.12 Part of the principles behind solidarity is to ensure mutual support between MS. This can be achieved through the provision of mutual aid.

- 8.13 Eighteen MS reported not having formal cross-border health agreements for pandemic influenza in place during the first four months of the crisis. However, many MS have general health agreements in place, such as Norway and Sweden who have the Nordic Health Preparedness Agreement, and the UK and Sweden who have a reciprocal agreement for the provision of ECMO. Bilateral agreements for cross-border healthcare also exist between France and Belgium, and France and Germany, though not specifically relating to influenza.
- 8.14 Sixteen MS did not seek assistance from other MS during the first four months, but those that did focussed on the following:
- Typed laboratory results
 - Vaccine solidarity issues, such as production, procurement, and technical assistance via the HSC
 - Contact tracing
 - Intensive care facilities, such as ECMO
- Three MS were asked for assistance and provided the following:
- Intensive care facilities (coordinated between hospitals)
 - Masks and disinfectants
 - Technical support staff to EU Agencies
- 8.15 For the mutual aid process to work effectively, plans and processes ideally need to be in place or pre-agreed prior to a crisis. However it is acknowledged that it can be difficult to convince planners that cross-sectoral issues are important until the issues become an operational concern.

Observation 7.0

It is considered appropriate that MS incorporate planning for the provision of mutual aid as part of generic business continuity planning for health services, including health sector supply and support services.

9.0 EU-wide Communications Systems

9.1 This objective focuses on the robustness and efficiency of communications systems utilised during the response. These include EWRS, HEDIS, Medisys and Arkadin and any tools that MS utilised as part of their response. Information in this section is sourced from the EU-wide survey and interviews held with the Commission (DG SANCO), ECDC, and EMA.

Early Warning and Response System (EWRS)

9.2 During the first four months of the crisis, EWRS was the communications tool that was accessed most frequently by participating MS. All participating MS reported using EWRS at least twice a day, with 13 reporting logging on more than six times a day. (Figure 6) Seventeen of the participating MS reported EWRS as an easy or very easy tool to operate, but two MS did report difficulties.

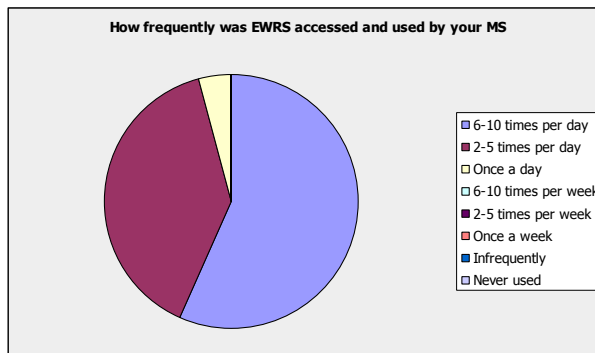


Figure 6: How frequently was EWRS accessed and used by your MS? Source: EU-wide survey

9.3 EWRS access and mail information for the review period is shown in Figure 7, 8 and 9. Comparison graphs showing data from 2008 and 2009 are contained in Appendix 9.0.

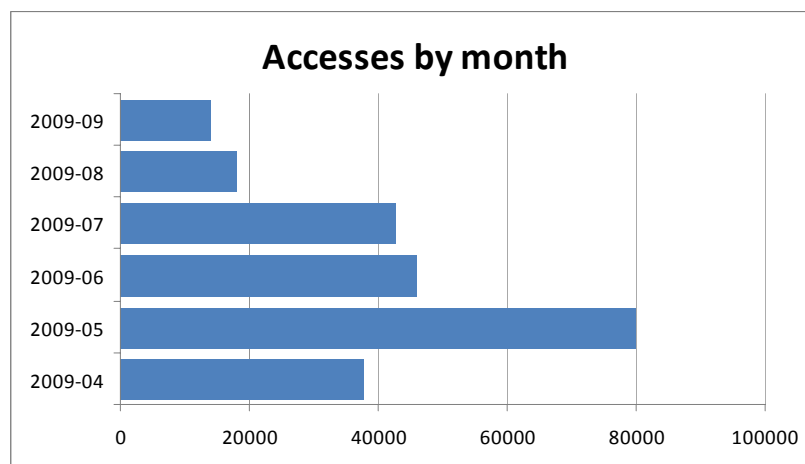


Figure 7: EWRS accesses by month. Source: ECDC

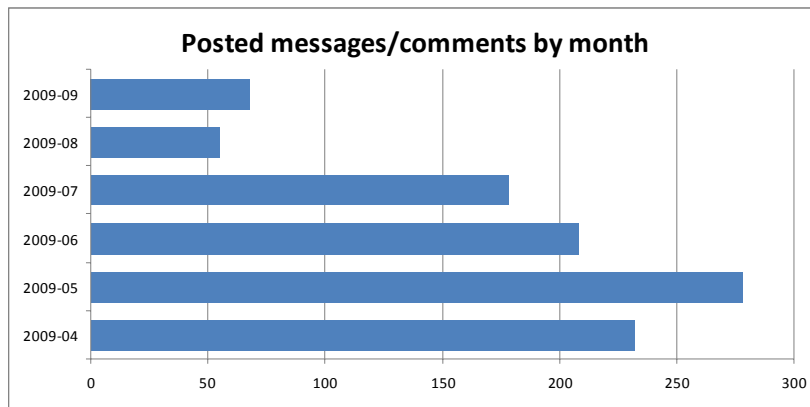


Figure 8: EWRS posted messages/comments by month. Source: ECDC

EWRS messages and comments posted for period April to September 2009 (does not include case reporting)

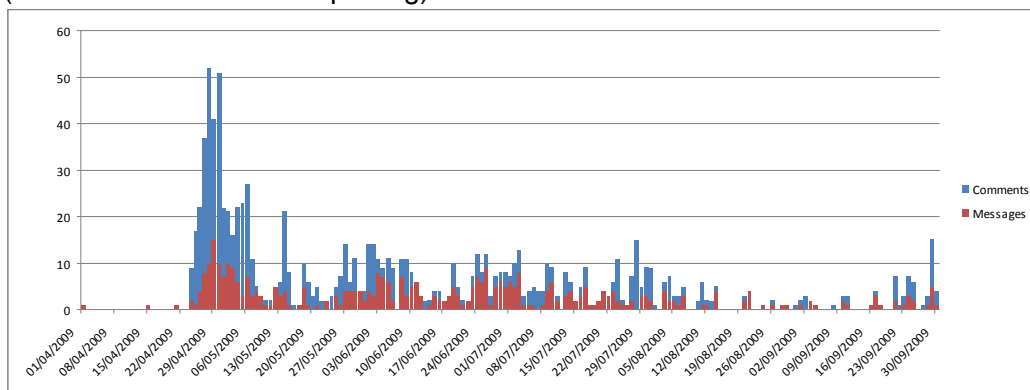


Figure 9: EWRS messages and comments posted for period April to September 2009. Source: ECDC

- 9.4 At the beginning of the crisis EWRS started as a notification tool, but was also used as a surveillance tool, a function that it was not designed to perform. An ad hoc form of EWRS was developed in response to this demand prior to TESSy going live.
- 9.5 Two areas of EWRS that received most comments concern the search function and excess information. (Figure 10) EWRS appeared to have excess information uploaded, resulting in important information being lost. As the crisis progressed and increasing amounts of information were uploaded, participating MS reported difficulties sorting through the information and tracing backwards in the system. Information to be uploaded needs to be clearly defined and adhered to by contributing European countries and Agencies. Reference is made to the Exercise Aeolus Report and the statement: “A clear policy is required, in advance of any incident, on the functions, usage and interplay of each system (RAS-BICHAT, EWRS, HEDIS)...”⁶⁶

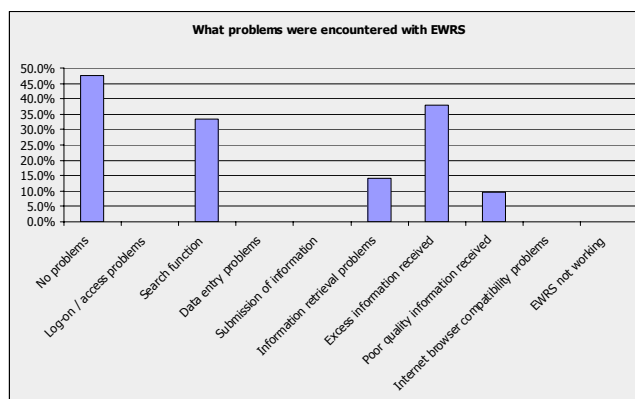


Figure 10: What problems were encountered with EWRS? Source: EU-wide survey

- 9.6 Eighteen participating MS reported that generally EWRS improved communications between them, but that it is not suitable in its current format for European countries with large numbers of cases to report. With a vast number of notifications and responses, the result is that users were unable to find what they are looking for. At the time of the crisis, it was recognised as the only tool available for reporting until other systems became available.
- 9.7 Clarity about the key function and role of EWRS is required. EWRS is designed as a notification and information tool, not a tool to manage the crisis. Clear instructions and guidance need to exist about the content of information, and where it should be posted by European countries and EU Agencies, and whether it is best suited to EWRS or another tool.

Observation 8.0

It is considered important that the Commission (DG SANCO) and ECDC (in agreement with the EWRS Committee) ensure that the use and role of EWRS is more clearly defined, including the process for notification and collation of information.

Improvements to EWRS suggested by MS for consideration include:

- Improvement to the search function by developing the text-based search engine
- Topics, themes or categories to be communicated by different threads for ease of searching – eg anti-virals, vaccines
- Improved notification system for new incoming notification messages
- Not using EWRS for reporting of case numbers, deaths, or general epidemiological information (This should now be improved due to the introduction of the TESSy platform)

See Observations 10.0 and 18.0

- 9.8 Because every crisis is different, and EWRS has to function in many crises, it may be beneficial to make it clear at the beginning of the crisis the type of information required to be uploaded on EWRS. EWRS needs to operate as a platform for important, crisis-related messages, but information is often uploaded that is irrelevant or less important. To combat this, it may be helpful to consider an informal 'chat' section be built into one of the tools to allow for MS to share this type of informal information. During the interviews it was reported that the introduction of EPIS may allow for this, but was not available for use during the review period.
- 9.9 During interview it was identified that EMA does not currently have access to EWRS, and this would have been helpful particularly during the early stages

of this crisis. Lack of access to EWRS for intelligence about the pandemic hindered EMA as they had no means of obtaining early information and alerts about the pandemic. EWRS access for EMA has previously been identified and requested by EMA. The legislative issues around this need to be resolved to ensure EMA is in a position to obtain the necessary information to aid its response to similar crises in the future.^a

Observation 9.0

It is considered appropriate that the Commission (DG SANCO) and the EWRS Committee discuss the possibility of developing a filtered version of EWRS to enable specific agencies, particularly EMA, to have permissive access. See Observation 10.0.

Health Emergency and Diseases Information System (HEDIS)

9.10 HEDIS is an EC system for distributing public health information about a crisis, and gives access to a large set of crisis tools. Twenty participating MS report using HEDIS during the crisis, with 15 participating MS generally agreeing it was either easy or very easy to operate. (Figure 11)

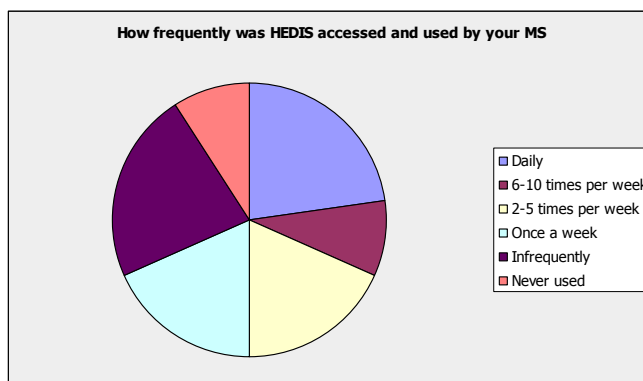


Figure 11: How frequently was HEDIS accessed and used by your MS? Source: EU-wide survey

9.11 A number of problems were reported about HEDIS, with the most common being information retrieval problems, poor quality information received, and log-on or access problems. Participating MS also found it difficult to submit data on the system. Six MS reported that it improved their ability to communicate with other European countries or EU agencies. It was generally felt that there should be a single platform for communications across the EU during a public health crisis, or at least have a clear indication when to use the most appropriate tool. (Figure 12)

^a It was agreed at the Barcelona 2010 meeting that the Commission (DG SANCO), ECDC and EMA would meet to discuss the further use of EU tools for EMA.

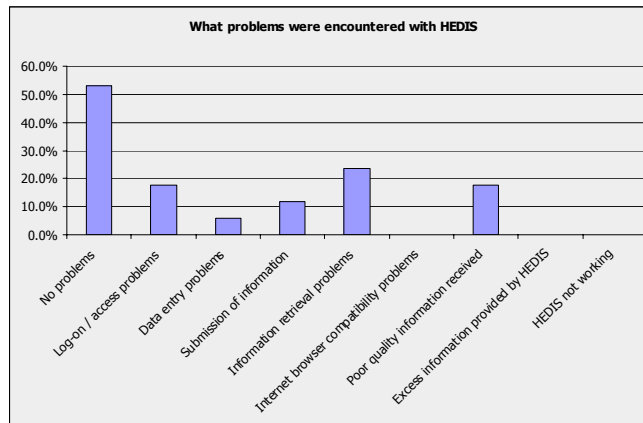


Figure 12: What problems were encountered with HEDIS? Source: EU-wide survey

- 9.12 There were few improvements to HEDIS suggested by participating MS, but development of clear guidelines about when to use the tool, would benefit as confusion and uncertainty still exist about when to use HEDIS and EWRS.
- 9.13 Ideally HEDIS should be constantly updated during a crisis to ensure the most recent and relevant information is available. Depending on the crisis and situation, HEDIS may need to be adapted to ensure that relevant EU agencies, as well as MS have access to the system.
- 9.14 The function and use of HEDIS needs to remain focussed, and the information must be relevant to the current situation to avoid information overload. In order for MS to effectively share information, policies and strategies with other MS, it may be appropriate for each MS to have a page on HEDIS where they can upload and publish the relevant information and strategies from their MS.
- 9.15 A page for Communicators was set up on HEDIS after the start of the current crisis with most of the HSC Communicators Network having access. As effective communications is important during any crisis, this should be considered as a regular feature for use in any future crisis.

Observation 10.0

It is considered important that the Commission (DG SANCO) establish a process to review and define the use of EWRS, HEDIS, and MediSys, including appropriate usage of these tools. Specific areas to focus on in the review are highlighted in Observations 8.0, 9.0, 11.0 and 12.0.

Observation 11.0

It is considered important that the Commission (DG SANCO) review HEDIS to improve the information retrieval and log-on and access issues. In addition MS should be given permission and the ability to input national data directly into HEDIS. See Observation 10.0

MEDISYS

- 9.16 Medisys is the Commission (DG SANCO) information system for access by MS to obtain public health information about the crisis. Fourteen of the MS who responded, reported that use of Medisys was either infrequent or never used. (Figure 13) Of those that did use it, all MS reported it generally being

an easy system to operate, and with few problems, but that its use during the crisis was limited.

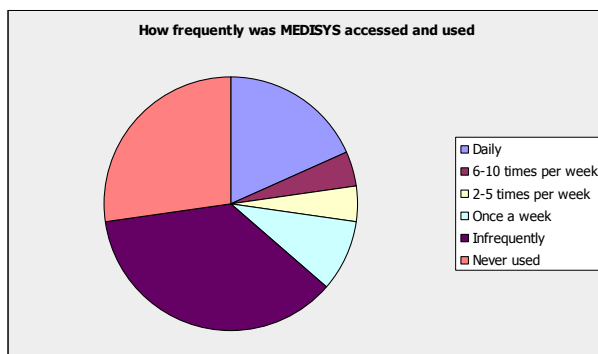


Figure 13: How frequently was MEDISYS accessed and used? Source: EU-wide survey

- 9.17 The majority of participating MS had no suggestions for improvements to Medisys, but it was mentioned that it would help if more non-English resources were included to be more geographically representative.

Observation 12.0

It is considered useful that the Commission (DG SANCO) ensure increased information and training is available for MS about the role and functions that MediSys provides in order to improve usage of the tool. See Observation 10.0.

Arkadin

- 9.18 The Arkadin audio-conferencing tool utilised by the Commission (DG SANCO) to communicate to all MS was used with varying frequency, with six participating MS either not using it, or only infrequently. (Figure 14) Of those that did use Arkadin for communications, 18 said that it was either easy, or very easy to use. Participating MS reported only a few problems using the system, mostly IT related, such as log-on and access problems, synchronising audio and web functions, and IT browser compatibility problems. One MS said that it was expensive for them to use.

