

Assessment Report on EU-wide Pandemic Vaccine Strategies

25 August 2010

Final Version



EUROPEAN COMMISSION



Directorate-General for
Health & Consumers



Assessment Report on EU-wide Pandemic Vaccine Strategies

Health Protection Agency

Emergency Response Division
Porton Down
Salisbury
SP4 0JG
United Kingdom
Tel: +44 (0)1980 612956
Fax: +44 (0)1980 612968
www.hpa.org.uk

CRISMART

Swedish National Defence College
Drottning Kristinasvägen 37
115 93 Stockholm
Sweden
Tel: +46 (8)5534 2595
Fax: +46 (8)5534 2700
www.crismart.org

Writing and Analysis Team

Professor Eric K. Stern, CRISMART
Stephanie Young, CRISMART

Dr Richard Amlôt, HPA
Anita Blake, HPA
Gillian Dacey, HPA
Professor Nigel Lightfoot CBE, HPA
Liz Morgan-Lewis, HPA
Hilary Mouldsdaile, HPA
Veronica Nelson, HPA
Neva Thakrar, HPA

Acknowledgements

The writing and analysis team wishes to thank all those who participated in the review process, particularly those who provided their valuable time to speak with us.

This page has been left blank intentionally.

Contents

Executive Summary	6
Résumé exécutif	13
List of Tables and Figures	21
1 Background and Introduction	25
1.1 Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009 (The TOR 1 Report).....	26
1.2 Assessment Report on the EU-wide Pandemic Vaccine Strategies	26
(The TOR 2 Report).....	26
2 The Purpose and Outline of the Report	26
2.1 Aim	28
2.2 Objectives	28
3 Methodology and Data.....	29
3.1 Methodological Points of Departure.....	29
3.2 EPVS Survey and the Strategic Questions	29
3.3 The Media Consulta Questionnaire (MC Questionnaire)	31
3.4 Communications Analysis.....	31
3.5 Confidentiality	32
3.6 Limitations.....	32
4 Context	34
4.1 International Events and Decisions.....	34
4.2 Administration of Vaccines.....	37
4.3 Stakeholders.....	38
5 Data and Observation Analyses	40
5.1 Advance Purchase Arrangements (APA) and Subsequent Procurement	40
5.2 National Planning Assumptions	45
5.3 Joint Procurement (JP)	48
5.4 Stockpiles	52
5.5 Pandemic Vaccination Strategies	56
5.5.1 Vaccination goals and reprioritisation.....	60
5.5.2 Reported vaccination goal shortfalls.....	65
5.6 Vaccine Safety and Efficacy	69
5.7 Vaccine Administration	77
5.8 Research Capacity	79
6 Communications Analysis.....	81
6.1 The EPVS Survey.....	81

6.2	MC Questionnaire Analysis.....	91
6.3	Opinion Research and Focus Groups.....	101
6.3.1	Summary of public polling and survey activities	102
6.3.2	Aims of polling and survey activities	102
6.4	Outcomes and Implications.....	103
6.5	Main Findings from the Communications Data	103
6.5.1	Health professionals.....	104
6.5.2	Specialised communication for‘ at risk groups’	104
6.5.3	Anti vaccination campaigns	104
6.6	Biggest Challenges Faced by Communicators	105
6.6.1	Effective channels of communication and new social media.....	105
6.6.2	Communications and logistics	105
6.6.3	Opinion research and focus groups.....	106
7	Conclusion	107
7.1	Strategic Overview.....	107
7.2	Main Observations.....	107
7.2.1	APA and subsequent procurement.....	107
7.2.2	National planning assumptions.....	108
7.2.3	Joint procurement(JP)	108
7.2.4	Stockpiles	108
7.2.5	Pandemic vaccination strategy	109
7.2.5.1	Vaccination goals and reprioritisation.....	108
7.2.5.2	Reported vaccination goal shortfalls	108
7.2.6	Vaccine safety and efficacy	109
7.2.7	Vaccine administration	110
7.2.8	Research capacity	111
7.3	Main Observations from the Communications Analysis.....	111
7.3.1	Communication on vaccine strategies	111
7.3.2	Health professional.....	111
7.3.3	Specialised communication for ‘at risk groups’	112
7.3.4	Anti vaccination campaigns	112
7.3.5	Biggest challenges faced by communicators.....	112
7.3.6	Effective channels of communication and new social media.....	113
7.3.7	Communications and logistics	113
7.3.8	Opinion research and focus groups.....	113
7.4	Challenges and Suggestions	114

Executive Summary

1. Introduction

The European Commission (EC) and the Member States (MS) were notified of the novel influenza (H1N1) outbreak on 24 April 2009 after the strain had been identified in Mexico and the United States of America. Subsequently, the EC, EU agencies and MS were prompted to initiate a response and implement pandemic influenza plans. The disease spread rapidly across North America, then to Europe and the rest of the world. On 11 June 2009 the World Health Organization (WHO) declared the novel influenza outbreak a pandemic by raising its pandemic alert from level five to level six.

2. Aim

The aim of the review is to capture the diverse pandemic vaccine strategies (with special emphasis on communications issues) developed by the MS, and their experiences in implementing them, in order to provide a point of departure for improving MS and EU preparedness for future pandemics.

3. Objectives

This review takes as its point of departure a set of strategic questions developed by a working group of interested MS and EU institutions and focuses on the following special areas of interest regarding pandemic vaccination strategies:

1. Advance purchase agreements (APAs) and subsequent procurement
2. National planning assumptions
3. Joint procurement and stockpiles
4. Pandemic vaccination strategies and goal shortfalls
5. Reprioritising pandemic vaccination strategy
6. Vaccine safety and efficacy
7. Vaccine administration
8. Research capacity
9. Communications campaigns and new social media

4. Points of departure and method

This report is a result of an EU-commissioned review led by the Health Protection Agency (HPA), as a contractor through its framework contract, and CRISMART, as a subcontractor. The report is structured around the above mentioned nine areas of special interest.

The assessment was divided into two main sections. The first section covers the first eight special interests which focus on a web-based survey called the "EU-wide

Pandemic Vaccine Strategy.” All 27 MS countries, as well as three EFTA countries, submitted their responses to this survey.

The second main section focuses primarily on the last area of special interest: communications campaigns and new social media. The data analysed for this area was collected from three main sources: 1) eight strategic questions on “Communication on vaccination and responses to events related to vaccination” from the web-based survey “EU-wide Pandemic Vaccine Strategy”; 2) a second web-based survey the “Media Consulta Questionnaire” submitted by 22 countries; and 3) data provided by countries who undertook focus groups on communications activities during the response to the pandemic (H1N1) 2009.

5. Main observations

The data from the two questionnaires and the communications studies provided many interesting observations. It is very important to note that the experiences were very different among the responding countries so there are obvious limitations to making broad generalisations based on the raw data. Nonetheless, the main findings in each of the key areas of interest are presented here:

5.1 APA and subsequent procurement

More than half of the responding MS reported that they had an APA prior to the H1N1 outbreak and that their APAs was activated by the WHO “phase 6” declaration. Nearly two-thirds ordered the H1N1 vaccines in connection with the WHO “phase 6” declaration. The most significant factor triggering a country to order the specific H1N1 vaccine was “scientific assessments”.

The majority of countries would like a future procurement contract to contain more flexible conditions under which the specified amount could be lowered/changed (e.g., because of new scientific evidence, quality or safety issues, or lower/higher demand).

5.2 National planning assumptions

Three main findings appeared from the data on national planning assumptions. First, respondents reported that national planning assumptions were influenced more by supranational organisations (such as ECDC and WHO) than by the planning assumptions of other countries. Second, national vaccination strategies, and planning assumptions to a lesser extent, influenced the number of H1N1 vaccines that were ordered in 2009/2010 more than, for example, financial constraints, pre-existing contracts, or solidarity considerations. Third, these same strategies and assumptions would most likely be used to determine future vaccine orders.

5.3 Joint procurement (JP) and stockpiles

The majority of the respondents expressed an interest in JP and indicated that this task should be centrally managed and coordinated by the EC before or in connection with a

WHO pandemic declaration. The respondents appreciated the fact that a JP arrangement would provide a number of advantages (stronger negotiation power, lower costs, and equitable access) as well as help to create a common understanding of liability issues. On the other hand, concerns were expressed that a JP arrangement should be carefully adapted to national requirements, logistics, context, and legal framework.

The findings suggest that the responding countries are open to vaccine stockpiles, and that conditions for supporting vaccine stockpiles within or outside the EU were quite similar. The most frequently chosen conditions included: if they foresee a national surplus and if the stockpile is centrally managed (as opposed to a decentralised arrangement) at the EU level (for intra-EU stockpile) or by WHO (for a stockpile for third countries). Another condition deemed significant for an EU vaccine stockpile would be that all MS in need would be provided equal access.

5.4 Pandemic vaccination strategies, goals and shortfalls

National pandemic vaccination strategies are now well established among the MS. These strategies have drawn upon multiple sources and reflect areas of expert consensus and dissensus. These strategies provide a point of departure for coping with future pandemics but will, of course, have to be adapted to the specific features of future events.

The majority of respondents reported pandemic vaccination goal shortfalls: experiencing difficulties in reaching their vaccination coverage goals for pregnant women, persons with underlying chronic diseases, and health care workers. The main reasons for these shortfalls were attributed to scepticism and/or limited interest on behalf of the health care workers and the general population. Other significant factors included the moderate character of the pandemic and the safety concerns of the H1N1 influenza vaccines.

Only four countries felt that they had reached their goals for their risk and target groups. The explanations for success were quite similar in all four cases. The following reasons were mentioned: universal vaccination; free vaccination; good annual influenza uptake; positive public attitudes towards authorities and vaccination; and the severity of first known H1N1 cases. Other reasons that were mentioned included early access to vaccine, joint key messages from authorities, and transparency in the process.

5.5 Reprioritising pandemic vaccination strategies and goals

Nearly two-thirds of the responding countries did NOT change the health care goals/objectives in their pandemic vaccination strategies, even after the characteristics of the H1N1 pandemic became more apparent. The majority attributed this to the fact that there was little or inconclusive evidence which justified making such changes. On the other hand, one-third of countries did alter their health care goals/objectives in their pandemic vaccination strategies. The majority of changes were made in the goals/objectives regarding protecting vulnerable/at risk groups and maintaining health

care services. The major reasons for making such changes were attributed to the fact that a clearer picture appeared regarding the groups at risk for serious infections, the degree of transmission, the hospitalisation rate, and the fatality rate.

5.6 Vaccine safety and efficacy

Both the EMA and national medicines agencies/authority were reported as the most significant sources of safety and efficacy information as well as substantial influences for countries' public responses on vaccine safety and efficacy issues. Yet the discrepancies among the European countries regarding safety and efficacy information proved to be problematic, especially when communicating with the public. For example, it was difficult to explain why one country considered vaccinating very young children dangerous and another country strongly encouraged vaccinating them.

Post-marketing surveillance information was considered sufficient and adequate, with well established procedures. Yet there still appears to be a need for more relevant information and current facts on, in particular, the safety and effectiveness of vaccines.

5.7 Vaccine administration

Three-quarters of the responding countries explicitly mentioned that they used the internet in some form and/or new social media to facilitate vaccine administration. Approximately half of the respondents used standard operating procedures, documents via administrative channels, and/or traditional information sources to convey product changes. Forums such as conferences, workshops, meetings and training sessions were infrequently used to convey changes in product use to health care professionals. Nearly all of the responding countries reported that information leaflets were provided to patients being administered the H1N1 vaccine in the 'appropriate language(s)' and nearly one-third provided information in the minority/local languages.

5.8 Research capacity

The majority of countries identified a need for enhanced public clinical research capacity (e.g., to carry out comparative effectiveness studies) in the EU. More than half indicated this capacity should be coordinated by an existing EU agency. Similarly, the need for improved rapid research funding mechanisms was noted. One respondent specifically emphasised that the most important issue regarding such research is maintaining objectivity and independence from the pharmaceutical industry, while another emphasised the key role of industry-driven research in vaccine development under current conditions.

5.9 Communication campaigns and new social media

5.9.1 Health professionals

One of the most important findings highlighted by both questionnaires used in the communications study was the significant role that health professionals play. Without their engagement and support, the effectiveness of vaccine communications was inhibited. Furthermore, the public were significantly influenced by the lack of positive encouragement to take the vaccine by health care workers.

5.9.2 Specialised communication for 'at risk groups'

The issue of global and specialised communication campaigns was raised in both questionnaires. Some countries had developed targeted communications for certain groups of people (such as young parents and pregnant women), whereas others preferred to employ global communications strategies. Consideration should be given to identifying the most effective means of communication with specific target groups when specialist communication campaigns are initiated.

5.9.3 Biggest challenges faced by communicators

One of the single biggest challenges to communicators during the onset of the H1N1 pandemic was the sheer volume of media and public inquiries. Communication systems need to be in place with appropriate training provided in advance of another pandemic. This would allow appropriate adjustments to be made in a non-crisis situation. Important factors to consider are streamlining coordination between national and EU government organisations and developing contingency measures for, among other things, additional staffing in communications teams. Another finding highlighted in the data was the need to integrate communications with other aspects of the H1N1 campaign including the authorisation, logistics and delivery efforts.

5.9.4 Effective channels of communication and new social media

The findings highlighted the uncertainties that exist around the use of new social media (such as Facebook, YouTube, etc.). In general, the opinions expressed for new social media were positive; however, countries had not evaluated the effectiveness of this media. Further research should be conducted to establish the impact of communication campaigns utilising new social media and whether the content of the actual 'message' is being communicated effectively. The findings also noted that the use of new media should not replace the traditional means of communications (e.g., conventional media, leaflets, brochures, letters, billboards, etc) since several population groups continue to rely on these approaches.

5.9.5 Opinion research and focus groups

Public polling and survey activities were broadly considered to be valuable to the work of communicators in MS; however, some concerns were raised. Five examples include: 1) carefully wording questions in order to be confident that the responses appropriately

reflected the issue of interest; 2) carrying out surveys in waves in order to monitor changing public opinions over time; 3) systematically monitoring online sources; 4) starting the communication monitoring process as early as possible; and 5) having contracts and plans in place to be able to prepare and execute polls quickly in order to be able identify future needs.

6. Conclusions

The report concludes with a number of key challenges and suggestions drawn from the analyses of the national responses to the strategic questions and supplementary material. The hope is that these will be considered so that preparedness for developing pandemic vaccine strategies in Europe will be improved and strengthened. The key challenges and suggestions include:

- **Better national coordination and cooperation within MS, among the MS and the EU** are necessary to improve the preparedness, planning and implementation of pandemic vaccination strategies. Coordination and cooperation with EMA and WHO should also be strengthened.
- **Improving access to appropriate epidemiological and surveillance information** at an early stage.
- **Improving performance on achieving vaccination strategy goals.** Most member states fell well short of their goals, though several did substantially better. There is a need to learn from these contrasting experiences, which are likely to be instructive in identifying best practices for future pandemics. An overwhelming number of respondents reported that they had not successfully met their vaccination strategy goals, and the evidence suggests that this was not a result of an error in establishing appropriate strategies or goals.
- **Better coverage of health care professionals** is essential to maintaining health care services in a pandemic. Low coverage of health care professionals is also an obstacle to reaching target/risk groups as well as the general public.
- **Future procurement contracts should be more flexible** and include conditions under which the specified amount can be changed and conditions for returning excess vaccines.
- Support appears to be strong for the **EC as one of the leading candidates for coordinating the task of arranging a joint procurement for interested MS** before the next pandemic. A joint procurement should be carefully adapted to national requirements, logistics, context and legal framework.
- **Coordination of timing and content of messaging** with other aspects of the vaccination campaign is important.
- **Implementation of specifically targeted communications** when certain risk groups have been identified or when it is known that other groups in society are harder to reach with communication.
- **Further research on tracking the use and effectiveness of new social media is needed.**

- **Enhancing rapid public research capacity in support of vaccination.** The majority of respondents identified a need for enhanced rapid public research capacity in Europe in future pandemics. More than half preferred coordination by a European level agency, while others proposed a consortium of clinical research centers distributed among the MS. Challenges will include devising funding mechanisms and instruments which will be not only be timely but also live up to acceptable standards of quality and equity. Similarly, it will be essential to find an appropriate and legitimate division of responsibility and labor between publicly and privately funded efforts.

Résumé exécutif

1. Introduction

La Commission européenne (CE) et les États membres (EM) ont été avertis de la nouvelle épidémie de grippe (H1N1) le 24 avril 2009 après que la souche ait été identifiée au Mexique et aux États-Unis. Ultérieurement, la Commission européenne, les agences et organismes de l'UE et les États membres ont été invité(e)s à organiser une réponse et à mettre en place des plans de lutte contre la pandémie grippale. La maladie s'est très rapidement répandue en Amérique du Nord, puis en Europe et dans le reste du monde. Le 11 juin 2009, l'Organisation mondiale de la Santé (OMS) a classé la nouvelle épidémie de grippe comme une pandémie en élevant le niveau d'alerte lié à la pandémie de grippe en le faisant passer de la phase 5 à la phase 6.

2. But

L'enquête a pour but de rassembler des informations sur les diverses stratégies de vaccination destinées à lutter contre la pandémie (avec une concentration spéciale sur les problèmes de communication) élaborées et développées par les États membres, et sur leurs expériences liées à leur mise en œuvre, pour constituer un point de départ pour l'amélioration de l'état de préparation des États membres et de l'UE en cas de pandémies futures.

3. Objectifs

Cette enquête a comme point de départ un ensemble de questions stratégiques élaborées par un groupe de travail représentant des États membres et institutions de l'UE intéressé(e)s et se concentre sur les centres d'intérêt spéciaux ci-dessous concernant les stratégies de vaccination destinées à lutter contre les pandémies :

10. Contrats d'achat dormants (APAs) et fourniture ultérieure
11. Hypothèses de planification nationales
12. Approvisionnement et stocks conjoints et communs
13. Stratégies de vaccination contre les pandémies et lacunes liées aux objectifs
14. Établissement d'un nouvel ordre de priorité pour les stratégies de vaccination contre les pandémies
15. Sécurité et efficacité des vaccins
16. Administration des vaccins
17. Capacités de recherche
18. Campagnes de communication et nouveaux médias sociaux

4. Points de départ et méthode

Ce rapport est le résultat d'une enquête commandée par l'UE et dirigée par la Health Protection Agency (HPA – Agence de protection de la santé britannique), en tant qu'agence missionnée contractante via son contrat cadre, et CRISMART, en tant que

partie sous-traitante. Le rapport est structuré autour des neuf centres d'intérêt spéciaux mentionnés ci-dessus.

L'évaluation a été divisée en deux sections principales. La première couvre les huit premiers centres d'intérêt spéciaux se concentrant sur une enquête en ligne intitulée « EU-wide Pandemic Vaccine Strategy – Stratégie de vaccination contre les pandémies à l'échelle de l'UE ». Les 27 États membres, et trois pays membres) de l'AELE, ont fait parvenir leurs réponses liées à cette enquête.

La seconde section principale se concentre principalement sur le dernier centre d'intérêt spécial : les campagnes de communication et les nouveaux médias sociaux. Les données analysées pour ce point ont été collectées auprès de trois sources principales : 1) huit questions stratégiques sur la « Communication liée à la vaccination et aux réponses à des événements associés à la vaccination » de l'enquête en ligne intitulée « EU-wide Pandemic Vaccine Strategy – Stratégie de vaccination contre les pandémies à l'échelle de l'UE »; 2) une seconde enquête en ligne intitulée « Media Consulta Questionnaire » proposée par 22 pays; et 3) des données fournies par des pays ayant organisé des groupes de travail spécialisés sur les activités de communication durant la réponse apportée dans le contexte de la pandémie (H1N1) de 2009.

5. Observations principales

Les données contenues dans les deux questionnaires et les études portant sur les communications ont eu pour résultat de nombreuses observations intéressantes. Il est très important de noter que les expériences ont été très différentes dans les pays répondants et il existe donc des limites évidentes pour des généralisations basées sur les données brutes. Les conclusions principales concernant tous les centres d'intérêt principaux sont néanmoins présentées ci-dessous :

5.1 Contrats d'achat dormants (APAs) et fourniture ultérieure

Plus de la moitié des États membres répondants ont déclaré avoir conclu un contrat d'achat dormant avant l'épidémie de grippe H1N1 et que leur contrat d'achat dormant avait été activé par la déclaration de la « phase 6 » faite par l'OMS. Quasiment les deux-tiers des États membres ont commandé les vaccins pour l'épidémie H1N1 dans un contexte lié à la déclaration de la « phase 6 » faite par l'OMS. Le facteur le plus déterminant ayant poussé les pays à commander les vaccins spécifiques pour l'épidémie H1N1 a été les « évaluations faites par les scientifiques ».

La majorité des pays souhaiteraient que les contrats d'approvisionnement futurs contiennent des conditions plus flexibles dans le cadre desquelles le volume spécifié pourrait être réduit/modifié (par ex., en raison de nouvelles informations scientifiques, de problèmes ayant trait à la qualité ou à la sécurité, ou d'une demande réduite/plus forte).

5.2 Hypothèses de planification nationales

Trois conclusions principales sont ressorties des données concernant les hypothèses de planification nationales. En premier lieu, les répondants ont signalé que les hypothèses de planification nationales étaient plus influencées par les organisations supranationales (comme l'ECDC et l'OMS) que par les hypothèses de planification d'autres pays. En second lieu, les stratégies de vaccination nationales, et les hypothèses de planification, dans une moindre mesure, ont eu une plus grande influence sur le nombre de vaccins H1N1 commandés en 2009/2010 que, par exemple, les contraintes financières, les contrats préexistants ou les considérations de solidarité. En troisième lieu, ces mêmes stratégies et hypothèses seraient très probablement utilisées pour déterminer les futures commandes de vaccins.

5.3 Approvisionnement conjoint et commun et stocks

La majorité des répondants ont fait part d'un intérêt pour un approvisionnement conjoint et commun et ont indiqué que cette tâche serait gérée et coordonnée à un niveau central par la Commission européenne avant une ou dans le contexte d'une déclaration de pandémie de l'OMS. Les répondants ont apprécié le fait qu'un accord d'approvisionnement conjoint et commun fournirait un certain nombre d'avantages (pouvoir de négociation plus fort, coûts plus bas et accès équitable) et contribuerait aussi à créer une compréhension commune des problèmes de responsabilité. D'un autre côté, certaines préoccupations ont été exprimées quand au fait qu'un accord d'approvisionnement conjoint et commun devrait être soigneusement adapté aux exigences nationales, à la logistique, au contexte et au cadre légal.

Les conclusions suggèrent que les pays répondants sont ouverts aux stocks de vaccins, et que les conditions pour maintenir des stocks de vaccins dans ou hors de l'UE ont été tout à fait similaires. Les conditions les plus fréquemment choisies ont inclus : s'ils prévoient un surplus national et si le stock est géré de manière centrale (par opposition à une gestion décentralisée) au niveau de l'UE (pour les stocks intra-UE) ou par l'OMS (pour un stock pour des pays tiers). Une autre condition jugée importante pour un stock de vaccins de l'UE serait que tous les États membres dans le besoin se voient offrir un accès égal.

5.4 Stratégies de vaccination contre les pandémies, objectifs et lacunes

Les stratégies de vaccination nationales destinées à lutter contre les pandémies sont maintenant bien établies dans les États membres. Ces stratégies sont venues de sources multiples et reflètent des avis consensuels et divergents des experts. Elles fournissent un point de départ pour le traitement des futures pandémies mais devront, bien entendu, être adaptées aux caractéristiques spécifiques des futurs événements.

La majorité des répondants ont signalé des lacunes liées aux objectifs de vaccination contre la pandémie : difficultés rencontrées pour atteindre leurs objectifs de couverture de vaccination des femmes enceintes, des personnes affectées par des maladies chroniques sous-jacentes et des travailleurs du secteur de la santé. Les raisons

principales de ces lacunes ont été imputées au scepticisme et/ou à un intérêt limité de la part des travailleurs de santé et de la population générale. D'autres facteurs importants ont inclus le caractère modéré de la pandémie et les inquiétudes quant à la sécurité des vaccins contre la grippe H1N1.

Seuls quatre pays ont pensé avoir réalisé leurs objectifs concernant leurs groupes à risque et groupes cibles. Les explications de la réussite ont été très semblables dans les quatre cas. Les raisons suivantes ont été mentionnées : vaccination universelle; vaccination gratuite; bon taux annuel de vaccination contre la grippe; attitudes positives du public vis-à-vis des autorités et de la vaccination et gravité des premiers cas connus de H1N1. Parmi les autres raisons mentionnées, on peut citer l'accès précoce au vaccin, les messages clés conjoints des autorités et la transparence du processus.

5.5 Établissement d'un nouvel ordre de priorité pour les stratégies de vaccination contre les pandémies et les objectifs

Approximativement les deux-tiers des pays répondants n'ont PAS changé leurs buts/objectifs sanitaires pour leurs stratégies de vaccination destinées à lutter contre les pandémies, même après que les caractéristiques de la pandémie H1N1 soient devenues plus apparentes. La majorité ont attribué ceci au fait qu'il existait peu de preuves ou des preuves insuffisantes pour justifier la réalisation de tels changements. D'un autre côté, un-tiers des pays ont changé leurs buts/objectifs sanitaires pour leurs stratégies de vaccination destinées à lutter contre les pandémies. La majorité des changements ont concerné des buts/objectifs liés à la protection des groupes vulnérables/à risque et le maintien des services de santé. Les principales raisons liées à la réalisation de tels changements ont été imputées au fait qu'un tableau plus clair est apparu concernant les groupes exposés à un risque d'infections graves, le degré de transmission, le taux d'hospitalisation et le taux de mortalité.

5.6 Sécurité et efficacité des vaccins

L'EMA (l'Agence européenne des médicaments) et les agences/autorités médicales nationales ont été citées comme constituant les sources les plus importantes d'informations sur la sécurité et l'efficacité mais aussi comme des influences importantes pour les réponses publiques des pays concernant la sécurité et l'efficacité des vaccins. Les divergences entre les pays européens concernant les informations sur la sécurité et l'efficacité se sont néanmoins avérées problématiques, particulièrement pour la communication avec le public. Par exemple, il s'est avéré difficile d'expliquer pourquoi un pays considérait la vaccination de très jeunes enfants comme dangereuse alors qu'un autre encourageait en fait vivement leur vaccination.

Les informations de surveillance post-marketing ont été considérées comme suffisantes et adéquates, avec des procédures bien établies. Il semble néanmoins demeurer un besoin d'informations plus pertinentes et de faits actualisés concernant, en particulier, la sécurité et l'efficacité des vaccins.

5.7 Administration des vaccins

Les trois-quarts des pays répondants ont explicitement mentionné avoir utilisé Internet, sous une forme ou sous une autre et/ou des nouveaux médias sociaux pour administrer les vaccins. Approximativement la moitié des répondants ont utilisé des procédures opérationnelles standard, des documents transmis via des canaux administratifs, et/ou des sources d'informations traditionnelles pour communiquer à propos des changements de produits. Des forums comme des conférences, des groupes de travail, des réunions et des modules de formation ont été rarement utilisés pour communiquer à propos des changements liés à l'utilisation des produits pour les professionnels du secteur de la santé. Presque tous les pays répondants ont signalé que les dépliants d'information étaient fournis aux patients recevant le vaccin H1N1 traduits dans la/les « langue(s) appropriée(s) » et presque un tiers d'entre eux ont fourni des informations dans les langues des minorités/locales.

