Health Protection Scotland

NHS National Services Scotland

The National Vaccination Programme To Protect The Scottish Population From Influenza A(H1N1) Infection

2009-2010

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INTRODUCTION

On 27 April 2009 a new strain of influenza was detected in Scotland, a matter of days after it had first been identified in Mexico and classified in the USA. Already on 24 April, UK government and public health organisations had begun preparations to respond to a potential pandemic. In line with the UK's overall response to civil contingencies and the pandemic influenza plan, UK-wide political, civil service and scientific advisory structures were put in place in May to manage the response to the pandemic. With the rapid spread of the virus on 11 June 2009, the World Health Organisation declared that a pandemic was occurring.

Within Scotland, the Scottish Government set up its own structures to manage the response to the pandemic which was composed of two phases: the containment phase, with the aim of limiting the spread of the infection, and the treatment phase, with the aim of mitigating its impact on health and ensuring the continued routine functioning of society.

As the pandemic evolved, it became clear that its impact would not be as severe as first feared. It mainly affected younger people who on the whole, had better health. However certain parts of the population were particularly at risk, especially children under 5 years of age, those with ongoing illnesses which could be complicated by the flu and pregnant women.

Because of this, UK Health Departments, after receiving expert scientific advice, decided to offer immunisation to large sections of the population to lower their chances of suffering significant disease. In addition, to limit the possible effect on health and social care provision, frontline staff were offered the vaccine.

The vaccination programme formed part of the overall UK pandemic response during the treatment phase, was planned and executed within this context and had the primary aim of mitigating impact not limiting spread. Key decisions were made by Ministers within the UK Civil Contingencies arrangements designed to manage a range of national emergencies. There was therefore relatively tight control over the implementation of the programme and a need to ensure that it was put in place consistently and on time across the country. Clearly in relation to a new virus, it was also important to keep the programme under a constant process of review as more evidence became available about the infection's epidemiological and clinical features and the levels and likely duration of virus circulation in the population.

These centralised UK-wide command control arrangements operating within a context of uncertainty about the infection had several ramifications on those charged with implementing the programme locally. Decisions could take time as evidence was gathered and reviewed and consensus sought across the UK countries. But once taken, they would then need to be implemented rapidly. The content of debates at a government level was confidential. However once a position had been reached the reasons for it were shared openly and quickly with the media. The relative novelty of the infection meant that it took time before the scientific evidence base for its effective management accrued. However control measures could not wait until this was fully complete.

Health Protection Scotland coordinated the influenza A(H1N1) vaccination programme. This entailed working directly with Scottish Government Health and Wellbeing Directorate, Scottish Prison Service, 20 NHS boards and through the last, the 32 local authorities and 1,024 General Practices. Scottish Government established a Steering Group to oversee the programme. The coordinated, stand-alone influenza A(H1N1) vaccination programme ceased on 31 March with its further implementation being integrated into the seasonal flu immunisation campaign.

This report details the planning and management of the programme, the lessons learnt and key conclusions and makes a series of recommendations. It is one of a number of reports on the pandemic including the independent review of the pandemic response jointly commissioned by all four UK administrations; the Government's capture through the civil contingencies process, of lessons learned and HPS's report on the overall health protection response to the pandemic in Scotland.

BACKGROUND

Influenza A(H1N1) Infection

The influenza A(H1N1) is a new strain of influenza virus of swine origin that first caused illness in Mexico in March and April 2009. The World Health Organisation has now classified this virus as Pandemic (H1N1) 2009. It is referred to in this report as influenza A(H1N1). In mid April the new virus was identified in two specimens in California (USA), it then spread globally. The first cases of influenza A(H1N1) were identified in Scotland on 27 April 2009. In On 11 June 2009 the World Health Organisation (WHO) signalled that a global pandemic of influenza A(H1N1) was underway and raised the worldwide pandemic alert level to Phase 6.