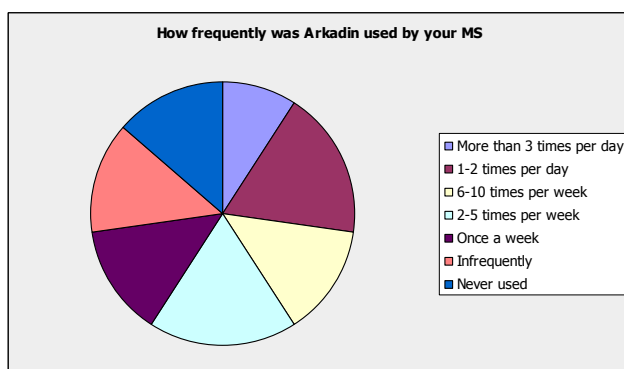


Figure 14: How frequently was Arkadin used by your MS? Source: EU-wide survey

- 9.19 Generally Arkadin was thought to be a very useful tool, as there is a requirement for an audio-conferencing system that allows for control of the conference and for participants to request the floor to speak. DG SANCO C3 have developed written Standard Operating Procedures for Arkadin, including participant ones which have been shared with all MS.

Other communications tools

9.20 When asked what other communications tools MS used during the crisis, audio-conferences, email, and telephone were all reported as commonly used both nationally and at EU levels. Other Agency websites such as ECDC, the Commission, WHO, and EMA were considered important at an EU level. SMS is a tool utilised by only a few participating MS, but all report positively about its use. As one MS described; personal discussions, phone calls, and email were used and all were effective and fast, but also less coordinated.

10.0 Coordination between National, EU and International Agencies

10.1 This objective is to assess the effectiveness of communications within and between national, EU and international participants. It focuses specifically on the liaison with and between MS, EU agencies and the Commission. Information for this section is sourced from interviews with ECDC, EMA and the Commission (DG SANCO), and the EU-wide survey.

DG-SANCO

10.2 The Health Emergency Operations Facility (HEOF) is the Commission's (DG SANCO) emergency command centre and forms a key part of the general infrastructure during public health emergencies. It provides the Commission's operational system and response capability.

10.3 The HEOF is also tasked with the provision of advice to the DG SANCO hierarchy and cross-sectoral communication with other Directorates General.

10.4 It operates at four different levels of alert – green, yellow, orange and red. Alert level red automatically activates the Commission's Public Health Emergency Management structure.

Meetings and audio-conferences

10.5 Part of the Commission's (DG SANCO) core role in a crisis is to provide coordination for all MS, and this is often provided through audio-conferences. These were held throughout the crisis, but in the early stages there were large numbers of audio-conferences both formal and informal, which accounted for lengthy meetings. In some cases, participating MS believed that because audio-conferences had been well practiced prior to the crisis it helped them structure their response, but the daily schedule of audio-conferences was tough physically, particularly for those smaller MS who had less personnel working on the crisis, and hence had to cover several roles and attend all the meetings. It should be noted that this review refers to only those audio-conferences co-ordinated by DG SANCO's Health Threat Unit)

10.6 It was also reported that the Commission (DG SANCO) frequently set up meetings and audio-conferences at very short notice, which at times caused problems providing appropriate personnel. Feedback in the survey about the success of these meetings is varied, but was generally felt to be positive.

10.7 Other feedback from participating MS reports that the use of audio-conferences are an effective tool to have once a day, to enable sharing of experiences and to learn from others. Used effectively, audio-conferences are positive and efficient tools. It was reported by participating MS that stricter audio-conference guidelines would assist and improve the effectiveness of interoperability within EU.

10.8 Interviews identified that audio-conference agendas were set by the Commission (DG SANCO), and all MS were asked for items, but often with no response. The Commission (DG SANCO) tried to ensure that there was a balanced agenda that represented the needs of all countries. Face to face meetings could also be considered. Though time-consuming, they tended to produce more discussions and contributions.

Observation 13.0

It is considered useful that at the onset of a crisis the Commission develop a schedule of audio-conferences that outline MS and EU Agency participation, including where possible advance notification of dates and times.

HSC / EWRS audio-conferences

- 10.9 Participating MS felt that the combined HSC and EWRS audio-conferences in the one meeting had both benefits and drawbacks. It was felt by many that these audio-conferences were often too long, and in some cases, representatives were unsure whether to vote or not at these meetings. It was reported by ECDC in interview and participating MS through the survey that the HSC Flu Section did not meet often or hold an audio-conference in the first four months.
- 10.10 In some cases, the material being discussed on the audio-conference was for one group only, such as the case definition. At times this appeared to result in confusion for some MS, as there was potential mismatch between the management component and the assessment part of the crisis, such as dealing with the case definition (formal) or school closures (informal).
- 10.11 The agenda for these audio-conferences needs to be much clearer to avoid prolonging meetings and to ensure best use of time, and in this instance may have been exacerbated by the combining of both groups (EWRS and HSC). At times the agenda for the meetings did not distinguish between the two groups. A clearly defined agenda will also enable all MS and other agencies who need to participate in sending the most appropriate person for that meeting. Concerns were expressed that the audio-conferences were not always seen to be strong with regards to decision taking and at times it was difficult to obtain a minimum level of agreement via audio-conference.
- 10.12 However, in some cases there did seem to be some agreement that it was beneficial to have both technical (EWRS) and political (HSC) representatives at the audio-conference as the groups focussed on different aspects of the response and complimented each other with information.
- 10.13 Overall, there seems to be no clear consensus on whether to have joined or separate HSC and EWRS audio-conferences. Benefits and detractions have appeared for both structures, and it may be that a compromise is needed, and that this could be dependant on the agenda. For the majority of meetings, participating MS indicated that two people represented their MS. Two MS reported they only had the option of sending one person to the meeting, whether they are EWRS or HSC focussed.

Observation 14.0

It is considered useful if at the onset of a crisis a review is undertaken by the Commission (DG SANCO) of the content of EWRS / HSC audio-conferences to better reflect MS needs during a specific crisis, including length, agenda and topic of the meetings, as well as the implications of holding combined meetings. This review should also include the role of the HSC Flu Section.

Coordination

- 10.14 In response to questions about the information and guidance participating MS were expecting from the Commission (DG SANCO), 19 expected EU-wide coordination, 12 expected policy guidance, and seven expected technical advice. When asked whether this was provided by the Commission, 9 MS reported that it was either partly provided or not provided. However 13 MS responded positively. The provision of information and guidance to MS may need to be reviewed in light of this to enable the Commission (DG SANCO) to fulfil expectations.
- 10.15 Nineteen MS indicated that the most important activity provided by the Commission (DG SANCO) was the sharing of information which centred largely on pandemic policies and case reporting. Also considered helpful by 15 MS were the provision of audio-conferences and the case definition; 13 MS found overall EU coordination helpful, and 13 MS found the HSC statements of benefit. These functions and outputs from DG SANCO therefore need to be communicated to all MS in an effective and timely manner.
- 10.16 It was felt by some participating MS that DG SANCO aligned its response with the first European country to be affected, and those European countries who started their response later felt left behind. European countries in the same stage of response may benefit from the sharing of experiences, particularly from those who have already experienced the situation. The Commission (DG SANCO) needs to be able to cater for all levels and stages of response across European countries.
- 10.17 The Commission (DG SANCO) reported that at times MS made decisions without informing them. There was a need to inform the Commission (DG SANCO) about changes in policy and the move from containment to mitigation, as well as vaccination priority groups. Early in the crisis, the Commission (DG SANCO) reported asking for specific information from all MS, and that at times this was not always forthcoming. The flow of information needs to be two way to ensure effective coordination and crisis management.
- 10.18 Participating MS reported that there needed to be improved lines of communication between the Commission and WHO. Although the Commission and WHO were regularly engaged in bilateral communication, this appears not to have been apparent to MS. One participating MS felt that DG SANCO coordination efforts came too late for them in the early phase of their response, whilst another participating MS felt they had to pursue their own policies regardless of the Commission's advice.

Observation 15.0

It is considered appropriate that the Commission clarifies its role and function for coordination during crisis response, including the dissemination of information to MS. This would ensure MS expectations of rapid coordination and information sharing are fulfilled.

Information sharing

- 10.19 The Commission (DG SANCO) collected information from EMA and FDA but often this was not shared with MS. Regular reports in particular were only internal and not shared with MS as they may contain contentious information

and are difficult to share. Therefore there needs to be improved methods for distribution of information to MS.

- 10.20 Differences between containment and mitigation strategies across Europe meant that the Commission (DG SANCO) ended up looking at the most pressing issues, and tended to move forward with the first wave. This resulted in later affected European countries being left behind, and in many cases the Commission (DG SANCO) did not discuss lessons identified for these later MS.
- 10.21 Liaison between the Commission (DG SANCO) and the GHSAG countries was reported as having worked well, especially as many of the GHSAG countries were the first to be affected by the novel influenza strain. This meant many of the necessary health connections were already in place. Some actions of other global organisations and countries did have an impact on DG SANCO, such as the initial decision by the USA to use vaccines that required one dose only for adults.
- 10.22 As the Commission is responsible for the legislation for pharmaceuticals within the EU, the move from pandemic Level 5 to 6 resulted in having to move quickly with market authorisations. Instead of taking up to two working weeks to complete the process, this was achieved in two working days.
- 10.23 The spread of disease and death has an impact on the public and can give rise to alarm. Hospitalisations are a key indication of the spread of disease. The fact that the majority of European countries ceased to report case numbers at end of July meant a loss of the overall picture and no accurate statistics from which the Commission (DG SANCO) could operate. Generally by July, trends were more important than actual numbers. The numbers of deaths that were reported then became a more relevant statistic.
- 10.24 Participating MS reported sharing data with other European countries, however sharing of important analysis before publication was less optimal despite the obvious European added value.

European Centre for Disease Prevention and Control (ECDC)

- 10.25 All participating MS reported they expected ECDC to provide risk assessments and situation reports about EU and global events. This was provided, with MS comments including:
- *“all provided – excellent and reliable”*
 - *“they were the entity that provided the most information and in a timely manner”*
- MS noted the willingness of ECDC to provide scientific support and information on the pandemic.
- 10.26 Eighteen MS also expected information from ECDC on case definition updates, 12 expected policy guidance, and 19 MS required technical advice. One MS reported expecting more information and reports from the situation in the Southern Hemisphere.
- 10.27 MS routinely provided information to ECDC, but this was not necessarily updated every day. All MS did provide daily case numbers, but five MS also submitted extra information including deaths, containment measures, antiviral

stockpile information, as well as planning assumptions and science committee reports.

- 10.28 ECDC reported getting MS to prepare beyond Phase 5 was difficult at times, and encouraged them to share information more. It felt that many European countries were reluctant to share information, but self-analysed instead. ECDC would like to have received more serological data and death information from MS, and to have been able to share this with other countries across Europe.
- 10.29 Information sharing and the case definition were ranked in the survey by participating MS as the most important activities and processes provided by ECDC. Risk group issues and coordination were also highly rated by participating MS. One MS commented that “technical advice and data analyses across EU and wider were invaluable”.
- 10.30 EMA felt that ECDC was very efficient at providing information and sending experts at short notice to provide technical support and advice.
- 10.31 The lack of efficient reporting processes from MS to ECDC were a cause for concern, particularly the requirement of double reporting with WHO, but also with the use of TESSy. Several participating MS reported that TESSy was not a particularly user-friendly system. Duplication of reporting and systems that were not compatible increased the time and effort by MS in providing up to date reports for ECDC. As there are varied responses from participating MS to the usability of the technical systems for reporting, it could be concluded that familiarity with the reporting tool may be a factor in the problems encountered by MS (see also 10.49).
- 10.32 Although most participating MS reported a good and positive relationship with ECDC through the sharing of information, three MS did report the opposite. This focused on infrequent communications and short deadlines for submission of information. It may be necessary to review the communications links between ECDC and MS to ensure that all MS have the same positive and productive relationship.

European Medicines Agency (EMA)

- 10.33 The main methods of contact for participating MS with EMA were through the national contact network and audio-conferences which were both considered very effective.
- 10.34 Thirteen MS were expecting technical advice from EMA, ten MS expected policy guidance, and eight MS expected EU-wide coordination. MS were also provided by EMA with studies on vaccine efficacy, development of marketing authorisations, and information on the scientific assessments of vaccines. Vaccination issues and information sharing were cited as the two most important activities provided by EMA for MS. Audio-conferences and coordination were also seen as important.
- 10.35 MS provided information to EMA in a variety of different forms, and EMA is aware this needs to be in a standardised format and timeframe if it is to respond more effectively. Some participating MS reported finding it difficult to share information with EMA, which ultimately hindered analysis and progress. EMA noticed the absence in some MS of communications between public

health authorities and respective National Competent Authorities (Medicines) (NCA). This culminated in a gap in information sharing, and a lack of coordination. Two participating MS reported that little practical or policy guidance was received by them from EMA. However, during the first four months EMA did feel that the level of information exchange with MS NCA representatives and WHO was exceptional.

Observation 16.0

It is considered important that MS public health authority and NCA representatives should endeavour to establish a direct means of communication between their agencies and with their respective counterparts, especially for public health events, including a pandemic.

- 10.36 EMA reported that MS needed to be more open with them about their liaison with pharmaceutical companies and contracts already in place. At times EMA felt they were caught in middle of dialogue between vaccines regulators and public health bodies, and would like to see an improvement in this level of communication. At times EMA was short of information, and reported that it would have been helpful if the Commission (DG SANCO) could coordinate this so that roles and responsibilities relating to vaccines are clarified early on.
- 10.37 EMA took part in all audio-conferences which worked well, especially when discussing companies that have issued licences. It felt that coordination with HSC committees could do with improvement, but believed there were good communications and information exchange between ECDC, the Commission (DG-SANCO and DG-Enterprise) and EMA.
- 10.38 To assist with improved information flow, EMA would like advice from DG-SANCO about actions expected by it, considering the strict remit under which EMA operates. At times, EMA was also concerned about how its proposed actions might affect other global players such as CDC and FDA.
- 10.39 As highlighted in Section 9.8 and Observation 9.0, EMA do not currently have access to EWRS, and this would have been helpful particularly during the early stages of this crisis.

World Health Organisation (WHO)

- 10.40 Through the survey, 17 MS reported exchanging information with WHO according to IHR. Audio-conferences (12 MS) and situation reports (14 MS) were also common points of contact between MS and WHO. Fifteen MS stated no communications difficulties with WHO, but five MS did comment that duplication of reporting (double reporting) between themselves and both WHO and ECDC was an issue.
- 10.41 Participating MS believed that information sharing was the most important activity provided by WHO. Risk group information, vaccine issues, the case definition and overall coordination were still important to MS, but less so.
- 10.42 Some participating MS commented that further information from WHO would have been helpful in the following areas:
- Recommendations for travellers
 - Further information about areas outside the EU
 - Publishing data received through IHR

Observation 17.0

It is considered important that MS and WHO strengthen lines of communication between the organisation and countries to improve the provision of information during pandemic preparedness and response.

- 10.43 The issue of double reporting appears as the single greatest problem with the reporting system between participating MS and WHO (refer section 10.49). Daily reporting by email was the preferred manner of communication.
- 10.44 At times the link between participating MS and WHO may not have been as effective as it could be. Improvements around coordination of changing pandemic levels and improvements in information flow would assist.
- 10.45 WHO need to make clear early on in the crisis whether it intends to issue travel recommendations. If so, then liaison with MS and the EC needs to take place as soon as practicable.
- 10.46 The efficiency of communications and liaison between the Commission (DG SANCO) and WHO were reported by MS participating in the survey as not being particularly effective in the early stages of the crisis. It was reported that at times the participating MS were left waiting by WHO, and the Commission (DG SANCO) stepped into the void that was sometimes left by WHO. At times this led to confusing messages for MS.
- 10.47 Two of the participating MS reported expecting WHO to have taken more of a lead in the case definition, and coordinate with the EU in a more timely fashion than was experienced.
- 10.48 This is one of the few public health crises that WHO Euro and the Commission have collaborated together on. Whilst the organisations felt that operations were generally effective, the current system may be too dependant on people, rather than systems and functions. At times the Commission (DG SANCO) felt out of the link, particularly on bilateral discussions between agencies such as WHO, ECDC and EMA.

Observation 18.0

It is considered relevant that the Commission and WHO strengthen cooperation and communication between their organisations to improve pandemic preparedness and response.

Reporting

- 10.49 The problems that arose from double reporting of case information by MS to EWRS and WHO from the onset of the crisis caused concern and frustration amongst participating MS. Double reporting resulted in a high administrative burden for MS, and it was felt that the output on valid information was not sufficient (Refer also Section 10.31).
- 10.50 Situation reports from participating MS appear to have been sent to WHO and EWRS at a variety of times and frequencies in the period up to 31 August 2009. The majority reported daily up until various dates, generally until the mitigation phase was started. Some MS decided to report when necessary, others reported after each case, some weekly, and others biweekly. This variation in reporting schedules could result in a confused and inaccurate

picture across the EU and WHO regions, hindering the overall coordination and understanding of the virus and spread of the pandemic. It was felt by ECDC that MS needed to be open and transparent when reporting the number of cases, as this could affect the quality of data being compiled about the developing crisis.

10.51 Influenza situation reports were distributed to a number of key organisations nationally and internationally, mainly via EWRS for European communications. Reports were most commonly sent to national health ministries and other government departments, as well as the media.

10.52 Case numbers were updated via EWRS on a daily basis by all MS except one, who updated twice daily for part of the first four months. Twelve MS were still reporting individual cases at 31 August 2009, with eight MS ceasing to report exact numbers either once a specific case number was reached, or when sustained community transmission started.

Observation 19.0

It is considered that a review of reporting processes is undertaken by ECDC and WHO Euro of the case reporting system and other similar systems to ensure an efficient process is developed for use between multiple receiving agencies.