5.8 Capacités de recherche

La majorité des pays ont soutenu la thèse d'un besoin lié à des capacités de recherche clinique publique renforcées (par ex., mener des études comparatives sur l'efficacité) dans l'UE. Plus de la moitié des pays ont indiqué que ces capacités devraient être coordonnées par une agence existante de l'UE. Le besoin de mécanismes de financement d'une recherche rapide et renforcée a aussi été noté. Un répondant a spécifiquement souligné que le problème le plus important concernant ladite recherche était le maintien d'une objectivité et d'une indépendance par rapport à l'industrie pharmaceutique alors qu'un autre a mis en avant le rôle clé joué par la recherche menée par l'industrie pour le développement de vaccins dans les conditions actuelles.

5.9 Campagnes de communication et nouveaux médias sociaux

5.9.1 Professionnels du secteur de la santé

L'une des conclusions les plus importantes mise en évidence dans les deux questionnaires utilisés par l'étude sur les communications a été le rôle important joué par les professionnels du secteur de la santé. Sans leur engagement et leur soutien, l'efficacité des communications liées aux vaccins aurait été faible. Le public a, en outre, été fortement influencé par l'absence d'encouragement positif à se faire vacciner de la part des travailleurs du secteur de la santé.

5.9.2 Communication spécialisée pour les « groupes à risque »

La question des campagnes de communication globales et spécialisées a été soulevée dans les deux questionnaires. Certains pays ont élaboré des communications ciblées pour certains groupes de personnes (comme les jeunes parents et les femmes enceintes), alors que d'autres ont préféré utiliser des stratégies de communication globales. Il faudrait identifier les moyens de communication les plus efficaces concernant des groupes cibles spécifiques quand des campagnes de communication spécialisées sont lancées.

5.9.3 Problèmes les plus importants rencontrés par les communicateurs

L'un des problèmes les plus importants rencontré par les communicateurs au début de la pandémie grippale H1N1 a été le volume très important de questions émanant des médias et du public général. Des systèmes de communication doivent être en place avec une formation appropriée fournie avant une autre pandémie. Ceci permettrait d'apporter des ajustements appropriés dans une situation normale. Les facteurs importants devant être pris en compte sont l'amélioration de la coordination entre les organisations nationales et gouvernementales de l'UE et l'élaboration de mesures d'urgence destinées, entre autres choses, à renforcer les effectifs des équipes en charge de la communication. Une autre conclusion mise en évidence par les données a été le besoin d'intégrer dans les communications d'autres aspects de la campagne H1N1 incluant l'autorisation, la logistique et les efforts liés à la livraison.

5.9.4 Canaux de communication efficaces et nouveaux médias sociaux

Les conclusions ont mis en évidence les incertitudes existantes entourant l'utilisation des nouveaux médias sociaux (comme Facebook, YouTube, etc.). En général, les opinions exprimées concernant les nouveaux médias sociaux ont été positives, même si certains pays n'avaient pas en fait évalué l'efficacité de ces médias. D'autres recherches devraient être menées pour évaluer l'impact des campagnes de communication utilisant les nouveaux médias sociaux et si le contenu du vrai « message » est communiqué de manière efficace. Les conclusions ont aussi souligné que l'utilisation des nouveaux médias ne doit pas remplacer les moyens de communication traditionnels (par ex., médias conventionnels, dépliants, brochures, lettres, affiches, etc.) compte tenu du fait que plusieurs groupes de la population continuent à dépendre de ces approches.

5.9.5 Sondages d'opinion et groupes spécialisés

Les activités de sondage de l'opinion du public et d'enquêtes ont été largement considérées comme précieuses pour le travail des communicateurs dans les États membres même si certaines préoccupations ont été exprimées. On peut citer cinq exemples à ce sujet : 1) Une formulation soigneuse des questions pour pouvoir être certain que les réponses étaient bien un reflet de la question concernée; 2) Mener des vagues d'enquêtes successives pour suivre l'évolution des opinions du public au fil du temps; 3) Contrôler systématiquement les sources « online »; 4) Commencer le processus de suivi et de contrôle de la communication le plus tôt possible; et 5) Avoir en place des contrats et des plans pour pouvoir être en mesure de préparer et de mettre en œuvre rapidement les sondages et d'identifier les futurs besoins.

6. Conclusions

Le rapport se conclut sur un certain nombre de problèmes clés et des suggestions résultant d'analyses des réponses nationales à des questions stratégiques et des documents supplémentaires. Il est espéré que ces éléments seront pris en compte pour permettre un état de préparation amélioré et renforcé pour le développement des

stratégies de vaccination liées aux pandémies en Europe. Les principaux problèmes et les principales suggestions incluent :

- **Une coordination et coopération nationales améliorées dans les États membres, parmi les États membres et dans l'UE** sont nécessaires pour améliorer l'état de préparation, la planification et la mise en œuvre des stratégies de vaccination liées aux pandémies. La coordination et la coopération avec l'EMA et l'OMS doivent aussi être renforcées.
- **Amélioration de l'accès à des informations épidémiologiques et de surveillance appropriées** lors d'une phase précoce.
- **Amélioration de la performance associée à la réalisation des objectifs liés à la stratégie de vaccination** : la plupart des États membres sont restés loin d'atteindre leurs objectifs, bien que plusieurs d'entre eux aient atteint une bien meilleure performance. Il est nécessaire de tirer des leçons de ces expériences contrastées, qui devraient s'avérer instructives pour identifier des bonnes pratiques pour des pandémies futures. Un nombre très important de répondants ont signalé ne pas avoir atteint leurs objectifs stratégiques de vaccination et les faits avérés suggèrent que ceci ne résultait pas d'une erreur liée à l'établissement de stratégies ou d'objectifs approprié(e)s.
- **Une meilleure couverture des professionnels du secteur de la santé** est essentielle pour maintenir le fonctionnement des services de santé en cas de pandémie. Une faible couverture des professionnels du secteur de la santé constitue aussi un obstacle pour le contact établi avec les groupes cibles/à risque et le public général.
- **Les futurs contrats d'approvisionnement devraient être plus flexibles** et inclure des conditions dans le cadre desquelles le volume spécifié peut être changé et des conditions pour le retour des excédents de vaccins.
- Un fort soutien s'est dégagé pour que la **Commission européenne soit l'un des candidats de pointe pour la coordination de l'organisation d'un approvisionnement conjoint et commun pour les États membres intéressés** avant la prochaine pandémie. Un approvisionnement conjoint et commun doit être soigneusement adapté aux exigences nationales, à la logistique, au contexte et au cadre légal.
- **La coordination du timing et des contenus des messages** avec les autres aspects de la campagne de vaccination est importante.
- **Mise en œuvre de communications spécifiquement ciblées** quand certains groupes à risque ont été identifiés ou quand on sait que d'autres groupes de la société sont plus difficiles à informer.
- **D'autres recherches et une recherche approfondie portant sur l'utilisation et l'efficacité des nouveaux médias sociaux sont nécessaires.**
- **Renforcement de la capacité de recherche publique rapide soutenant la vaccination.** La majorité des répondants ont identifié un besoin de capacité de recherche publique rapide accrue en Europe en cas de futures pandémies. Plus de la moitié des répondants ont préféré une coordination par une agence de

niveau européen, le reste des répondants ayant proposé un consortium de centres de recherche clinique répartis dans les États membres. Les problèmes incluront la conception des mécanismes et instruments de financement qui ne devront pas seulement être rapides mais devront aussi correspondre à des normes de qualité et d'équité acceptables. De la même manière, il s'avérera essentiel de trouver une division appropriée et légitime des responsabilités et des tâches à exécuter entre les efforts financés par le secteur public et le secteur privé.

List of Tables and Figures

Table 1	Abbreviations and Acronyms
Table 2	Countries responding to the EU-wide Pandemic Vaccine Survey
Table 3	Timeline of the Key International Events and Decisions
Table 4	List of Stakeholders
Table 5	Prioritised health care goals/objectives in pandemic vaccination strategies
Table 6	Key comments from those countries stating that they successfully fulfilled their vaccination goals
Table 7	Suggestions for improving safety and efficacy information on centrally authorised influenza vaccines
Table 8	Wish-list for post-marketing surveillance information from EMA
Table 9	Proposed forum for receiving post-marketing surveillance information from EMA
Table 10	Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorised pandemic vaccine
Table 11	Application of weighted preference method - Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorised pandemic vaccine
Table 12	Key comments and examples of successful pandemic vaccination communication campaigns
Table 13	Key comments and examples of difficulties or failures in pandemic vaccination communication campaigns
Table 14	Key comments on positive and negative experiences on the use of communication tools
Table 15	Key comments and suggestions on how to improve future pandemic communication with key stakeholders
Table 16	Key comments regarding when vaccination communication strategies were adapted/modified in relation to other EU countries
Table 17	Key comments on the biggest communication challenges faced during the H1N1 crisis
Table 18	Key messages immediately prior to and during the vaccination phase of the H1N1 pandemic
Table 19	Key comments on the issue of specific messages for specific patient groups
Table 20	Key comments on responses to anti-vaccination campaigns
Table 21	Key comments on innovative information campaigns
Table 22	Summary of survey and polling activities in responding countries

Figure 1	When the administration of vaccines started
Figure 2	Factors that triggered your country to order H1N1 vaccine
Figure 3	Elements included in procurement contracts
Figure 4	Factors guiding national planning assumptions
Figure 5	Factors influencing the number of ordered vaccines
Figure 6	Factors influencing the amount of pandemic influenza vaccines to procure in the future
Figure 7	Advantages for a future JP of pandemic vaccines
Figure 8	Disadvantages for a future JP of pandemic vaccines
Figure 9	Conditions for an EU stockpile for deployment of pandemic vaccines to MS with acute shortages
Figure 10	Conditions acceptable for a stockpile outside EU
Figure 11	Initial goal(s)/public health objective(s) of your pandemic vaccination strategy
Figure 12	The goal(s)/public health objective(s) of your pandemic vaccination strategy for a future pandemic with the same characteristics as the H1N1 pandemic
Figure 13	Sources influencing final decisions on risk and target groups
Figure 14	Factors for maintaining initial goals/health care objectives in pandemic vaccination strategy
Figure 15	Altered initial healthcare goals/objectives in pandemic vaccination strategy
Figure 16	Reasons for changing goals/objectives in pandemic vaccination strategy
Figure 17	Risk or target groups that fell short in national vaccination coverage goals
Figure 18	Reported reasons for difficulties in reaching coverage goals
Figure 19	Sources of information on the safety and efficacy of centrally authorised H1N1 vaccines
Figure 20	Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorised pandemic vaccine
Figure 21	How were changes in recommendations on product use communicated to health care professionals
Figure 22	Specific communication strategies vs global communication strategies on the influenza H1N1 pandemic
Figure 23	Ways in which communication strategy on pandemic vaccination were developed during the H1N1 pandemic
Figure 24	Ways in which strategies on pandemic vaccination during future pandemics would be developed
Figure 25	Use of communication tools for the pandemic vaccination campaigns
Figure 26	Major topics covered in communication campaigns

Figure 27	Communication measures and channels used to communicate with primary target groups (general public, risk groups, etc.,) during the H1N1 crisis
Figure 28	Communication measures and channels used to communicate with secondary target groups (doctors, pharmacists, industry) during the H1N1 crisis
Figure 29	Level of contact with communicators in MS national regulatory agency immediately prior to and during the vaccination phase
Figure 30	Focus group or other opinion research carried out on public attitudes to vaccination

Table 1: Abbreviations and Acronyms

Acronym	Explanation
A(H1N1) or H1N1	2009 Pandemic Influenza Strain
APA	Advance Purchase Agreements
AEFI	adverse events following immunisation
CDC	US Center for Disease Control
CHM	Commission on Human Medicines
CHMP	Committee for Medicinal Products for Human Use
CRISMART	National Centre for Crisis Management Research and Training (Sweden)
DGs	Directorate Generals of the European Commission
DG SANCO	Directorate General for Health & Consumers
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EFTA	European Free Trade Association
EMA	European Medicines Agency
EPIS	Epidemic Intelligence Information System
EU	European Union
EPVS Survey	EU-wide Pandemic Vaccine Strategy Survey.
EWRS	Early Warning and Response System(on communicable disease)
GP	General Practitioner
HPA	Health Protection Agency (UK)
HSC	Health Security Committee
IHR	International Health Regulations
MC	Media Consulta
MC Questionnaire	Media Consulta Questionnaire
MoH	Ministry of Health
MMWR	Morbidity and Mortality Weekly Report

MS	Member State(s)
PCR	Polymerase chain reaction
PHEIC	Public Health Emergency of International Concern
PREG	Pharmacovigilance Rapid Response Expert Group
SMS	Short Message Service (text messaging)
TOR 1	Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009
WHO	World Health Organization
WHO HQ	World Health Organization Headquarters
WHO SAGE	World Health Organization's Strategic Advisory Group of Experts

1 Background and Introduction

1.1 Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009 (The TOR 1 Report)

On 24 April 2009, the European Commission (EC) and Member States (MS) were notified of a novel influenza outbreak identified in Mexico and the United States of America. This prompted the EC, European Union (EU) Agencies and MS to initiate a response including the implementation of pandemic influenza plans. The disease spread rapidly across North America, the EU and the rest of the world. On 11 June 2009, WHO (World Health Organization) raised the pandemic influenza alert from level five to level six, declaring the outbreak a pandemic.

A report was commissioned by the European Commission (EC), which was led by the Health Protection Agency (HPA). The aim of the report was to review and examine the response in Europe by MS, EU Agencies and the EC during the first four months (24 April to 31 August 2009) of the H1N1 pandemic. The final report was submitted to the EC on 16 April 2010 and titled "Assessment Report on the EU-wide Response to Pandemic (H1N1) 2009". It is often referred to as the "The TOR 1 Report." The assessment included seven objectives and addressed data, analyses and observations in seven key areas. As this report covered a broad range of issues and focused on the first four months, it was deemed advisable to narrow and deepen the focus in further efforts to continue the learning from the experience of the H1N1 Pandemic.

1.2 Assessment Report on the EU-wide Pandemic Vaccine Strategies (The TOR 2 Report)

At a meeting in Barcelona (03 and 04 February 2010), it was agreed that a series of *strategic questions* relating to pandemic influenza vaccine strategy should be developed, the answers to which would provide learning and added value to all MS. The development of these strategic questions was steered by a small working group¹ of interested Member States, the EC, and EU agencies. The Health Security Committee Section (HSC) on Influenza Preparedness and Response was consulted as well. The answers to these questions should have an added value exchange among the Member States so that lessons can be learned from the MS vaccination responses to the H1N1 influenza pandemic. Member States agreed to provide a response to these questions to the Directorate General for Health and Consumers (DG SANCO) by 14 May 2010. By 9 June responses had been received from all Member States.

¹ This working group (Steering Group) included representatives from Belgium, Bulgaria, France, Germany, Greece, Spain, Sweden, and the UK as well as from DG SANCO, EMA, ECDC, HPA, and CRISMART.

The formulation, distribution and analysis of these strategic questions are all part of a wider piece of work being conducted on behalf of DG SANCO which also includes:

- The development and provision of a pandemic influenza vaccination self-assessment tool for internal use by MS. Together 46 strategic questions were developed to create the EU-wide Pandemic Vaccine Strategy Survey (hereafter, EPVS Survey).
- A review of the communications aspects (public, media and health professionals) of pandemic vaccines and vaccination with the assistance of the Health Security Committee Communicators' Network.

The self assessment tool to be used when filling up the EPVS Survey was provided to the Member States in the form of a document entitled: "Support Tool for EU Member States' Internal Review of Pandemic Vaccine Strategy" (23 April 2010).

This report presents, in consolidated form, the results of the strategic questions and supplementary communications studies. These studies have been conducted and this report written by a joint HPA/CRISMART team working in consultation with the above mentioned working group of interested Member States and EU Agencies.

2 The Purpose and Outline of the Report

The purpose of the report is to describe, compare, and contrast the experiences of the Member States as formulated in the responses to the two questionnaires. With an eye to providing an overview of the various vaccine strategies developed by the Member States, the formulation of potential best practices and challenges for the future can be identified.

The analysis of the aggregated material is intended to provide elements for discussion at a conference on lessons learnt from the public health response to the influenza H1N1 pandemic that will be organised in July 2010 by the upcoming Belgian Presidency. As such, it will contribute to ongoing efforts regarding review of the Pandemic Influenza Preparedness and Response Planning in the European Community².

² "Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on Pandemic Influenza Preparedness and Response Planning in the European Community." (2005) COM 2005 607. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0607:FIN:EN:PDF>

2.1 Aim

The aim of the review is to capture the diverse pandemic vaccine strategies (with special emphasis on communications issues) developed by the Member States, and their experiences in implementing them, in order to provide a point of departure for improving MS and EU preparedness for future pandemics.

2.2 Objectives

This review takes as its point of departure a set of strategic questions developed by the above-mentioned working group and focuses on the following aspects of pandemic vaccine strategy (broadly defined):

- Advance purchase agreements (APAs) and subsequent procurement
- National planning assumptions
- Joint procurement and stockpiles
- Pandemic vaccination strategies and goal shortfalls
- Reprioritising pandemic vaccination strategies
- Vaccine safety and efficacy
- Vaccine administration
- Research capacity
- Communications campaigns and new social media

3 Methodology and Data

3.1 Methodological Points of Departure

The current report obtained information from two web based questionnaires, the TOR 1 report, focus group discussions, and correspondence with influenza and EU experts. It is important to note that the two questionnaires were significantly different and circulated to different audiences within MS and EFTA countries at different times.

The analysis of the collected data makes use of a combination of qualitative and quantitative methods³ in developing and communicating findings. The analysis draws upon comparative methodology⁴ in order to compare and contrast the experience and vaccine strategies of the participating countries. Appropriate categorisations enable structured and focused comparisons⁵. The responses have been anonymised. The analyses of communications surrounding the pandemic vaccine strategies focused on content, channels, target groups and stakeholders⁶. “Good practice,” challenges, and areas for improvement have been identified in the hope of encouraging an exchange of information and experiences.

3.2 EPVS Survey and the Strategic Questions

The EPVS Survey contains 46 of the strategic questions. These strategic questions were identified as having added value for exchanging lessons learned among the Member States on the vaccination response to the influenza H1N1 pandemic.

Respondents were asked to complete a series of: yes /no questions, multiple choice questions, ranking priorities, and free text questions. Respondents were provided with a hard copy of the questions for ease of reference and asked to complete an online version of the questionnaires. The online version of the EPVS Survey was available for completion by Member States from 23 April 2010 with an agreed deadline of 14 May 2010. By 9 June responses had been received from all EU Member States, and three EFTA countries.

³ c.f. King, G., Keohane, R., and Verba S. (1994) *Designing Social Inquiry*. Princeton: Princeton University Press.

⁴ c.f. Ragin, C. (1987) *The Comparative Method: Moving Beyond Qualitative and Quantitative Strategies*. Berkeley: The University of California Press; George, Alexander and Andrew Bennett (2004) *Case Studies and Theory Development in the Social Sciences*. Cambridge, Mass: MIT Press.

⁵ George and Bennett, 2004.

⁶ Brugha, R. and Varvasovszky Z. (2000) “Stakeholder analysis: A review.” *Health Policy and Planning*. Vol 15 (3) 239. Oxford University Press; Krippendorff, Klaus (2003) *Content Analysis: An Introduction to Its Analysis*. Sage Publications.

Table 2: Countries responding to the EPVS Survey

1	Austria
2	Belgium
3	Bulgaria
4	Cyprus
5	Czech Republic
6	Denmark
7	Estonia
8	Germany
9	Greece
10	Finland
11	France
12	Hungary
13	Ireland
14	Italy
15	Latvia
16	Liechtenstein
17	Lithuania
18	Luxembourg
19	Malta
20	Netherlands
21	Norway
22	Poland
23	Portugal
24	Romania
25	Slovakia
26	Slovenia
27	Spain
28	Sweden
29	Switzerland
30	United Kingdom

3.3 The Media Consulta Questionnaire (MC Questionnaire)

At the Steering Group meeting of the HSC Communicators' Network on 5 February 2010, it was agreed that Media Consulta (MC) ⁷ should develop a questionnaire to find out about the needs of the MS in order to be able to assist them in the future. The questionnaire was approved by DG SANCO and the Steering Group members and it was sent out in March 2010.

It was agreed that a number of questions would be added to this questionnaire to gain an understanding of the communications strategies used by members of the HSC Communicators' Network during the vaccination campaign of the H1N1 pandemic and the challenges they faced during this period. The questionnaire was split into four main sections:

1. HSC Communicators Network;
2. H1N1 Crisis Management;
3. Crisis Communication Guidelines; and
4. Future of the Network.

For the purposes of this report, the focus is on each participating country's communications as they related to the pandemic (H1N1) 2009 vaccination campaign.

Although developed independently, this questionnaire was designed in a similar manner to the EPVS Survey. Respondents were provided with a hard copy of the questions for ease of reference and asked to complete an online version of the questionnaires. Respondents were asked to complete a series of questions: multiple choice, yes /no; and free text. Twenty-two countries submitted responses.

3.4 Communications Analysis

The information for the communications analysis section was derived from a variety of sources:

1. Eight of the 46 strategic questions from the EPVS Survey specifically related to communications;
2. The MC Questionnaire;
3. The relevant observations contained within the TOR 1 report; and
4. Data provided by countries who undertook focus groups on communications activities during the response to the pandemic (H1N1) 2009.

⁷ Media Consulta is an independent international PR and advertising agency in Europe, providing expertise in the areas of corporate communication, youth marketing, and political communication.

3.5 Confidentiality

In order to respect the integrity and confidentiality of the individual country survey respondents, the names of the countries have been removed and the data presented in this report is described collectively. Therefore strategic questions one (name of country) and two (name of person/group filling up the survey) have not been included in this report.

3.6 Limitations

A total of 36 surveys were electronically submitted from 30 countries. Some countries submitted more than one response to the online survey. The statistical on-line website compiled all of the submitted responses. Therefore certain adjustments had to be done manually in order to properly analyse the data and prevent duplicate country responses from skewing the results.

Another challenge was the fact that when a responding country indicated that the question was non-applicable, it was still registered as a response by the web-based survey program. For example, most of the questions did not apply to the very few countries that did not procure pandemic H1N1 influenza vaccines. Therefore responses reported non-applicable or left blank, had to be manually deleted from the total response count. This process was time-consuming but all attempts were made to ensure that the statistical data results were as accurate as possible.

A third challenge was analysing the strategic questions where the respondents were asked to rank priorities, factors or conditions. A statistical problem arose because several respondents were able to select more than one choice, for example, as their first priority, which in many ways skewed the findings. When such incidents occurred, this limitation was recognised and appropriate means were taken to compensate for it.

A number of other limitations were encountered. The fact that the survey was only available in English, which is a second or third language for the majority, may have had an impact on how the respondents interpreted the actual questions as well as their ability to properly formulate their answers. Although there was limited time to fill up the EPVS Survey, the deadline was extended an additional three weeks in order to provide the respondents with more time. Consequently, eleven more countries responded, resulting in the fact that all 27 EU MS participated.

The limited time factor may have also been a significant impact on who actually filled in the questionnaires and whether or not this/these person(s) had the time to consult their colleagues regarding questions which required supplementary information or data from another department. In retrospect, it became apparent that a few of the questions were awkwardly or ambiguously worded, which may have also skewed the results.

Lastly, it is very important to note that the responding countries reported very different experiences so there are obvious limitations to making broad generalisations based on the raw data.

Despite these limitations, the majority of MS replied to both the EPVS Survey and the MC Questionnaire. These contributions have shaped the suggestions for improvement in crisis response as well as identified some of the potential challenges for the future.

4 Context

4.1 International Events and Decisions

Table 3: Timeline of the Key International Events and Decisions⁸	
April 15	Novel influenza A (H1N1) identified and isolated in USA.
April 21	MMWR on the detection of two human cases of H1N1 infection in California (USA).
April 24	International Health Regulation (IHR) Event Information Site posting confirms an outbreak of severe respiratory disease in Mexico caused by the H1N1 virus.
April 25	WHO declares the H1N1 outbreak in Mexico and USA as a Public Health Emergency of International Concern (PHEIC).
April 27	First confirmed cases reported in the EU (i.e., Spain and UK). Declaration of Phase four by WHO.
April 30	Declaration of Phase five by WHO. Extraordinary EU Council of Health Ministers. European Centre for Disease Prevention and Control (ECDC) publishes first of its updateable Pandemic Risk Assessments (updated at intervals thereafter). EU agreement on Common Case Definition for new pandemic infection.
May 2	WHO publishes instructions on how to obtain Polymerase Chain Reaction (PCR) kits from United States Center for Disease Control (CDC).
May 5	WHO technical consultation to assess knowledge of severity of disease caused by H1N1 and its implications.
May 8	Publication by WHO of expected timelines for availability of candidate viruses for vaccine production by reverse genetics, classical re-assortment and whole virus distribution.
May 18	High level consultation before and at the World Health Assembly including request for some delay in declaring Phase 6 by some Member States.
May 19	Recommendation by the WHO Strategic Advisory Group of Experts

⁸ Supplied by ECDC with contributions from the Commission and Steering Group members

	(WHO SAGE) on pandemic vaccines.
May 26	WHO issues characteristics of the emergent influenza A (H1N1) viruses and recommendations for vaccine development (Endorsed by the European Medicines Agency/EMA on June 4).
June 8	EU Council of Health Ministers.
June 11	Declaration of Phase six by WHO.
June 12	EMA launches pandemic management plan.
Early July	Swedish Presidency technical meeting on the pandemic and then informal Council meeting agrees on the unsustainability of containment strategies.
July 13	WHO recommendations on pandemic (H1N1) 2009 vaccines.
July 14-15	Meeting convened by ECDC with Member States and WHO to devise a new EU pandemic surveillance strategy.
August 5 -	Briefing note on safety of pandemic vaccine by WHO.
August 13 -	Health Security Committee / Early Warning and Response System statement on School Closures and Travel Advice.
August 20	WHO issues a revision of its guidance on pharmacological management.
August 25	“Health Security Committee’s Early Warning and Response System Statement on Influenza A(H1N1) 2009: Target and priority groups for vaccination” is made available ⁹ .
September 15	Publication by ECDC of pandemic surveillance strategy is made available.
September 19	Adoption by EC of a Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Pandemic (H1N1) 2009.
September 30	Authorisation of the first two pandemic vaccines by EC following the positive scientific opinion of Committee for Medicinal Products for Human Use (CHMP)/EMA on September 24.
Late September	First use of pandemic vaccine in Europe (i.e., Hungary) followed within two weeks by Belgium, Italy and Sweden.
October 12	Extraordinary EU Council of Health Ministers meets and adopts conclusions on a strategic approach to Pandemic Influenza (H1N1) 2009.

⁹ Note *Risk Groups* means people considered more likely to experience severe disease and *Other Target Groups* are others to whom vaccines are offered early.