Like seasonal flu, infection with influenza A(H1N1) may be sub-clinical or cause an unpleasant but self-limiting disease. However the virus may cause severe illness in a minority of people e.g. bronchitis or viral or secondary bacterial pneumonia. Other complications can include otitis media, tonsillitis, septic shock, meningitis and encephalitis. The groups that are most at risk of hospitalisation and death are those with underlying medical conditions and pregnant women. Children with neuro-developmental problems are at particularly high risk. Pregnant women are also at increased risk of influenza-related hospital admission compared with non-pregnant women and this risk increases with increasing length of gestation. Complications in pregnant women include pneumonia and cardio-respiratory complications.

Influenza A(H1N1) in Scotland

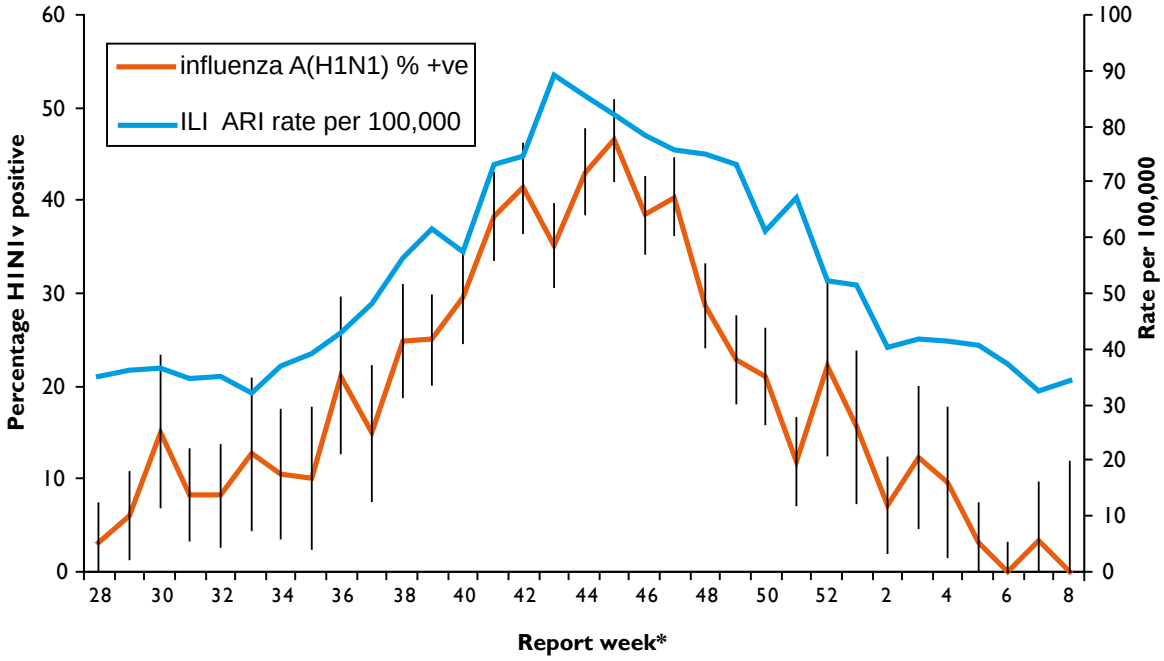
HPS was given the responsibility of coordinating the health protection response to the pandemic. In the containment phase, this entailed implementing surveillance and investigation; contributing to UK-wide risk assessments; participating in UK Scientific Advisory Committees, briefing Scottish Government issuing guidance to NHS and other services and coordinating interventions to limit further spread. This entailed detecting and treating cases, tracing their contacts and limiting the chance of further spread, managing outbreaks including school and other institutional closures and implementing port health restrictions and infection control measures in healthcare settings. In the treatment phase, surveillance, investigation and risk assessment processes were amended and continued. With regard to control, emphasis was switched to measures to limit impact i.e. treatment and care, infection control and immunisation. HPS worked closely with the other health protection agencies in the UK to ensure a consistent UK response.