(This observation has been resolved during the writing period of this report)

Observation 20.0

It is considered useful that clearly defined reporting processes are developed for MS by ECDC and WHO Euro to use in future public health crises, including reporting instructions, outline schedules and instructions, when to cease reporting and how to share analysis in confidence.

11.0 Coordination of Public Health and Control Measures

11.1 This objective is to examine the coordination of public health and control measures at national level and across the EU. It focuses specifically on transport and travel, education and social mixing, personal countermeasures, and the movement of people and goods. Information for this section is derived from the EU-wide survey and interviews conducted with the Commission (DG SANCO), ECDC, and EMA.

Transport and travel

11.2 As the influenza outbreak is believed to have started in Mexico and the USA, and spread to Europe by international air travel, the implications for travel and any ensuing restrictions, warning and advice were key issues early in the crisis. It was never an issue in the EU to close borders, this was due to discussion during planning before the pandemic.

11.3 Eighteen participating MS reported issuing travel advice or warnings about travel to an affected area, as defined by ECDC (see Appendix 10.0). In the first few weeks, six participating MS advised against travel to Mexico. The USA was also mentioned by three participating MS with regard to travel advice and issued specific advice regarding travel to that country.

11.4 There were mixed reactions from participating MS to the provision of coordination at EU level about travel advice and messaging. Views ranged from 'no coordination' to 'very helpful'. However, the general overall response was positive. It was felt that EU-wide coordination allowed MS to become aware of the actions of other European countries, as well as enabling support for decisions made by individual MS. The common approach and guidance issued by ECDC was welcomed.

11.5 Nineteen participating MS reported providing pandemic influenza advice to travellers returning from affected areas, including measures to be taken if symptoms of an ILI occurred, as well as a description of the symptoms. Information was made available by European countries at ports and airports from the end of April, and via the internet in line with ECDC information. Leaflets and travel advice were available at entry and exit points, with passengers generally advised not to travel if they felt unwell, and to contact a doctor if they developed ILI symptoms within seven days of their return from an ECDC defined affected area.

11.6 Early in the outbreak, 19 participating MS reported that arriving passengers directly from Mexico and the USA were issued leaflets explaining actions to take if they developed symptoms. (Figure 15) Posters, flyers and video monitors were also used to inform passengers. Nine participating MS reported undertaking contact tracing, and these contacts were then offered prophylactic treatment and informed about health monitoring issues. Contacts abroad were informed through international tracing procedures. In the majority of cases there was no routine screening of travellers, but passengers from Mexico were given advice if they felt unwell.

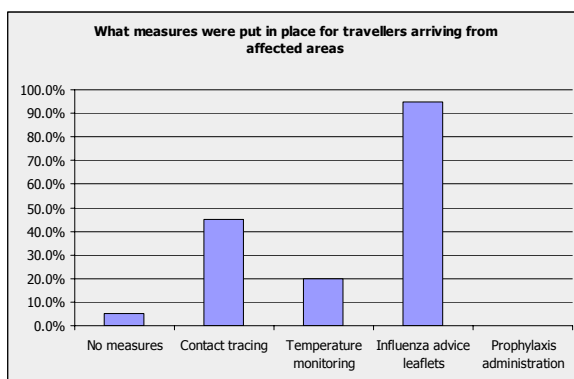


Figure 15: What measures were put in place for travellers arriving from affected areas? Source: EU-wide survey

- 11.7 Five participating MS maintained these health screening and advice measures at least up until 31 August 2009. Other MS reported keeping the measures in place whilst they were in the containment phase, or until a specified date.
- 11.8 Contact tracing for aircraft passengers was reported as a key activity in the early stages of the crisis, and participating MS had varying processes for this. Active tracing of contacts was undertaken and where necessary, people were offered anti-viral prophylaxis and advice. In many participating MS this process was in place during the whole of the containment phase and referred to anyone who came into close contact with confirmed cases. On aircraft, this included passengers sitting in the same row and several rows in front and behind. There was some variation in these parameters with three participating MS selecting only those two rows either side of the affected person, up to three rows in two MS, and five rows in one MS. For those cases that were suspected and confirmed, some participating MS extended the contacts to include household members. In many participating MS, contact tracing and provision of anti-viral prophylaxis ceased at the end of July or once they had moved into the mitigation phase.
- 11.9 ECDC published risk assessment guidelines for infectious diseases transmitted on aircraft, and participating MS applied health measures according to their national situation, but this varied across the EU, as some MS implemented processes earlier than others.

Observation 21.0

It is considered appropriate that MS are encouraged to further share information on contact tracing policies in a coordinated manner, including when to initiate contact tracing, to whom to report, and when to stop. However, it is recognised that the implementation of contact tracing in each country is the individual responsibility of each MS.

In addition, work started by the Commission (DG JLS) prior to the pandemic on the sharing of passenger information at points of entry and the legal implementation must be continued.

- 11.10 Fourteen participating MS stated that having a common approach for travel advice and coordination at EU level was very helpful during the response, particularly concerning travel information. For three MS it validated their decision making and policies. All participating MS provided travel advice and

messages according to ECDC guidance, and even when travel restrictions were not implemented, MS found that the common approach across the EU assisted with maintaining their policy. They also found it useful to know details of other MS policies that were being implemented. However, two MS felt that the decision to issue travel advice and messaging at EU level was delayed and did not offer much assistance. Keeping MS informed of travel advice policies and intentions is important, particularly in regional areas close to borders where an outbreak may be regional in nature but crosses international borders.

11.11 When asked specifically about health screening at border points, ten participating MS did not implement any health checks at entry points, and 14 participating MS did not implement health checks at exit points. Two MS reported implementing temperature monitoring at entry points and symptomatic surveillance at international airports. (Figure 16)

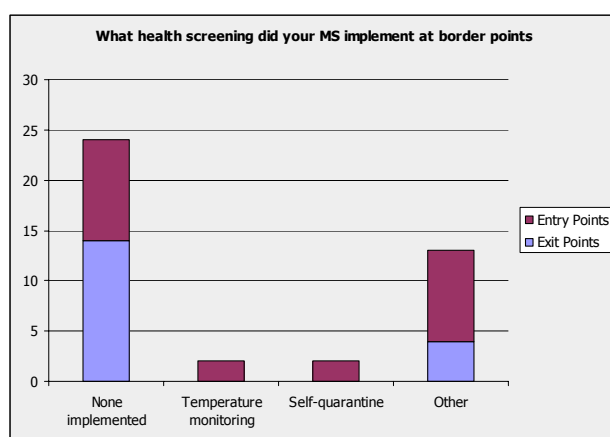


Figure 16: What health screening did your MS implement at border points? Source: EU-wide survey

11.12 There appears to be a wide variation in the dates that travel advice, warnings or restrictions was issued within the MS. In some cases travel advice was issued, but there were no restrictions from April to end August 2009. Some participating MS amended their travel advice and warnings in conjunction with other MS policy changes, and in accordance with EC advice. Some participating MS had variations to this but all initiated travel advice at the end of April. Some had restrictions in place until mid June, others to the end of August or the end of the containment phase.

Observation 22.0

It is considered useful that MS share information regarding travel advice and that the Commission aim for a coordinated and common approach to travel information and restrictions across Europe.

11.13 The methods used to distribute information to travellers varied across participating MS, but some were more common than others. These were the use of posters, leaflets, and flyers at airports and ports containing advice to travellers. Less frequently used by participating MS were websites and information lines for travellers. Other methods used to distribute information at travel hubs included use of electronic screens. Some participating MS deployed external agencies, such as the Red Cross, to assist with the distribution of information at ports and airports.

Schools

- 11.14 Prior to, and early in the pandemic as part of pandemic preparedness, ECDC provided evidence based advice regarding schools and a pandemic.⁶⁷ This identified the types of school closure and posed a series of questions for all MS to consider when contemplating school closures.
- 11.15 In some participating MS, the issue of schools and school closures was a prominent issue. Six MS reported implementing a school closure policy at some stage between 24 April and 31 August 2009. The triggers identified by participating MS for initiation of school closures include:
- Reactive closure, by different health authorities
 - Only if schools heavily affected, school authorities could choose
 - Individual school decision
 - Close school and classes when confirmed H1N1 detected
 - Depends on local epidemiological situation as assessed by public health authorities
 - Individual basis based on risk assessment by public health authorities
 - 50% of pupils affected in one class or school
- 11.16 Many participating MS reported that the onset of the summer school holidays did negate the need for taking the decision to close schools as they were already closed. In participating MS with early school holidays this was possible, for those with later school holidays, the impact on closures appears to have been greater. Issues relating to continued learning for children were considered the responsibility of the school or local authorities.
- 11.17 Fourteen participating MS reported not closing schools, and of the five MS that did, the period over which schools were closed ranged from five school days up to 8-13 school days. In all cases of school closure, this was done via notification of the head teacher, and the final decision was made either by the school or local health authorities.
- 11.18 For those participating MS that closed schools, they evaluated the effectiveness of the action through the potential slowing in infection rates by monitoring and reviewing case figures locally and nationally.

Mass gatherings

- 11.19 The majority of participating MS reported that their strategy for mass gatherings meant that no cancellation of events was necessary. Six participating MS did report however, that they had steps in place, and were prepared should the need arise. Only one MS reported advising an event should end prematurely – a youth camp with an accelerating number of influenza infections.
- 11.20 Eight participating MS reported issuing advice to the public on attending mass gatherings or public events. This was in line with general personal measures, and included advice for symptomatic people to not attend the event, but to self-quarantine and stay at home.

Personal countermeasures

- 11.21 ECDC and WHO issued early advice around the use of personal countermeasures. Much of the public health measure guidance was already published by ECDC and only required updating for this crisis to ensure the documents were user-friendly and not conflicting.
- 11.22 Participating MS were asked about a number of personal countermeasures they recommended to different groups. (Figure 17) All participating MS advised the public about hand washing and hygiene, as well as sneeze / cough etiquette. Eighteen participating MS advised people to practice social distancing, i.e. stay at home, if they had symptoms of influenza like illness.

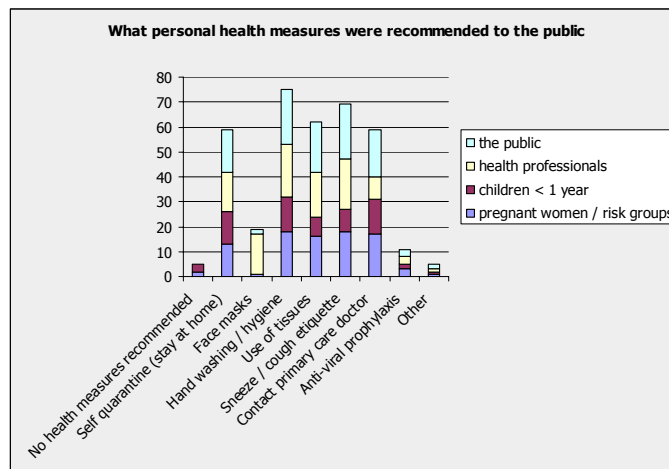


Figure 17: What personal health measures were recommended to the public?
Source: EU-wide survey

- 11.23 Face masks, when recommended, were generally only advised by participating MS for use by health care professionals. Two MS did state that face masks were recommended for the public and at-risk groups. Use of masks was discouraged by many MS as documented in WHO recommendations. Some participating MS made masks available for those that needed them, with one MS including as part of their pandemic influenza plan that every household should buy at least 50 masks per person to stockpile to last for a 12 week period in case of a pandemic.
- 11.24 For groups such as undocumented migrant populations, the application of personal countermeasures may be more difficult. As these groups are often not reported, they may fall outside the health system. Initial reports from Southern Hemisphere countries point to these groups and indigenous populations being hardest hit by H1N1.⁶⁸ Ensuring that these groups receive the messages and appropriate countermeasures may be a challenge for some MS.

Influenza diagnosis

- 11.25 All participating MS reported using laboratory diagnosis to identify and confirm cases of pandemic H1N1. Eleven participating MS also relied on clinical diagnosis by a doctor. One MS reported using a joint telephone and web-based system for diagnosis once it was operational later in the response.

11.26 Participating MS continued undertaking laboratory diagnosis of suspected cases for varying lengths of time, and to different parameters. (Figure 18) Fourteen participating MS used laboratory confirmation only during the containment phase. Six MS reported still doing laboratory diagnosis at 31 August. Only one MS reported testing until they reached a specified case number.

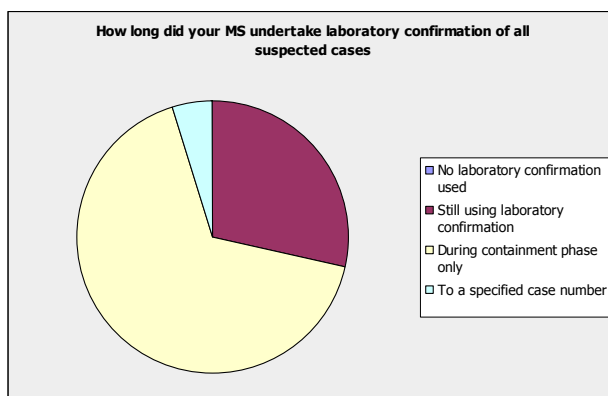


Figure 18: How long did your MS undertake laboratory confirmation of all suspected cases? Source: EU-wide survey

11.27 Once participating MS had moved to the mitigation phase, the laboratory testing tended to be confined to risk groups, particularly pregnant women and severe hospitalised cases. The change from containment to mitigation also acted as a trigger for seven MS where the move from laboratory confirmation of cases to clinical or self-diagnosis of H1N1 occurred.

11.28 All but one participating MS used the services of reference laboratories for pandemic influenza confirmation. Many participating MS used their own national reference laboratories, with four participating MS utilising the services of the WHO Collaborating centre in the UK, until their own systems were operational.

12.0 Coordination of Public and Media Messages

- 12.1 This objective is to evaluate the response to media-quests at national level and coordination of public and media messages across the EU. It specifically focuses on communicating health messages to the public, communicating the burden of disease, and communicating national and EU policy. Information for this section is sourced from the EU-wide survey, the HSC Communicators' Network survey, and interviews held with ECDC, EMA and the Commission (DG SANCO).
- 12.2 A survey of MS communications response was undertaken by the Health Security Committee Communicators Network in July 2009, and some of the responses from the survey have informed the discussion in this report.
- 12.3 The crisis communications infrastructure varied greatly across participating MS, and in most MS the crisis response team included the communications team. The number of people working in MS communications teams ranged from one in smaller MS up to 25 and 34 at the height of the crisis in larger MS. These differences in size and operating capacity will no doubt have an impact on the approach and capability of individual MS communications.
- 12.4 There appeared to be varied start dates for the integration of crisis communications into the alerting and response systems to the crisis. This ranged from starting immediately on 24 April, to not being involved until 29 or 30 April 2009.

Health messages to the public

- 12.5 All participating MS reported a variety of methods of communicating messages to the public regarding pandemic influenza. The most common method used by all participating MS involved use of websites, both official and via other organisations. The use of leaflets was used by 20 MS, with many participating MS undertaking a nationwide leaflet drop. Freephone lines were also set up in several participating MS, and were operational 24/7, in some cases staffed by medical personnel. Flyers and posters were also widely used by MS, and posted in hospitals, airports and other public places. These methods were implemented by participating MS at varying times during the first four months, but the majority were in place by 15 June 2009.
- 12.6 MS need to report non-conflicting health messages during a public health emergency. This is important because of the many international media, news and online sources and readily available instant news services. Ideally messages need to be coordinated between MS, particularly those with mutual borders, to ensure citizens do not receive mixed or wrong messages depending on the area they are in. ECDC reported that there were limitations on coordinated communications when MS policies differ.
- 12.7 Participating MS used various techniques to gauge public awareness to the pandemic. The most common methods used included analysis of website usage and media evaluation. (Figure 19) In order to distribute messages to the public a variety of methods were used, with all participating MS reporting they utilised websites.

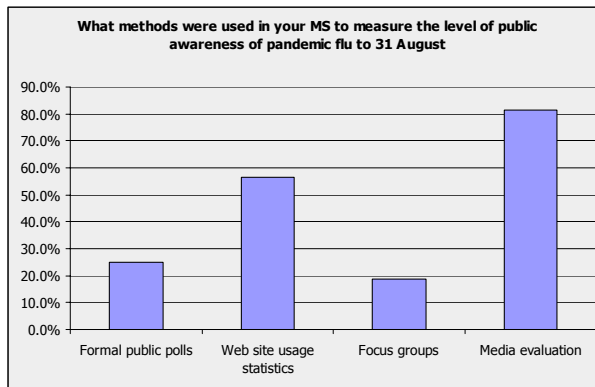


Figure 19: What methods were used in your MS to measure the level of public awareness of pandemic 'flu to 31 August 2009? Source: EU-wide survey

12.8 Other equally important methods used by 20 participating MS to distribute messages to the public included the use of TV, leaflets and brochures, with 18 participating MS using radio and newspapers. (Figure 20) Less frequently used methods included six MS using social networking websites, others used outdoor and static advertising, as well as involving commercial agencies to assist with marketing the strategy. These less commonly used methods may warrant further investigation as not all societal groups have access to computers or television.