November	First weekly meeting of the EMA Pharmacovigilance Rapid Response Expert Group (PREG) group to review difficult adverse events following immunisation (AEFI).
November 5	European benefit-risk strategy published by EMA, ECDC and Heads of the European Medicines Agency.
November 11	Weekly global pharmacovigilance teleconference convened by WHO starts.
December 1	EU Council of Health Ministers meets.
December 3	First EMA weekly pharmacovigilance report published.
December 22	Adoption of the EU Council of a Council Recommendation on Seasonal Influenza.

4.2 Administration of Vaccines

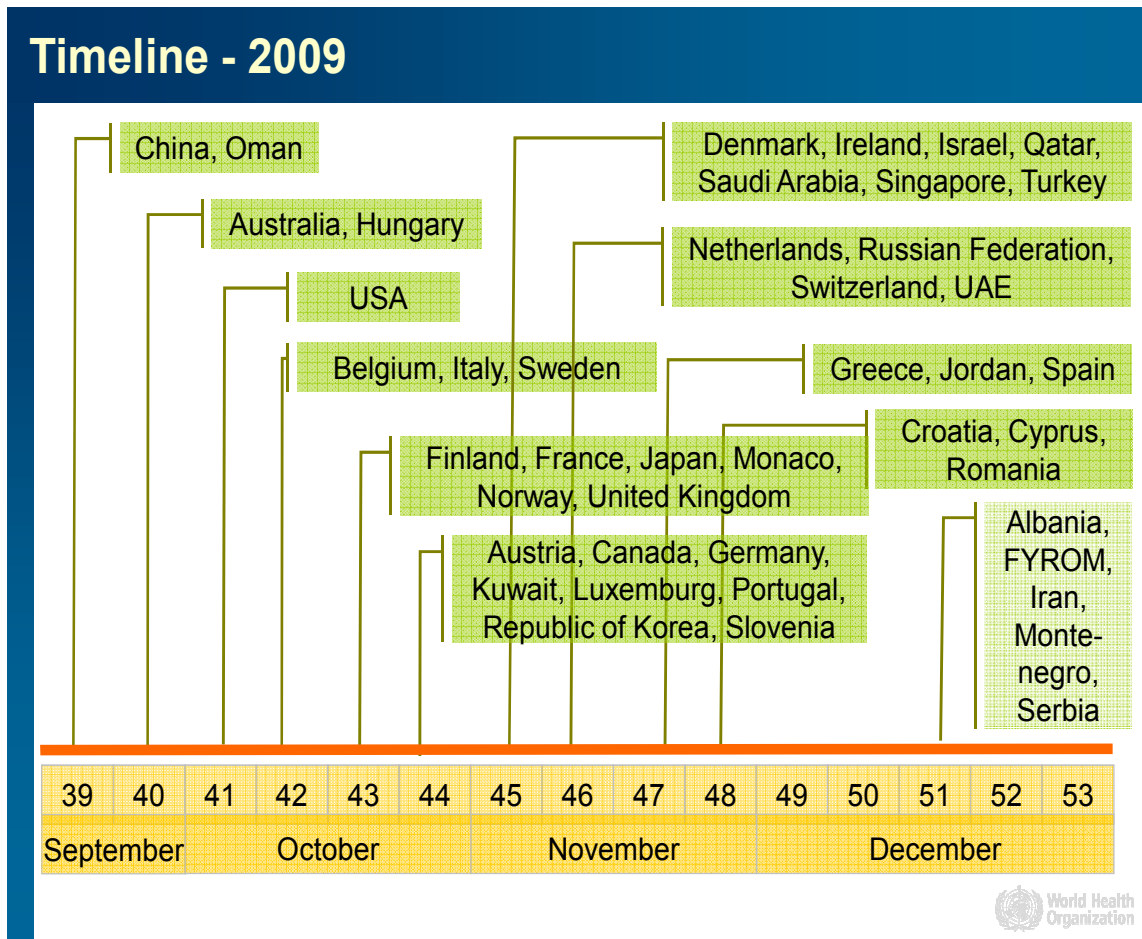


Figure 1: When the administration of vaccines started¹⁰

Additions to Figure 1: Estonia started its vaccination campaign against H1N1 week 51 and Malta started its vaccination campaign against H1N1 week 52.

¹⁰ Source: WHO Geneva

4.3 Stakeholders

When approaching the problem of pandemic vaccine strategy it is important to take into account the large number of stakeholders. In its document 'Template for rapid national evaluations of the 2009-2010 pandemic response' ECDC included a list of potential key stakeholders in national pandemic responses. This provides useful context.

Table 4: List of Stakeholders¹¹	
International	International organisations EU public health assessment EU public health management EU Medicines Regulatory Agency Other international groups
National	National Surveillance Institute MoH Medicines Regulatory Agency Other national groups Professionals who immunise
Regional/local	Regional authorities Healthcare providers Other regional or local Professionals who immunise
Citizens	Patient organisations Politicians Vocal pandemic denialists Other citizen groups
Industry	Vaccine manufacturers Pharmaceutical companies Pharmacies Other industrial groups Professional pharmaceutical industry bodies (e.g., EVM and IFPMA)

Other stakeholders could also be EU organisations such as :

¹¹ Penttinen, P., Pedzinski, B., and Nicoll, A., (2007) Template Pandemic Evaluations ECDC. Downloaded on May 14, 2010. Available at: http://www.ecdc.europa.eu/en/healthtopics/h1n1/documents/1002_template_pandemic_evaluations_ecdc.xls

- ASPHER - Associations of Schools of Public Health in the EU Region;
- EFN - European Federation of Nurses Associations;
- EPF - European Patients' Forum;
- EPHA - European Public Health Alliance;
- EUPHA - European Public Health Association;
- HOPE - European Hospital and Healthcare Federation;
- CPME - Standing Committee of European Doctors;
- PGEU - The Pharmaceutical Group of the European Union;
- UEMO- European Union of General Practitioners;
- IAPO - International Alliance of Patients' Organizations;
- EFA - European Federation of Allergy and Airways Diseases Patients' Associations.

5 Data and Observation Analyses

The data collected from 38 of the 46 strategic questions on the EPVS Survey have been analysed and are presented in the following sections. The remaining eight strategic questions, all of which are related specifically to communications, are included in the communications section.

Please note that the order of the strategic questions in this section is not the same as in the questionnaire; that is, 1-46. They have been reshuffled in order to strengthen the logic of the presentation.

5.1 Advance Purchase Arrangements (APA) and Subsequent Procurement

When the WHO officially declared a pandemic (WHO Phase six), some Member States had advance purchase agreements established with producers, others were in negotiation with industry and some had no procurement procedures in place. In Europe, countries with existing APA were likely to be at some advantage when the H1N1 pandemic hit.

To support the objective that all Member States should have timely access to vaccines for their priority groups, those countries with secured supplies of vaccines were encouraged to share sufficient amounts with those Member States who had not yet concluded purchase agreements.¹² In addition, the EC worked to facilitate procurement of pandemic vaccines with discussions on joint procurement taking place with interested Member States.¹³

3. Did your country have an advance purchase agreement (APA) for a pandemic influenza vaccine? (30 respondents)

Yes

No

¹² Health Council – 12 October 2009. Commission Staff Working Documents accompanying the Communication from the Commission on Pandemic (H1N1) 2009 on Joint procurement of vaccine against influenza A(H1N1).

¹³ http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf

4. Was your APA inevitably triggered by the WHO declaration of phase 6? (22 respondents)

- Yes**
- No**

When asked about APA, 17 out of 30¹⁴ respondents reported that they had a APA prior to the H1N1 outbreak and 11¹⁵ of 22 respondents stated that their APA were activated by the WHO “Phase six” declaration. There appears to be some sort of discrepancy in the data here. 17 respondents reported having APA prior to the H1N1 outbreak and 22 reported on the triggering of their APA. This suggests that five countries did not have APA prior to the H1N1 outbreak but had APA by the time WHO declared it a pandemic. In short, it appears as if five countries made arrangements for an APA sometime between 15 April and 11 June 2010.

5. At what stage did your country order the specific pandemic H1N1 influenza vaccines? (30 respondents)

- Initial stage of the outbreak, before WHO declaration of pandemic**
- At/after WHO declaration of pandemic**
- Did not order pandemic H1N1 influenza vaccines**

23 of 30 reported that they ordered the H1N1 vaccines in connection with or shortly after WHO phase six (i.e., pandemic) declaration and five reported that they had ordered the H1N1 vaccine during the initial stage of the outbreak, before the WHO had declared H1N1 a pandemic.

By cross analysing it was revealed that only three countries with APA prior to the WHO pandemic declaration ordered the specific H1N1 vaccine in the initial stage of the outbreak or before the WHO pandemic declaration; whereas, 14 of those with APA ordered H1N1 vaccines at/after the WHO pandemic declaration.

¹⁴ Strategic question #3

¹⁵ Strategic question #4

6. What triggered your country to order pandemic H1N1 influenza vaccines? Please rank if several answers apply. Please rank items below in order of importance (1 most important), and add others as required. (27 respondents)

- Having an APA
- Scientific assessment
- Other countries ordering pandemic H1N1 influenza vaccines
- Pressure from industry
- Public pressure
- WHO declaration of pandemic
- Other, please specify

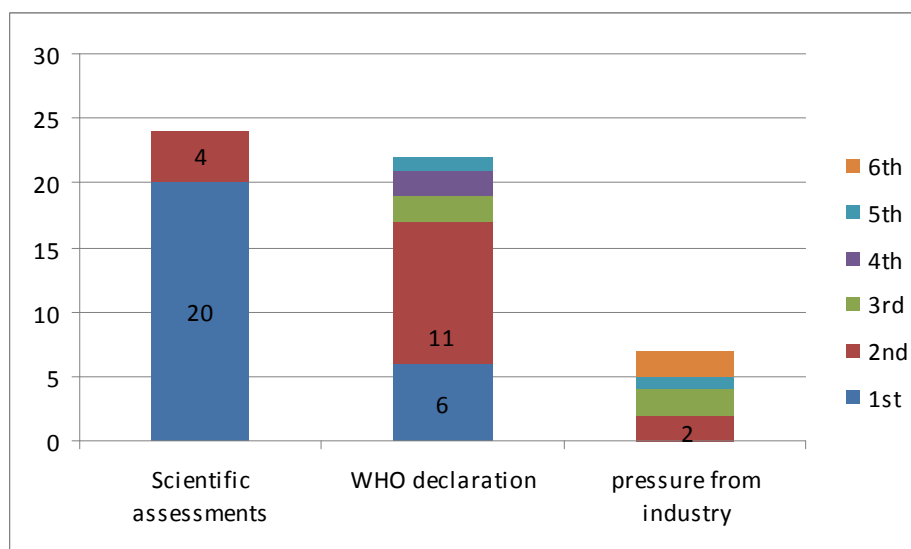


Figure 2: Factors that triggered your country to order H1N1 vaccine (total of 27 respondents)

When asked to rank (on a scale of one to five, one being most significant) the most significant factors triggering a country to order the specific H1N1 vaccine, 24 of 27 the respondents ranked “scientific assessments” as one of the most significant factors (20 ranking it first) and 22 of 27 ranked the WHO pandemic declaration as a significant factor (11 ranking it second). Also interesting to note is the fact that only seven of 27 respondents even mentioned “pressure from industry” as a contributing factor and when they did do so it was ranked as a less significant factor (two ranking it second, two ranking it third, one ranking it fifth, and two ranking it sixth). Please note that the sixth ranking category was added since two countries indicated that it applied.

A cross analysis was done for those who reported that their APA was NOT triggered by the WHO pandemic declaration in order to find out what motivated them to order H1N1 vaccines. Of the 11 respondents which stated that their APA was not triggered by the WHO declaration, eight ranked scientific assessments as their number one trigger for ordering the H1N1 vaccine.

On the other hand, of the ten respondents that reported their APA was indeed triggered by the WHO declaration, nine stated that they were triggered to order the H1N1 vaccines at/after the WHO declaration.

Furthermore, of the ten respondents who had APA for a pandemic influenza vaccine, all of them stated to varying degrees that their APA triggered them to order the H1N1 vaccine and nine of them to varying degrees were triggered by the WHO pandemic declaration to order the H1N1 vaccine. Of the ten respondents who reported that their APA was triggered by the WHO pandemic declaration, all of them also stated that they were triggered, in varying degrees, by the WHO pandemic declaration to order the H1N1 vaccine.

Of the 20 respondents that ordered the specific H1N1 vaccine because they felt triggered to do so, to varying degrees, by the WHO pandemic declaration, they reportedly placed their orders at/after WHO declared the outbreak a pandemic.

The findings suggest that the most significant factor of those listed was scientific assessments, the WHO declaration was the second most significant factor, and pressure from industry was reported the least influential factor triggering countries to order the H1N1 vaccine.

**7. Which elements were contained in your procurement contract?
(28 respondents)**

- Quantity**
- Price**
- Delivery date(s)**
- Distribution arrangements**
- Liability arrangements**
- Conditions under which the amount ordered can be lowered**
- Conditions under which the contract becomes void**
- Other, please specify ...**

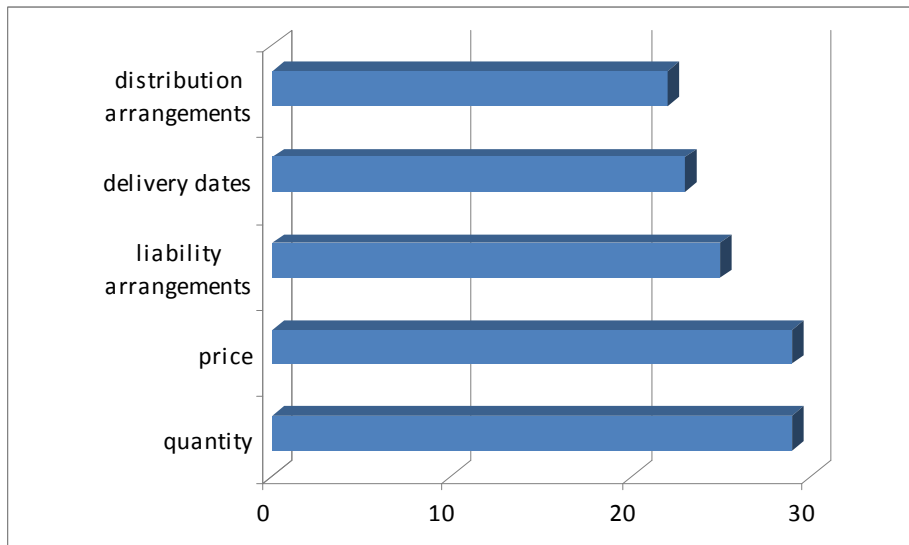


Figure 3: Elements included in procurement contracts (total of 28 respondents)

Of the 28 respondents reporting on their procurement contracts, 28 had included quantity and price, 25 liability arrangements, 23 delivery date(s), and 22 distribution arrangements.

8. In hindsight, which elements would you add to your procurement contract if you were to draft it again? (23 respondents)

When asked which elements should be included in future procurement contracts¹⁶, 15 of the 23 respondents would like to add conditions under which the specified amount could be lowered/changed (e.g., because of new scientific evidence, quality or safety issues, or lower/higher demand). Other mentioned issues included dealing with excess vaccines, economic sanctions for delayed vaccine delivers, conditions under which a contract becomes void.

In summary, more than half of the responding states reported that they had an APA prior to the H1N1 outbreak and that their APA were activated by the WHO phase six declaration. Nearly two-thirds ordered the H1N1 vaccines in connection with or shortly after WHO phase six declaration. The most significant factor triggering a country to order the specific H1N1 vaccine was “scientific assessments”. Perhaps a bit surprisingly, “pressure from industry” was the least significant factor. The majority of countries would like in a future procurement contract to add conditions under which the specified amount could be lowered/changed (e.g., because of new scientific evidence, quality or safety issues, or lower/higher demand). Other mentioned issues included dealing with

¹⁶ Strategic question #8

excess vaccines, economic sanctions for delayed vaccine deliveries, conditions under which a contract becomes void.

5.2 National Planning Assumptions

Vaccination is considered as potentially the most effective public health measure during a pandemic. However specific pandemic vaccines can only be developed once the pandemic influenza strain has been isolated. The availability of any pandemic vaccine early in a pandemic is limited in quantity due to the time it requires to develop a well-matched pandemic vaccine and by the capacity to produce it.¹⁷ The potential need for a large scale vaccination campaign poses additional challenges for the procurement and acquisition of pandemic vaccines.

9. On which elements did you base your national planning assumptions for the H1N1 pandemic? Please rank if several answers apply. (27 respondents)

- Epidemiological evidence
- Planning assumptions developed by another country
- ECDC planning assumptions
- WHO
- Other, please specify ...

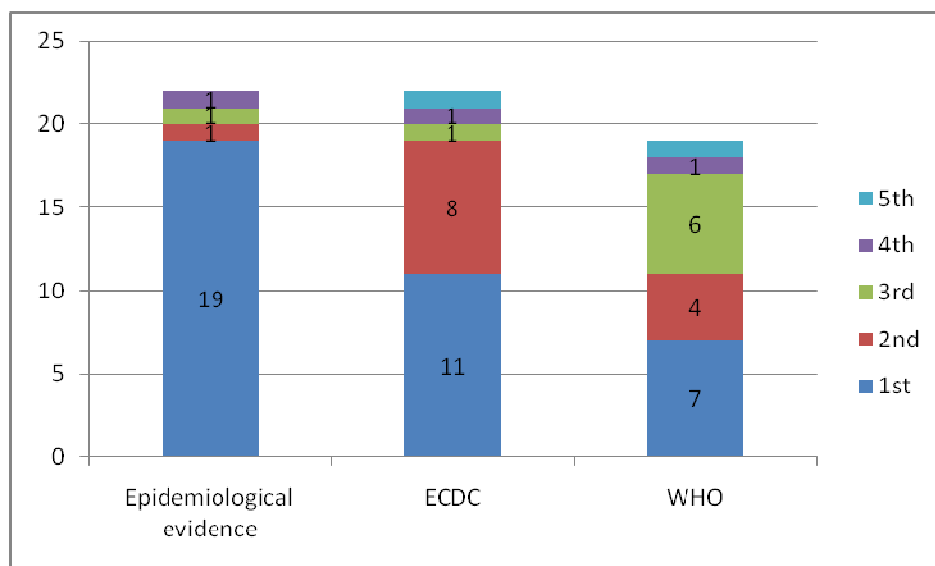


Figure 4: Factors guiding national planning assumptions (total of 27 respondents)

¹⁷Pandemic influenza vaccine manufacturing process and timeline:
http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090806/en/index.htm

Three main factors stood out when the 27 respondents ranked the factors that steered their national planning assumptions: “epidemiological evidence”, ECDC, and WHO. Both “epidemiological evidence” and ECDC each received a total of 22 rankings; however, 19 of the respondents ranked “epidemiological evidence” as the most significant factor (ranking it first) and only 11 ranked ECDC as the most significant factor (ranking it first). Thereby one can conclude that “epidemiological evidence” was the most significant factor, followed by ECDC and then WHO.

10. What influenced your decision on the amount of pandemic influenza vaccines to procure? Please rank if several answers apply. (26 respondents)

- National vaccination strategy against pandemic H1N1 influenza
- Planning assumptions
- Initial assumption of a two-dose schedule
- Financial constraints
- Limited global pandemic influenza vaccine manufacturing capacity
- Solidarity considerations of not exhausting the limited global pandemic influenza vaccine manufacturing capacity
- Pre-existing contract
- Other, please specify ...

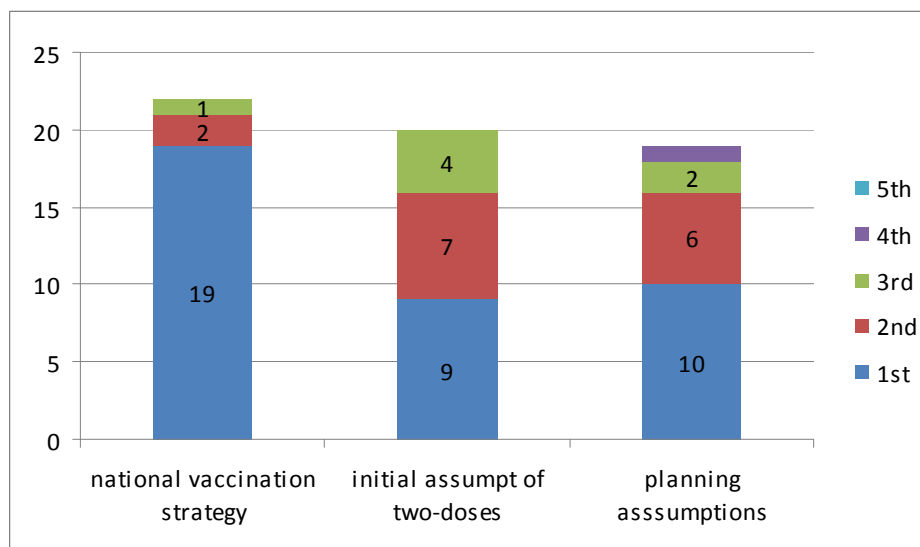


Figure 5: Factors influencing the number of ordered vaccines (total of 26 respondents)

Three main factors, again, stood out when the 26 respondents were asked to rank the factors that influenced the number of vaccines they chose to order: national vaccination strategy (22 rankings); initial assumption of a two-dose schedule (20); and planning assumptions (19). Here we can see that national vaccination strategy not only received the most rankings but the highest rankings as well, with 19 ranking it as the most significant factor. The second most significant factors were: initial assumption of a two-dose schedule; and planning assumptions, with the former ranking slightly higher than the latter.

By cross analysing the number of countries that had APA (strategic question #3) with the number of responding countries that reported they were influenced by a pre-existing contract to order a certain amount of vaccines (strategic question #10). Of the 17 responding countries that had APA, in eight of them the amount of vaccines procured were significantly influenced (all rankings clustered between first, second and third) by this APA.

11. In hindsight, what would influence your decision on the amount of pandemic influenza vaccines to procure in a future influenza pandemic with the same characteristics as the H1N1 pandemic? Please rank if several answers apply. (26 respondents)

- National vaccination strategy against pandemic H1N1 influenza
- Planning assumptions
- Financial constraints
- Limited global pandemic influenza vaccine manufacturing capacity
- Solidarity considerations of not exhausting the limited global pandemic influenza vaccine manufacturing capacity
- Pre-existing contract
- Other, please specify ...

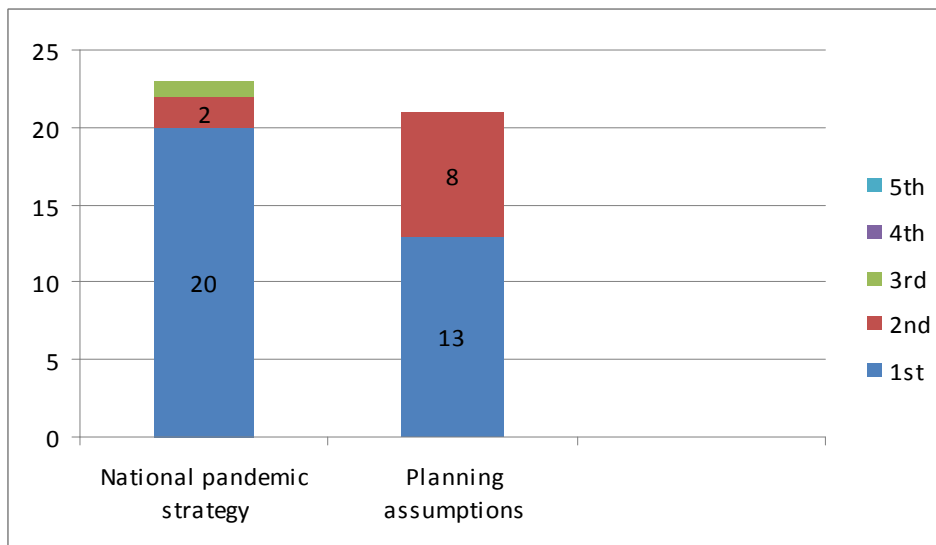


Figure 6: Factors influencing the amount of pandemic influenza vaccines to procure in the future (26 respondents)

Two main factors stood out when the 26 respondents were asked to rank the factors that would influence the amount of pandemic influenza vaccines to procure in the future: national vaccination strategy against pandemic H1N1 influenza (23 rankings); and planning assumptions (21). Again we can see here that the national vaccination strategy not only received the most rankings but the highest rankings as well, with 20 ranking it as the most significant factor (first). The second most significant factor was planning assumptions, which received fewer rankings and lower placements (13 ranking it first and 8 ranking it second).

In summary, three main findings appeared from the data on national planning assumptions. First, national planning assumptions appeared to be influenced more by supranational organisations (such as ECDC and WHO) than by other countries' planning assumptions. Second, national vaccination strategies, and planning assumptions to a lesser extent, influenced the number of H1N1 vaccines that were ordered in 2009/2010 more than, for example, financial constraints, pre-existing contracts, or solidarity considerations. Third, these same strategies and assumptions would most likely be used to determine future vaccine orders.

5.3 Joint Procurement (JP)

To support the objective that all Member States should have timely access to vaccines for their priority groups, those countries with secured supplies of vaccines were encouraged to share sufficient amounts with those Member States who had not yet

concluded purchase agreements.¹⁸ In addition, the EC worked to facilitate procurement of pandemic vaccines with discussions on joint procurement taking place with interested Member States¹⁹.

12. Would your country be interested in the future in joint procurement of pandemic influenza vaccines? (27 respondents)

- Yes
- No

15. If yes (interested in joint procurement), at what stage should joint procurement take place? (21 respondents)

- Advance purchase stage
- Initial stage of the outbreak, before WHO declaration of pandemic
- At/after WHO declaration of pandemic
- Other, please specify ...

16. If yes (interested in joint procurement), who should coordinate? (21 respondents)

- The European Commission
- The Member States coordinate among themselves
- WHO
- Other, please specify ...

When asked if interested in a future JP for pandemic influenza vaccines,²⁰ 21 of the 27 respondents were positive to the idea; six were clearly negative to the idea of a JP. Of those interested in a JP, 19²¹ were of the opinion that a JP should take place in advance, in the initial stage of a pandemic, or before a WHO pandemic declaration. Only three stated that a JP should take place at/after a WHO pandemic declaration.

¹⁸ Health Council – 12 October 2009. Commission Staff Working Documents accompanying the Communication from the Commission on Pandemic (H1N1) 2009 on Joint procurement of vaccine against influenza A(H1N1).

¹⁹ http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff1_en.pdf

²⁰ Strategic question #12

²¹ Strategic question #15

Furthermore 17 of 21 respondents²² felt that the EC should coordinate a JP, only four reported that the MS should coordinate themselves, and none choose WHO as potential coordinator for a JP. In short, the MS are positive to a future JP coordinated by the EC if it is negotiated before WHO officially declares a pandemic.

13. What advantages do you see to this approach? Please rank if several answers apply. (25 respondents)

- Advantages:
- Stronger negotiation power
- Lower price
- Equitable access to vaccines
- Common understanding over liability
- Other, please specify ...