A key part of the response was monitoring the spread and impact of the infection. During the pandemic the Scottish Influenza Surveillance Reporting scheme collected information on the number of consultations for influenza-like illness (ILI) or acute respiratory illness (ARI) from 984 (96%) of the 1024 Scottish General Practices. From the establishment of reporting from this system (17 August) there was an increasing trend until mid to late November followed by a sharp decline in December and a rise to a further, smaller peak in late December, followed a decreasing trend (see Figure 1). This was mirrored by the trend

for the proportion of swabs taken from a sample of those attending their GPs which were positive for the virus.

As at 31 March 2010, a total of 1542 confirmed cases of influenza A(H1N1) infection had been hospitalised[1]. There have been 69 deaths in those with confirmed influenza A(H1N1) infection, at least 69% (47/68) were known to have underlying medical conditions including diabetes (6), a respiratory condition (15), obesity (9), renal/liver conditions (12), congenital abnormalities (9), immuno-suppression (8), pregnancy (3) and a malignant illness (6). In some cases, there were multiple conditions present.

Figure 1: Swab positivity and ILI ARI GP consultation rates



* Appendix 2 gives the date for each report week.

Immunisation Policy in Scotland

Immunisation policy in Scotland is set by the Scottish Government (SG). The SG works very closely with the UK Government and other devolved administrations to ensure that, as far as possible, a consistent approach to immunisation policy is taken across the UK. Both the UK Government and devolved administrations receive independent advice on immunisation from the Joint Committee on Vaccination and Immunisation (JCVI). The vaccines for public health vaccination programmes are usually procured through a UK contract. Contracts with the key service providers, general practices, are almost always based on UK negotiations. For the duration of the pandemic, Government decisions on immunisation policy were taken through civil contingencies structures with expert advice received from the Scientific Advisory Group for Emergencies (SAGE) and JCVI.

In mid-June 2009, and based on the existing evidence and independent expert advice, the Cabinet Secretary of Health and Wellbeing announced a commitment to delivering a vaccination programme that would offer vaccination against influenza A(H1N1) to 100% of

the population, this initial announcements confirmed that the phasing of the programme would be prioritised initially to target those at greatest risk of influenza.

The public health aims of the vaccination programme were to:

a) protect those who are at most risk of serious illness or death should they develop influenza;

b) reduce the transmission of the influenza A(H1N1) virus within health and social care premises;

c) indirectly protect those who may have a suboptimal response or are too young to be immunised;

d) avoid disruption to essential care services.

These aims correspond in general terms to those of the annual seasonal influenza vaccination programme. Because of constraints on the availability of the new vaccines, due to the manufacturing schedules, the implementation of the programme was to be phased. The commencement date and roll out of the programme was also dependent upon the licensing and rate of production of the vaccines and the outcome of contract negotiations with general practitioners. The latest scientific information on the likely spread and nature of the virus was reviewed by JCVI and SAGE with Ministers considering their advice and its implications. As a result decisions were made to modify the programme where appropriate.

On 2 July 2009, a letter was sent by Scottish Government to key personnel in the NHS, local authorities and emergency planning asking them to prepare for the forthcoming vaccination programme. On 13 August 2009 the Scottish Government announced details of the clinical priority groups for phase 1 of the programme:

i. Individuals aged six months and up to 65 years in the current seasonal flu vaccine clinical at risk groups;

ii. Pregnant women;

iii. Household contacts of the immuno-compromised;

iv. People aged 65 years and over in the current seasonal flu vaccine clinical at risk groups.

Ministers also agreed that frontline health and social care staff workers would be vaccinated alongside the first priority groups as they are at increased risk of infection and of transmitting that infection to susceptible patients. Frontline health workers eligible for vaccination would be those eligible for seasonal influenza vaccine as detailed in the national guidance on seasonal flu immunisation i.e.

- Healthcare workers with direct patient contact;
- Social care staff who are employed to provide personal care to children and adults, both in care homes and in the community.