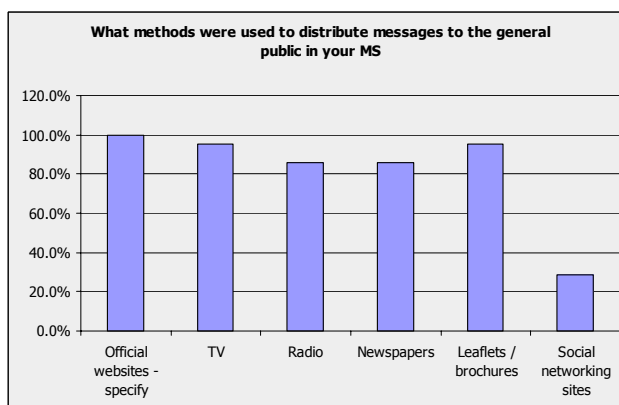


Figure 20: What methods were used to distribute messages to the general public in your MS? Source: EU-wide survey

12.9 Twelve participating MS (Figure 21) did not have a system for assessing whether the public had read and understood the messages being distributed about influenza. Those participating MS that did assess public understanding commonly used media review techniques, with three MS using formal public polls and two MS using focus groups. Three MS also monitored internet traffic of websites and emails along with calls to influenza help-sites and help-lines.

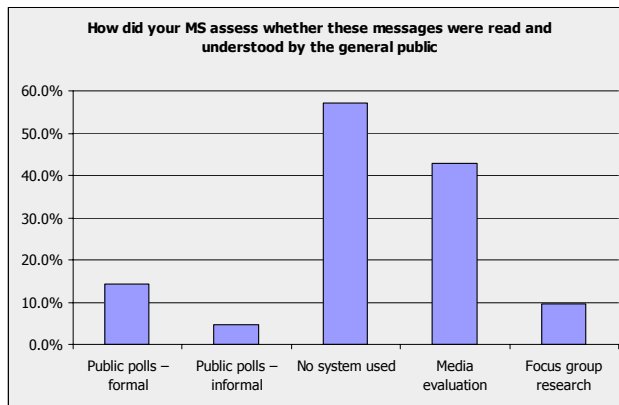


Figure 21: How did your MS assess whether these messages were read and understood by the general public? Source: EU-wide survey

- 12.10 The high number of participating MS who report not assessing public understanding is of concern, and it is important that all MS health departments are aware of how their public message campaigns are received and understood by the public and targeted audiences.
- 12.11 There appears to have been an effort by participating MS to communicate with at risk, or vulnerable groups, and those not speaking the native language. Again, websites were the most common tool used, but some innovative techniques were also used, including developing partnerships with organisations such as homeless charities and migrant groups, as well as distributing leaflets and posters in religious buildings and social areas. These practices should be further developed and formalised to ensure these groups are not excluded.
- 12.12 Groups such as vulnerable people and undocumented migrants have different needs and requirements, and for whatever reason, may be outside mainstream society. As these groups are reported to have increased susceptibility to catching influenza, improved communication with them is important.⁶⁴

Observation 23.0

It is considered appropriate that MS incorporate alternative methods of communication within their communications strategies to ensure groups including undocumented migrants and organisations providing services to vulnerable groups receive the necessary public health messaging.

- 12.13 When communicating the change in policy from containment to mitigation, participating MS reported utilising the traditional methods of communication, such as websites, radio, TV, and newspapers. The predominant method for communication of changes in strategy was the use of official government websites combined with press conferences, press releases and briefings.

Health messages to health professionals

- 12.14 A number of different methods were used by participating MS to communicate with health professionals. (Figure 22) The use of websites, including intranet sites, was the most common form of communication and used by 19 MS who responded to the survey. Fifteen of the participating MS reported using internal health bulletins which were also seen as a vital method of communication with this group. As health professionals were under pressure

during the crisis, official information in some participating MS was also shared through leadership briefings, presentations, workshops and communicating with unions. Centrally generated newsletters were also sent out to regional health authorities in several participating MS, and in a few MS 24/7 helplines were initiated for health professionals to access.

12.15 The objectives for communications with healthcare professionals within participating MS focussed on guidance and direction by providing instructions, definitions and situation updates, as well as clinical updates for case management, how to protect self and others, and advice regarding pregnant women. There was also a requirement to give information related to the methods and criteria for analysis, sampling and laboratory diagnosis. ECDC reported that it was difficult to communicate with clinical personnel and doctors as there are different prescribing guidelines between MS, and as such they could provide background for prescribing only.

12.16 Communications methods that were less frequently used by 13 participating MS included professional publications such as journals. This may be due to the less frequent issue of the product, and the longer lead times for publication. As the crisis was fast moving in the early stages, shorter and less formal internal health bulletins may have provided the most effective form of print communication with health professionals.

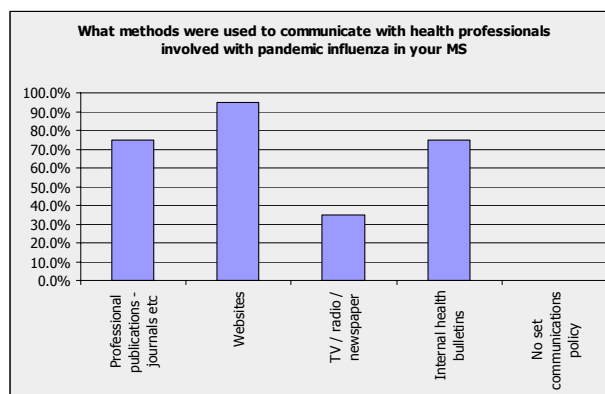


Figure 22: What methods were used to communicate with health professionals involved with pandemic influenza in your MS? Source: EU-wide survey

12.17 When assessing whether health professionals had received the messages, nine from 17 participating MS reported not following this up. Of the remainder, they included monitoring of feedback through on-line channels, such as frequently asked questions, as well as via regular reporting channels from local and regional levels to national health authorities.

Media relations and perception

12.18 A number of participating MS have used a variety of methods to assess whether the media understood the messages they were reporting, and to ensure accuracy of communications. It is necessary to ensure that the content and intention contained in messages sent from health authorities is distributed with the correct intent to the public. In five MS the media news reports are screened for accuracy and understanding. In one MS, there were face to face briefings with government health officials. Other participating MS report using a variety of media monitoring strategies, including follow-up

discussions with journalists. Seven MS indicated they do not measure the extent of media understanding of the influenza messages they are publishing.

- 12.19 Participating MS have reported generally positive relations with the media during the initial response. Information is regularly updated and professional spokespeople are used by MS. This has been assisted by policies of active communications, and in some cases public health experts are fronting the media.

Observation 24.0

It is considered important that MS monitor the accuracy of public health messages issued by the media during a crisis, and develop systems that assess the level of public understanding of the issued messages.

- 12.20 Press briefings and conferences were generally high in number during the first few weeks and months, with up to daily briefings. These were scaled back as the pandemic progressed. Later on in the crisis, briefings and press conferences were less often, once a week and with more use of the websites for releases. There were some reports of media fatigue, but interest appears to be re-kindled with new case specific information.

- 12.21 One MS did report some low-level criticism of authorities handling of the crisis, however, generally there appears to have been responsible reporting by the media.

HSC Communicators' Network (HSC COMNET)

- 12.22 The HSC at its meeting of 5 and 6 November 2008 agreed to the setting up of a HSC Communicators' Network, and the HSC COMNET worked in its first EU-wide crisis. Responses from participating MS about the effectiveness of the HSC COMNET in enabling coordination between European countries was generally seen as positive, with 14 MS viewing the network as either effective or very effective in achieving this. Seven of the participating MS reported it had no effect either way, but there were no responses suggesting ineffectiveness. (Figure 23)

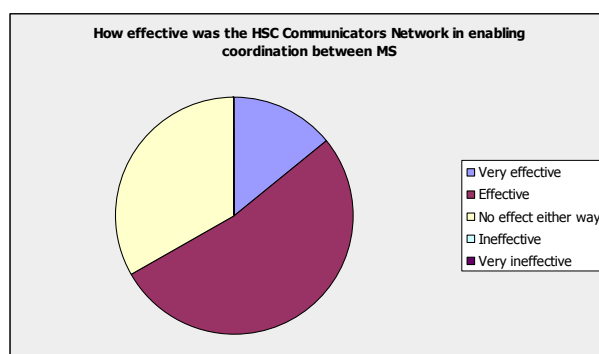


Figure 23: How effective was the HSC Communicators Network in enabling coordination between MS? Source: EU-wide survey

- 12.23 At times during the crisis the sharing of information by the HSC COMNET was faster than EWRS, and as the HSC COMNET were willing to share this information, it may have led to information not being processed through formal channels. The HSC COMNET needs to keep the Commission informed, and not only have bilateral discussions with MS and EU agencies.

As the crisis progressed, integration of the HSC COMNET within the response improved. The HSC COMNET needs to develop key operating principles to ensure it works for all MS not just a few.

- 12.24 ECDC reported a need to keep communicators and technical experts in contact with each other to ensure that correct messages were published. The input of technical experts can help communicators ensure that accurate information is published without error, such as the example concerning Guillain Barre Syndrome and vaccination.
- 12.25 The HSC COMNET has evolved throughout the crisis, and what was initially an informal group has progressed to a more formal network. Previously the HSC and MS would find out information via the media rather than each other, and now that the HSC COMNET is more integrated, it allows the HSC to discuss the situation and measures, knowing that the HSC COMNET can follow up and communicate the outcomes.
- 12.26 One of the statements from Exercise Aeolus⁶² highlighted that the HSC COMNET needed to establish a framework for more efficient sharing of local information across the EU. This seems to have been generally achieved, however the HSC COMNET would benefit from further development, and the formation of a strategic work plan.

Observation 25.0

It is considered important that the HSC COMNET develop a strategic work plan that incorporates roles, including the relationship and links with the main HSC Committee, responsibilities, and structures for improved information flow.

13.0 Anti-viral Medicines

Note

It should be noted that due to their volume and complexity, it was considered that vaccination issues would be assessed in a separate review process, which was launched in March 2010. The responses to the questions related to vaccines and vaccination strategy that have been obtained under this assessment will be considered in the context of this separate review process. This section therefore only focuses on anti-viral medicines

- 13.1 The objective is to analyse the availability and use of vaccines and anti-viral medicines. It specifically focuses on access to antiviral medicines and guidance on their effective use, susceptibility testing, and the pandemic vaccine. Information for this section is sourced from the EU-wide survey and interviews held with EMA, ECDC and the Commission (DG SANCO).

Access to anti-viral medicines

- 13.2 When developing anti-viral policies, participating MS were split about engaging in consultation with other European countries or organisations. Eleven MS reported engaging in consultation with the Commission, Committees (HSC and EWRS) and organisations providing scientific advice including ECDC, WHO, EMA, CDC and FDA. Much of this was undertaken in the planning stages prior to April, but also via audio-conference and bilateral discussions during the crisis.
- 13.3 During the containment phase, participating MS issued public messages about anti-virals and their usage, and of those that made anti-virals available, anti-virals were only for the patient and close contacts. Anti-virals were generally only available on prescription. One MS did state that anti-virals were not used. At this early stage, some participating MS were cautious about prescribing anti-virals in view of possible resistance emerging. Several MS made public early on that they had ample stockpiles of anti-virals for the population. These MS also report being open with the media and public about the facts, focussing on safety and efficacy of anti-virals.
- 13.4 Participating MS tended to target specific groups during the containment phase for anti-viral prophylaxis, particularly travel related and contacts, and household contacts. (Figure 24) To a lesser extent, workplace and school contacts were also given medication. High risk groups, health care personnel, and other key workers were less likely groups to receive prophylaxis during the containment phase unless affected by influenza.
- 13.5 For those participating MS that moved to the mitigation stage, distribution of anti-viral prophylaxis decreased, with six MS not giving prophylaxis at all (see graph below). Those groups at risk and hospitalised, or confirmed with influenza and hospitalised were still being considered for prophylaxis. The variations in participating MS anti-viral prophylaxis policies may result in confusion for members of the public who see one European country taking a course of action, and a neighbouring MS following a different line.

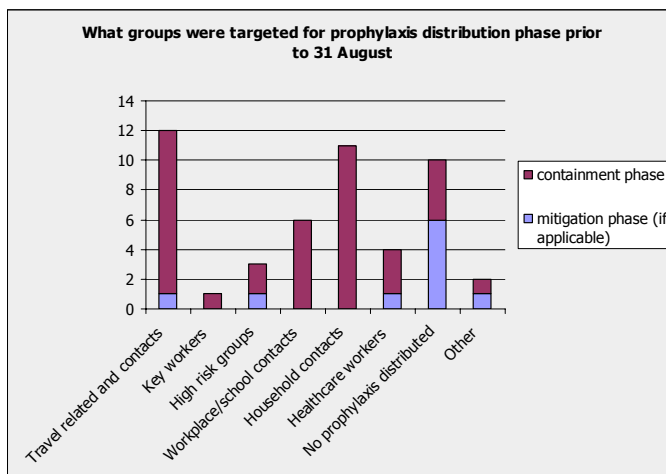


Figure 24: What groups were targeted for prophylaxis distribution phase prior to 31 August 2009? Source: EU-wide survey

Observation 26.0

It is considered valuable that where possible MS continue to share data and the rationale for decision making regarding national anti-viral (and vaccine) prescribing policies for use in the different stages of a pandemic to inform the response across Europe.

- 13.6 Distribution policies and processes for anti-viral medicines varied, but 20 of the participating MS opted for the patient or a patient representative to collect from a doctor, hospital or pharmacy. In five MS and during the early stages of the crisis, local health authorities delivered anti-virals to the patient's home address. (Figure 25)

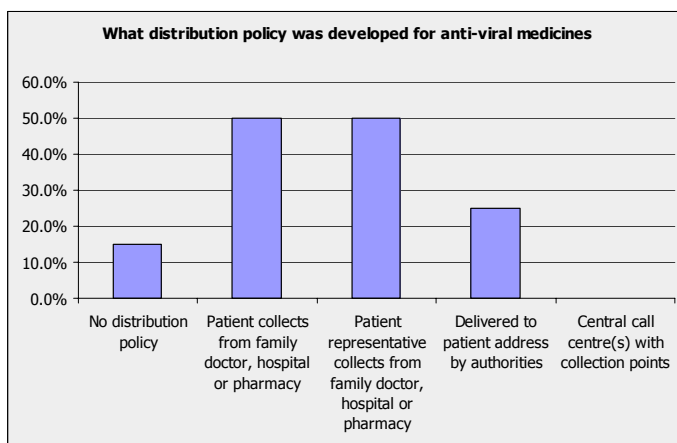


Figure 25: What distribution policy was developed for anti-viral medicines? Source: EU wide survey

- 13.7 On 8 May 2009 EMA through CHMP recommended that Oseltamivir capsules could be used for up to two years beyond the initial stated shelf-life of five years to seven years. These recommendations were only to be used during a pandemic declared by WHO. Zanamivir also obtained a similar extension at end of May 2009.

Guidance on effective use

13.8 The criteria for prescribing anti-virals varied between participating MS, but during the containment phase, most based the decision on the case definition (13 MS) or prescription by a primary care doctor (13 MS). A few MS used specific parameters to prescribe anti-virals, including underlying medical condition, ILI, pregnancy, children younger than 15, and adults over 65 (Figure 26). Once into the mitigation phase, the criteria for prescription changed with MS reducing the prescribing to that based on the case definition (4 MS) or through visiting a primary care doctor (8 MS).

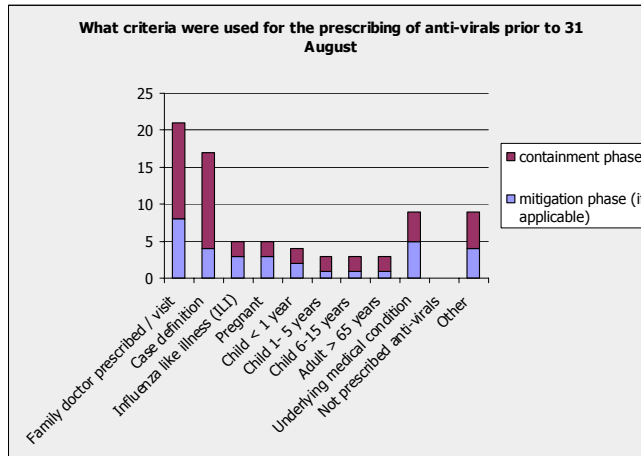


Figure 26: What criteria were used for the prescribing of anti-virals prior to 31 August 2009? Source: EU wide survey

13.9 Guidance on the effective use of anti-virals was predominantly issued to the public through websites, TV, radio, and newspapers. Some participating MS also used mass distribution leaflets to deliver the anti-viral messages. Three MS did not issue any guidance relating to anti-viral usage.