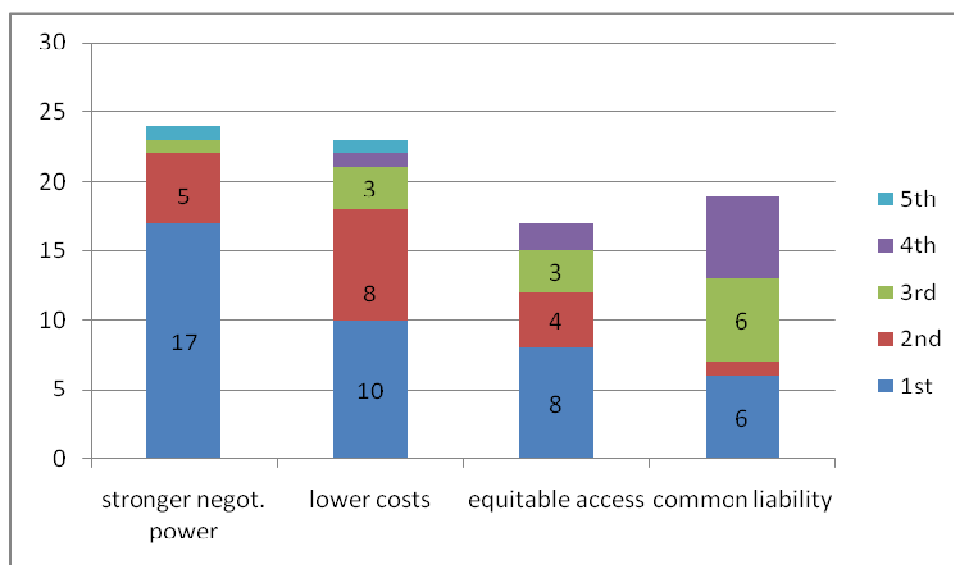


Figure 7: Advantages for a future JP of pandemic vaccines (25 respondents)

The 25 respondents were able to rank their answers and to select the same rank position for more than one advantage. According to the responses, stronger negotiating power ranked the highest (first or joint first) with 17 out of the total 35 rankings. This is

nearly twice as many as any other factor. It is important to note here that several respondents chose more than one answer for their “first” advantage; therefore, if you add all of the first rankings, which equals 35, they total more than the actual number of respondents.

According to 24 respondents, stronger negotiation power was a clear advantage of a JP, and of those 17 ranked this the highest. A total of 23 respondents indicated that another advantage of a JP was lower costs; ten ranking this the highest. Equitable access and common understanding of liability were also considered advantages (receiving 17 and 19 rankings respectively) although to a lesser degree.

14. What disadvantages do you see to this approach? Please rank if several answers apply. (29 respondents)

- Lower flexibility for national requirements
- Less influence to stimulate local production capacity
- More complex logistics
- Other, please specify ...

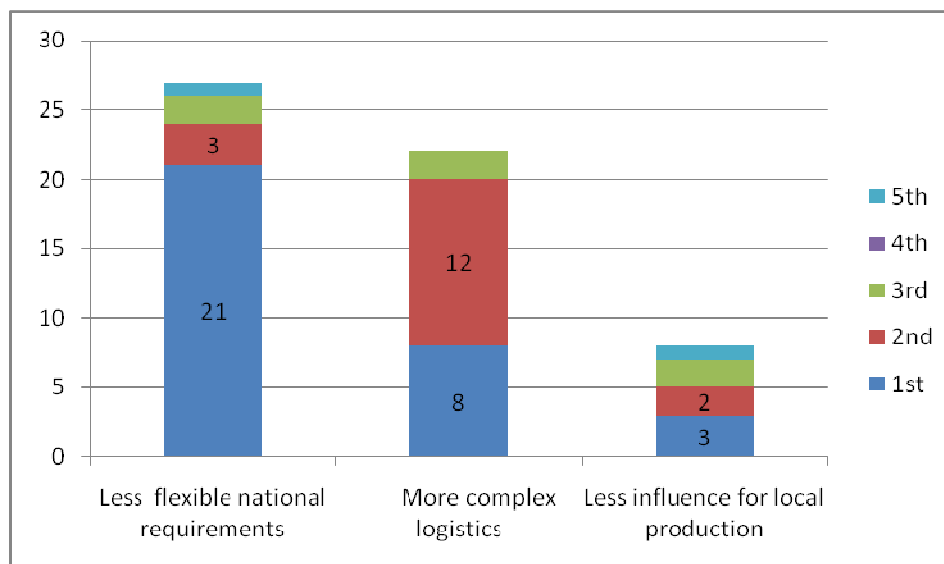


Figure 8: Disadvantages for a future JP of pandemic vaccines (29 respondents)

Two main disadvantages of JP were indicated by the 29 respondents: less flexible national requirements and more complex logistics. 27 chose less flexible national requirements as a disadvantage to JP; of which 21 of these ranking it as the most significant. 22 selected more complex logistics as a disadvantage to JP, with eight

ranking it first and 12 ranking it second. Concerns over less influence to stimulate local production capacity were ranked by only eight countries. When given the opportunity to specify their answers, two countries mentioned differing legislation as an obstacle to JP. Another country respondent observed after evaluating its national strategy on pandemic vaccine procurement that the distribution of vaccines was a major challenge. The same respondent also noted that in future pandemics new strains will appear and therefore using the same timeline from the isolation of the new strain to the delivery of a pandemic vaccine JP might be a major obstacle for delivering timely vaccines. For antivirals, where stockpiling is possible, JP may be seen in a different light. Based on these findings, one can draw the conclusion that any future JP will need to be adapted to the concerns of the MS regarding differing national requirements and contexts.

In summary, the majority of the respondents are interested in a JP and indicate that this task should be coordinated by the EC before or in connection with a WHO pandemic declaration. The respondents appreciated the fact that a JP would provide a number of advantages (stronger negotiation power, lower costs, and equitable access) as well as help create a common understanding of liability issues. On the other hand, concerns were expressed that a JP should be carefully adapted to national requirements, logistics, context, and legal framework. It should be noted that any JP would increase the complexity of logistics in sourcing and delivering the vaccine.

5.4 Stockpiles

The moderate severity of the disease (for most) has meant that vaccine uptake has been markedly less than expected leading to surplus stockpiles in most Member States. There are ongoing discussions about surplus stockpiles at EU level and negative publicity²³ in recent months has surrounded this issue.

43. In addition to your national procurement of pandemic influenza vaccines, on what conditions would your country be willing to contribute to an EU stockpile of pandemic vaccines for deployment to EU MS with acute shortages of pandemic influenza vaccines during a pandemic? Please rank if several answers apply. (21 respondents)

- If all EU MS have equal access in case of need**
- If my country foresees that there will be a surplus of the nationally procured pandemic influenza vaccines**

23 See Wodarg, Wolfgang (26 January 2010) Hearing on “The handling of the H1N1 pandemic: more transparency needed?” at the Social, Health and Family Affairs Committee of the Parliamentary Assembly of the Council of Europe.

- If the stockpile is held and managed centralised at EU level
- If the stockpile is held and managed decentralised, equally spread over the EU MS
- Other, please specify ...

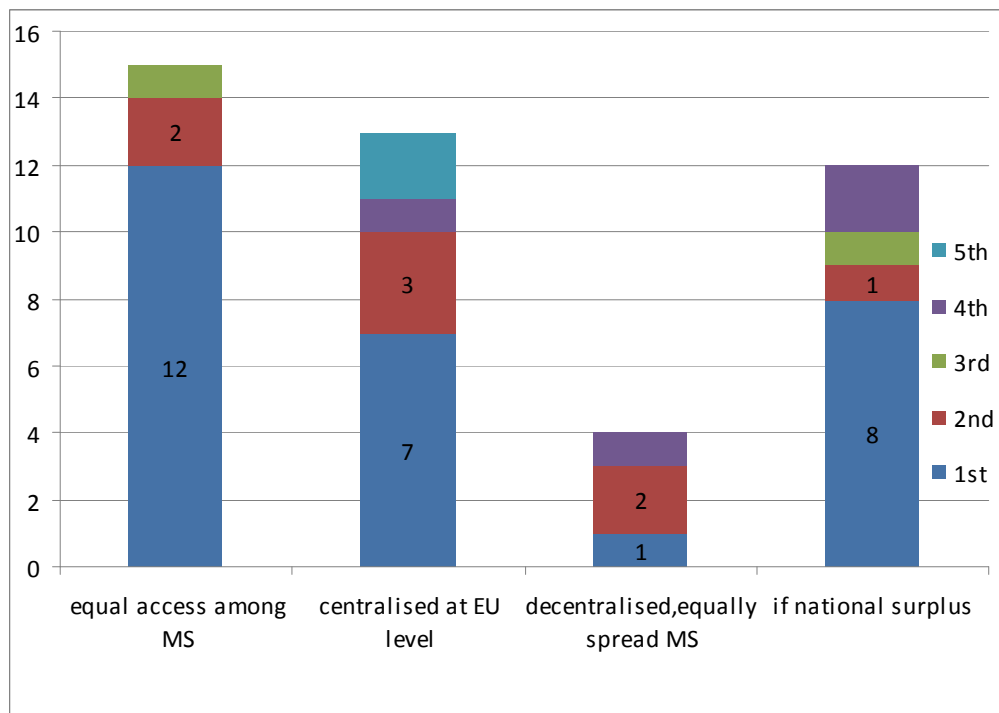


Figure 9: Conditions for an EU stockpile for deployment of pandemic vaccines to MS with acute shortages (21 respondents)

The majority of countries would be willing to contribute to an EU stockpile of pandemic vaccines (in addition to their own national procurement) for deployment to EU MS with acute shortages of pandemic influenza vaccines during a pandemic if: the stockpile was managed centrally at the EU level (14 of 23 in support of this); and/or if all MS in need would have equal access (16 of 23 in support of this). Only four favoured a stockpile that was decentralised, and equally spread among the MS. Another significant consideration for 12 countries would be if a national surplus was foreseeable.

When given the opportunity to add free text, one country wrote, “Difficult to raise funds for an EU stockpile.” One country replied, “This is a highly political issue not to be limited to these questions,” and another confirmed this claim “This is a political decision!” Another country came to the conclusion after evaluating its national strategy on pandemic vaccine procurement that “distribution of vaccines was a challenge”, implying that this would be even more of a challenge at the supranational level. This same country also voiced concern over the issue of timely vaccine deliveries when asked

about JP. Despite these concerns, this country felt that JP of antivirals was feasible when stockpiling them was possible.

44. On what conditions would your country contribute to a stockpile of pandemic vaccines for deployment to countries outside the EU? Please rank if several answers apply. (23 respondents)

- If the stockpile is held and managed by WHO
- If my country foresees that there will be a surplus of the nationally procured pandemic influenza vaccines
- Other, please specify ...

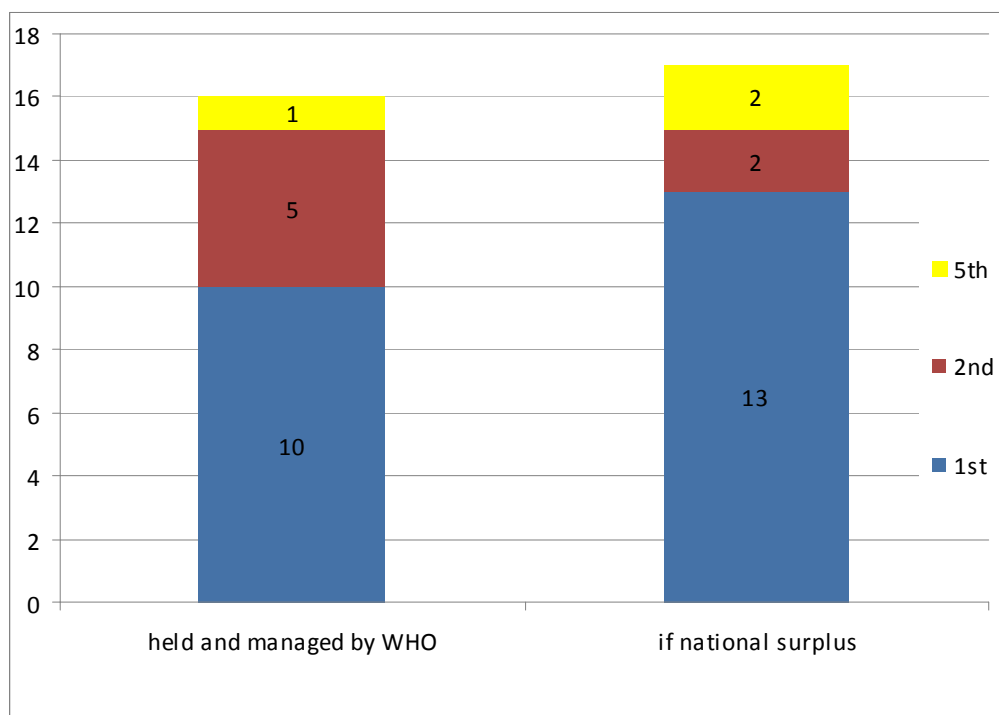


Figure 10: Conditions acceptable for a stockpile outside EU (23 respondents)

When asked whether a country would be willing to contribute to a pandemic vaccine stockpile for deployment outside the EU, only two choices were presented although the responding country was able to specify other choices or add comments. No dramatic difference appeared in the responses although the condition of a national surplus was selected by 17 (vs 16 for held and managed by WHO) and ranked a bit higher. Several comments were made stating that possible stockpiling is a highly political issue. In addition, concerns were raised regarding financing such an endeavour.

In summary, the findings of these two strategic questions suggest that the conditions for eventual vaccine stockpiles within or outside the EU were quite similar. The most frequently chosen conditions included: if they foresee a national surplus and if the stockpile is centrally managed (vs decentrally managed) at the EU level (for an intra-EU stockpile) or by WHO (for a stockpile for third countries). Another condition deemed significant for an EU vaccine stockpile would be that all MS in need would be provided equal access.

5.5 Pandemic Vaccination Strategies

The development of pandemic vaccination strategies is initially determined by Member States' public health objectives such as the need to protect the most vulnerable people, to limit spread of infection and to maintain essential services in society. However, it is influenced by a wide range of variables which include the reality of the infection (it is very hard to limit the spread of influenza, especially pandemic influenza), epidemiology, severity (however that is defined), health service structures and available resources (financial and personnel). The initial limited availability of vaccines and the potential need for a large-scale vaccination campaign also play a factor, as does any advance purchase agreement.

17. Did your country have an explicit pandemic vaccination strategy in its pandemic preparedness plan? (29 respondents)

- Yes
- No

When asked if they had an explicit vaccination strategy in their pandemic preparedness plans, 24 of 29 respondents said yes.

18. What was the initial goal(s)/public health objective(s) of your pandemic vaccination strategy? Please rank if several answers apply. (29 respondents)

- Reducing overall transmission
- Protecting vulnerable (at risk) populations
- Maintaining healthcare services
- Maintaining other essential services
- Protecting everyone
- Other, please specify ...

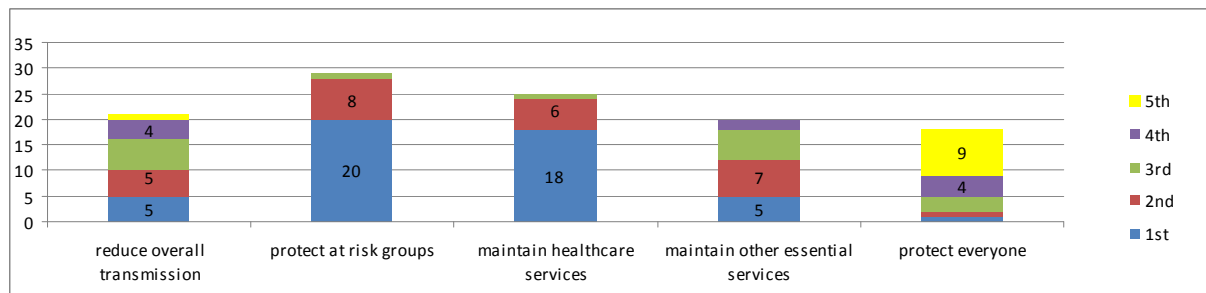


Figure 11: Initial goal(s)/public health objective(s) of your pandemic vaccination strategy (29 respondents)

All 29 respondents selected protecting the risk groups/most vulnerable, of which 20 ranked first and eight ranked it second. It is important to note here that some respondents choose more than one objective as their first priority; 20 chose maintaining health care services and 18 chose maintaining essential services. In fact there occurred 49 first rankings.

Nonetheless, clear trends are visual in the bar graph above. In terms of total numbers and highest rankings, both protecting at risk groups and maintaining health care services were of greatest importance. Protecting everyone was most often ranked as the least important goal.

23. In hindsight, what would be the goal(s)/public health objective(s) of your pandemic vaccination strategy for a future pandemic with the same characteristics as the H1N1 pandemic? Please rank if several answers apply. (29 respondents)

- Reducing overall transmission
- Protecting vulnerable (at risk) populations
- Maintaining healthcare services
- Maintaining other essential services
- Protecting everyone
- Other, please specify ...

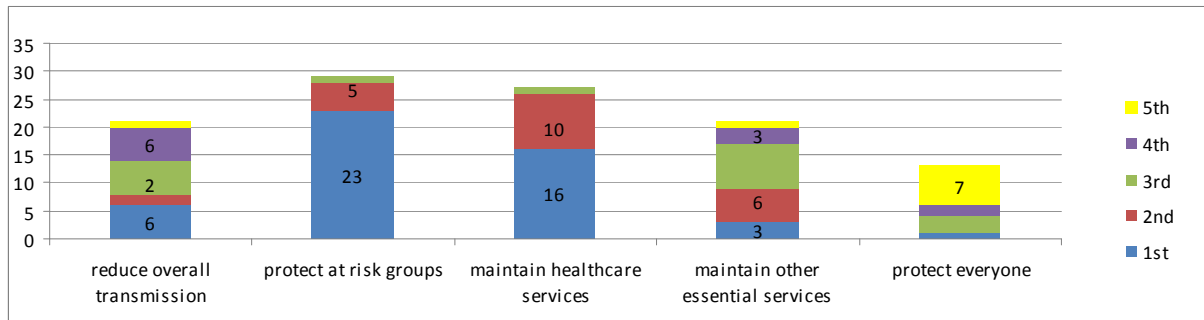


Figure 12: The goal(s)/public health objective(s) of your pandemic vaccination strategy for a future pandemic with the same characteristics as the H1N1 pandemic (29 respondents)

Again, several respondents selected more than one objective as their first priority; therefore a total of 49 first rankings appeared. Nevertheless, there are obvious trends. All 29 respondents selected protecting the risk groups/most vulnerable, of which 23 and 16 ranked it as their respectively first and second goals for a future pandemic. Once more, protecting at risk groups and maintaining health care services were of greatest importance as illustrated by their total numbers and highest rankings. Protecting everyone was for a second time most often ranked as the least important goal.

Table 5: Prioritised health care goals/objectives in pandemic vaccination strategies		
	Initial health care goals/objectives ²⁴	Future health care goals/ objectives ²⁵
protecting the most vulnerable	29 of 29	29 of 29
maintaining health care services	25 of 29	27 of 29

²⁴ Strategic question #18

²⁵ Strategic question #23

By combining the main results of strategic questions 18 and 23 into a table format, one can easily compare and conclude that initial health care goals and future health care goals remain quite stable. As one country stated, "Maintaining health care services will always be the most important objective of every pandemic." And it would appear that the H1N1 pandemic has reaffirmed this assertion.

24. Which one(s) of the following opinions influenced your final decision on risk group and other target groups for vaccination? Please rank if several answers apply. (27 respondents)

- WHO Strategic Advisory Group of Experts (SAGE) on Immunization recommendations – July 2009²⁶**
- HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for vaccination – August 2009²⁷**
- ECDC guidance on the use of specific pandemic influenza vaccines during the H1N1 2009 pandemic – August 2009²⁸**
- Recommendations of the US Advisory Committee on Immunization Practices (ACIP), August 2009²⁹**
- Commission Staff Working Document on vaccination strategies against pandemic (H1N1) 2009 – September 2009³⁰**
- Expert guidance developed within your country**
- Information provided by pharmaceutical industry**
- Other, please specify ...**

²⁶ http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090713/en/index.html

²⁷ http://ec.europa.eu/health/ph_threats/com/Influenza/docs/HSC_EWRS_statement_en.pdf

²⁸ http://ecdc.europa.eu/en/publications/Publications/0908_GUI_Pandemic_Influenza_Vaccines_during_the_H1N1_2009_Pandemic.pdf

²⁹ http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s_cid=rr5810a1_e

³⁰ http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff5_en.pdf

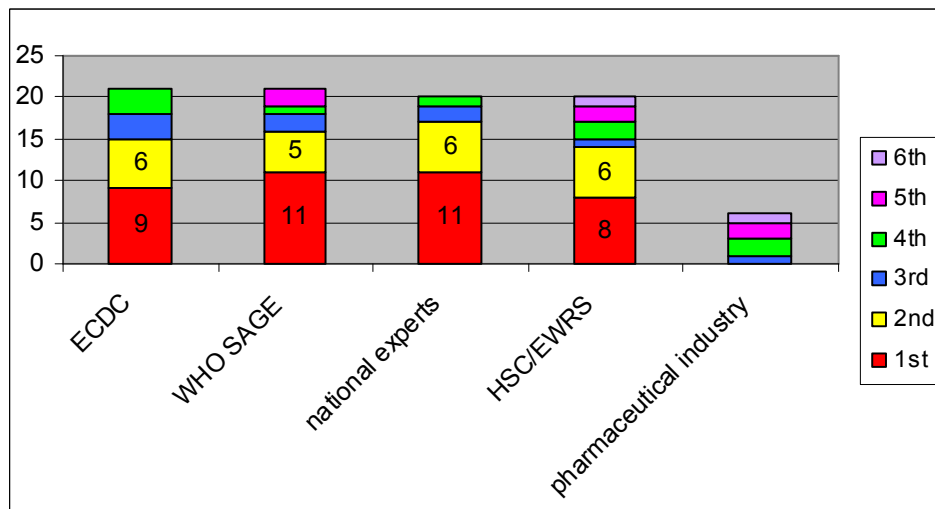


Figure 13: Sources influencing final decisions on risk and target groups (27 respondents)

Opinions influencing countries' final decisions on risk and other target groups for vaccination came from a variety of sources with quite similar rankings clustered around first and second place: ECDC (21), WHO SAGE (21), national experts (20), and HSC/EWRS (20). Again it is obvious here that a few respondents undoubtedly picked several answers for their first and second rankings. Likewise, a sixth ranking category was added since a few respondents ranked sources as such. The one striking exception is that very few selected the pharmaceutical industry as a significantly influential factor in their final decision making; just six countries ranked it and none ranked it as the single most influential factor.

In summary, national pandemic vaccination strategies seem to be well established. One potential risk in a future pandemic situation is that they could be automatically reused without consciously reflecting upon whether or not they are truly appropriate to the situation. However, the sources of information used in creating these national pandemic vaccination strategies appear to be taken from a number of sources therefore providing room for constructive feedback, diverse expertise, and differing opinions. It is notable that the pharmaceutically industry is not considered by the respondents as significantly influential.

5.5.1 Vaccination goals and reprioritisation

As a pandemic progresses the strategy needs to be reviewed regularly to take into account epidemiological, clinical and pharmaceutical evidence as it becomes available. The most common strategies are: protect the most vulnerable people; and maintain essential services and the same strategies can apply across various actions.

19. Did the goal(s)/public health objective(s) of your pandemic vaccination strategy alter after the characteristics of the pandemic became clearer? (29 respondents)

- Yes
- No

Of 29 respondents, 18 reported that they did NOT change their health care goals/objectives in their pandemic vaccination strategies even as the picture of the H1N1 pandemic became clearer.

22. If no (strategy did not change), what made you maintain the initial goal(s)/public health objective(s) of your pandemic vaccination strategy? Please rank if several answers apply. (13 respondents)

- The fixed amount of procured vaccine
- The scientific evidence was considered not conclusive enough to change the initial goal(s)/public health objective(s)
- Precautionary approach, in view of the uncertainty on how the pandemic may evolve
- Other, please specify ...

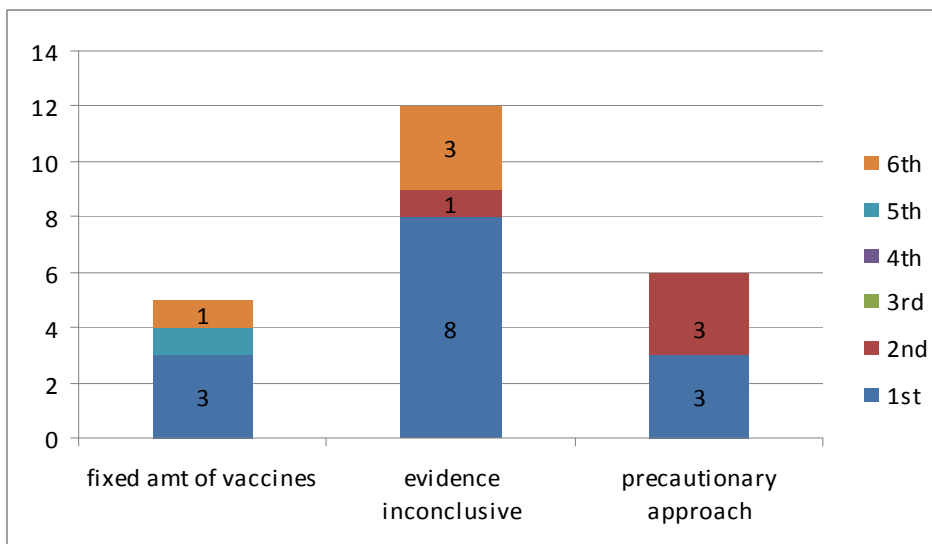


Figure 14: Factors for maintaining initial goals/health care objectives in pandemic vaccination strategy (13 respondents)

From the 18 respondents who did NOT change their health care goals/objectives in their pandemic vaccination strategies, 13 responded to the strategic question regarding the reasons for maintaining them. The majority attributed this decision to inconclusive scientific evidence; 12 selected this reason of which eight ranked it as the first/most significant reason. In view of uncertainty on how the pandemic may evolve, six chose to take a precautionary approach and stick to their initial goals/objectives. Of the three available options, the fact that a country had a fixed amount of procured vaccines was of least significance to maintaining pre-established health care goals/objectives. Note that a sixth ranking category was added since respondents provided them.

20. If yes (strategy did change), what was the goal(s)/public health objective(s) of the altered strategy? Please rank if several answers apply. (10 respondents)

- Reducing overall transmission
- Protecting vulnerable (at risk) populations
- Maintaining healthcare services
- Maintaining other essential services
- Protecting everyone
- Other, please specify ...