On 4 September 2009 the Scottish Government issued further guidance on the priority staff and occupational groups including definitions for staff providing healthcare in non healthcare settings that would also be included in the vaccination programme:

- Prison officers and staff in other secure institutions who are providing informal healthcare;
- Staff providing informal healthcare in schools for children with special needs

The guidance also made clear that offshore doctors who work on oil and gas platforms and helicopter pilots who transport them and patients should also be treated as healthcare workers.

A Government letter was issued on 21 October which outlined the launch of the programme in primary care.

A further Chief Medical Officer letter was issued on 3 November 2009, to provide further guidance on the prioritisation within priority groups for making use of the initial limited vaccine supply. This recommended that the following groups were vaccinated first:

- Those in the clinical at-risk groups who are youngest i.e. pre-school and school aged children (especially those with significant morbidity due to one or more risk factors);
- Pregnant women (taking note that risk from influenza A(H1N1) illness increases with gestation); and
- Those deemed to be at highest risk on the basis of professional/clinical judgement.

In addition, boards and GPs were advised to prioritise the vaccination of children and young adults who have special needs due to significant physical disabilities.

An announcement by the Cabinet Secretary for Health and Wellbeing on 19 November 2009 provided details of the Phase 2 priority groups for the H1N1 vaccination, (with details contained in the CMO letter 3 December 2009). Phase 2 offered vaccination to all young children aged over six months and up to five years of age. The rational for the inclusion of this group was that children under the age of five years consistently had the highest levels of hospital admissions with the influenza A(H1N1) infection.

The phase 2 programme also included the vaccination of poultry workers.

The JCVI advice of 18 November 2009 noted that vaccination of carers for elderly or disabled persons – whose welfare may be at risk if their carers fall ill – may have benefits although it did not recommend vaccination of this group. After further discussion and consideration by UK Health Departments, this group was not included in phase 2 of the programme.

Having considered the JCVI advice of 3 February 2010 and following Ministerial discussions across the four nations, a decision was made that during the spring/summer (1 April to 30 September), any new entrants to the priority groups identified for phase 1 of the programme should be offered H1N1 vaccination, including frontline health and social care workers.

Within this the largest group will be pregnant women, with approximately 1100 women identified as pregnant each week in Scotland.

Influenza A(H1N1) Vaccines

As the exact nature of a strain of the influenza virus that will cause a pandemic cannot be predicted, influenza vaccines against a new pandemic virus could not be produced until a specific strain had started to circulate, was detected and characterised. Prior to this pandemic, however, vaccine manufacturers had developed and tested new types of influenza vaccines that could be adapted when a pandemic arose. These vaccines were given preliminary approval in the EU as part of the pre-pandemic preparedness work. These monovalent (i.e. single strain) vaccines were developed with antigen from influenza A H5N1 influenza viruses – a virus to which most people have no immunity. The influenza A(H1N1) vaccines were therefore the same as these H5N1 vaccines except that the virus antigen comes from the WHO pandemic declared strain A/California/07/2009/.

At a UK level, the Advance Purchase Agreements that were in place should the WHO declare a pandemic, were activated and contracts signed with two vaccine manufacturers (Baxter and GlaxoSmithKline (GSK)).

On 1 October 2009 the European Commission announced that it had approved a licence for Pandemrix® manufactured by GSK. Pandemrix® vaccine is a split virion, inactivated vaccine. On 9 October 2009 the European Commission announced that it had approved a licence for Celvapan® manufactured by Baxter Healthcare Ltd.

The initial schedule for the Pandemrix® vaccine at the start of the programme was:

- Children aged 6 months up to 10 years: 0.25ml, repeated after an interval of at least three weeks;
- Adults and children aged 10 years and above: a single injection of 0.5ml;
- Immuno-compromised individuals aged 10 years and above: 0.5 ml repeated after an interval of at least three weeks.

For Celvapan® it was: Adults and children aged 6 months and above: 0.5ml, repeated after an interval of at least three weeks

The vaccine products available for use in the UK were inactivated (i.e. did not contain live virus).