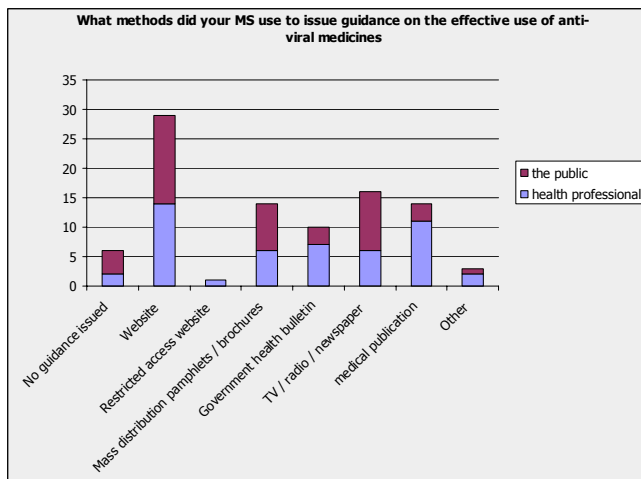


Figure 27: What methods did your MS use to issues guidance on the effective use of anti-viral medicine? Source: EU wide survey

13.10 Health professionals were also targeted by participating MS to receive anti-viral guidance, and again the website was the most common method, but medical publications were also used. (Figure 27) Government health bulletins were issued in seven participating MS along with leaflets to target health professionals.

- 13.11 When assessing the level of compliance by the public to collection of anti-virals and adherence to prescription guidelines, 12 participating MS report that no review was carried out. Those that responded reported a variety of different methods to gauge public compliance including:
- monitoring of anti-viral sales and checking stock levels
 - monitoring calls received at call centres
 - providing follow-up calls to people who had received treatment
 - operational feedback from health care workers involved in the distribution of anti-virals
- 13.12 Considering the time placed on using anti-virals for containing and treating the disease, it would be beneficial to have a greater in-depth indication of how effective the public were adhering to guidance and prescription.

Observation 27.0

It is considered useful that MS develop processes to assess the response by health professionals and the public to antiviral prescribing, distribution, collection and usage processes and policies.

- 13.13 With regards to anti-viral resistance and side-effects, 16 participating MS reported carrying out surveillance, and this was predominantly undertaken by public health organisations or national influenza laboratories. In some cases doctors and pharmacies were used to undertake the surveillance. Some surveillance on anti-viral resistance was carried out by three participating MS, mostly via national public health or medicines agencies. The Community Network Reference Laboratory documented surveillance reports via Surveillance Outputs and also to WHO. This should enable sharing of information on anti-viral resistance and side-effects.
- 13.14 Ten participating MS report that surveillance of side-effects of anti-virals would follow normal national legislative procedures. Three MS asked for informal feedback from doctors based on clinical symptoms, but no other surveillance. One MS developed a separate enhanced reporting scheme on adverse drug reactions associated with pandemic countermeasures.
- 13.15 EMA issued advice to health professional and pharmacists on variations such as dilution of anti-virals for paediatric use due to a shortage of made up doses. At the beginning May, they also produced guidance on the use of Oseltamivir in children aged less than one year, and use of Oseltamivir and Zanamivir in pregnant and breastfeeding women.

Susceptibility testing

- 13.16 Thirteen participating MS reported having their own reference laboratory which undertook testing for anti-viral susceptibility. Anti-viral susceptibility profiles were determined by all 13 MS for neuraminidase inhibitors and seven participating MS also looked at the anti-viral susceptibility profiles for M2 inhibitors. Of those participating MS who used WHO collaborative centres for testing, seven MS reported receiving results on the anti-viral susceptibility of the viruses that were shared.
- 13.17 Anti-viral susceptibility profiles for neuraminidase inhibitors were determined by ten participating MS using genotypic, or nucleic acid analysis. Phenotypic analysis was used by eight MS in tests. Of the eight MS that indicated they

reviewed M2 inhibitor anti-viral susceptibility, seven used genotypic analysis, and four also used phenotypic analysis.

13.18 Reporting of virus testing to WHO was undertaken by 15 participating MS, and the main method of doing this was by the Euroflu and flunet websites, and well as weekly reporting to WHO. This information was also passed to ECDC by the Community Network of Reference Laboratories and published in the weekly Influenza Surveillance Overview.

13.19 The decision to test people for the presence of the H1N1 virus was based on a variety of situations. (Figure 28) The highest group that were tested were fatalities – nine of 13 participating MS tested. The next most common groups undergoing testing were from patients admitted to intensive care (six of 13 MS) and those who continued to show symptoms whilst receiving treatment (six of 13 MS).

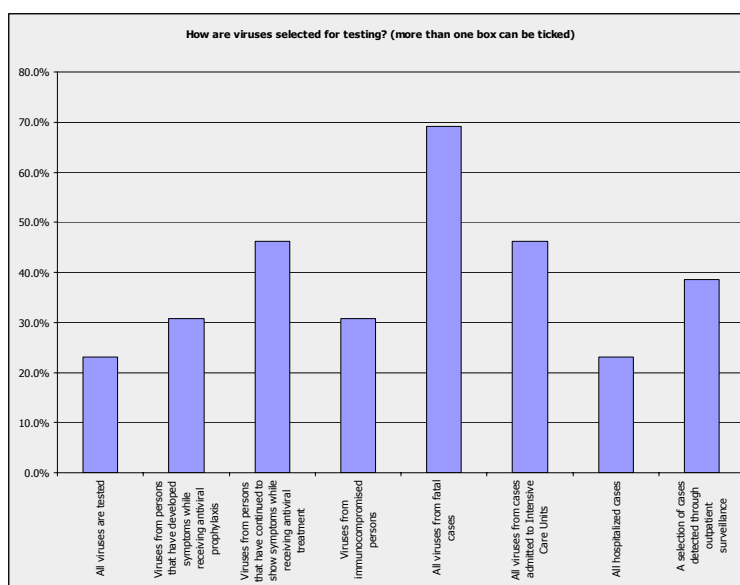


Figure 28: How are viruses selected for testing? Source: EU wide survey

13.20 Seventeen participating MS said they had not conducted clinical trials for anti-virals or vaccines during the review period up to 31 August 2009. Twelve MS also stated they did not undertake regular resistance testing during the review period.

13.21 Discussions occurred between EMA, ECDC and manufacturers regarding safety trials, and there was a need to obtain information quickly on H1N1 strain. It was the first time the EMA paediatric committee were able to have input into such a process.

13.22 Oseltamivir had already been approved for use before this pandemic started, but an assessment was completed via EMA in five days on Oseltamivir for those populations for whom no product information was available. The normal process was followed but in a condensed timeframe.

14.0 Appendices

Appendix 1.0 – Protocol Document

Response to Pandemic (H1N1) 2009

Protocol

Aim

The aim of this paper is to set out the review protocol and define the scope of review being undertaken.

Brief

In place of Exercise Tor, DG SANCO has requested a review of the current outbreak of Pandemic (H1N1) 2009 across Europe.

Aim

The aim is to examine the response at Member State and Commission level to the first three months of the outbreak (pre- and pandemic phases) of Pandemic (H1N1) 2009.

Objectives

The objectives for the review are specifically to:

1. Review pandemic response and interoperability between national responses
2. Examine the effectiveness of business continuity plans (where implemented)
3. Evaluate the robustness and efficiency of communications systems utilised during the response at national and EU level
4. Assess the effectiveness of communications within and between national, EU and international participants
5. Examine the coordination of public health and control measures at national level and across the EU
6. Evaluate the response to media-quests at national level and coordination of public and media messages across the EU
7. Analyse the availability and use of vaccines and anti-viral medicines
8. Evaluate the operation of the Health Emergency Operations Facility (HEOF)

Scope

EU-wide

The work will focus on the coordination aspects (including public health and control measures; public and media messages, communication systems) across Europe, the interoperability between national plans and the effectiveness of communications between stakeholders at EU level.

National/Agency Level

The national/agency level evaluation will focus on the activity at national level, including the operations and systems in place. This includes the HEOF review.

Local level

Only for those Member States who specifically request it and require additional support from the HPA. To be agreed with the EC on a case-by-case basis.

Population

The population groups from which information may be obtained include:

EU-wide

- Members of EWRS and HSC committees
- Members of HSC Communicators Network
- DG SANCO (incl. HEOF members)
- Participating EU agencies

National/Agency Level

- Responder from across government departments (i.e. cross sectoral)
- National scientific/technical bodies involved in response

Local Level

- Health and other local responders

Method of data collection / analysis

The methods of data and information collection may include the following:

- Face-face interviews by members of the Planning Group
- Web-based questionnaire
- Observational assessments by the members of the Planning Group

Parameters

In order to meet the objectives, the following will be reviewed during the process:

1. Pandemic Preparedness Plans
 - Interoperability between national plans
2. Business Continuity
 - Impact on services
 - Managing concomitant incidents
 - Mutual aid
 - Foreseeable degradation
3. Communications systems
 - EWRS
 - HEDIS
 - Medisys
 - ARKADIN
4. Communications
 - Liaison with MS, EU agencies and the Commission
5. Coordination of public health and control measures
 - Transport and travel
 - i. Travel advice
 - ii. Travel restrictions/border closures
 - iii. Health screening/border control
 - Education and social mixing/distancing
 - i. School closures
 - ii. Social events, work related activities and mass gatherings
 - Personal countermeasures
 - Movement of people and goods
 - i. Cross border movements of workers and other travellers
 - ii. Cross border movement of susceptible animals
 - Authorisations and processes for novel medicines (e.g. pre-pandemic and novel strain viruses)

6. Coordination of public and media messages
 - Health messages to the public
 - Communicating the burden of disease
 - Communicating national/EU policy

7. Vaccines and anti-viral medicines
 - Access to anti-viral medicines
 - Guidance on effective use
 - Susceptibility testing
 - Pre-pandemic vaccine
 - Pandemic specific vaccine

Appendix 2.0 – EU-wide Pandemic (H1N1) 2009 Evaluation Survey

EU-wide Pandemic (H1N1) 2009 General Survey

1. Aim

The aim of the review is to examine the response at Member State and Commission level to the first four months of the outbreak (24 April to 31 August) of Pandemic H1N1 2009.

2. Purpose

The purpose of the evaluation is to learn lessons from the containment phase and the early weeks of mitigation phase of the pandemic (H1N1) 2009 crisis. It is also intended to inform the ongoing response to current pandemic and future crises.

3. Survey Procedure

This survey is the mechanism by which the Health Protection Agency (HPA) will be obtaining information from Member States to achieve the objectives of the EU-wide Pandemic Influenza Evaluation.

Your assistance in completing this survey is invaluable. Please complete all sections and answer each question as fully as possible. The scope of the questionnaire is such that you may want to consult relevant colleagues in your Member States as necessary. We expect to receive only one agreed, completed questionnaire per Member State.

The sharing of this information in detail will ensure that we are able to obtain as clear a picture as possible of activities across the EU during the first 4 months of the pandemic response.

When considering your responses, please remember that we are only looking at the period from 24 April until 31 August 2009. Please only include information that covers this time period unless it is specifically requested. Member States have been following differing policies of containment and mitigation at various stages over the review period, and this is acknowledged in the relevant sections of the questionnaire.

Data will be analysed by the HPA and all information received will be treated confidentially. Critically, the evaluation focuses on processes involved in the pandemic response, not on individuals.

We realise that you may already have answered questions similar to this as part of other evaluations, and we are extremely grateful for your making the time to complete this questionnaire given your heavy workload.

A draft report will be submitted to the European Commission (DG-SANCO) at the end of November 2009. This will be discussed at a conference planned for the end of January 2010 to which Member States and European Agencies will be invited.

4. Survey Content

The survey includes the following sections:

- **Generic Section**
This section covers events and general information, some of which is outside the evaluation period dates.
- **Section 1**
This section covers national influenza plans and the interoperability of national plans across the EU.
- **Section 2**
This section covers business continuity planning and resilience of sectors.
- **Section 3**
This section covers some of the communications tools utilised – EWRS, HEDIS, Medisys, and Arkadin.
- **Section 4**
This section covers the liaison and communication between national, EU and international partners
- **Section 5**
This section covers the public health and control measures within MS
- **Section 6**
This section covers communications with the media, and public and media messaging
- **Section 7**
This section covers the availability and use of antiviral medicines and pandemic vaccines

Notes about the survey:

- It is available via weblink
- It does not have to be completed in one session
- Work may be saved and returned to later
- Questions do not have to be completed sequentially
- It is possible to change answers up until the survey is submitted
- It is also available in pdf format so it can be distributed for consultation
- Responses can be collated and inserted via the weblink once they have been checked and approved by the individual responsible for the survey in your Member State.
- Where MS (Member State) appears in the survey, note this includes all EU and EFTA countries

Generic Questions

This section covers events and general information, some of which lies outside the evaluation period dates.

Question	Answer Format
1. When was the last revision of your national or agency pandemic influenza plan	2009 2008 2007 2006 and earlier No flu plan No revision undertaken
2. When was your national or agency flu plan last tested	2009 2008 2007 2006 and earlier No flu plan Never been tested
3. Have joint influenza exercises and training been held with other MS	Yes No If Yes please specify exercise name and date
4. Which government department or agency led your MS response to pandemic influenza	
5. When did the move from containment to mitigation occur in your MS	Still in containment phase Date – please specify
6. What was the trigger for the move from containment to mitigation in your MS	Number of cases Sustained community transmission Neighbouring MS policy Other – please specify
7. Describe the key strategic issues your MS encountered in the containment phase	
8. Describe the key strategic issues your MS encountered in the mitigation phase	Not yet in mitigation phase If in mitigation phase, free text
9. What review activities regarding pandemic influenza has your MS or lead department undertaken to date	No review activities Informal staff surveys Formal structured debriefing Public inquiry Internal government review External commissioned review Other – please specify
10. Would your MS be willing to	Yes

share the outcomes of these reviews with other MS and European agencies	No Partly
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SECTION 1

This section covers national influenza plans and the interoperability of national plans across the EU.

Question	Answer Format
11. What consultation has taken place between your MS and neighbouring MS in the development of pandemic influenza plans prior to the pandemic	Regular consultation Some consultation Consultation with some MS but not all No consultation Other – please specify
12. How has this consultation improved your own MS plans and response	
13. Has your MS consulted with other MS regarding development of EU pandemic influenza plans and policy pre 24 April 2009	Yes No Not known If Yes, which MS and what elements of the plan
14. Was there liaison with other MS or EU agencies during the development of flu policy and guidance	Yes No Not known If Yes, please specify
15. What consultations were held with neighbouring MS regarding any joint response strategies	Regular audioconferences Joint policy development Other, please specify
16. Describe up to 3 key issues that demonstrated EU interoperability of influenza planning during the period 24 April to 31 August	
17. Describe up to 3 key issues that hindered or could improve EU interoperability of influenza planning during the period 24 April to 31 August	

SECTION 2

This section covers business continuity planning and resilience of sectors.

Question	Answer Format
18. Which sectors (if any) in your MS have been significantly impacted by the flu response up to the 31 August 2009	Health – please specify sectors Transport Utilities Waste Finance / Banks Central government Local government No services affected Other – please specify
19. Were any sectors or services impacted that were not expected	Yes No Unknown If Yes – please specify
20. What steps (if any) have been put in place to mitigate the impact on services	
21. Where any cross border agreements in place to access or supply health services or resources (eg ECMO) with other MS from 24 April to 31 August	No agreement in place Agreement present If agreement present please describe and specify MS involved
22. Has health assistance been requested from other MS or EU agencies during this crisis	Yes No Not Known If Yes – please describe and include who coordinated this
23. Has health assistance been provided to other MS, or EU agencies during this crisis	Yes No Not known If Yes – please describe and include who coordinated this
24. What pressures (if any) did primary care services experience during the containment phase	Please describe services and associated pressures
25. What pressures (if any) did primary care services experience during the mitigation phase	Not in mitigation Please describe services and associated pressures

SECTION 3

This section covers some of the communications tools utilised – EWRS, HEDIS, Medisys, and Arkadin.