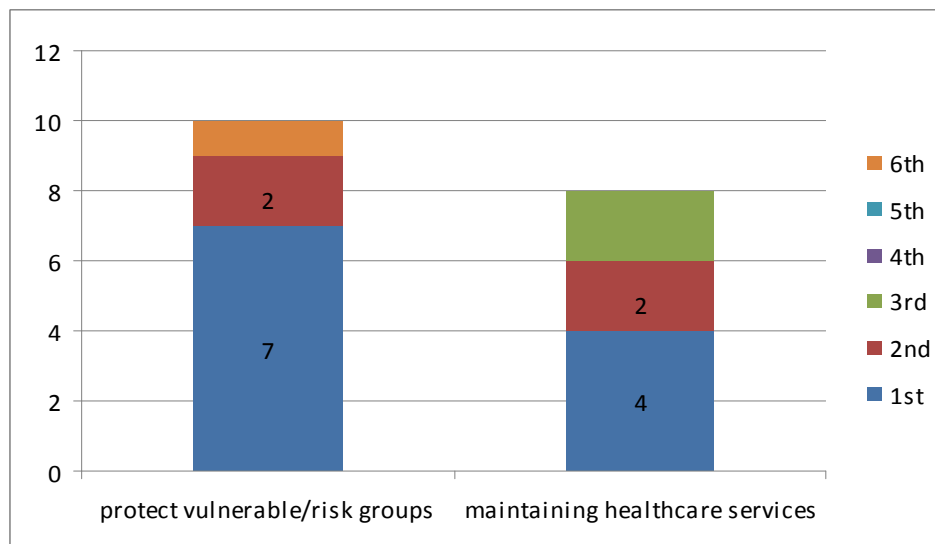


Figure 15: Altered initial healthcare goals/objectives in pandemic vaccination strategy (10 respondents)

Of the 11 countries that reported altering their goals/objectives in their pandemic vaccination strategy, ten responded to the strategic question regarding the goal/objective of the altered strategy. The main reasons selected were protecting the vulnerable/at risk groups (ten of which seven ranked it first) and maintaining health care services (eight of which four ranked it first). Three other options were also available for this question: reducing overall transmission (receiving four diverse rankings), maintaining other essential services (receiving five diverse rankings), and protecting everyone (receiving three diverse rankings). These choices were selected significantly less often and their rankings were spread across the entire range with no clear clustering.

21. If yes (strategy did change), what made you change the goal(s)/public health objective(s) of your pandemic vaccination strategy? Please rank if several answers apply. (11 respondents)

- A clearer picture on the degree of transmission of the pandemic influenza**
- A clearer picture of the hospitalisation rate**
- A clearer picture of the case fatality rate**
- A clearer picture of which groups were really at risk for a severe outcome of infection**
- More limited supply of vaccines than anticipated**
- Logistical issues (distribution, formulation, syringes/needles)**
- Opposition from certain groups (please specify) ...**
- Limited interest of population to get vaccinated**
- Other, please specify ...**

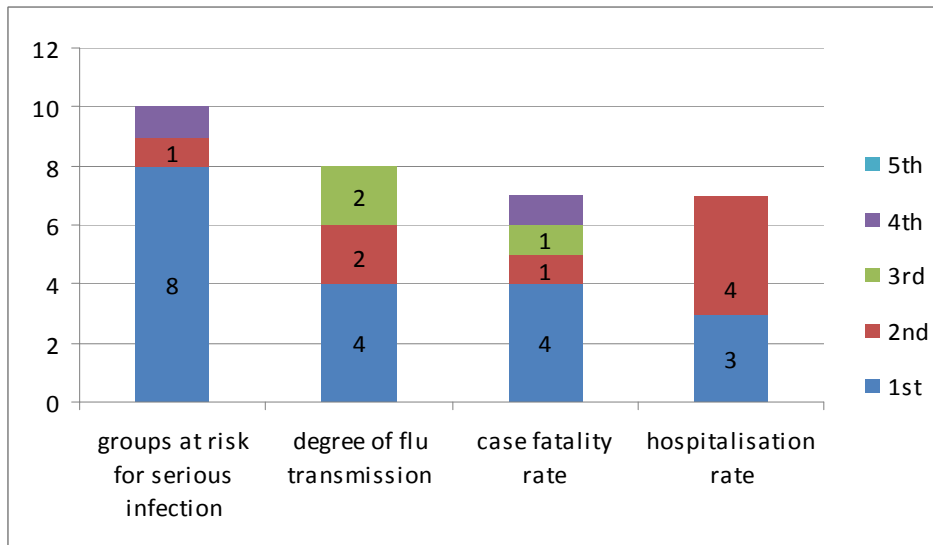


Figure 16: Reasons for changing goals/objectives in pandemic vaccination strategy (11 respondents)

In connection with the previous question, the respondents were asked to select which reasons influenced their decision to change their initial goals/objectives in their pandemic vaccine strategy. The clearer picture of the groups at risk for serious infections was ranked as the most significant factor in eight of the ten who reported that this influenced their decision. The clearer picture of the degree of transmission, clearer picture of the hospitalisation rate, and the clearer picture of the fatality rate were the second most significant factors. The three were fairly similar in total numbers and to a lesser degree in terms of rankings therefore justifying second place for all three.

In summary, nearly two thirds of the respondents (18 of 29) did NOT change their health care goals/objectives in their pandemic vaccination strategies, even after the characteristics of the H1N1 pandemic became more apparent. This was attributed, by the majority of them (12 of 18), to the fact that there was little or inconclusive evidence which justified making such changes.

On the other hand, 11 countries did alter their health care goals/objectives in their pandemic vaccination strategies. The majority of changes were made in the goals/objectives regarding protecting vulnerable/at risk groups and maintaining health care services. The major reasons for making such changes were attributed to the fact that a clearer picture appeared regarding the groups at risk for serious infections, the degree of transmission, the hospitalisation rate, and the fatality rate.

5.5.2 Reported vaccination goal shortfalls

On 7 July 2009, SAGE discussed issues relating to vaccines and made a statement on target and priority groups.³¹ The statement highlighted that some groups of the population appeared to be at increased risk for severe disease and death from infection. The statement included a recommendation that a step-wise approach to vaccinating particular groups be considered.

In August 2009 the HSC and EWRS committees issued a statement on Influenza A (H1N1) 2009 target and priority groups for vaccination.³² The priority groups identified were indicative and countries were advised that they may wish to adapt the prioritisation in line with their epidemiology, health service provision and resources.

25. Did your country reach its vaccination coverage goals/expectations for its risk and other target groups? (22 respondents)

Yes

No

If yes, what were in your opinion the key elements that contributed to reaching your country's vaccination coverage goals/expectations?

Only four of 26 respondents felt that they reached their vaccination coverage goals for their risk and other target groups; that is, 22 reported that they had experienced shortfalls or difficulties. Four countries were unable to answer this question because two “did not have coverage set” and two “did not order vaccines or they were unavailable.”

According to the four countries that stated that they had successfully met their vaccination coverage goals, the reasons included: universal vaccination, free vaccination, good annual influenza uptake, positive public attitudes towards authorities and vaccination, severity of first cases, early access to vaccine, joint key messages from authorities, and transparency in the process.

³¹ WHO recommendations on pandemic (H1N1) 2009 vaccines

³² HSC/EWRS Statement on Influenza A(H1N1) 2009: target and priority groups for vaccination

Table 6: Key comments from those countries stating that they successfully fulfilled their vaccination goals

<ul style="list-style-type: none">• <i>Broad consensus of strategy on local, regional, and national level</i>• <i>Early access to vaccine</i>• <i>Joint key messages from authorities</i>• <i>Transparency in process</i>• <i>Public's positive attitudes towards authorities and vaccinations</i>• <i>Vaccine free of charge</i>
<ul style="list-style-type: none">• <i>well maintained seasonal influenza vaccination</i>• <i>development in pandemic some fatal cases just before start campaign</i>• <i>high general trust in government pandemic measures</i>
<p><i>"Public perception of the severity of the disease (first case of death). Traditionally good vaccine coverage and public acceptance for vaccines included in the national vaccination programme."</i></p>
<p><i>"The entire population was offered vaccine. We did not have any definite coverage goals."</i></p>

26. If no (did not reach vaccination coverage goals/expectations), for which risk and other target groups did you fall short? Please rank if several answers apply. (20 respondents)

- Persons with underlying chronic diseases**
- Pregnant women**
- Young children**
- Elderly**
- Healthcare workers**
- Other essential workers**
- Other, please specify ...**

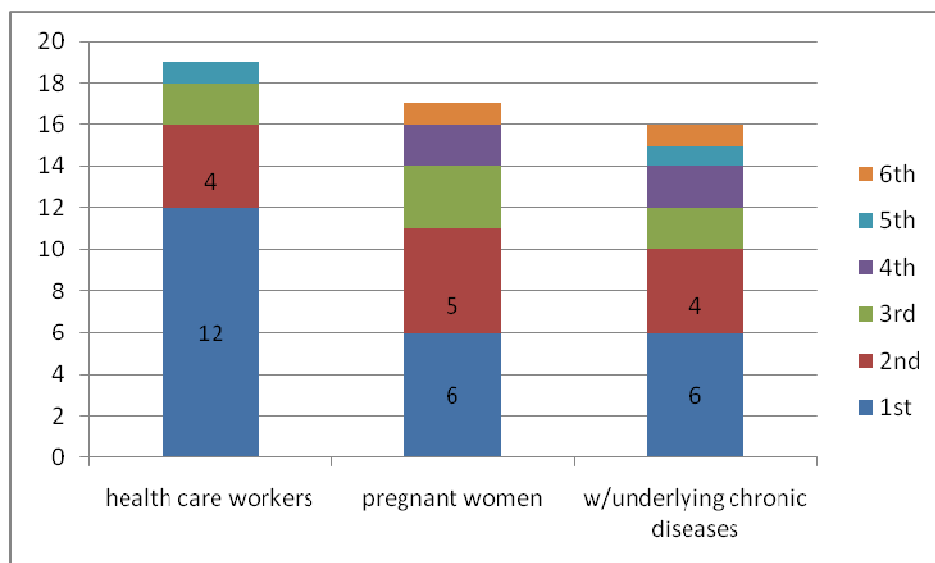


Figure 17: Risk or target groups that fell short in national vaccination coverage goals (20 respondents)

Nearly all (19) of the 20 respondents stated that they had fallen short of their national vaccination goals for health care workers, of which 12 ranked this first. Furthermore, 18 countries reported that they had been unable to meet their coverage goals for pregnant women, and 17 for persons with underlying chronic diseases.

27. What were the reasons? Please rank if several answers apply. (21 respondents)

- Insufficient vaccine supply
- Limited interest/scepticism in population
- Limited interest/scepticism in healthcare workers
- Healthcare workers having difficulties to cope with multi-dose vials
- Concerns over the safety of using pandemic influenza vaccines in groups where limited clinical data were available (e.g. young children, pregnant women)
- Anti-vaccination views
- Lack of communication on vaccination issues
- Moderate character of the pandemic
- Other, please specify ...

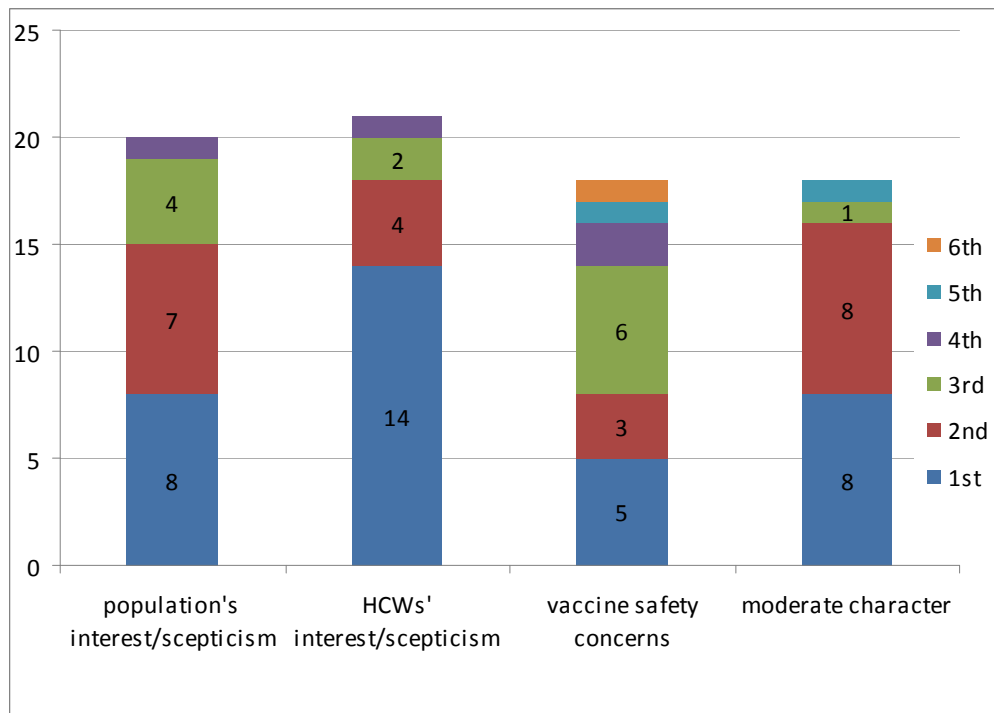


Figure 18: Reported reasons for difficulties in reaching coverage goals (21 respondents)

All of the 21 respondents who reported difficulties in achieving their vaccination coverage goals attributed this to scepticism and/or limited interest on behalf of the health care workers. They ranked this differently, but the majority clustered in the first and second rankings: of the 21 respondents, 20 attributed this difficulty to scepticism and/or limited interest among the general population, of which eight ranked it first. The moderate character of the pandemic also contributed to the lower uptake in coverage groups (18, of which eight ranked this first). Other contributing factors were the concerns over the safety of the pandemic influenza vaccines (18 of which five ranked this first, three second and six third).

It is important to point out that it is obvious from the totals for the first and second rankings that a few respondents ranked more than just one factor for these rankings. For example, the total of first rankings (35) and second rankings (22) exceed the total of number of respondents (21).

In summary, the majority of respondents reported vaccination goal shortfalls with 22 reported experiencing difficulties. Only four of 26 respondents felt that they had reached their goals for their risk and target groups. The explanations for success were quite similar in all four cases. These reasons were mentioned by at least three of the four: universal vaccination, free vaccination, good annual influenza uptake, positive public attitudes towards authorities and vaccination, and the severity of first known cases. Other reasons that were mentioned

included early access to vaccine, joint key messages from authorities, and transparency in the process.

Nearly all of the respondents reporting difficulties in meeting their national vaccination goals felt to varying degrees that they had failed to properly target health care workers. Furthermore, coverage goals for pregnant women and persons with underlying chronic diseases were reportedly low. The main reasons for these shortfalls were attributed to scepticism and/or limited interest on behalf of the health care workers and the general population. Other significant factors included the moderate character of the pandemic and the safety concerns of the H1N1 influenza vaccines.

5.6 Vaccine Safety and Efficacy

Pandemic vaccine manufacturers are required to collect information on the safety and effectiveness of the vaccine while it is being used. This includes information on its side effects and its safety in children, the elderly, pregnant women, patients with severe conditions and people who have problems with their immune systems. All Member States have a legal obligation³³ to report safety data for the authorised pandemic vaccines and enter that information into EudraVigilance.³⁴ A weekly report is generated from this database which is sent to all National Medicines Competent Authorities.

In addition, the EMA conducts a weekly evaluation of the data and the PREG considers any relevant information from this. A weekly safety report is published on the EMA website. The WHO acknowledges that new technologies are involved in the production of some pandemic vaccines and supports the importance of the highest possible quality of post-marketing surveillance to allow countries to adapt vaccination policies as appropriate.³⁵

39. Through which source(s) did you get information on the safety and efficacy of the centrally authorised pandemic H1N1 influenza vaccines? Please rank if several answers apply. (24 respondents)

EMA

National medicines agency/authority

³³ The reporting obligations of the various stakeholders are defined in the Community legislation, in particular Regulation (EC) No 726/2004, Directive 2001/83/EC as amended and Directive 2001/20/EC.

³⁴ EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).

³⁵ WHO recommendations on pandemic (H1N1) 2009 vaccines.

- ECDC
- HSC meetings
- WHO HQ
- WHO EURO
- Pharmaceutical industry
- Other, please specify ...

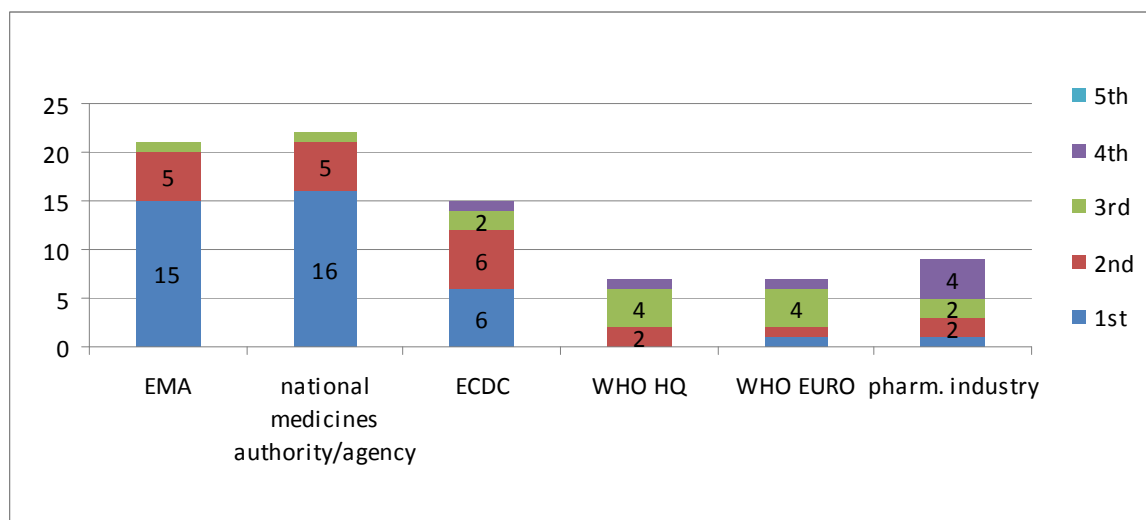


Figure 19: Sources of information on the safety and efficacy of centrally authorised H1N1 vaccines (24 respondents)

Both EMA and the national medicines agencies/authority ranked similarly as significant sources of safety and efficacy information. Of the total 24 respondents, 21 selected EMA as a significant information source: 15 ranked EMA first and five ranked EMA second. Likewise, 22 countries indicated that their national medicines agencies/authorities were significant information sources, of which 16 ranked it as their primary source and five as a secondary source. ECDC was also among the top three sources with 15 responses, although it was ranked lower.

It is also worth noting that the respondents were also given the choices “WHO HQ” (eight ranked this choice) and “WHO EURO” (nine ranking this choice). One country specifically indicated that it checked both since it wanted to select simply “WHO”. Unfortunately, due to the difficulties in tracking down all of the specific combination of answers, we were unable to identify if there were other similar cases. Nine respondents selected the pharmaceutical industry as a source for H1N1 vaccine safety and efficacy information, yet most of these ranked it lower.

40. How could information on the safety and efficacy of centrally authorised pandemic influenza vaccines be improved in a future pandemic? (13 respondents)

Table 7: Suggestions for improving safety and efficacy information on centrally authorised influenza vaccines	
Actual suggestions and comments	# of respondents agreeing
<i>No improvements needed, worked well, implemented measures appropriate</i>	6
<i>Concrete recommendations stated clearly and simply</i>	3
<i>Provide useful information earlier</i>	2
<i>Early/concrete information provided directly from EMA [to public health authorities]</i>	3
<i>One overarching body giving recommendations</i>	1
<i>Timeline for when further information will be available/distributed</i>	1
<i>Publicly accessible database on suspected adverse effects</i>	1
<i>Try to minimise discrepancies between the European countries regarding safety and efficacy information</i>	1

This question was answered by 13 respondents and of these six stated that safety and efficacy information on centrally authorised influenza vaccine worked well and appropriate measures were implemented when needed. Three respondents requested that recommendations be stated more clearly and simply.

Receiving concrete information early was also considered useful and desirable, but one country admitted that useful information will probably be unavailable in the first stages of the next pandemic. Another country raised the issue that discrepancies between the countries using the pandemic vaccines were difficult to communicate to the public. (See also the section on Communications Analysis in this report.)

41. Please supply a wish-list of what you want regarding post marketing surveillance information from EMA and identify which forum should receive this information. (13 respondents)

Table 8: Wish-list³⁶ for post-marketing surveillance information from EMA	
<i>Actual comments</i>	<i># of respondents agreeing</i>
<i>No improvements needed, information was sufficient and adequate, procedures are well established, and/or should continue as they currently are</i>	4
<i>Regular pharmacovigilance reports, recently published scientific studies</i>	6

Of the 13 responding countries, four felt that post-marketing surveillance information was sufficient and adequate, that procedures were well established, and that changes are not needed. The need for more current and relevant reports on vaccines safety, vaccine effectiveness, unusual cases, and updates was expressed. One country thought that post-marketing surveillance information from EMA should be first distributed to the experts before it is made available for the public. Another country stressed the importance of early warning procedures for MS regarding safety problems. Another country suggested that certain results be published rapidly and passed on to national agencies or bodies.

Table 9: Proposed forum for receiving post-marketing surveillance information from EMA³⁷	
<i>Actual comments</i>	<i># of respondents agreeing</i>
<i>National authorities (Ministries of Health, medicine agencies, public health authorities)</i>	4
<i>ECDC, WHO</i>	1
<i>On-line web site (like VAERS in USA)</i>	1
<i>EWSR</i>	1

Since this was an open-ended question, the countries had to provide their own answers. It was attached to the end of another question, which may explain why there are so few

³⁶ This table summarises the data from the first part of question 41

³⁷ This table summarises the data from the second part of question 41

responses. Eight individual countries provided suggestions for a forum for receiving post-market surveillance information from EMA. The most frequent reply provided for this question was that the national health/medicines authorities should receive post-marketing surveillance information from EMA.

42. If there were a serious safety and/or efficacy issue with a centrally authorised pandemic influenza vaccine, what would influence your public health response? Please rank if several answers apply. (24 respondents)

- CHMP opinion by EMA
- Commission Decision to suspend, revoke, withdraw or vary the marketing authorisation of a pandemic influenza vaccine
- Advice by national medicines agency/authority
- ECDC guidance
- HSC meetings
- WHO HQ
- WHO EURO
- Pharmaceutical industry
- Other, please specify ...

Both a table (Table 10) and a bar graph (Figure 20) are provided for the responses collected for strategic question 42. The responses are a bit more complex to analyse if one simply looks at the bar graph alone since the last five categories to the right (ECDC, WHO HQ, WHO EURO, pharmaceutical industry) appear to be quite similar.

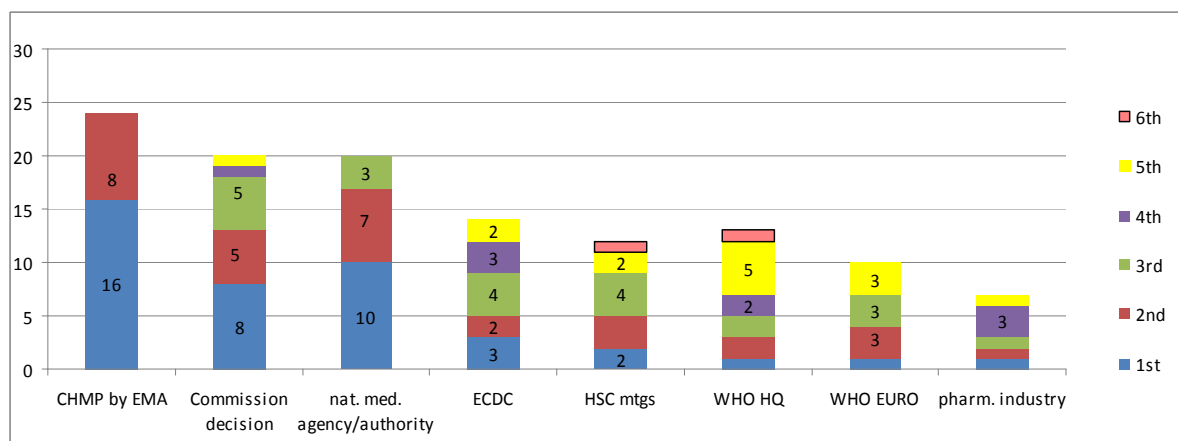


Figure 20: Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorized pandemic vaccine (24 respondents)

If the same data is put into a table format we begin to see more clearly the fine distinctions in the last five categories: ECDC, HSC meetings, WHO HQ, WHO EURO, and pharmaceutical industry.

Table 10: Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorised pandemic vaccine

	CHMP by EMA	Commission decision	nat. med. agency/authority	ECDC	HSC mtgs	WHO HQ	WHO EURO	pharm. industry
Ranked first	16	8	10	3	2	1	1	1
Ranked second	8	5	7	2	3	2	3	1
Ranked third	0	5	3	4	4	2	3	1
Ranked fourth	0	1	0	3	0	2	0	3
Ranked fifth	0	1	0	2	2	5	3	1
Ranked sixth	0	0	0	0	1	1	0	0
Total rankings	24	20	20	14	12	13	10	7

The rankings displayed in Table 10 appear to cluster into four groups. The first group (highlighted in pink) includes the first three choices: CHMP opinion by EMA, Commission Decision to suspend, revoke, withdraw or vary the marketing authorisation of a pandemic influenza vaccine, and advice by national medicines agency/authority. These three were chosen most often and received higher rankings and few, if any, low rankings. The second group (in yellow) appears to be ECDC since with its rankings are significant and received a fair number of rankings (although fewer than the first three groups). The third group (in green) includes HSC meetings, WHO HQ and WHO EURO. The last group (in blue), which appears to have been ranked least significant and received the fewest number of rankings, is the pharmaceutical industry.

In order to test the assumptions we made for the data from strategic question 42, we decided to apply a weighted preference method; each ranking corresponds to a proportionate number of points. For example, each first ranking is worth six points, each second ranking is worth five points, each third ranking is worth four points, and so on. The results of this application are presented in Table 11.

Table 11: Application of weighted preference method - Influences on public response in the event of a serious safety/efficacy issue regarding a centrally authorised pandemic vaccine

		CHMP by EMA	Commission decision	nat. med. agency/ authority	ECDC	HSC mtgs	WHO HQ	WHO EURO	pharm. industry
Ranked first	X6	16 X 6 = 96	8 X 6 = 48	10 X 6 = 60	3 X 6 = 18	2 X 6 = 12	1 X 6 = 6	1 X 6 = 6	1 X 6 = 6
Ranked second	X5	8 X 5 = 40	5 X 5 = 25	7 X 5 = 35	2 X 5 = 10	3 X 5 = 15	2 X 5 = 10	3 X 5 = 15	1 X 5 = 5
Ranked third	X4	0	5 X 4 = 20	3 X 4 = 12	4 X 4 = 16	4 X 4 = 16	2 X 4 = 8	3 X 4 = 12	1 X 4 = 4
Ranked fourth	X3	0	1 X 3 = 3	0	3 X 3 = 9	0	2 X 3 = 6	0	3 X 3 = 9
Ranked fifth	X2	0	1 X 2 = 2	0	2 X 2 = 4	2 X 2 = 4	5 X 2 = 10	3 X 2 = 6	1 X 2 = 2
Ranked sixth	X1	0	0	0	0	1 X 1 = 1	1 X 1 = 1	0	0
Total rankings		136	98	107	57	48	41	39	26

Unfortunately we were not able to process this data using the on-line website because 1) it included non-applicable responses in its calculations; 2) it could not process and add choices from the free text responses into its calculations; and 3) it did not take into consideration that a few respondents selected several choices as their individual rankings (e.g., ranked three choices as their first ranking, two for their second, and did not rank anything as third, fourth or fifth).