As is common with many vaccines, the main product purchased (Pandemrix® by GSK) included an adjuvant to help boost the immune response. Because the type of adjuvant was not dependent on the strain of virus, it was prepared before the pandemic and was contained in vials separate from the antigen. The adjuvant and antigen therefore required mixing before being injected. Both adjuvant and antigen were only available in multi-dose vials. These factors made the practical implementation of the programme in clinical and other settings more challenging than other vaccinations.

In December, the JCVI considered new evidence from clinical trials and updated the vaccine schedule for children aged 6 months up to 10 years to one single dose of 0.25ml Pandemrix®. For children that are immuno-compromised the schedule remained the two dose schedule.

Public Communications

In line with the Scottish and UK Pandemic Planning frameworks, public communications on the pandemic in Scotland were the responsibility of Scottish Government and were carried out within the context UK-wide decision making. This included information on immunisation.

The development of most of the information materials provided on H1N1 immunisation was led by the Department of Health on behalf of the other devolved administrations. They were based partly on the findings of the regular UK-wide polling commissioned by Government, of public knowledge attitudes and views to the evolving pandemic and this common approach across the four nations ensured consistency of messaging to the public.

Unlike other national vaccination programmes, the social marketing of H1N1 vaccination was developed using generic images and messages primarily prepared as part of the management of the response to a national outbreak and emergency. The relatively short timescales made the implementation of a public information campaign a demanding task.

GOVERNANCE, STRUCTURES AND PROCESSES

Background

As indicated, the vaccination programme was one of key elements of the Scottish health protection response in the treatment phase of the pandemic which was coordinated by HPS. Since its formation in 2003, the organisation has been responsible for ensuring a consistent and cohesive response in Scotland to health protection priorities partly through coordinating specified national programmes.

Experience from these programmes has highlighted that once policy has been determined and sufficient resources allocated to deliver it, effective implementation of a vaccination programme depends on the following elements being in place and meshed together:

- Informing the public of the need for immunisation and listening to and addressing their concerns so that they can decide whether to come forward for the procedure (public communications);
- Ensuring professionals and organisations know of the need for the immunisation, what their role is in meeting it and giving them access to education and training so that they can vaccinate those coming forward (service communications including education and training);
- Identifying who needs immunisation, calling and recalling them to a clinical service, recording when and what vaccine they have received, if they suffer any complication from this and reporting on all of these (data management);
- Ensuring that those providing the immunisation have sufficient vaccines which are appropriately and safely stored and administered, with all waste being securely disposed (procurement and logistics);
- Providing a clinical service to vaccinate those coming forward which is timely, accessible, safe and efficient (service delivery);
- Monitoring that those who require the vaccine are taking up the offer, their health is being protected and they do not suffer any adverse impacts (epidemiology and surveillance).

Programme Management Aims

The aims of the H1N1 vaccination programme management were to:

- Be accountable to the Scottish Government Health Directorates (SGHD) and the NHS National Services Scotland (NSS) Board for the effective implementation of the national H1N1 vaccination programme;

- Establish and coordinate a national programme of work ensuring readiness for implementation of the new vaccine as recommended by the JCVI and Scottish Government;
- Coordinate local NHS board implementation groups to ensure that the H1N1 vaccination programme was effectively implemented especially through links with local Primary Care services.

Governance

On 15 May 2009 the Scottish Government Health Directorates met with HPS to discuss the development of an H1N1 vaccination programme. The initial remit was to plan for the possible delivery of H1N1 vaccination to the entire population. Delivery would be subject to a number of planning assumptions including a phased delivery model with prioritised groups and a two dose vaccination schedule with a minimum three week interval between them. Scottish Government subsequently wrote to the Chief Executive of NHS National Services Scotland (NSS) confirming NSS as the board responsible for the national level coordination of the programme with HPS leading this with input from other NSS Divisions. NSS was given the task of working in partnership with NHS boards, responsible for delivery of the programme to their local populations. HPS' Corporate Management Team regularly received updates on the risks and issues associated with the programme and following standard procedures, where appropriate these were reported to the NSS Chief Executive and Board

An H1N1 vaccination programme Steering Group was established by the Scottish Government, chaired by Mr George Brechin, Chief Executive Officer NHS Fife. This provided an oversight of the National Programme. The group met on a monthly basis with representation from a wide range of experts selected by Scottish Government. It reported to the Scottish Government on how well the programme was being implemented, including a regular review of the key risks and issues. It also advised the H1N1 Coordination Group led by HPS.