EWRS

Question	Answer format
26. How frequently was EWRS accessed and used by your MS	6-10 times per day 2-5 times per day Once a day 6-10 times per week 2-5 times per week Once a week Infrequently Never used
27. How easy was EWRS to operate by your MS (such as input of data, accessing information)	Very easy Easy Neither easy or difficult Difficult Very difficult
28. What problems were encountered with EWRS	No problems Log-on / access problems Search function Data entry problems Submission of information Information retrieval problems Excess information received Poor quality information received Internet browser compatibility problems EWRS not working Other – please specify
29. How did EWRS affect the ability to communicate with other MS and EU agencies	Improved No change Difficult Not used Other – please comment
30. What improvements would you suggest for EWRS (if any)	

HEDIS

Question	Answer Format
31. How frequently was HEDIS accessed and used by your MS	Daily 6-10 times per week 2-5 times per week Once a week Infrequently Never used

32. How easy was it for your MS to operate (such as accessing information)	Very easy Easy Neither easy or difficult Difficult Very difficult
33. What problems were encountered with HEDIS	No problems Log-on / access problems Data entry problems Submission of information Information retrieval problems Internet browser compatibility problems Poor quality information received Excess information provided by HEDIS HEDIS not working Other – please specify
34. How did HEDIS affect your MS ability to communicate with other MS, EU agencies	Improved No change Difficult Not used Other – please comment
35. What improvements would you suggest for HEDIS (if any)	Free text

MEDISYS

Question	Answer Format
36. How frequently was MEDISYS accessed and used	Daily 6-10 times per week 2-5 times per week Once a week Infrequently Never used
37. How easy was it to operate and access information	Very easy Easy Neither easy or difficult Difficult Very difficult
38. What problems were encountered with MEDISYS	No problems Log-on / access problems Information retrieval problems Internet browser compatibility problems Poor quality information received Excess information received MEDISYS not working Other – please specify
39. What improvements would you	Free text

suggest for MEDISYS (if any)	
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ARKADIN

Question	Answer Format
40. How frequently was Arkadin used by your MS	<ul style="list-style-type: none"> More than 3 times per day 1-2 times per day 6-10 times per week 2-5 times per week Once a week Infrequently Never used
41. How easy was Arkadin to operate	<ul style="list-style-type: none"> Very easy Easy Neither easy or difficult Difficult Very difficult
42. What problems were encountered with Arkadin	<ul style="list-style-type: none"> No problems Log-on / access problems Synchronising audio and web functions Information display problems Information retrieval problems Internet browser compatibility problems Tool not working Other – please specify

Other

Question	Answer Format
43. What other communications tools were utilised within your MS, and how useful were these	

SECTION 4

This section covers the liaison and communication between national, EU and international partners. There are specific questions for interaction with each agency

DG-SANCO and other DGs (eg DG Enterprise)

Question	Answer Format
44. What information or guidance was your MS expecting from DG-SANCO	Not expecting any Policy guidance Technical advice EU-wide coordination Other - please specify
45. Was this guidance provided by them	Yes No Partly
46. What type of health or influenza information did your MS share with other MS and DG-SANCO	No information provided Influenza policies – please specify Case numbers Scientific advice EWRS reporting Other – please specify
47. Did you use forums such as the HSC, to obtain information from other MS and / or provide own policy updates	Yes No Partly If yes – please specify
48. What activities or processes provided by DG-SANCO did your MS find most helpful	Please rank items below in order of importance (1 most helpful and 5 least helpful), and add others as required Coordination Case definition Information sharing HSC statements Vaccine issues Audioconferences HEOF operations Other – please specify
49. Please describe the effectiveness and efficacy of crisis coordination by DG-SANCO, and the benefit – if any – on the response of your MS	
50. Please describe the usefulness of HSC interactions , and the benefit – if any – on the response of your MS	
51. Were your MS delegates for the	HSC Member

HSC/EWRS audioconferences HSC members, EWRS members or did both participate	EWRS Member Both Did not participate Other (please specify)
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EMEA

Question	Answer Format
52. What contact did your MS have with EMEA between 24 April and 31 August?	Via national contact network No contact Audioconferences Other – please specify
53. What information or guidance was your MS expecting from EMEA, and was it provided by them	Not expecting any Policy guidance Technical advice EU-wide coordination Other - please specify
54. What activities provided by EMEA did your MS find most helpful	Please rank items below in order of importance (1 most important), and add others as required Coordination Information sharing Vaccine issues Audioconferences None of the above Other – please specify

ECDC

Question	Answer Format
55. What information or guidance was your MS expecting from ECDC, and was it provided by them	Not expecting any Case definition updates Risk assessment Policy guidance Technical advice Produce situation reports of EU and world Other - please specify
56. What information was your MS required to provide to ECDC	No information provided Daily case numbers Other – please specify
57. What activities and processes provided by ECDC did your MS find most helpful	Please rank items below in order of importance (1 most helpful and 5 least), and add others as required Coordination Daily audioconferences Information sharing

	Case definition Vaccine issues Risk group information None of the above Other – please specify
58. Please describe the reporting processes and their effectiveness from your MS to ECDC	Free text
59. With regards the ECDC – MS relationship, please describe how this worked for your MS – ie what worked, what did not	Free text

WHO (HQ and EURO)

Question	Answer Format
60. What information exchange took place between your MS and WHO	None / not known Situation report Global reporting system (GOARN) IHR Audioconferences Other – please specify
61. Were there any communications difficulties with WHO	Yes No Not known If yes, please specify
62. What information or activities provided by WHO did your MS find most useful	Please rank items below in order of importance (1 most helpful and 5 least helpful), and add others as required Coordination Audioconferences Information sharing Case definition Vaccine issues Risk group information None of the above Other – please specify
63. What support or information from WHO was missing that would have been helpful	
64. Please describe the reporting systems and their effectiveness from your MS to WHO	

Reporting

Question	Answer Format
65. How often were situation reports released in your MS up to 31 August	No situation reports issued Daily (including weekends) Monday – Friday Other – please specify
66. To whom were situation reports distributed prior to 31 August	No situation reports issued ECDC DG-SANCO WHO Other government departments Other MS – please specify Other – please specify
67. How often were case numbers updated in these situation reports prior to 31 August	No situation report compiled Once a day Twice daily Other – please specify
68. When did the reporting of case numbers stop within your own MS up to 31 August	Still reporting individual cases Once sustained community transmission started Once specified number reached Other – please specify

SECTION 5

This section covers the public health and control measures implemented within MS

NB. You may find it helpful to obtain input from your Communications Team in answering some of these questions

Travel and transport

Question	Answer Format
69. Did your MS issue any travel advice or warnings about travel to an affected area (as defined by ECDC)	Yes No If Yes – please specify to where and over what period of time
70. How did coordination at EU level assist your MS with deciding to issue travel advice and messages	
71. What health screening did your MS implement at border points	Entry points None implemented Temperature monitoring Self-quarantine Other – please specify Exit points None implemented Temperature monitoring Self-quarantine Other – please specify
72. Between what dates did you issue travel advice, warning, or restrictions, and when were these lifted	
73. What pandemic influenza information (if any) did your MS issue to incoming air and sea passengers	
74. What measures were put in place for travellers arriving from affected areas	No measures Contact tracing Temperature monitoring Influenza advice leaflets Prophylaxis administration Other – please specify
75. Over what time period were these measures above in place	
76. Please describe the contact tracing policy, including triggers, used in your MS from 24 April to	Free text Did it change during the period from 24

31 August	April to 31 August For how long did you pursue the policy
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Schools

Question	Answer Format
77. Did your MS implement a school closure policy at some point between 24 April and 31 August	Yes No
78. What were the criteria or triggers for recommending school closure in your MS	
79. If a school closure policy was implemented what was the recommended duration for closure	Did not close schools < or = 4 school days 5 school days 6 school days 7 school days 8-13 school days 14 or > school days Other – please specify
80. How were school closure requirements communicated to schools and pupils	No schools closed School website Local radio / TV No formal system in place Notification via school head teacher
81. Who was involved in the decision to close schools, and who made the final decision to close	No schools closed National Government Federal Government Local health decision School decision Other – please specify
82. How did you ensure continued learning for students whilst schools were closed	
83. How did you evaluate the effectiveness of school closures in slowing the spread of infection between 24 April and 31 August	

Mass gatherings

Question	Answer format
84. What was your strategy for the potential cancellation of mass gatherings or similar events with	

large numbers of people	
85. Did your MS advise cancellation of any mass gatherings or public events	Yes No Not known If yes – please specify
86. Did your MS issue any public advice on attending mass gatherings or public events	Yes No Not known If yes – please specify

Personal Countermeasures

Question	Answer Format
87. What personal health measures were recommended to: a) the public b) health professionals c) children < 1 year d) pregnant women / risk groups PLEASE PROVIDE AN ANSWER FOR EACH GROUP (A TO D)	No health measures recommended Self quarantine (stay at home) Face masks Hand washing / hygiene Use of tissues Sneeze / cough etiquette Contact primary care doctor Anti-viral prophylaxis Other – please specify

Influenza diagnosis

Question	Answer Format
88. What diagnostic methods were used by your MS for identification of pandemic (H1N1)	No diagnostic methods used Laboratory diagnosis Clinical diagnosis by doctor Self-diagnosis Other – please specify
89. How long did your MS undertake laboratory confirmation of all suspected cases	No laboratory confirmation used Still using laboratory confirmation During containment phase only To a specified case number Other – please specify
90. At what point did your MS move from laboratory confirmation of suspected cases to clinical or self-diagnosis	
91. Did your MS use the services of reference laboratories	YES No Not known If yes – please specify whether in your MS, or cross border

SECTION 6

This section covers communications with the media, and public and media messaging

Note: The HSC Communicators Network have already completed an evaluation, so some questions are omitted here

Question	Answer Format
92. What methods were used in your MS to measure the level of public awareness of pandemic flu to 31 August	Formal public polls Web site usage statistics Focus groups Media evaluation Other – please specify
93. What methods were used to distribute messages to the general public in your MS	Official websites - specify TV Radio Newspapers Leaflets / brochures Social networking sites Other please specify
94. How did your MS assess whether these messages were read and understood by the general public	Public polls – formal Public polls – informal No system used Media evaluation Focus group research Other – please specify
95. What methods were used to inform at-risk groups and those not able to speak the native language	No provision made for these groups Leaflets / brochures TV / radio / newspaper Other – please specify
96. What methods were used to communicate with health professionals involved with pandemic influenza in your MS	Professional publications - journals etc Websites TV / radio / newspaper Internal health bulletins No set communications policy Other – please specify
97. What evaluation was carried out concerning compliance of the public to collection and adherence to prescription of antivirals	
98. How did your MS communicate the change in strategy from containment to mitigation	
99. How were national pandemic influenza policies and messages	Professional publications - journals etc Official websites

<p>issued to health professionals</p>	<p>Social networking sites TV / radio / newspaper Specialist media Internal health bulletins No set communications policy Other – please specify</p>
<p>100. How did your MS assess whether these policies and messages were received by health professionals</p>	
<p>101. How did you measure the extent to which pandemic messages were understood by the media</p>	
<p>102. How effective was the HSC Communicators Network in enabling coordination between MS</p>	<p>Very effective Effective No effect either way Ineffective Very ineffective</p>

SECTION 7

This section covers the availability and use of antiviral medicines and pandemic vaccines

Question	Answer Format
103. Did your MS consult with other MS or organisations regarding development of antiviral policies	Yes No Not known If Yes – please describe who consulted, and nature of advice
104. What public messages were issued in your MS regarding influenza anti-viral medicines prior to 31 August	a) Containment Phase b) Mitigation Phase (if applicable)
105. What groups were targeted for prophylaxis distribution prior to 31 August during the: a) containment phase b) mitigation phase (if applicable)	Travel related and contacts Key workers High risk groups Workplace/school contacts Household contacts Healthcare workers No prophylaxis distributed Others - please specify
106. What distribution policy was developed for anti-viral medicines	No distribution policy Patient collects from family doctor, hospital or pharmacy Patient representative collects from family doctor, hospital or pharmacy Delivered to patient address by authorities Central call centre(s) with collection points Other – please specify
107. What criteria were used for the prescribing of anti-virals during the: a) containment phase b) mitigation phase (if applicable)	Family doctor prescribed / visit Case definition Influenza like illness (ILI) Pregnant Child < 1 year Child 1- 5 years Child 6-15 years Adult > 65 years Underlying medical condition Not prescribed anti-virals Other – please specify

Question	Answer Format
108. What methods did your MS use to issue guidance on the effective use of anti-viral medicines to: a) the public b) health professionals	No guidance issued Website Restricted access website Mass distribution pamphlets / brochures Government health bulletin TV / radio / newspaper Medical publication Other – please specify
109. What guidance did your MS issue to health professionals about anti-viral use for H1N1	
110. What surveillance did your MS carry out on issues of antiviral resistance and side effects if any	No surveillance undertaken Surveillance undertaken - Please specify

Question	Answer Format
111. Does your reference laboratory perform testing for antiviral susceptibility	Yes No Unknown
112. If yes, for which class of drugs do you determine antiviral susceptibility profiles	Neuraminidase inhibitors M2 inhibitors (adamantanes) Other – please specify
113. If yes, how do you determine the antiviral susceptibility profiles for neuraminidase inhibitors (more than one option can be selected)	Genotypic (virus nucleic acid analysis) Phenotypic (virus susceptibility analysis, i.e. determination of 50% inhibitory concentration values) Other
114. If yes, how do you determine the antiviral susceptibility profiles for M2 inhibitors (more than one option can be selected)	Genotypic (virus nucleic acid analysis) Phenotypic (virus susceptibility analysis, i.e. determination of 50% inhibitory concentration values) Other
115. How are viruses selected for testing? (more than one box can be ticked)	All viruses are tested Viruses from persons that have developed symptoms while receiving antiviral prophylaxis Viruses from persons that have continued to show symptoms while receiving antiviral treatment Viruses from immunocompromised persons All viruses from fatal cases All viruses from cases admitted to Intensive Care Units All hospitalized cases A selection of cases detected through

	outpatient surveillance Other
116. If no to Q111, do you receive results from the WHO Collaborating Centre on the antiviral susceptibility profile of the viruses you have shared	Yes No Not known
117. How did you report the results of viruses tested to WHO	

Question	Answer Format
118. Has your MS conducted clinical trials for pandemic influenza antivirals or vaccines during the evaluation period	Yes No Not known If yes, please describe
119. Did your MS do regular resistance testing during the evaluation period	Yes No Not known If yes, please describe process and reporting method

Question	Answer Format
120. How has your MS procured vaccine supplies	Not sourced vaccine Direct from EU supplier Own MS manufacturer Via third party Made available from another country Other – please specify
121. Does your MS plan to donate some of the national stockpile to other countries	Yes No Other If yes, please specify
122. Prior to 31 August what was your strategy for vaccination	No vaccination planned Targeted groups Whole population Optional vaccination obtained via family doctor Identified key groups for vaccination Other – please specify
123. Did you issue your own vaccination strategy, or did you use the EU vaccination statement	EU vaccination statement MS vaccination strategy Other – please specify No vaccination strategy issued

CONCLUSION

Question	Answer Format
124 If your MS would like to comment about certain issues in greater detail, or comment about issues not covered above, please describe here.	

Thank you for taking the time to complete this survey. Your answers are important to the evaluation process and will be taken into consideration when analysing all the data received from MS and other EU agencies.

Appendix 3.0 – Interview Topics - EMA

Preparedness and response

- EMA preparedness activities – exercising, training
- Consult with MS / EU over plan development
- Identification and effectiveness of reporting arrangements
- Identify key strategic issues encountered by EMA during the response
- Review activities undertaken to date
- Identify key issues concerning overall EU response that worked well and those that need to be improved
- Identify key areas in EMA impacted by response

Communications tools

- Effectiveness, usage and access to EWRS, HEDIS, Medisys, Arkadin
- Identify any problems or improvements to EWRS, HEDIS, Medisys
- Ability of EMA to link into communications tools
- Contribution and extraction of information from EWRS, HEDIS

Liaison issues

- Discussion of contact and liaison with EC (DG SANCO), MS and other agencies
- Expectations of information and guidance from EC, ECDC, MS, other agencies
- Information supply and submission by EMA
- Effectiveness and structure of audio-conferences
- Usefulness of development of case definition
- Notification processes with and between WHO

Public health measures

- Involvement by EMA with public health and control measures – advice, guidance

Communications

- Anti-viral and vaccine information to the public and the medical profession
- Methods and effectiveness of communicating EU / EMA policy and guidance

Anti-virals and vaccines

- Authorisation process for novel antiviral groups (Tamiflu, Relenza)
- Coordination and effectiveness of authorisation process, including special measures
- Issue of scientific guidance for anti-virals
- Consultation undertaken with MS and ECDC regarding anti-viral usage
- Clinical trials and susceptibility testing for vaccines
- Pandemic vaccines and the use of mock ups, approval processes, and access
- Development of vaccine processes and agreements with commercial organisations

Appendix 4.0 – Interview Topics – the Commission (DG SANCO)

The following list of topics were discussed with the Commission (DG SANCO)

Preparedness and response

- DG SANCO preparedness activities – exercising, training
- Key issues concerning overall EU response that worked well, and those that need to be improved
- Identify areas within DG SANCO particularly impacted by the response
- Effectiveness of reporting arrangements
- Identify key strategic issues encountered by DG SANCO during the response
- Identify any review activities undertaken to date

Communications tools

- Effectiveness, usage and access to EWRS, HEDIS, Medisys, Arkadin
- Identify any problems or improvements for EWRS, HEDIS, Medisys
- Contribution and extraction of information from EWRS, HEDIS, Medisys
- Appropriate use of tools by MS, EU Agencies

Liaison issues

- Discussion of contact and liaison with MS, EU Agencies and WHO
- Expectations of information supply and guidance from WHO, MS, and EU Agencies
- Effectiveness, structure and schedule of audio-conferences
- Usefulness of development of case definition
- Notification processes with and between WHO, MS and EU Agencies
- Key coordination issues for DG SANCO during response
- Issues surrounding double reporting of case numbers

Public health measures

- Issues regarding travel advice, warnings within EU
- Issues regarding schools and closures
- Involvement with public health and control measures – advice, guidance

Communications

- Methods and effectiveness of communicating EU policy and guidance
- Role and effectiveness of HSC Communicators Network
- Daily line to take and reporting to hierarchy

Anti-virals and vaccines

- Use of anti-virals in special groups and general usage
- Vaccine authorisation process, including special measures
- Approval processes and access to pandemic vaccines
- Vaccine processes and agreements with commercial organisations
- Development of vaccine strategy
- Vaccine stockpiles and support to MS

Appendix 5.0 – Interview Topics – ECDC

The following list of topics were discussed with ECDC

Preparedness / interoperability

- Level and effectiveness of consultation with MS, EC, WHO, EU Agencies
- Key indicators of interoperability between ECDC and others
- Development of case definition – challenges, benefits
- Revision, exercising of pandemic response plans

Communications (Media)

- Initial communications actions by ECDC
- HSC-CN – links to ECDC, relations with MS main HSC
- Methods of messaging to the public and health professionals
- Ability to assess level of understanding of messages issued to public and health professionals
- Communications flows to EC, WHO, EU Agencies and MS