Application of the weighted preference method suggests that our previous assumptions were more or less valid. Table 11 emphasises perhaps more clearly now that a CHMP opinion by the EMA (highlighted in pink) is by far the most significant factor reported by the respondents that would influence their public health response in the event of a safety and/or efficacy issue with a centrally authorised pandemic vaccine. A decision by the Commission to suspend, withdraw or vary the marketing authorisation of a pandemic influenza vaccine and advice from their respective national medicines agency/authority (both highlighted in pink) also influence significantly. The second (in yellow) and third (in green) groups cluster in a similar pattern as they did in Table 10. The last group (in blue) illustrates more dramatically the fact that the pharmaceutical industry is regarded as the least significant influence for the countries when dealing with the public's response to vaccine safety and efficacy issues.

In summary, both the EMA and national medicines agencies/authority were reported as the most significant sources of safety and efficacy information as well as substantial influences (together with a Commission Decision to suspend, withdraw, or vary the marketing authorisation) for countries' public responses on vaccine safety and efficacy issues. On the other hand, very few countries considered the pharmaceutical industry as a significant influence in either of these areas.

When asked to provide suggestions for improving information on the safety and efficacy of centrally authorised pandemic influenza vaccines, a number of countries made the effort to include positive experiences in their responses emphasising that the current procedures worked well and were adequate. Under usual circumstances, once the CHMP has given a positive recommendation of a vaccine to the European Commission, it can take 60 to 90 days for the EC to authorise it. During the H1N1 pandemic it took only 48 hours to centrally authorise three vaccines. Only two MS nationally produced and nationally authorised H1N1 vaccines.

Some of the areas mentioned for improvement were the timing and clarity of recommendations. A few claimed that information is needed early but they also understood that useful disease information will probably be unavailable, even in the first stages of the next pandemic.

The discrepancies between the European countries regarding safety and efficacy information proved to be problematic, especially when communicating with the public. (See also the communications analyses later in this report.) For example, it was difficult to explain why one country considered vaccinating very young children dangerous and another country actually encouraged vaccinating them.

Post-marketing surveillance information was considered sufficient and adequate, with well established procedures. It is important, however, to point out here that there were few, if any, major AEFI (adverse event following immunisation) reported, so the system of investigating and responding to an AEFI was essentially untested. Yet there still appears to be a need for more relevant information and current facts on, in particular, the safety and effectiveness of vaccines.

5.7 Vaccine Administration

37. How were changes in recommendations on product use communicated to health care professionals and how successful were these? (22 respondents)

Of the 22 respondents, 15 countries explicitly mentioned that they used the internet in some form (e.g., emails, websites, e-newsletters) and/or new social media (e.g., text messages) in conveying changes in recommendations on product use to health care professionals. The other more frequent methods used included standard operating procedures, documents via administrative channels and traditional information sources. The media was used reportedly less than we had expected since it is perhaps not considered the most professional or appropriate forum to distribute medical information to health care professionals. Six of 22 respondents stated using press conferences or releases for spreading information to health care professionals on product changes. Forums such as conferences, workshops, meetings and training sessions were not often used to convey changes in product use to health care professionals.

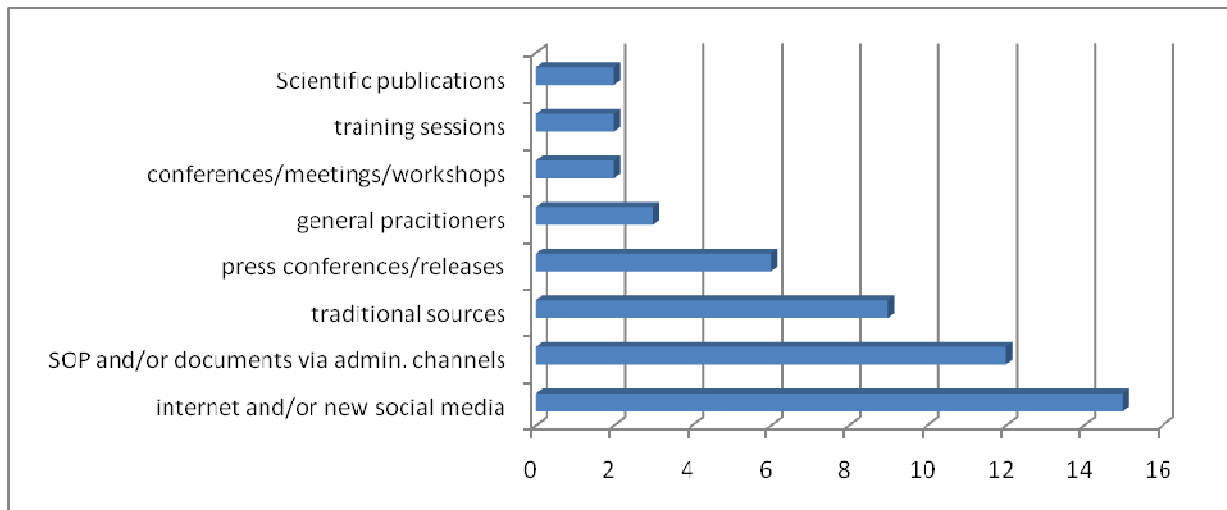


Figure 21: How were changes in recommendations on product use communicated to health care professionals (22 respondents)

Some of the difficulties mentioned by the respondents included:

“Several training sessions delivered by DG SANCO and other health care services throughout the country, however the adherence of the professionals was low”

“Because no direct information channels existed between national authorities and general practitioners, it was difficult to communicate in a timely and understandable manner the changes in the recommendations.”

On the other hand, one country expressed a more positive experience:

“We used the following means of communication: website, press conference, poster, local meetings of GPs organised by the chief medical officers (regional, subregional), organisation of conference on pandemic influenza vaccination, direct letter to GPs, and to health care services.

We do not perform formal evaluation, but during this communication period (from November to the end of December) the vaccine coverage doubled in the general population to an estimated 30%, which reflects the effectiveness of our communication campaign.”

In total seven countries stated that they felt that communication in this area worked well.

38. Did patients who received pandemic vaccine in your country receive a patient leaflet in appropriate language, if not, how was this information communicated? (26 respondents)

Only three of the 26 respondents reported that they did NOT provide information leaflets to the patients who received a H1N1 vaccine, but information was provided orally via the health care provider administering the vaccine. Two replies were very ambiguous and difficult to categorise.

“Who gets shot has received information on vaccine based on the available knowledges [sic].”

“All health care professionals were delivered all information to be able to deal directly with the patients.”

Both of these ambiguous replies suggest that information was provided to patients but perhaps not in the form of a leaflet.

Of the 26 respondents, 19 countries reported providing information leaflets to patients receiving the H1N1 vaccine, of which 6 explicitly reported that information was also provided in minority/local/appropriate languages. One country wrote that the health care workers were also informed of the fact that leaflets in other European languages were

available on the EMA website. Another country reported that translation services were made available.

In summary, three quarters of the responding countries explicitly mentioned that they used the internet in some form (e.g., emails, websites, e-newsletters) and/or new social media (e.g., text messages). Roughly half of the respondents used standard operating procedures, documents via administrative channels, and/or traditional information sources to convey product changes. The media was reportedly used less than we expected perhaps since it is not the ideal forum for distributing detailed medical information. Six of 22 respondents stated using press conferences or releases for spreading information to health care professionals on product changes. Forums such as conferences, workshops, meetings and training sessions were not often used to convey changes in product use to health care professionals.

When asked if patients being administered the H1N1 vaccine received information leaflets in the appropriate language, nearly all of the respondents said yes. Only three of the 26 respondents reported that they did NOT provide information leaflets to the patients who received a H1N1 vaccine, but that information was provided orally via the health care provider administering the vaccine. Nearly one third of the countries affirmed that they provided information in minority/local/appropriate languages.

5.8 Research Capacity

All pandemic vaccine manufacturers are required to collect information on the safety and effectiveness of the vaccine while it is being used. This includes information on its effectiveness, side effects and its safety in children, the elderly, pregnant women, patients with severe conditions and people who have problems with their immune systems.

Many MS have been carrying out reviews and research programmes into pandemic influenza vaccine use and effect as a support to pharmacovigilance, which is focused at the EU level in the EMA. The wide interest in this research area is in part due to the unprecedented speed at which the vaccine manufacture technology was driven and the procedures which ensured swift authorisation.

Enthusiasm to publish vaccine research findings may prove a conflict of interest between identification of data for scientific publication use and that required for public health.

45. Is there a need for public clinical research capacity (US NIH-like) in the EU (for example to carry out comparative effectiveness studies)? (26 respondents)

Yes

No

Of 26 respondents, 23 supported a need for public clinical research capacity (e.g., carry out comparative effectiveness studies) in the EU.

46. If yes, how should this capacity be coordinated? (21 respondents)

Public consortium, coordinating a network of clinical trial centres in various Member States

Existing EU Agency, coordinating a network of clinical trial centres in various Member States. Please specify which Agency...

Public/private partnership

Other, please specify ...

Of 21 countries that answered this question, 17 indicated this capacity should be coordinated by an existing EU agency (of which six specified ECDC, and six EMA). Nine chose “public consortium, coordinating a network of clinical trial centres in various Member States” and only three indicated that this could be a task for private-public partnership(s). One country specifically stressed that the most important issue regarding such research is maintaining objectivity and independence from the pharmaceutical industry. Note that the total response count (17+6+3=26) is higher than the total number of respondents (21). When this was cross checked, it was revealed that a few respondents were able to choose more than one answer.

In summary, the majority of countries supported a need for public clinical research capacity (e.g., to carry out comparative effectiveness studies) in the EU. On the one hand it was indicated that this capacity should be coordinated by an existing EU agency, or on the other hand by a network of clinical trial centres in various MS. Private-public partnerships do not seem to be a popular option here. Concern was also expressed over the importance of maintaining objectivity and independence from the pharmaceutical industry.

6 Communications Analysis

6.1 The EPVS Survey

The EPVS Survey included eight strategic questions on a variety of communication issues including a specific focus on how vaccine communications were conducted. The forthcoming section considers the responses to each of the communication questions in turn.

28. Have you elaborated and implemented a specific communication strategy on vaccination or was it part of a global communication strategy on the influenza H1N1 pandemic? Please describe. (25 respondents)

Of the 25 respondents, 12 stated that their communications concerning the vaccine formed part of their '*global communications strategy*' or did not specify a specialised vaccination strategy. One country stated that their country '*didn't have the vaccine*' therefore suggesting their global communication campaign would not have covered the topic.

The remaining 12 countries all confirmed that they developed specific vaccination communication strategies. However, the findings did not give any indication as to whether or not those countries who did implement a specialised vaccination communication campaign achieved better vaccine uptake.

Two countries in particular provided interesting reasons as to how and why their vaccine communications developed:-

The first country described its vaccination communication campaign as part of a series of staged and procedural campaigns. As the H1N1 pandemic advanced through its different stages:

We 'launched an information campaign with three distinct information blocks, first sensitise the public to a possible H1N1 pandemic, secondly inform about the protective measures (hygiene measures etc) and from the end of October onwards.... the third campaign block focused only on [the] vaccination'.

The second country's vaccination communications campaign was in reaction to a surprise '*anti-vaccination campaign and scepticism among some of the health care workers*'. The campaign was developed with assistance from scientific and medical

experts and targeted health care workers and the general population with vaccination communication messages.

29. How did your country develop its communication strategy on pandemic vaccination during this pandemic? (27 respondents)

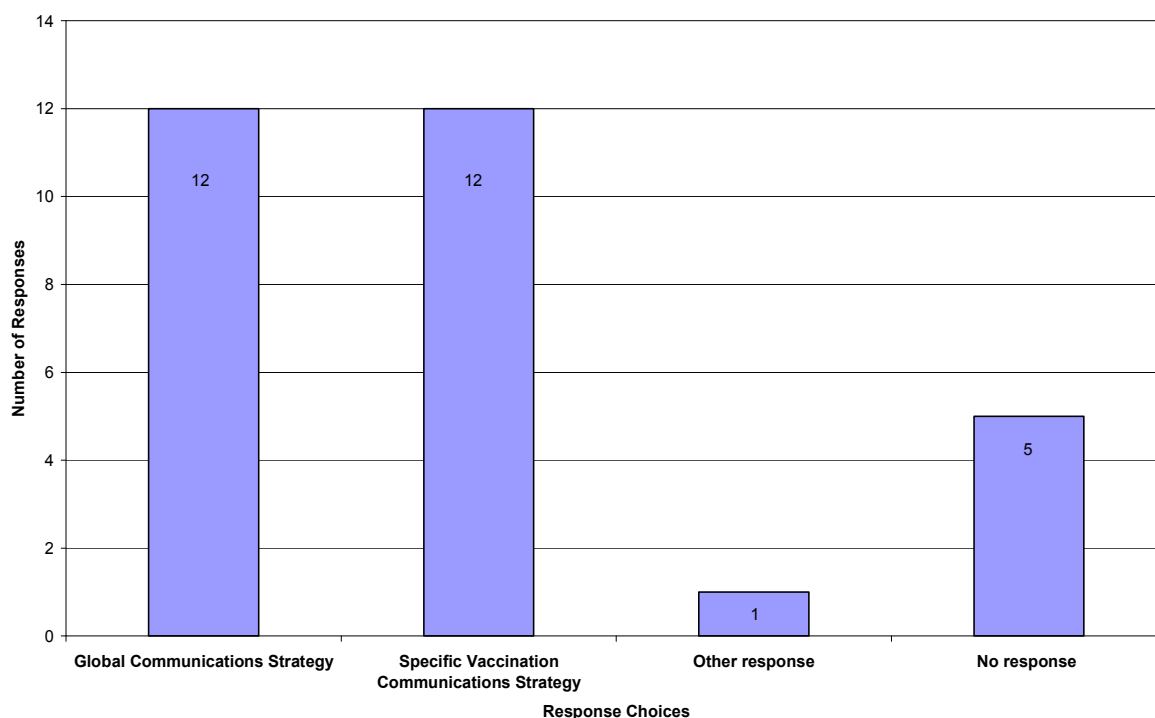


Figure 22: Specific communication strategies vs global communication strategies on the influenza H1N1 pandemic (27 respondents)

Of the 27 respondents, 18 felt that they depended upon their *'in-house'* departments and ministries to assist with the development of their communication campaigns, such as Ministries of Health, Directorates of Health and Departments of Health. Eight countries confirmed that they received some support from specialised communications companies. One country reiterated that it did not use the vaccine and therefore did not conduct any vaccine communications.

In isolation these findings appear to indicate a preference for using in-house communications resources. However, these findings coupled with the responses to question 30, highlight a potential change in future attitudes.

30. How would your country develop strategies on pandemic vaccination during future pandemics? (27 respondents)

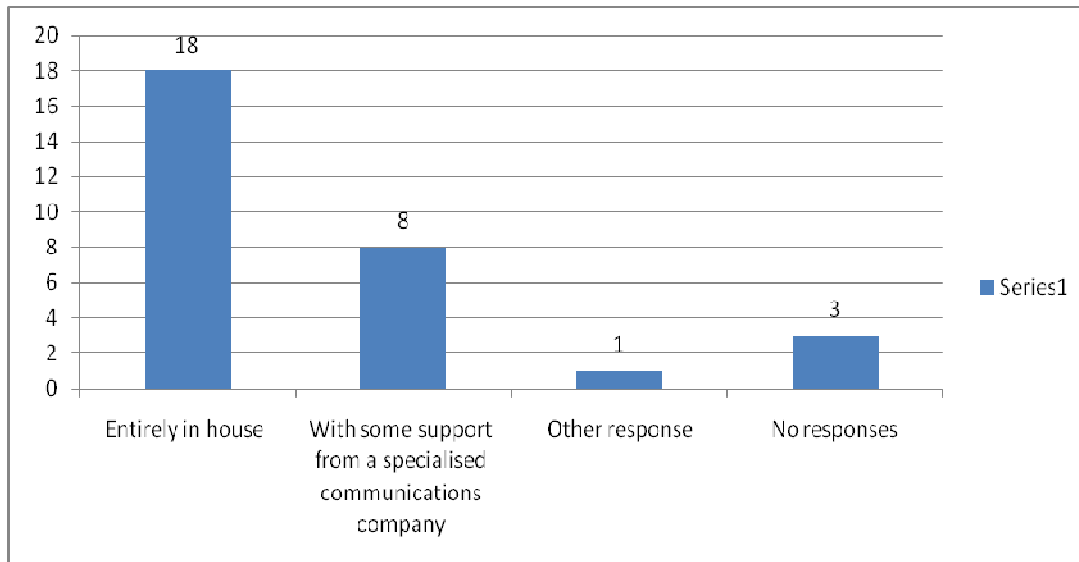


Figure 23: Ways in which communication strategy on pandemic vaccination were developed during the H1N1 pandemic (27 respondents)

Of the 27 respondents, 18 stated they would continue to use an 'in-house' strategy to deal with any future pandemics and 8 explained they would seek support from specialised communications companies in the future.

This is interesting in comparison to the response to question 29. The increased potential trend towards external communication firms could lead one to speculate that some countries feel that they would benefit from more external support to enhance their in-house communication efforts. Other reasons for entirely in-house information campaigns may also be attributed to the fact that there is no internal structure in place to deal with such campaigns since in most countries there is only one or two person(s) in charge of communications.

31. Can you give examples(s) of successful communication on pandemic vaccination during the pandemic in your country? (27 respondents)

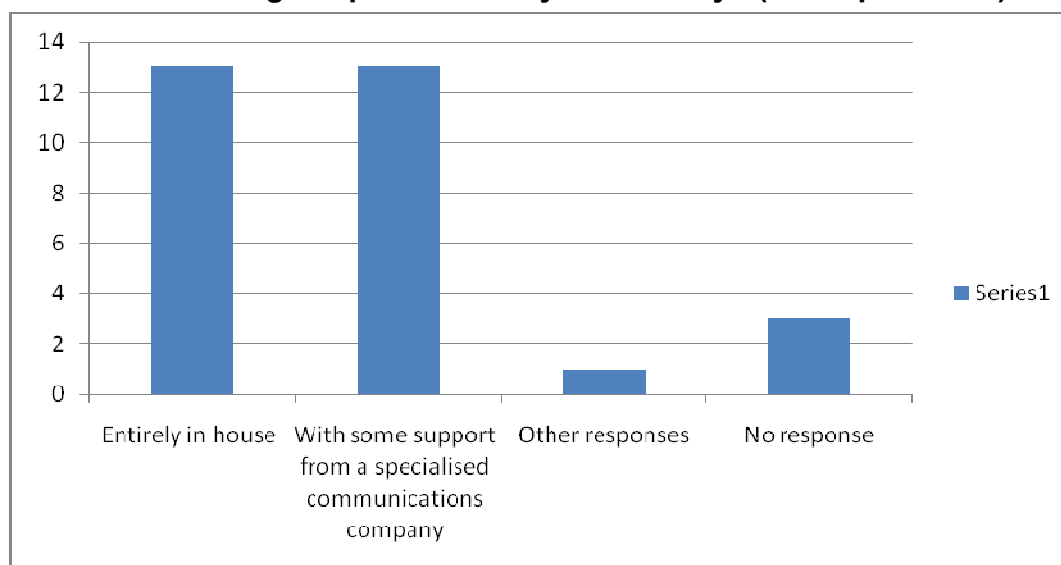


Figure 24: Ways in which strategies on pandemic vaccination during future pandemics would be developed (27 respondents)

Table 12: Key comments and examples of successful pandemic vaccination communication campaigns
<i>'Our communication towards pregnant women and small children was a success ... [it] improved our... collaboration with [other] stakeholders'</i>
<i>'We focused upon three key messages 'Protect yourself, protect others, stop the spread'</i>
<i>'We set-up a call centre for health professionals – for easily available advice... [and]... we 'debated with vaccine opponents'</i>
<i>'We 'distributed H1N1 reference books for journalists' and guidelines for business continuity measures'</i>
<i>[We sent] 'sms messages to the general public with specific information on the pandemic'</i>
<i>'We set up workshops for health professionals involved in the vaccination drive'</i>
<i>'Bannering campaign: cheap and very effective. Banner pointed towards dedicated part of our website. All public authorities (ministries, agencies, local, etc) and many stakeholders and partners put the banner on their website'</i>
<i>'Involvement of key experts in infectious diseases helped to streamline the messages'</i>
Two countries cited the use of local radio as being particularly useful

Of the 27 respondents, 23 cited various examples of what they believed to be successful communications. The above quotes illustrated that each country attempted to deal with the H1N1 pandemic in a holistic manner by considering all of the social as well as medical ramifications of the pandemic.

From the quotes above one can ascertain that countries recognised the need to:

- Target specific groups such as pregnant women;
- Take proactive steps to inform the media about the pandemic;
- Involve key experts to ensure accurate and streamlined messages;
- Use modern communication methods such as text messaging;
- Use interactive methods such as workshops in order to build confidence in the H1N1 vaccine amongst healthcare workers; and
- Tackle any vaccination fears and or criticisms ‘head on’ through an open debate.

32. Can you give examples(s) of difficulties or failures in communication on pandemic vaccination during the pandemic in your country? (22 respondents)

Only one country stated that they did not experience any communication difficulties or failures. Some of the most interesting comments to the above question are set out below.

Table 13: Key comments and examples of difficulties or failures in pandemic vaccination communication campaigns
<i>‘Better cooperation with other NGOs (e.g. health care professional representatives). Moreover, internet should have been used in a more efficient way’</i>
<i>‘[Difficulties] in persuading certain groups that the vaccine was an effective protection against a real risk - for example, parents of young children who might generally have concerns about vaccine safety. We made considerable efforts to address this with very targeted PR activity in the consumer media and web forums for example’</i>
<i>‘We had difficulties convincing young people to get vaccinated. Generally they are a group that are hard to reach with health messages. Our usual way of communicating with the public is not adapted to young people. We didn’t have enough knowledge or the strategies for communicating with young people’</i>
<i>‘We failed in convincing healthcare professionals of importance and necessity of pandemic vaccination of selected groups which resulted in limited interest in population to get vaccinated’</i>

'In the beginning, health care workers underestimated the risk of severe disease both for the general population and for the health care workers. Finally the anti-vaccination campaign was more extensive and better organised than it was expected'

'Sceptical healthcare workers especially a few doctors (community GPs and hospital consultants) who instilled doubt in their patients'

'The main failure in communication on pandemic vaccination was that the vaccines delivery administration was started too late in our country'

'Due to the long process for the vaccines to be allowed to be used in [x country], the regular communication was temporarily stopped just before the vaccination campaign started (we had to wait for the market authorisation while in other countries vaccination had already started)'

'Although medical staff and GPs belonged to priority groups for vaccination and communication towards them was set up to point out the importance of vaccination, some of them openly opposed to it. The impact of one negative opinion from a person with a medical background in the media can do a lot of damage to the official communication. A lot of time and energy was spent in reacting to anti-vaccination lobbies' messages via, for instance, mail, callcenter'

From the above comments it is clear that a number of countries found it challenging to communicate with new population groups who would not usually be the target of influenza vaccination campaigns such as young parents and pregnant mothers. It was apparent that some countries used specialised communication methods to target specific groups, while others used global communications strategies. One country highlighted an instance when the media reported a story at the start of its vaccine campaign alleging that a man had died shortly after receiving the vaccine. It was believed that this story impacted upon the up-take of the vaccine in that particular country.

Both of the above issues should be taken into consideration and developed in future communication guidelines.

Two countries reported a disconnect between their communications campaign and the availability of the vaccine:-

One country explained that the communications campaign was effective however; administration of the vaccine was started too late.

The second country explained regular communications with regard to the vaccine were temporarily halted until the vaccine was authorised for use. The media interpreted this lack of information as being related to safety issues and concerns about the vaccine.

This example demonstrates the importance of close linkage between the communication campaign and the authorisation, logistics and delivery efforts.

Five commented on the difficulties they experienced specifically with regard to convincing sceptical health care workers:

- Of the potential severity of the H1N1 pandemic;
- Of the necessity of the vaccine;
- To be vaccinated themselves; and
- To lend their support to the vaccination campaigns.

All five countries alluded to the fact that the absence of positive endorsements from health care workers resulted in a *'limited interest in [the general] population to get vaccinated [since]... [the] general public is extremely influenced by healthcare workers'*.

When European authorities prepare future pandemic plans, securing support from health care workers must be prioritised alongside pre-empting and countering any vaccine scepticism.

33. New communication tools (e.g. use of social media (Facebook, Twitter, others ...), YouTube, podcast, others... Did your country make use of these tools for its communication on the pandemic vaccinations? (26 respondents)

Of the 26 respondents, only six countries reported using new communication tools such as Facebook, Twitter, YouTube and other such social media vehicles.

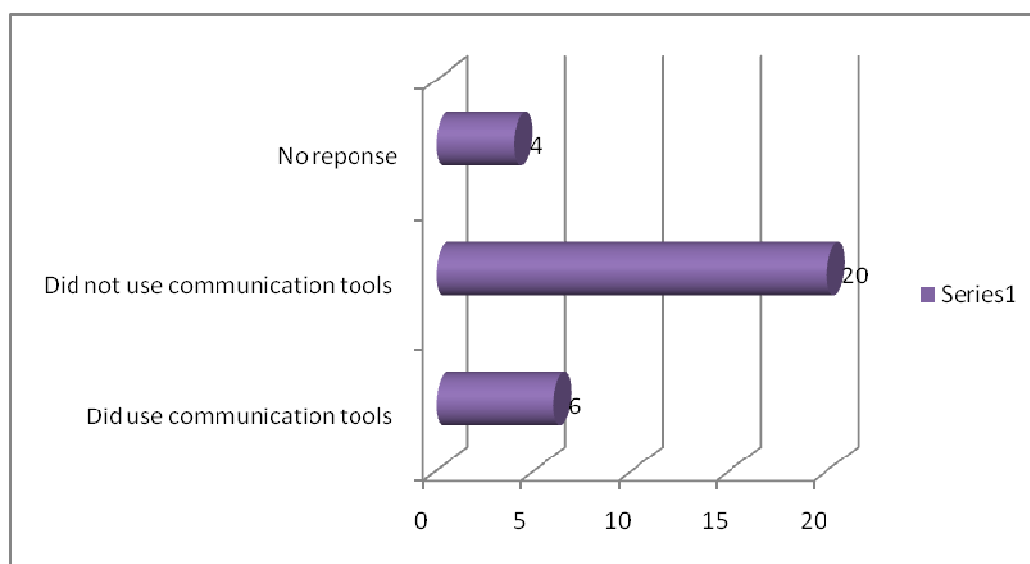


Figure 25: Use of communication tools for the pandemic vaccination campaigns (26 respondents)

34. Which positive or negative experiences are you able to share on the use of these (communication) tools? (four respondents)

Only four countries responded to the above question. Three countries commented that they welcomed the use of new media; however, the comments below highlight that not all of them were convinced that the use of new media made a significant impact upon the target audiences.

Table 14: Key comments on positive and negative experiences on the use of communication tools
<i>'The positive experience was that we dared try something we hadn't done before. We got positive reactions from the media and other stakeholders. The not so positive experience is that we did not achieve a great effect, meaning that we did not by using social media manage to reach the young people with the message or convince them to get vaccinated'</i>
<i>'On the whole, we felt our use of social media was successful. You are, in effect, engaging openly with the public and have to accept there will be challenges and people spreading inaccurate information which needs to be rebutted but we always felt we had a strong story to tell. In the event of another pandemic, we would have stepped up our online activity even earlier and would reasonably expect these media to be even more significant in a future event'</i>
<i>'New tools that were introduced during pandemic influenza: • Free-of-charge phone service concerning pandemic influenza and vaccination operated by trained health personnel • Free blog • Facebook • Twitter • RSS • New website dedicated completely to pandemic influenza. Basically the use of new communication tools was not a negative experience. The young age groups extensively used these sources of information. However, some people are unfamiliar with the use of such tools which might cause difficulties in sharing information. That's why the new tools cannot substitute, but rather complement the traditional means of communication. It needs special expertise and additional human resources to enhance the use of these activities'</i>
<i>'Used Facebook forum'</i>

With the continuing growth and use of new social media tools in society, further research is required to establish whether mediums such as Facebook, etc are an effective means of communication. Further thought should be given as to how European authorities could harness these new social media vehicles to maximise communication impact. However, as noted by the penultimate country in the table above, it is important that new social media tools complement rather than replace existing communication methods as some target audiences will remain dependent upon them. It should be noted that measuring and evaluating the success of new social media tools is unlikely to be an exact science.

35. In a future pandemic, what would you do differently in order to improve the communication with key stakeholders (e.g. health care professionals, patient groups, vulnerable groups [e.g. youth, pregnant women])? (23 respondents)

Table 15: Key comments and suggestions on how to improve future pandemic communication with key stakeholders
<i>'We also need to concentrate more on communication towards specific target groups'</i>
<i>'For instance, early on, we tracked greater levels of anxiety among some minority ethnic groups so we would be on the alert and pay attention to this during a future event'</i>
<i>'Have to concentrate much more on communication with health care professionals as well as communication with media as both of these key stakeholders may have a huge influence on general public'</i>
<i>'Target more mothers of school children as they are the best group to target as if convinced will get the rest of the family to take the vaccine'</i>
<i>'It would be extremely important to launch special communication campaigns on pandemic vaccination'</i>
<i>'More intensive preparatory work with primary health care and occupational health actors'</i>
<i>'Earlier involve[ment] key stakeholders in information'</i>

At least five countries out of the 23 respondents specifically stated that they would concentrate on communicating with healthcare workers and other such stakeholders such as the media *'as both ... have a huge influence on the general public'*.

One country tracked public opinions and in particular noted a *'greater level of anxiety among[st] some ethnic minority groups'*. The country explained that such trends should be taken into consideration at the onset of any future pandemics.

A further two countries also commented on the need to target specific groups which might be hard to reach or reassure. One of the two countries suggested specifically targeting more mothers of school children as the mother is the most likely member to convince the remainder of the family to take up the vaccine.

One country stated that it would be *'extremely important to launch [a] special communications campaign on the pandemic vaccination'* perhaps to counteract any anti-

vaccination campaign which at least one country commented on during the course of their replies.

In question 28 of the EPVS Survey, 12 countries of 25 stated that they employed a global H1N1 communications strategy. Despite this, the above findings indicate that a number of countries would like to target specific audiences with their messages. Therefore, it is suggested that future global communication strategies are planned to allow for 'topic or audience specific' campaigns to be included within the overall communications strategy.

36. When you elaborated/implemented your communication strategy on vaccination, have you taken into account what was done in other EU countries? If yes can you give examples of what was adapted/modified to take that into account? (22 respondents)

One country stated they did not use pandemic vaccines in their country.

Table 16: Key comments regarding when vaccination communication strategies were adapted/modified in relation to other EU countries
<i>'Yes, we have taken into account other experiences, and especially the fact that some countries have chosen not to buy vaccines and that some others have bought limited amount of vaccines'</i>
<i>'We were following what other MS did through the HSC communicators network and that information made us more aware of difficult areas and risks that we could take into account in our own planning'</i>
<i>'It was helpful to participate in the work of HSC Communication Network, and in Vaccine Workshop Programmes'</i>
<i>'HSC Crisis Communicators' Network which gave us the opportunity to exchange between the members of the network the messages we were issuing to the public. We, for example, adapted our recommendation about the wearing of hygiene masks so that they would match the recommendations of ECDC, etc'</i>

Of the 22 respondents, 15 explained that the actions of other MS did have some influence on their own vaccination communication campaigns, whereas four countries stated that they were not influenced by the actions of other Member States. One country in particular discussed how it took into account that some countries bought vaccines while other countries chose not to.

As noted in the previous section on vaccine safety and efficacy, discrepancies between the countries using the pandemic vaccines and between the information on safety and efficacy issues in different countries presented challenges in terms of communicating with the public.

Three countries cited the usefulness of the HSC Communicators' Network as a tool which assisted in the exchange of information.

6.2 MC Questionnaire Analysis

The EPVS Survey produced findings to inform future vaccination communications. The MC Questionnaire took a broader approach and asked a series of general communication questions in relation to the H1N1 pandemic. This section will provide a short synopsis of the relevant communication questions and responses.

2.1(a). What major topics have been covered in your communication campaign during the H1N1 crisis? (14 respondents)

During the H1N1 pandemic it was important to demonstrate which topics were prioritised by various countries for the purposes of their communication plans. Of the 14 respondents, the data showed that vaccinations and hygiene were the two major topics covered in communication campaigns.

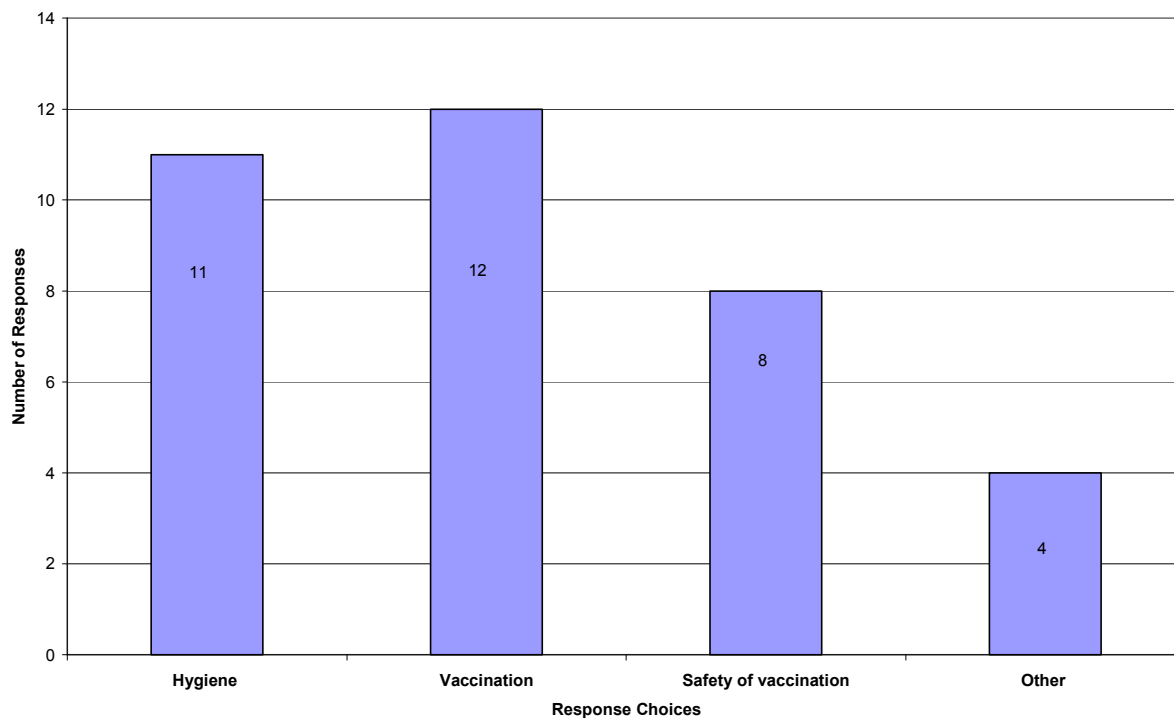


Figure 26: Major topics covered in communication campaigns (14 respondents)

Four of the 14 respondents selected 'other' as their response. The four respondents prioritised 'other' topics such as providing:

- Information for schools, teachers and parents;
- Targeted communications for pregnant women and other vulnerable individuals;
- Advice on prompt health consultations
- Reassurance that the health services of the particular country could cope.

2.1(b). Which communication measures and channels have you used to communicate with primary target groups (general public, risk groups etc.) during the H1N1 crisis? (13 respondents)

The EPVS Survey queried whether countries made use of new social media tools. The MC Questionnaire was broader in its questioning, as it aimed to establish which communication channels were the most popular overall.

Thirteen countries responded. The respondents were able to choose as many of the options as applied to them.

The bar chart highlights that information materials, press releases and press conferences were the most popular methods of communication with the general public and the 'at risk' groups. Conversely direct mailings were the least used communication channel in respect of the overall H1N1 communications campaigns

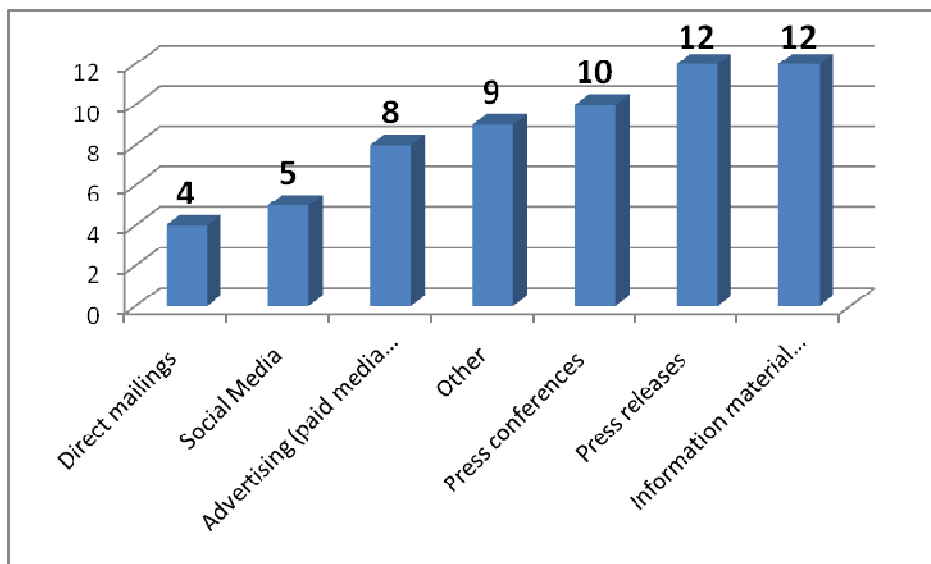


Figure 27: Communication measures and channels used to communicate with primary target groups (general public, risk groups etc.) during the H1N1 crisis (13 respondents)

The chart above also shows new social media, such as Facebook and YouTube were also used to a lesser extent. In consideration of the EPVS Survey's new social media findings, one can deduce that the above answers support earlier observations.

This area of communications requires further research, since:

- As yet there is no conclusive measure of how effective each of the above communications channels is (the above responses are based on subjective attitudes); and
- At the present time, authorities appear to be uncertain as to whether the messages disseminated in this way are being delivered accurately and effectively via the chosen communication channel.

2.1(c). Which communication measures and channels have you used to communicate with secondary target groups (doctors, pharmacists, industry) during the crisis? (14 respondents)

The questionnaire continued the above line of questioning in order to establish whether there was any differentiation between the communication channels used for primary and secondary target groups.

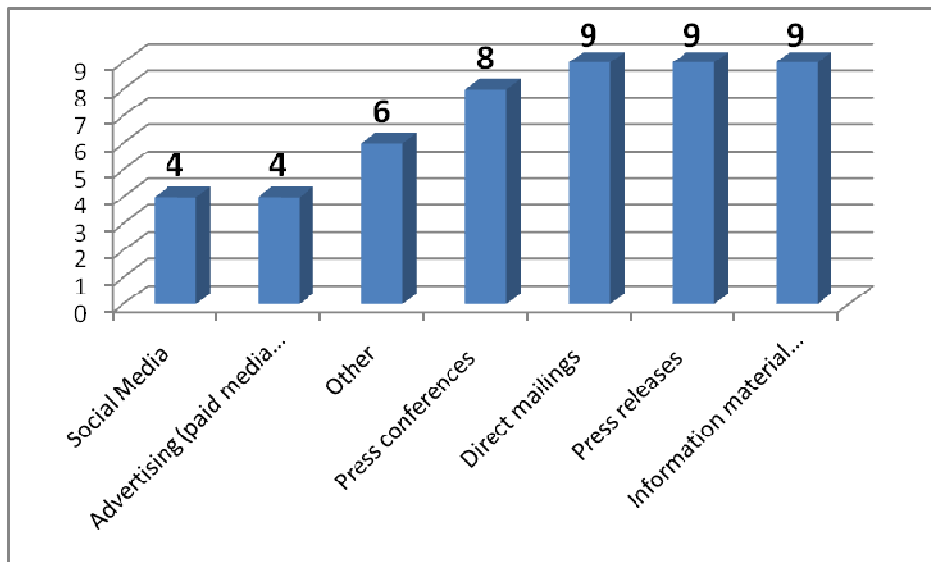


Figure 28: Communication measures and channels used to communicate with secondary target groups (doctors, pharmacists, industry) during the H1N1 crisis (27 respondents)

In a similar manner to question 2.1 (b), respondents were able to choose as many options as applicable. Consistent with the previous question, press releases and information materials were two of the most popular communication channels. However, when communicating with secondary target groups unlike the previous question, direct mailing was also equally popular.

Despite the above findings, they do not indicate whether the actual 'message' received was effective. The TOR 1 Report indicates that participating MS did attempt to use various techniques to assess which websites were most utilised by members of the public (see TOR 1: p. 51, paragraph 12.7). MS also used formal public polls, website usage statistics, focus groups and media evaluations to measure levels of public awareness (see TOR 1: p. 52, paragraph 12.8) with regard to pandemic flu. It might be possible to hone these research tools to assist in measuring the effectiveness of the 'message'.

Perhaps another way to assess the effectiveness of the actual 'message' would be to measure vaccine uptake following a specific vaccination communication message distributed through some of the communications channels set out above. The EPVS Survey findings for questions 28 and 32 clearly highlighted that in a number of instances

respondents experienced difficulties in persuading health care workers to support the H1N1 vaccine efforts. Therefore one may conclude that although the communication channels were effective; the actual content of the message was not and will require further consideration.

2.2(b). What were the biggest communication challenges faced during the H1N1 crisis? (21 respondents)

The overriding issue faced by communicators was the risk communication around the H1N1 vaccine. Some of the main themes derived from this question are set out below:

Table 17: Key comments on the biggest communication challenges faced during the H1N1 crisis
Co-ordination of messages among all involved: participants within the Government, the authorities, regional and local stakeholders
The distribution of vaccines in communities where there was not enough vaccines yet, public opinion against vaccination, especially in social media
Meeting the big demand on information from the media, public and health care system when the situation is unsure and constantly changing and the resources are limited
Need for speed, working under time pressure. Dealing with uncertainty and contradictions
Timeliness and speed
Lack of confidence in official recommendations. Lack of confidence in vaccine efficacy and in necessity to be vaccinated
Media, politicians

Of the 21 respondents, four highlighted that co-ordination of messages among all relevant organisations, including different authorities and health professionals, was a huge challenge. This, coupled with the large volume of demand for information from the media and the public, identified by three countries, and the need for timeliness and speed of response, highlighted by two countries, meant that communicators, in common with colleagues in other disciplines, were working under significant workload and time pressures. Lack of confidence in official recommendations and public authorities was highlighted by four countries as a significant challenge. One country identified that criticism of over-reaction by health authorities and of links between experts and pharmaceutical industries undermined trust and confidence in public officials.

From the responses it is clear that coordination of communication messages within MS amongst authorities is crucial and consuming of both time and resources, during a crisis

when both of these are stretched. In preparing plans for future pandemics and health emergencies, consideration might be given to developing national communication systems to streamline coordination between partner organisations within a country. While the volume of media and public inquiries cannot be estimated in advance, contingency measures should be in place for additional staffing in communications teams.

Effective risk communications emerges as a key skill when dealing with all audiences, especially when seeking to build or restore trust in public authorities. It is clear too that the support and engagement of health professionals is a prerequisite for communication of any future mass public vaccination campaign. Sharing of good practice from case studies and the development of training and guidance on risk communication may serve to better equip communications teams across the EU in the future.

2.3(a). What were the key messages immediately prior to and during the vaccination phase of the H1N1 pandemic? (20 respondents)

Table 18: Key messages immediately prior to and during the vaccination phase of the H1N1 pandemic
<i>'We stressed that the vaccine was safe. That was our main challenge'</i>
<i>'Practical information about the vaccination (Opening date of the vaccination centres, definition of the priority groups for vaccination, explanation about the place and the procedure to get vaccinated'</i>
<i>'Invitation via tv-commercials, billboards, posters in public transportation and internet to do a "vaccine-check" on the internet. Purpose: to find out whether I am part of a risk group and whether I should get vaccinated or not.'</i>
<i>'We give information about the different phases of vaccination program. Who are the target groups that must get the vaccine. That the vaccine is very important to prevent the disease.'</i>
<i>'Risk groups should get vaccinated to protect themselves from serious illness and/or death'</i>
<i>'The national authorities are well prepared'</i>

The above themes were clearly aimed at persuading 'at risk groups':

- The vaccine was safe;
- The best way to protect themselves
- They should take the opportunity to be vaccinated against the H1N1 pandemic.

2.3(b). Were there any specific messages for specific patient groups e.g. pregnant women, if so what were they? (22 respondents)

Table 19: Key comments on the issue of specific messages for specific patient groups
<i>'Yes, for priority groups, pregnant women and person with underlying conditions: to get vaccinated as soon as possible. For pregnant women and children from 6-23 months: to get vaccinated with [non-adjuvant] vaccine'</i>
<i>'Balancing known risk of flu against unknown possible risk of vaccine for pregnancy, protecting the unborn baby'</i>
<i>'Specific Q&A and leaflets have been elaborated about the vaccination of risks groups, especially pregnant women, babies, young children... All of them were posted on our website'</i>
<i>'Several specific messages for medical risk groups and pregnant women, for example that they should avoid contact with people with the flu until they were vaccinated and that pregnant women didn't have a higher risk of getting the virus, but a higher risk of complications if they were infected.'</i>

From the comments above it is clear that certain countries took particular care and effort to communicate to at 'risk groups' such as pregnant women. The findings of both questionnaires indicate that communications with 'at risk groups' does require further consideration either in terms of a specialised campaign or one that is encompassed within the global communications strategy since they appear to be one of the hardest groups to reach and reassure.

2.3(d). What level of contact did you have with communicators in your Member State national regulatory agency immediately prior to and during the vaccination phase? (21 respondents)

Ten of the 22 respondents had daily or more frequent phone/email contact with communicators in their MS national regulatory agency immediately prior to and during the vaccination phase.

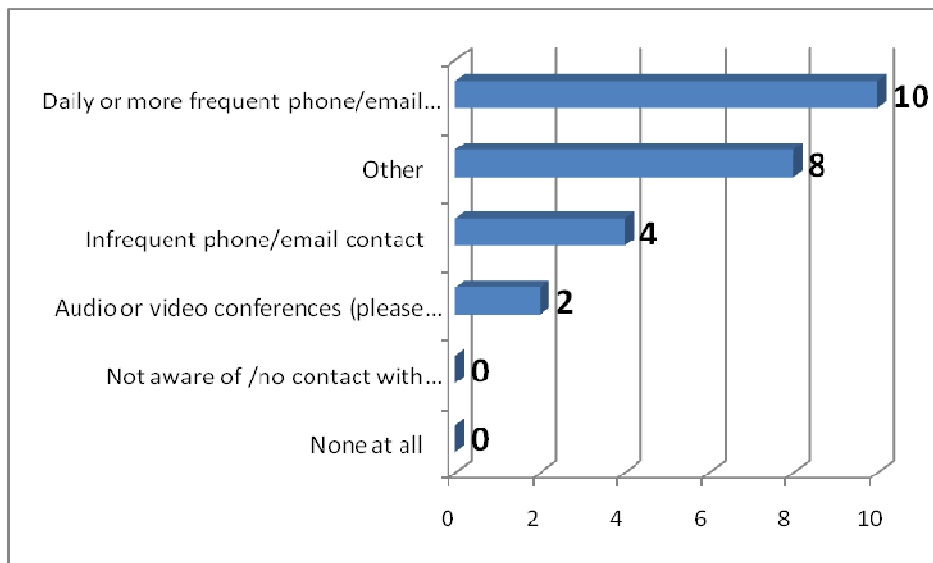


Figure 29: Level of contact with communicators in MS national regulatory agency immediately prior to and during the vaccination phase (22 respondents)

Eight respondents chose 'other' contact frequency which included some of the following:

- Regular meetings;
- Email contacts but not every day or week;
- Infrequent phone/email contact, mostly contact with technical experts;
- Frequent contact by phone, email and meetings but not necessarily daily;
- During the licensing we communicate together about the safety and efficiency of the vaccine; and
- Conferences.

2.3(e). How did you respond to anti-vaccination campaigns?

This was an open ended question and there were varied answers on the response to anti-vaccine campaigns. Some responders simply ignored the anti-vaccine campaigns whilst others set up interviews, press releases and updated websites with counter balanced messages.

Table 20: Key comments on responses to anti-vaccination campaigns
'No anti-vaccination campaigns'
Ignore[ed] them; [gave them] information based on scientific evidence
With distribution of correct information, via campaigns and internet.
'As convincing people reluctant to any vaccination is really hard, health authorities choose not to organize a dedicated communication campaign towards that part of the population. Nevertheless, in the framework of the H1N1 crisis, the anti-vaccination feeling expressed by some people also came from a wrong risk perception of the H1N1 flu (mild disease) and concerns about the safety of the vaccines available (rumours...). Therefore, we tried to raise awareness of risk groups, while indicated that people without any risk factors could also develop a serious form of H1N1 flu. We also engage in a completely transparent communication on the safety of vaccine: we explained the process of fabrication and the guarantee brought by the marketing authorisations..., published pharmacovigilance bulletins every week and tried to mobilise more experts and health professionals to answer the rumours on the safety of vaccine'
'Offering to the population all the needed answers and information in order to demonstrate the benefits of vaccination'
'That there is no scientific evidence to the contrary'

All those who responded reported that they had sought to clarify misunderstandings and answer criticisms with accurate factual information. Spokespeople and ministers carried out interviews, took part in TV debates and appeared in court. The websites of anti vaccination groups were monitored and one country responded reporting that they had established a hot line for questions from the public and had direct contact with the public through email via a dedicated website. Particularly pertinent was the observation from one Member State that it proved extremely difficult to counter emotive argument on the part of the anti vaccination lobby with factual scientific information.

Three member states reported that there were no anti vaccination campaigns in their countries and one Member State noted that the anti vaccination campaign which was run did not meet with much interest or success, so the health communicators did not address it.

Monitoring the messages and arguments of anti vaccination campaigns is critical to developing a rebuttal strategy. Thought might be given to sharing intelligence and counter messages once developed, so that where anti vaccine campaigns cross member state boundaries, health communicators are similarly linked and briefed to deal with the issues raised.

2.3(f). Did you carry out any focus group or other opinion research on public attitudes to vaccination during this phase? (21 respondents)

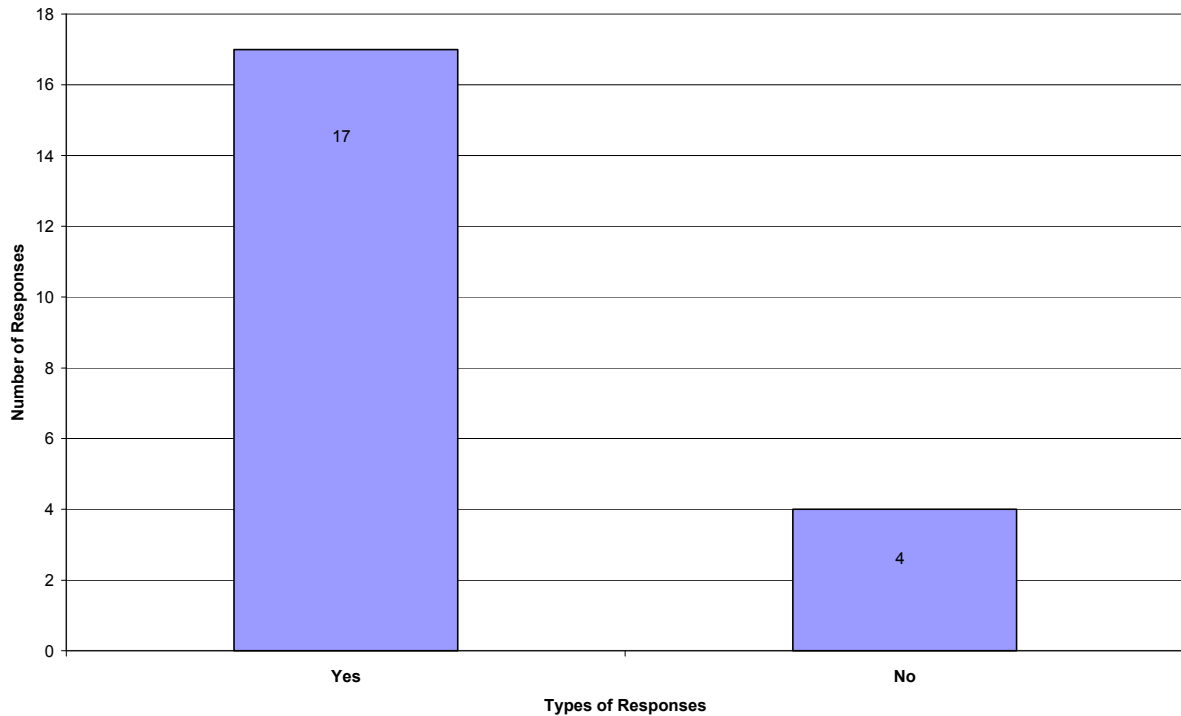


Figure 30: Focus group or other opinion research carried out on public attitudes to vaccination

Only four reported conducting any primary focus group or opinion research with regard to public attitudes to the H1N1 vaccine.

2.3(g). If you are willing to share a summary of any innovative campaigns you have run to inform the public/health professionals/specific patient groups/the media immediately prior to or during the vaccination phase of the H1N1 pandemic, please supply brief details (in not more than 600 words). (four respondents)

Four responses were received to the above open ended question. The key comments can be found below.

Table 21: Key comments on innovative information campaigns

'Telephone survey done in June / September / November and December 2009 results already shared

'Vaccination [.....] was taken very negatively, as unnecessary. The reaction media was that [our country] spent too many millions and no pandemic...'