Scientific Advice

- Initial priorities regarding issue of scientific advice
- Liaison with agencies for development of advice
- Feedback regarding scientific advice
- Policies for contact tracing of airline passengers
- Method for distributing advice to industry and responders
- Development of policy and guidance – already written or developed as the crisis developed (proactive or reactive)
- Identify key areas of guidance development
- Advice regarding personal countermeasures
- Advice regarding risk groups - children, pregnant women

Anti-viral and Pandemic Vaccine Issues

- Guidance for anti-virals usage and distribution
- Special groups (e.g. children) and anti-virals
- Development of vaccine statement

Liaison

- Effectiveness of liaison between ECDC and MS, EC, EMA and WHO
- Participation in meetings and audio-conferences, including HSC / EWRS
- Consultation with WHO regarding move from pandemic Level 5 to 6
- Issue surrounding case numbers and double reporting
- Information flow and expectations to and from MS

Surveillance

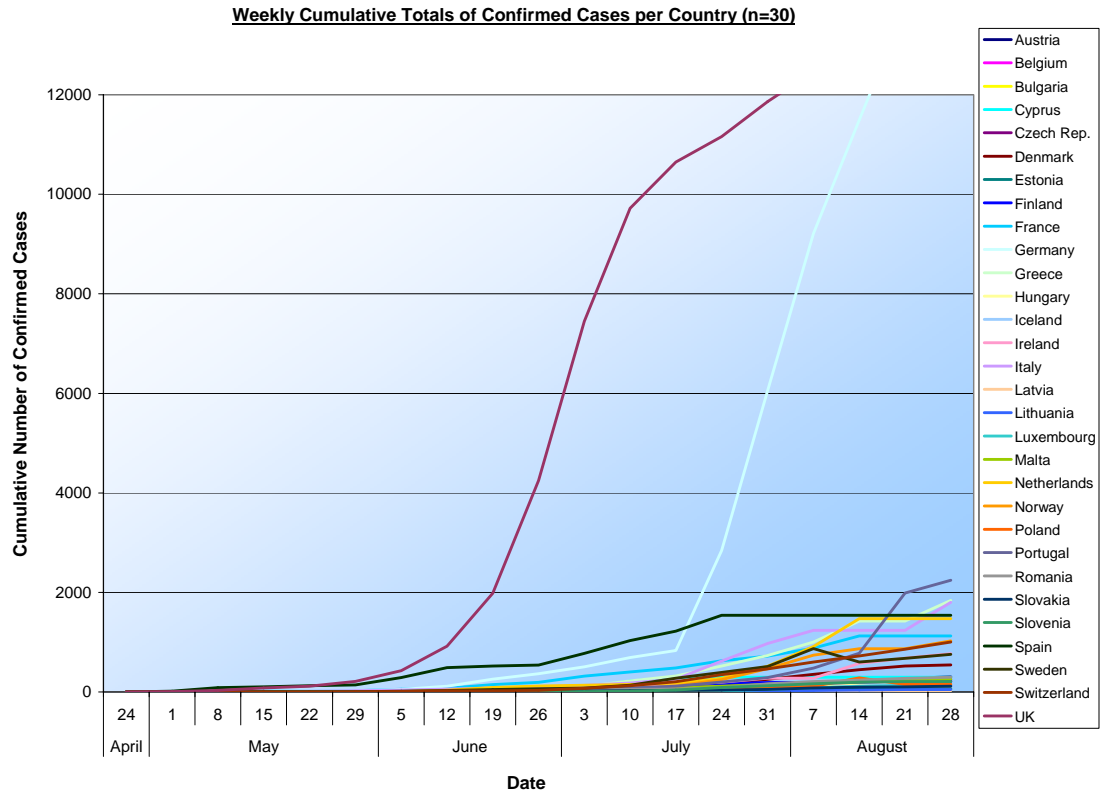
- Contact tracing guidance
- Identification of risk groups
- EWRS – problems, issues, improvements
- Guidance surrounding schools and closures

Appendix 6.0 - Health Council Decisions from Extra-ordinary Meeting 30 April

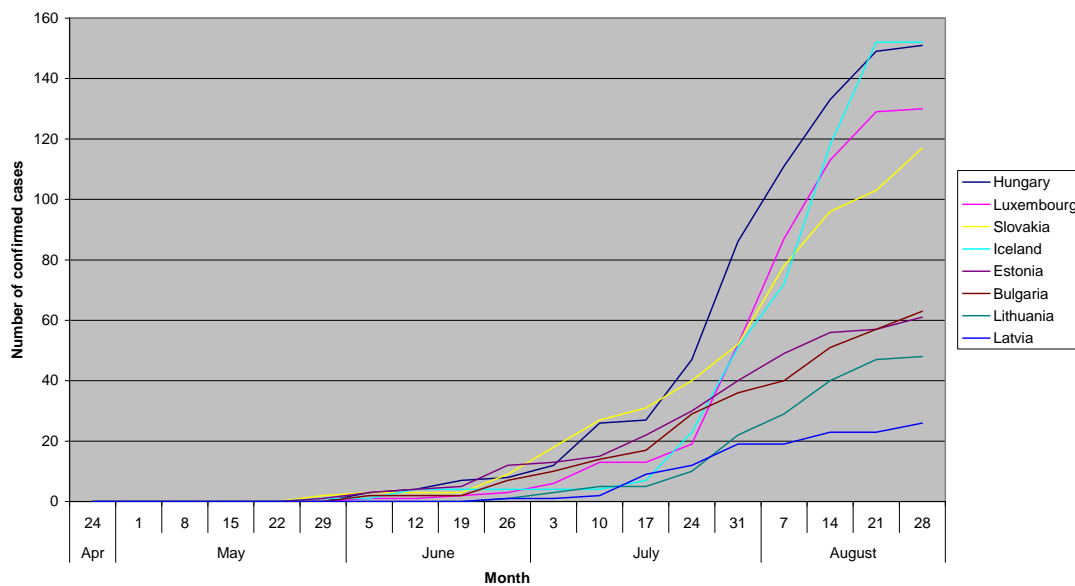
- Calls on Member States to take all necessary measures for public health protection in accordance with WHO recommendations issued on the basis of IHR
- Invites Member States to take all appropriate measures if necessary including travel, based on consultations at EU level
- In field of monitoring and surveillance, to share information on evolution of the virus
- To apply a common case definition
- To work together through the Health Security Committee in providing accurate, timely and consistent information to citizens
- Called on Commission to facilitate information sharing and cooperation between the Member States on risk evaluation, risk management, and medical countermeasures
- Promote the funding of measures for cooperation on preparedness and response to health threats under existing Community programmes

Appendix 7.0 - Graphs of Case Numbers

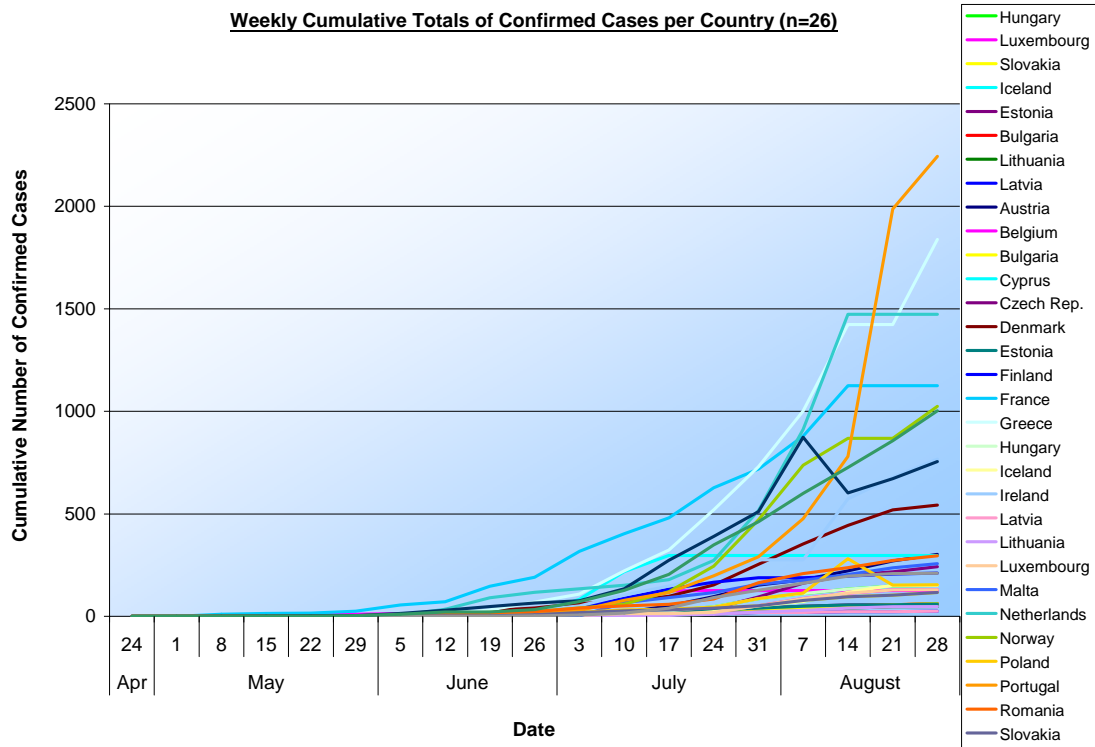
Graphs of case numbers as reported by Member States to ECDC between 24 April and 31 August 2009



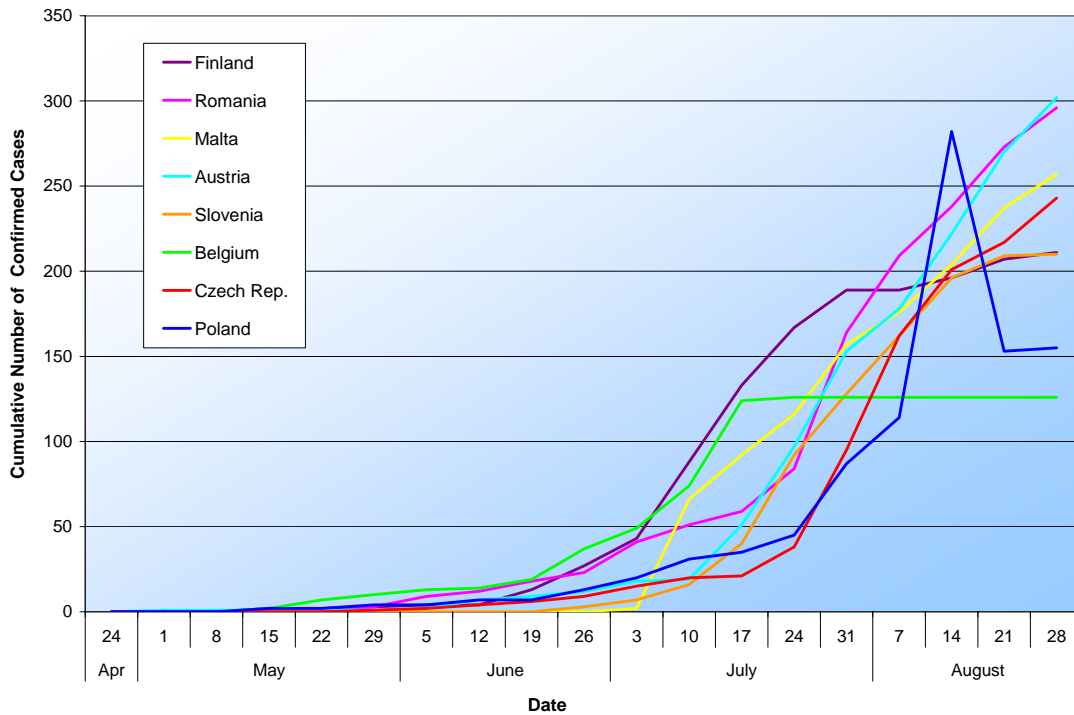
First Quartile Apr - Aug



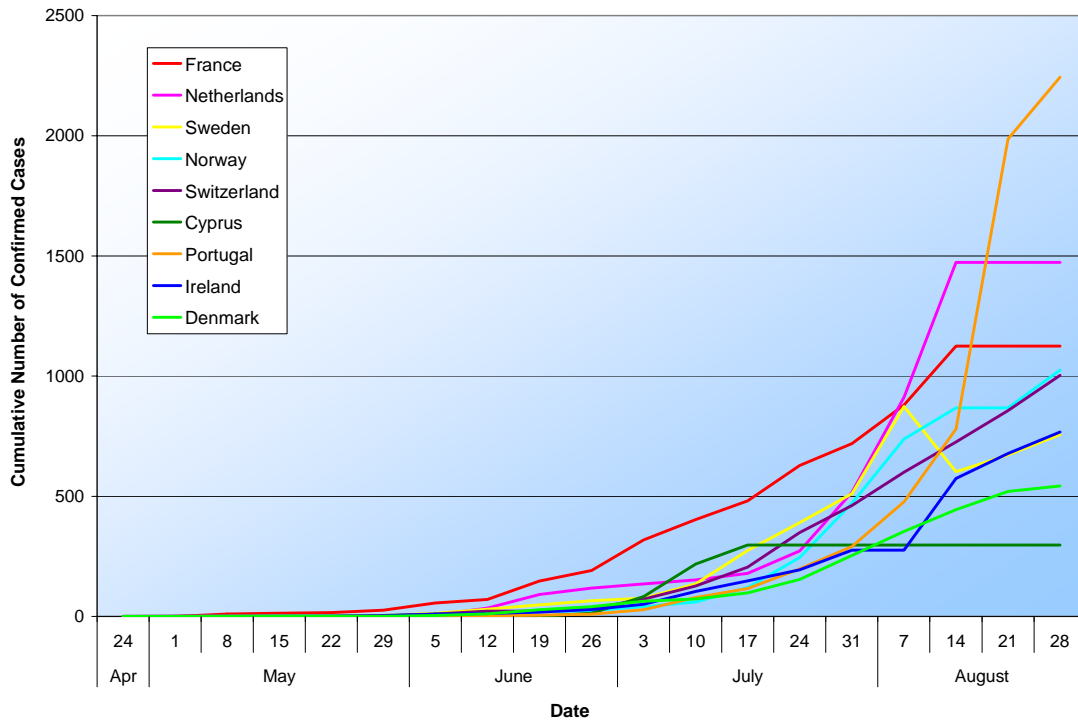
Weekly Cumulative Totals of Confirmed Cases per Country (n=26)



Weekly Cumulative Totals of Confirmed Cases per Country (n=8)



Weekly Cumulative Totals of Confirmed Cases per Country (n=9)



Appendix 8.0 - European Union Case Definition

European Union Case Definition

The following wording is inserted in the Annex to Decision 2002/253/EC:

'NOVEL INFLUENZA VIRUS A(H1N1) (THE SO-CALLED SWINE INFLUENZA VIRUS A(H1N1) AND MEXICAN INFLUENZA VIRUS) (1)

Clinical criteria

Any person with one of the following three:

- fever > 38 °C AND signs and symptoms of acute respiratory infection,
- pneumonia (severe respiratory illness),
- death from an unexplained acute respiratory illness

Laboratory criteria

At least one of the following tests:

- RT-PCR,
- viral culture (requiring BSL 3 facilities),
- four-fold rise in novel influenza virus A(H1N1) specific neutralising antibodies (implies the need for paired sera, from acute phase illness and then at convalescent stage 10-14 days later minimum).

Epidemiological criteria

At least one of the following three in the seven days before disease onset:

- a person who was a close contact to a confirmed case of novel influenza A(H1N1) virus infection while the case was ill,
- a person who has travelled to an area where sustained human-to-human transmission of novel influenza A(H1N1) is documented,
- a person working in a laboratory where samples of the novel influenza A(H1N1) virus are tested.

Case classification

A. Case under investigation

Any person meeting the clinical and epidemiological criteria

B. Probable case

Any person meeting the clinical AND epidemiological criteria AND with a laboratory result showing positive influenza A infection of an unsubtypable type.

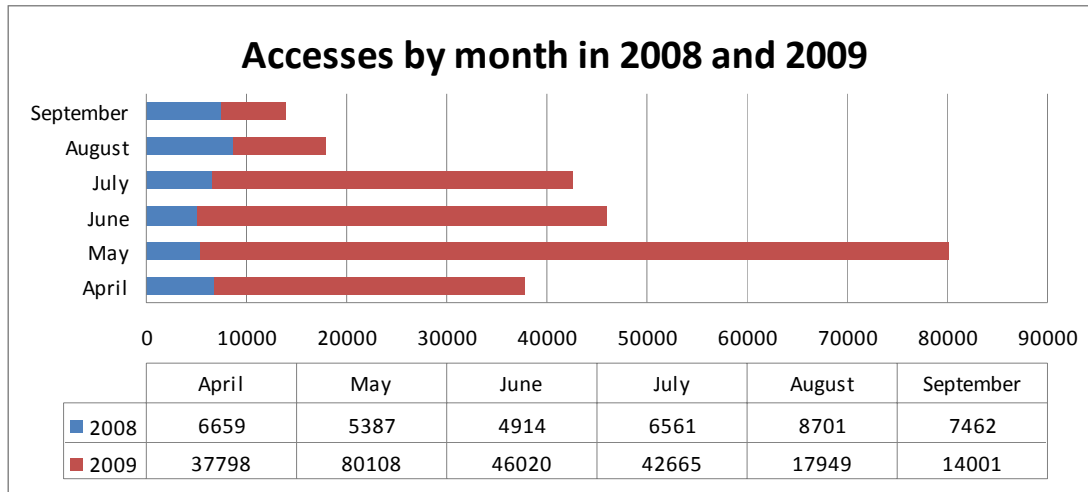
C. Confirmed case

Any person meeting the laboratory criteria for confirmation

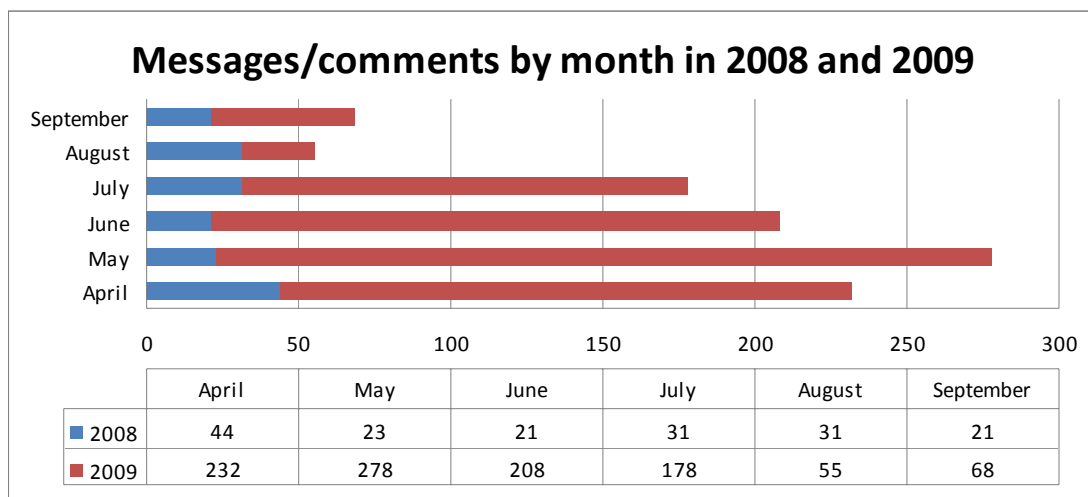
(1) The name will be changed in line with the definition provided by the World Health Organisation.'. EN 1.5.2009 Official Journal of the European Union L 110/

Appendix 9.0 - EWRS Comparison Graphs – access statistics

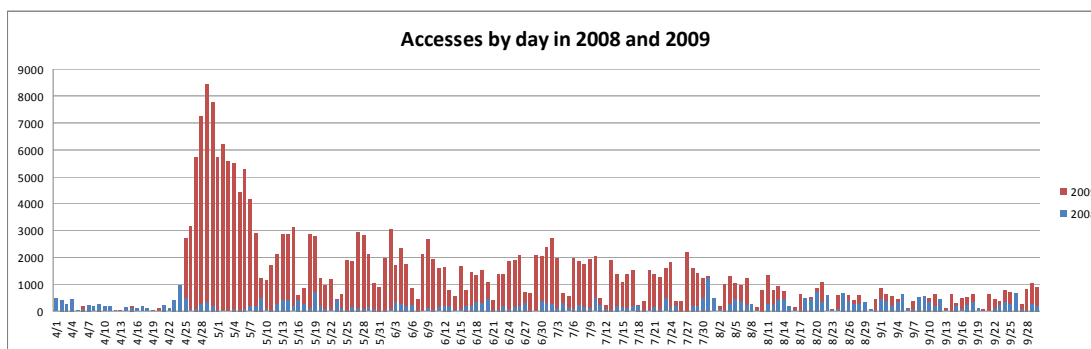
EWRS Comparison graphs for 2008 and 2009 showing access statistics by month and day, and messages and comments by month.



Source: ECDC



Source: ECDC



Source: ECDC

Appendix 10.0 - Affected Areas Definition – from ECDC

“Areas where community transmission is currently occurring. Areas not smaller than the third administrative geographical level shall be considered when declaring an affected area. Removal of an area from affected areas shall be done when the criteria for community transmission are no longer met.

Third administrative level is counted from the country being the first administrative level. Sustained human-to-human transmission resulting in community outbreaks may affect large areas of a country. However, in the perspective of the implementation of public health measures, at an initial stage of the spread, smaller areas may be considered, but not smaller than the third administrative level (the first being the country).

Public health authorities responsible for a population are best placed to declare whether they are experiencing community transmission in their areas as well as when it later ceases. “

15.0 References

1. HPA(2009) DG SANCO HEOF Operations and Influenza A(H1N1) Report, Emergency Response Division, Porton Down.
2. European Commission DG SANCO press releases available at http://ec.europa.eu/health/dyna/press_rel/ph_press_en.cfm
3. WHO Regional Office for Europe influenza press releases available at <http://www.euro.who.int/MediaCentre/HTRes?HTCode=influenza&language=English&HTSubmit>
4. ECDC surveillance and updates 2009 Pandemic Influenza A(H1N1) available at http://www.ecdc.europa.eu/en/healthtopics/H1N1/Pages/epidemiological_update.aspx
5. WHO situation updates – Pandemic (H1N1) 2009 available at <http://www.who.int/csr/disease/swineflu/updates/en/index.html>
6. CDC Briefing on Public Health Investigation of Human Cases of Swine Influenza retrieved from <http://www.cdc.gov/media/transcripts/2009/t090423.htm>
7. Interview with Secretary of Health, Jose Angel Cordova Villalobos, Mexico retrieved from http://portal.salud.gob.mx/redirector?tipo=0&n_seccion=Boletines&seccion=2009-04-23_3868.html
8. WHO Swine Influenza – Update 3 27 April 2009 retrieved from http://www.who.int/csr/don/2009_04_27/en/index.html
9. ECDC Situation Report Swine Influenza Mexico/United States April 27, 2009 retrieved from http://ecdc.europa.eu/en/healthtopics/Documents/090427_InfluenzaAH1N1_Situation_Report_0800hrs.pdf
10. WHO Influenza A(H1N1) - Update 5 29 April 2009 retrieved from http://www.who.int/csr/don/2009_04_29/en/index.html
11. WHO Influenza A(H1N1) – Update 18 6 May 2009 retrieved from http://www.who.int/csr/don/2009_05_06d/en/index.html
12. WHO Influenza A(H1N1) – Update 20 - 7 May 2009 retrieved from http://www.who.int/csr/don/2009_05_07a/en/index.html
13. WHO Influenza A(H1N1) – Update 32 – 18 May 2009 retrieved from http://www.who.int/csr/don/2009_05_18/en/index.html
14. WHO Influenza A(H1N1) – Update 41 – 29 May 2009 retrieved from http://www.who.int/csr/don/2009_05_29/en/index.html
15. WHO Influenza A(H1N1) – Update 46 – 10 June 2009 retrieved from http://www.who.int/csr/don/2009_06_10a/en/index.html
16. E Depoortere, J Mantero, A Lenglet, P Kreidl, D Coulombier. Influenza A(H1N1)V in the Southern Hemisphere – Lessons to Learn for Europe? Euro Surveill. 2009; 14(24), available at <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19246>
17. Changes in reporting requirements for pandemic (H1N1) 2009 virus infection - Pandemic (H1N1) 2009 briefing note 3 (revised) retrieved from

- http://www.who.int/csr/disease/swineflu/notes/h1n1_surveillance_20090710/en/index.html
18. WHO Pandemic (H1N1) 2009 - update 60 – 31 July 2009 retrieved from http://www.who.int/csr/don/2009_08_04/en/index.html
 19. WHO/Europe outbreak update, 31 August 2009 retrieved from http://www.euro.who.int/influenza/AH1N1/20090831_5
 20. Statement by WHO Director-General, Dr Margaret Chan, 27 April 2009 retrieved from http://www.who.int/mediacentre/news/statements/2009/h1n1_20090427/en/
 21. Transcript of Virtual Press conference with Dr Keiji Fukuda, Assistant Director-General ad. Interim for Health Security and Environment World Health Organization 27 April 2009 retrieved from http://www.who.int/mediacentre/swineflu_presstranscript_2009_04_27.pdf
 22. Statement by WHO Director-General, Dr Margaret Chan, 29 April 2009 retrieved from http://www.who.int/mediacentre/news/statements/2009/h1n1_20090429/en/
 23. Joint FAO/WHO/OIE Statement on influenza A(H1N1) and the safety of pork retrieved from http://www.who.int/mediacentre/news/statements/2009/h1n1_20090430/en/
 24. How to handwash? Retrieved from http://www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf
 25. Information from Ministry of Health, Brazil retrieved from http://portal.saude.gov.br/portal/arquivos/pdf/influenzaa_h1n1_090620091.pdf
 26. WHO DG Statement following the meeting of the Emergency Committee 11 June 2009 retrieved from http://www.who.int/csr/disease/swineflu/4th_meeting_ihr/en/index.html
 27. Pandemic influenza in pregnant women - Pandemic (H1N1) 2009 briefing note 5 retrieved from http://www.who.int/csr/disease/swineflu/notes/h1n1_pregnancy_20090731/en/index.html
 28. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pandemic (H1N1)2009 (p.4) available at http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf
 29. N Collin, X de Radiguès, the World Health Organization H1N1 Vaccine Task Force. Vaccine production capacity for seasonal and pandemic (H1N1) 2009 influenza. Vaccine 2009 Jun 27 available at <http://download.thelancet.com/flatcontentassets/H1N1-flu/prevention/prevention-21.pdf>
 30. Pandemic influenza vaccine manufacturing process and timeline - Pandemic (H1N1) 2009 briefing note 7 retrieved from http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090806/en/index.html
 31. Recommended use of antivirals - Pandemic (H1N1) 2009 briefing note 8 retrieved from http://www.who.int/csr/disease/swineflu/notes/h1n1_use_antivirals_20090820/en/index.html
 32. Pandemic (H1N1) 2009 - update 62 (revised 21 August 2009) retrieved from http://www.who.int/csr/don/2009_08_21/en/

33. Influenza activity in Europe is coming to an end for the 2008-2009 Season. EISS Weekly Electronic Bulletin 24 April 2009, Issue N°302 - 2/8 available at http://www.ecdc.europa.eu/en/activities/surveillance/EISN/Newsletter/SUN_EISN_INF_L_Bulletin_2009week16.pdf
34. ECDC Threat Assessment – UPDATE 24 April 2009 – 19:00 hours retrieved from http://www.ecdc.europa.eu/en/healthtopics/Documents/0904_TA_Swine_influenza_US.pdf
35. ECDC Situation Report – Infections of novel flu virus (A/H1N1) April 28, 2009 9:00 hours retrieved from http://ecdc.europa.eu/en/healthtopics/Documents/090428_InfluenzaAH1N1_Situation_Report_0800hrs.pdf
36. ECDC Situation Report – Influenza A(H1N1) infection – update 3 May 2009, 10:30 hours CEST retrieved from http://www.ecdc.europa.eu/en/healthtopics/Documents/090503_InfluenzaAH1N1_Situation_Report_1030hrs.pdf
37. The Scottish Government. News Release Update on A(H1N1) virus – 14/06/2009 retrieved from <http://www.scotland.gov.uk/News/Releases/2009/06/13184241>
38. WHO Europe update. Confirmed cases of influenza A(H1N1) virus in Europe continue to rise retrieved from http://www.euro.who.int/influenza/AH1N1/20090619_1
39. Department for Health Promotion and Disease Prevention, Malta. Confirmation of cases (Influenza A H1N1 (v)) – 2 July 2009 retrieved from <http://www.sahha.gov.mt/showdoc.aspx?id=1210&filesource=4&file=pr1139.pdf>
40. ECDC Situation Report. Influenza A(H1N1)v infection. Update 2 July 2009 retrieved from http://ecdc.europa.eu/en/healthtopics/Documents/090702_Influenza_AH1N1_Situation_Report_1700hrs.pdf
41. ECDC Interim Risk Assessment. Influenza A(H1N1) 2009 pandemic 20 July 2009 retrieved from http://ecdc.europa.eu/en/healthtopics/H1N1/Documents/1001_RA_090720.pdf
42. ECDC Situation Report. Influenza A(H1N1)v infection. Update 25 July 2009 retrieved from http://ecdc.europa.eu/en/healthtopics/Documents/090725_Influenza_AH1N1_Situation_Report_1700hrs.pdf
43. ECDC Daily Update. Pandemic (H1N1) 2009. Update 27 August 2009 retrieved from http://ecdc.europa.eu/en/healthtopics/Documents/090827_Influenza_AH1N1_Situation_Report_1700hrs.pdf
44. European Influenza Surveillance Network. Weekly Electronic Bulletin. 28 August 2009 retrieved from http://www.ecdc.europa.eu/en/activities/surveillance/EISN/Newsletter/SUN_EISN_INF_L_Bulletin_2009week34.pdf
45. European Commission DG SANCO. Regular coordination meetings with Member States retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/coordination_meetings_en.pdf
46. European Commission DG SANCO. Pandemic Influenza H1N1. What the Commission is doing retrieved from http://ec.europa.eu/health/communicable_diseases/diseases/influenza/h1n1/index_en.htm#fragment4

47. Extraordinary Meeting of Employment, Social Policy, Health and Consumer Affairs Council on 30 April 2009. Influenza A/H1N1 Infection. Adoption of Council Conclusions retrieved from http://ec.europa.eu/health-eu/doc/council_concl.pdf
48. Commission Decision of 30 April 2009. Official Journal of the European Union. OJ L110, 1.5.2009, p. 58 retrieved from <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:110:0058:0059:EN:PDF>
49. ECDC Health Information. Influenza A(H1N1) virus: How to protect yourself 4 May 2009 retrieved from [http://www.ecdc.europa.eu/en/healthtopics/Documents/0905_Influenza_A\(H1N1\)_how_to_protect_yourself.pdf](http://www.ecdc.europa.eu/en/healthtopics/Documents/0905_Influenza_A(H1N1)_how_to_protect_yourself.pdf)
50. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pandemic (H1N1)2009 p4 retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf
51. ECDC Interim Guidance. Mitigation and delaying (or 'containment') strategies as the new influenza A(H1N1) virus comes into Europe. 6 June 2009 http://ecdc.europa.eu/en/publications/publications/0906_gui_influenza_ah1n1_mitigation_and_delaying_strategies_for_the_influenza_in_europe.pdf
53. Swedish Presidency of the European Union. Expert meeting: 'Influenza Preparedness and Response – Lessons Learned and Next Steps', Jönköping 2–3 July 2009 retrieved from http://www.se2009.eu/en/meetings_news/2009/7/3/exchange_of_experience_necessary_in_the_eu_s_fight_against_the_influenza_pandemic
54. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pandemic (H1N1)2009 p4 retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf
55. European Commission DG SANCO. Regular coordination meetings with Member States retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/coordination_meetings_en.pdf
56. ECDC Meeting Report. Surveillance and Studies in a Pandemic: Fourth Meeting of the SSiaP Working Group, Stockholm, July 2009 retrieved from http://ecdc.europa.eu/en/publications/Publications/0908_MER_Surveillance_and_Studies_in_a_Pandemic_Meeting_Report.pdf
57. Health Security Committee/ Early Warning and Response System. Statement on school closures. 13 August 2009 retrieved from http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_school_en.pdf
58. Health Security Committee/ Early Warning and Response System. Statement on Influenza A(H1N1) Symptomatic Individuals Travelling. 13 August 2009 retrieved from http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/statement_travel_en.pdf
59. EMA Press Release. European Medicines Agency gives guidance for use of antiviral medicines in case of a novel influenza A/H1N1 pandemic 08 May 2009 retrieved from <http://www.ema.europa.eu/humandocs/PDFs/EPAR/tamiflu/28514809en.pdf>

60. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pandemic (H1N1)2009 p4 retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf
61. EMA Press Release. WHO declares influenza pandemic – European Medicines Agency initiates crisis-management plan retrieved from <http://www.ema.europa.eu/pdfs/human/press/pr/36704209en.pdf>
62. European Commission DG SANCO. Regular coordination meetings with Member States retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/coordination_meetings_en.pdf
63. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pandemic (H1N1)2009 p9 retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/docs/com481_2009_en.pdf
64. EU Health Security Committee (HSC) / Early Warning and Response System (EWRS). HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for vaccination. 25 August 2009 retrieved from http://ec.europa.eu/health/ph_threats/com/Influenza/docs/HSC_EWRS_statement_en.pdf
65. Interim document: technical guidance on generic preparedness planning for public health emergencies retrieved from http://ec.europa.eu/health/ph_threats/Bioterrorisme/keydo_bio_01_en.pdf
66. HPA (2009). Exercise Aeolus Final Report April 2009. Emergency Response Division, Porton Down
67. ECDC. Managing schools during the current pandemic (H1N1) 2009 – Reactive and proactive school closures in Europe, 20 July 2009 available at http://ecdc.europa.eu/en/activities/sciadvise/Lists/ECDC%20Reviews/ECDC_DispForm.aspx?List=512ff74f-77d4-4ad8-b6d6-bf0f23083f30&ID=631
68. Baker MG, Kelly H, Wilson N. Pandemic H1N1 influenza lessons from the southern hemisphere. Euro Surveill. 2009;14(42):pii= 19370. Available at <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19370>