'2-days Specialised Conference was organised for health professionals. They had an excellent possibility not only to get all urgent information and to be trained on the different topics of the Pandemic Influenza from different perspectives, but also to get vaccinated. The huge interest of the health professionals from different regions of the country was shown'

At the time of the questionnaire one country had already begun to assess how well its communication campaign had performed in respect of the various target audiences.

Another country spoke about the negativity that stemmed from the pandemic apparently failing to take hold in that particular country. The purchasing of the vaccine and the related communications were deemed to be a waste of money.

The third country spoke about a successful conference that was aimed at health care workers. This appears to be an example of how support and engagement of health professionals can be encouraged.

6.3 Opinion Research and Focus Groups

Individuals who responded positively to questions in the survey relating to whether they undertook any public survey or polling activities were re-contacted. Respondents were asked to share any available data or summary of their surveys, and additionally were asked a series of questions relating to these activities including:

- Why did you conduct this study / polling / survey? What were your aims?
- Who commissioned it? (e.g., Ministry of Health, Government Agency, etc.,)
- Who carried out the work? (e.g., Market Research Company, academic institution, etc.,)
- What do you consider to be the most interesting results of the study?
- Can you give some specific examples of how the results were used? (e.g., did they inform policy decisions? Did they help you develop or evaluate promotional campaigns?)
- Having completed this work, what would you do differently next time?

Responses were received from six countries.

6.3.1 Summary of public polling and survey activities

The table below provides an overview of the public polling and survey activities undertaken by those countries who responded to the request for information.

Table 22: Summary of survey and polling activities in responding countries		
Country	Dates of data collection	Sample size (N) and Methodology
Country A	<ol style="list-style-type: none"> 1. 28 July - 10 Aug 2009 2. 14 Oct - 24 Oct 2009 	<ol style="list-style-type: none"> 1. N=1,005 2. N=1,002 Quota sampling face to face interviews included
Country B	<ol style="list-style-type: none"> 1. 28 - 29 Oct 2009 2. 18 - 19 Jan 2010 	<ol style="list-style-type: none"> 1. N=502 2. N=500 Two questions included in an omnibus survey
Country C	<ol style="list-style-type: none"> 1. 27 July - 23 Aug 2009 2. 11 - 19 Oct 2009 3. 14 - 17 Dec 2009 	<ol style="list-style-type: none"> 1. N=2000 2. N=2000 Probability sample selected from population register. Telephone (84% response rate) & postal survey 3. N=1008, Telephone survey.
Country D	<ol style="list-style-type: none"> 1. April 2009 2. 11 - 14 Aug 2009 	<ol style="list-style-type: none"> 1. N=1000 2. N=1000 Telephone survey
Country E	18 survey waves from 29 April to 21 Dec using "risk and crisis barometer"	<ol style="list-style-type: none"> 1. N=500 Phone surveys

6.3.2 Aims of polling and survey activities

The most common reason cited for undertaking public survey activities was to establish the concerns and intentions of the general public prior to or during a communications campaign. Questions related specifically to public knowledge and attitudes, feelings about risks and safety, attitudes to government intervention measures, the communications campaigns, and public trust in the activities of the government. In addition, the polling activities were used to test whether sensationalist media headlines

relating to public worry and panic were a true reflection of the attitudes of the public, and whether communications campaigns needed to be adapted to take these issues into account. Finally, surveys undertaken in the autumn and winter of 2009/2010 consistently contained questions relating to the uptake and willingness of different groups to undertake vaccination, and any reasons for non-compliance.

In most countries the research was commissioned by the health authorities, such as the Ministry for Health. Market Research Companies were used in all countries to conduct the work, either via stand-alone telephone or postal surveys, or by including specific flu-related questions within an omnibus survey.

6.4 Outcomes and Implications

A number of outcomes were identified as being particularly useful to communicators and policy makers. For example: understanding that for many people the first point of contact for flu-related queries was their general practitioners; that the preferred information sources were doctors and flu experts; that trust in government spokespersons was good, with the exception of politicians; that the public were not as worried as the media were suggesting and that satisfaction rates were high, were all outcomes that were useful for the commissioning organisations. Surveys that focused on vaccination coverage identified areas of the population where coverage was low, and provided insights into the relationship between pandemic vaccination uptake and seasonal flu vaccination compliance.

As a result, the surveys were used to inform policy decisions, to confirm the value of communication strategies and in some cases the outcomes of the surveys were made publically available and were highlighted in specific press releases. Specific examples were also given such as: letting experts (e.g. paediatricians, epidemiologists, etc) talk to the media, and not politicians; sharing the data with agencies tasked with monitoring adverse events following immunisation; tailoring communications to specific population groups, such as pregnant women; and supporting communication by the local health authorities to have the information 'closer to home' for the public. . Using surveys and public polls was broadly considered to be an important approach to support real-time monitoring of, for example, vaccination uptake, and to perform timely evaluation of the impact of the pandemic on the general public.

6.5 Main Findings from the Communications Data

Having analysed the findings of both the EPVS Survey and the MC Questionnaire, this final section identifies some of the key points which should underpin further work in the area of pandemic communications planning.

6.5.1 Health professionals

One of the most important findings highlighted by both questionnaires was the importance of health professionals. Without their engagement and support, the effectiveness of vaccine communications was inhibited.

In questions 28 and 32 of the EPVS Survey, countries discussed the anxiety they experienced from health care workers which was passed onto members of the public. In question 2.3(g) of the MC Questionnaire one country discussed how it planned a dedicated conference for health professionals and appears to indicate that it was positively received.

It may be prudent to commission focus group research involving health professionals to understand what methods could be used to inform and engage them in the H1N1 communications campaign and are willing to endorse it and lend support to it.

6.5.2 Specialised communication for 'at risk groups'

Both questionnaires discussed the differences of opinion regarding global and specialised communication campaigns. Some countries did develop targeted communications for certain groups of people such as young parents and pregnant women, whereas others preferred to employ global communications strategies.

Initial research conducted by one country as mentioned in question 35 of the EPVS Survey reported upon a greater level of anxiety amongst ethnic minority groups.

In consideration of these findings, countries should be encouraged to consider specialist targeted communications where appropriate, i.e., when certain groups of the population are more susceptible to the disease, as was the case for the H1N1 pandemic.

If more specialist communication campaigns are initiated, consideration should be given to identifying the most effective means of communication with specific target groups.

6.5.3 Anti vaccination campaigns

Early intelligence and an understanding of the messages and arguments of anti vaccination campaigns can be gained from monitoring of relevant websites.

The sharing of intelligence and counter messages once developed, could allow health communicators to be more effective in responding to anti vaccine campaigns which overlap member state boundaries.

6.6 Biggest Communication Challenges

One of the single biggest communication challenges was the sheer volume of media and public inquiries received during the H1N1 crisis. Consideration might be given to putting communication systems in place within countries to streamline coordination between organisations and developing contingency measures for additional staffing in communications teams to support communication.

Effective risk communications emerges as a key skill when dealing with all audiences, especially when seeking to build or restore trust in public authorities.

The development of training and guidance on risk communication and the structured sharing of good practice from case studies may serve to better equip communications teams across the EU in future health emergencies to support the risk communication.

6.6.1 Effective channels of communication and new social media

Each questionnaire respectively highlighted the uncertainties that exist around the use of new social media such as Facebook, YouTube, etc., in questions 33 and 34 of the EPVS Survey and questions 2.1(a) and (b) of the MC Questionnaire.

The overriding feelings surrounding new social media were positive, however, countries were generally unsure about the effectiveness of the medium.

Further research may be useful to establish the levels of impact of new social media methods and whether the content of the actual 'message' is being communicated effectively.

The findings also noted that the use of new media should not replace traditional means of communications especially since other sectors of the population will continue to rely on traditional communication methods.

6.6.2 Communications and logistics

Both questionnaires highlighted the need for communications to be integrated with other aspects of the H1N1 campaign such as the logistics of vaccination delivery as discussed in question 32 of the strategic questions survey and 2.3.(d) of the MC Questionnaire.

6.6.3 Opinion research and focus groups

Public polling and survey activities were broadly considered to be valuable to the work of communicators in Europe. Some concerns were raised on the importance of carefully wording questions in order to be confident that the responses appropriately reflected the issue of interest, and the need for a number of survey waves was highlighted, in order to gain a picture of the changing nature of public opinion. The importance of systematically monitoring online sources was also highlighted by respondents, and the need to start as early as possible was also highlighted. The need for polls that were prepared and could be executed very quickly with contracts in place to deliver them was consistently identified as a future need.

7 Conclusion

This concluding section builds upon the key findings of this assessment. The intention here is to provide a presentation of the challenges and a few possible suggestions, which may serve to improve MS and the EU's ability to respond to potentially global pandemics and transmitted infectious diseases in the future.

7.1 Strategic Overview

The data gathered during the course of this review indicates substantial diversity of approach among the responding states with regard to pandemic vaccine strategies in general and communications strategies in particular. Responding countries have for example varied considerably with regard to the degree of prior preparation to ensure access to vaccination (e.g. access to Advance Purchase Agreements), scope and focus of vaccination campaigns (ranging from no vaccination, risk/targeted groups only, to aspirations to vaccinate the entire population); strategic consistency/flexibility with regard to the chosen strategy; and use/non-use of new social media as a communications tool. Some Member States have been forward leading (or proactive) in their approach - acting aggressively upon intelligence regarding impacts in other parts of the world (or other Member States). Others have taken a slower (more reactive) "wait and see" approach.

It is important to bear in mind that this variation is a product of different historical experiences (experiences of the H1N1 pandemic), degrees of exposure, national monitoring systems, political-administrative structures and cultures, among other things.

However, this diversity of experience and strategic postures does suggest that Member States (and others in similar situations) can benefit greatly from more systematic exchange of experiences and enhanced regional cooperation.

7.2 Main Observations

7.2.1 APA and subsequent procurement

More than half of the responding Member States reported that they had an APA prior to the H1N1 outbreak and that their APA were activated by the WHO "Phase six" declaration. Nearly two-thirds ordered the H1N1 vaccines in connection a WHO "Phase six" declaration. The most significant factor triggering a country to order the specific H1N1 vaccine was "scientific assessments". Perhaps a bit surprisingly, "pressure from industry" was the least significant factor.

The majority of countries would like in a future procurement contract to add conditions under which the specified amount could be lowered/changed (e.g., because of new scientific evidence, quality or safety issues, or lower/higher demand). Other mentioned issues which should be included were dealing with excess vaccines, economic sanctions for delayed vaccine deliveries, conditions under which a contract becomes void.

7.2.2 National planning assumptions

Three main findings appeared from the data on national planning assumptions. First, national planning assumptions appeared to be influenced more by supranational organisations (such as ECDC and WHO) than by other countries' planning assumptions. Second, national vaccination strategies, and planning assumptions to a lesser extent, influenced the number of H1N1 vaccines that were ordered in 2009/2010 more than, for example, financial constraints, pre-existing contracts, or solidarity considerations. Third, these same strategies and assumptions would most likely be used to determine future vaccine orders.

7.2.3 Joint procurement (JP)

The majority of the respondents expressed an interest in a JP and indicated that this task should be coordinated by the EC before or in connection with a WHO pandemic declaration³⁸. The respondents appreciated the fact that a JP would provide a number of advantages (stronger negotiation power, lower costs, and equitable access) as well as help create a common understanding of liability issues. On the other hand, concerns were expressed that a JP arrangement should be carefully adapted to national requirements, logistics, context, and legal framework.

7.2.4 Stockpiles

The findings suggest that conditions for supporting vaccine stockpiles within or outside the EU were quite similar. The most frequently chosen conditions included: if they foresee a national surplus and if the stockpile is centrally managed (vs decentrally managed) at the EU level (for intra-EU stockpile) or by WHO (for a stockpile for third countries). Another condition deemed significant for an EU vaccine stockpile would be that all MS in need would be provided equal access.

³⁸ One informant suggested, however, that alternative models for joint procurement such as the revolving fund arrangements currently in place in the Americas should also be considered. For further information on this subject, see: http://www.paho.org/english/hvp/hvi/revol_fund.htm

7.2.5 Pandemic vaccination strategy

National pandemic vaccination strategies seem to be well established in the MS. One potential risk in a future pandemic situation is that they could be automatically reused without consciously reflecting upon whether or not they are truly appropriate to the situation. However, the sources of information used in creating these national pandemic vaccination strategies appear to be taken from a number of sources therefore providing room for constructive feedback, diverse expertise, and differing opinions.

7.2.5.1 Vaccination goals and reprioritisation

Nearly two thirds of the countries did NOT change their health care goals/objectives in their pandemic vaccination strategies, even after the characteristics of the H1N1 pandemic became more apparent. The majority attributed this to the fact that there was little or inconclusive evidence which justified making such changes. On the other hand, one third of countries did in fact alter their health care goals/objectives in their pandemic vaccination strategies. The majority of changes were made in the goals/objectives regarding protecting vulnerable/at risk groups and maintaining health care services. The major reasons for making such changes were attributed to the fact that a clearer picture appeared regarding the groups at risk for serious infections, the degree of transmission, the hospitalisation rate, and the fatality rate.

7.2.5.2 Reported vaccination goal shortfalls

The majority of respondents reported vaccination goal shortfalls, experiencing difficulties in reaching their vaccination coverage goals. Only four countries felt that they had reached their goals for their risk and target groups. The explanations for success were quite similar in all four cases. The following reasons were mentioned by at least three, if not all, of the four: universal vaccination, free vaccination, good annual influenza uptake, positive public attitudes towards authorities and vaccination, and the severity of first known H1N1 cases. Other reasons that were mentioned included early access to vaccine, joint key messages from authorities, and transparency in the process.

Nearly all of the respondents reporting difficulties in meeting their national vaccination goals felt that they had missed health care workers. Coverage goals for pregnant women and persons with underlying chronic diseases were also reportedly low. The main reasons for these shortfalls were attributed to scepticism and/or limited interest on behalf of the health care workers and the general population. Other significant factors included the moderate character of the pandemic and the safety concerns of the H1N1 influenza vaccines.

7.2.6 Vaccine safety and efficacy

Both the EMA and national medicines agencies/authority were reported as the most significant sources of safety and efficacy information as well as substantial influences for countries' public responses on vaccine safety and efficacy issues. On the other hand,

very few countries considered the pharmaceutical industry as a significant influence in either of these areas.

When asked to provide suggestions for improving information on the safety and efficacy of centrally authorised pandemic influenza vaccines, a number of countries made the effort to include positive experiences in their responses emphasizing that the current procedures worked well and were adequate. Some of the areas mentioned for improvement were the timing and clarity of recommendations. A few claimed that information is needed early but they also understood that useful disease information will probably be unavailable, even in the first stages of the next pandemic.

The discrepancies between the European countries regarding safety and efficacy information proved to be problematic, especially when communicating with the public. For example, it was difficult to explain why one country considered vaccinating very young children dangerous and another country actually encouraged vaccinating them.

Post-marketing surveillance information was considered sufficient and adequate, with well established procedures. Yet there still appears to be a need for more relevant information and current facts on, in particular, the safety and effectiveness of vaccines.

7.2.7 Vaccine administration

Three quarters of the responding countries explicitly mentioned that they used the internet in some form (e.g., emails, websites, e-newsletters) and/or new social media (e.g., text messages). Roughly half of the respondents used standard operating procedures, documents via administrative channels, and/or traditional information sources to convey product changes. The media was reportedly used less than one may expect; 6 of 22 respondents stated using press conferences or releases for spreading information to health care professionals on product changes. Forums such as conferences, workshops, meetings and training sessions were not often used either to convey changes in product use to health care professionals.

When asked if patients being administered the H1N1 vaccine received information leaflets in the appropriate language, nearly all of the respondents said yes. Only three of the 26 respondents reported that they did NOT provide information leaflets to the patients who received a H1N1 vaccine, but that information was provided orally via the health care provider administering the vaccine. Nearly one third of the countries affirmed that they provided information in minority/local/appropriate languages.

7.2.8 Research capacity

The majority of countries supported the claim that there is a need for public clinical research capacity (e.g., carry out comparative effectiveness studies) in the EU. More than half indicated this capacity should be coordinated by an existing EU agency (of which six specified ECDC and six EMA). Nine chose “public consortium, coordinating a network of clinical trial centres in various Member States” and only three indicated that this could be a task for private-public partnership(s). One respondent specifically emphasised that the most important issue regarding such research is maintaining objectivity and independence from the pharmaceutical industry, while another emphasised the key role current played by industry-driven vaccine research under present conditions.

7.3 Main Observations from the Communications Analysis

The increased potential trend towards external communication agencies could lead one to speculate that some countries feel that they would benefit from more external support to enhance their in-house communication efforts.

7.3.1 Communication on vaccine strategies

Countries recognised the need to :

- Target specific groups such as pregnant women;
- Take proactive steps to inform the media about the pandemic;
- Involve key experts to ensure accurate and streamlined messages;
- Use modern communication methods such as sms messaging;
- Use interactive methods such as workshops in order to build confidence in the H1N1 vaccine amongst health care workers; and
- Tackle any vaccination fears and or criticisms ‘head on’ through an open debate.

7.3.2 Health professionals

One of the most important findings highlighted by both questionnaires was the importance of health professionals. Without their engagement and support, the effectiveness of vaccine communications was inhibited.

Countries mentioned the anxiety they experienced from health care workers which was passed onto members of the public. In an attempt to deal with anxiety, one country planned a special conference for health professionals, which was apparently well received. It may be prudent to commission focus group research involving health professionals to understand what methods could be used to inform and engage them in the pandemic vaccination communications campaigns in order to ensure health care professionals are willing to endorse and lend support to them.

7.3.3 Specialised communication for ‘at risk groups’

The issue of global and specialised communication campaigns was raised in both questionnaires. Some countries had developed targeted communications for certain groups of people (such as young parents and pregnant women), whereas others preferred to employ global communications strategies. Initial research conducted by one country reported a greater level of anxiety amongst ethnic minority groups. More research on this topic would be worthwhile for increasing effectiveness of information campaigns, especially in light of the current globalisation trends.

In consideration of these findings, countries should be encouraged to consider specialist targeted communications where appropriate; that is, when certain groups of the population are more susceptible to a highly communicable disease as was the case for the H1N1 pandemic.

If more specialist communication campaigns are initiated, consideration should be given to identifying the most effective means of communication with specific target groups.

7.3.4 Anti vaccination campaigns

Early intelligence and an understanding of the messages and arguments of anti vaccination campaigns can be gained from monitoring relevant websites, including newspapers, popular mass media sites, government organizations, Facebook, chat forums, among others.

The sharing of intelligence, and counter messages once developed, could allow health communicators to be more effective in responding to anti vaccine campaigns which can often easily and quickly cross Member State boundaries.

7.3.5 Biggest challenges faced by communicators

One of the single biggest challenges to communicators during the onset of the H1N1 pandemic was the sheer volume of media and public inquiries. Consideration should be given to putting communication systems in place and to train how well they work before

another pandemic strikes. Therefore appropriate adjustments can be implemented in a non-crisis situation. Important factors to consider are streamlining coordination between national and EU MS government organisations and developing contingency measures for, among other things, additional staffing in communications teams.

Effective crisis communication skills are extremely important when dealing with the public, especially when seeking to build or restore trust in public authorities.

The development of training and guidance on crisis communication and the structured sharing of good practices from case studies may serve to better equip communications teams across the EU in future health crises.

7.3.6 Effective channels of communication and new social media

The findings highlighted the uncertainties that exist around the use of new social media (such as Facebook, YouTube, etc.). In general, the opinions expressed for new social media were positive; however, countries were generally unsure about the effectiveness of this media. Further research should be conducted to establish the impact of communication campaigns utilising new social media and whether the content of the actual 'message' is being communicated effectively. The findings also noted that the use of new media should not replace the traditional means of communications (e.g., leaflets, brochures, letters, billboards, etc.) since several other population groups continue to rely on these approaches.

7.3.7 Communications and logistics

Another finding highlighted in the data was the need to integrate communications with other aspects of the H1N1 campaign including the authorisation, logistics and delivery efforts.

7.3.8 Opinion research and focus groups

Public polling and survey activities were broadly considered to be valuable to the work of communicators in MS; however, some concerns were raised. Five examples include: 1) carefully wording questions in order to be confident that the responses appropriately reflected the issue of interest; 2) carrying out several surveys in waves in order to capture changing public opinions; 3) systematically monitoring online sources; 4) start the communication monitoring process as early as possible; and 5) preparing and executing polls quickly in order to be able identify future needs.

7.4 Challenges and Suggestions

On the basis of the analyses of the national responses to the strategic questions and supplementary material as well as the additional communications studies presented above, it is possible to identify a number of key challenges and suggestions salient to the project of improving preparedness for developing pandemic vaccine strategies in Europe:

Better national coordination and cooperation within MS, among the MS, and the EU are necessary to improve preparedness, planning and implementation of pandemic vaccination strategies.

Enhanced coordination of vaccination strategies within MS, among MS, and the EU (as well as other highly relevant actors such as the WHO) provide better conditions for coping effectively with a pandemic. The likelihood of success is enhanced by greater transparency and improved coordination in the planning, decision making, and implementation, and communication processes. Coordinated and appropriate messaging by the various authorities is vital to maintaining public and media trust. Increasing public trust for vaccines and authorities will also stimulate a more constructive and legitimate decision-making, planning and implementation process. If the public has a high degree of trust and confidence in government and health care institutions, citizens will be more inclined to actively participate in and contribute to government policies and strategies.

Improving access to appropriate epidemiological and surveillance information at an early stage

The respondents heavily emphasised the importance of such access. Access to appropriate epidemiological and surveillance information in the early stages of a pandemic provides a knowledge base for better informed strategic vaccination choices. Each pandemic is unique. Therefore, the sooner the key characteristics of a new pandemic have been properly identified, the sooner targeted strategic measures and vaccination goals can be implemented. Here, it is essential to point out that the MS also play a role in this since they are responsible for submitting epidemiological information to central monitoring organisations, such as ECDC and WHO.

Improving performance on achieving vaccination strategy goals

Finding ways of improving performance on achieving vaccination strategy goals such as protecting the most vulnerable, reducing overall transmission and maintaining health care services stands out as a vital challenge. An overwhelming number of respondents (22 of 26) reported that they had not successfully met their vaccination strategy goals, and the evidence suggests that this was not a result of an error in establishing

appropriate strategies or goals. In fact, the majority of responding countries asserted that they would pursue the same or similar vaccination strategy goals in a future pandemic.

Better coverage of health care professionals is essential to maintaining health care services in a pandemic. Low coverage of health care professionals is an obstacle to reaching target/risk groups as well as the general public.

Maintaining health care services will always be a top priority in any pandemic and the key to maintaining health care services is ensuring that health care professionals are fit to work. Low vaccine coverage of health care professionals is an obstacle to maintaining health care services and reaching target/risk groups as well as the general public. The first link in this chain is a higher uptake of health care professionals. A serious problem arises if health care services cannot be maintained, because health care workers have not been vaccinated and thus fall ill. This dilemma is twofold:

- 1) There is a lack of health care workers who can properly administer vaccines and care for patients.
- 2) It is difficult to convince the public to get vaccinated when the people administering the vaccines question the merits of the vaccine and/or are not getting vaccinated themselves.

Compulsory vaccination of health care workers is a highly controversial topic. Pandemic planners need to find a way to get health care professionals more actively engaged so their valuable knowledge and experiences can be considered in the planning process. Without their engagement and support, the effectiveness of vaccine communications is inhibited. Such involvement is key to building support among this vital group for the proposed pandemic policies and strategies. It is too late to try to build this trust and utilise this knowledge once a pandemic has already hit.

Future procurement contracts should be more flexible and include conditions under which the specified amount can be changed and conditions for returning excess vaccines.

Quite a few of the responding Member States expressed an interest in enhanced flexibility with regard to advance purchase contracts. From the contracting country's perspective, it is clear that maximising not only guaranteed access to vaccine, but also increased flexibility that can help to minimise costs and better calibrate orders to changing prognoses regarding the ongoing development of the pandemic. Convincing vaccine providers to provide such flexibility is likely to pose a challenge and might well require finding ways of enhancing the negotiating power of contracting Member States. A forum for discussions among MS of how to develop advance purchase contracts could be useful.

The EC is a leading candidate for coordinating the task of arranging joint procurement before the next pandemic.

In the strategic questions survey, an overwhelming number³⁹ of MS supported the idea of a joint procurement arguing that it would provide stronger negotiation power, lower costs, more equal access, and address liability concerns. Furthermore, the vast majority⁴⁰ felt the EC was the best candidate for coordinating the task of arranging a joint procurement.

Coping with volume of inquiries and improving risk communication

One of the single biggest communication challenges was the sheer volume of media and public inquiries received during the H1N1 crisis. Consideration might be given to putting communication systems in place within countries to streamline coordination between organisations and developing contingency measures for additional staffing in communications teams to support communication. Effective risk communication emerges as a key skill when dealing with all audiences, especially when seeking to build or restore trust in public authorities.

Coordination of timing and content of messaging with other aspects of the vaccination campaign is important.

Messaging should be managed in such a fashion as to ensure that maximum interest and motivation among target groups are generated (see below) and timed appropriately in relationship to the pandemic threat cycle and availability/deliverability of vaccine.

Implementation of specifically targeted communications when key risk groups have been identified

The strategic choice whether to implement a global or a specialised communication campaign will depend heavily on the characteristics of the pandemic and the ability to isolate specific risk groups. When possible, it is helpful to identify and target risk groups and consider the best means for reaching them. Developing a tailored message to such groups, which includes correct facts in the most appropriate form/language at the most appropriate time, increases the chances for success. For example, young people were identified to be a major risk group in the onset of the H1N1 pandemic and these are the same people who are the main consumers of the new social media. Several countries ran vaccine information campaigns utilising websites, Facebook, Twitter, text messaging and school involvement in order to target this risk group. Communications must be better integrated with other aspects of vaccine campaigns.

³⁹ Strategic question #12, 21 of 27 respondents

⁴⁰ Strategic question #16,17 of 21 respondents

Further research on tracking the use and effectiveness of new social media

The media context and media consumption patterns are constantly changing. Communications designed to support vaccine strategies should not only take advantage of traditional media channels but also be open to the possibility that new forms of media may provide a valuable alternative (particularly with regard to some target groups). The development of new media or new channels will always be one step ahead of the authorities and therefore it is important to keep one's eyes, ears and minds open.

Additional research should be conducted in order to assess the impact and effectiveness of new social media in vaccination campaigns and how they can best be applied in targeting certain risk groups and/or the general public. In addition, studies should explore whether the content of the "actual message" in social media is being communicated properly and effectively. Nonetheless, the findings of this report suggest that the use of new social media should not replace the more traditional means of communication (since many population groups still rely heavily upon them). The new social media should be seen as a potential complement rather than a replacement.

Enhancing rapid public research capacity in support of vaccination

The majority of respondents identified a need for enhanced rapid public research capacity in Europe in future pandemics. More than half preferred coordination by a European level agency, while others proposed a consortium of clinical research centers distributed among the MS. Challenges will include devising funding mechanisms and instruments which will be not only be timely but also live up to acceptable standards of quality and equity. Similarly, it will be essential to find an appropriate and legitimate division of responsibility and labor between publicly and privately funded efforts.