Regular updates on progress were also provided at the weekly meetings of NHS Chief Executives and meetings of the Directors of Public Health.

Programme Structures

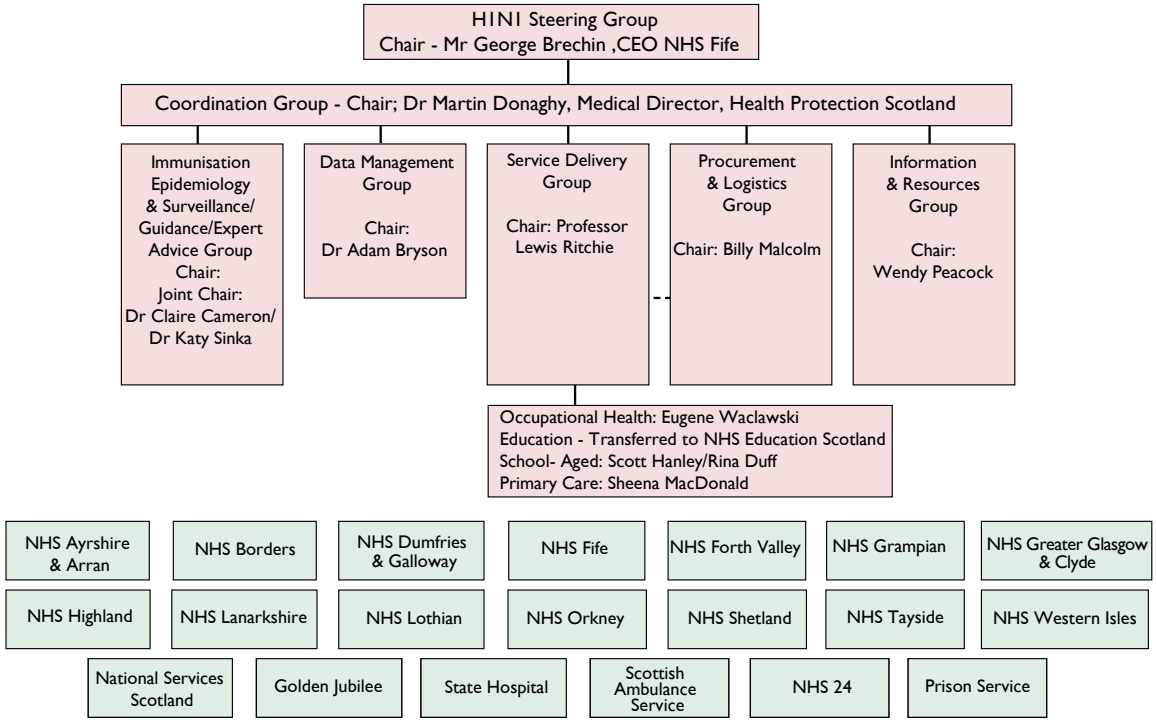
HPS established a national H1N1 vaccination programme structure with representation from a wide range of stakeholders including the Scottish Government, NHS territorial NHS boards, NHS National Services Scotland, NHS Health Scotland. The organisational chart is outlined below. The structure was approved by the H1N1 Steering Group and communicated to NHS boards on 21 July 2009.

The structure was based on the key elements identified as being needed to effectively implement a vaccination programme and especially those put in place for the HPV vaccination programme. However, there were substantial differences to this last, namely:

- Planning and management had to take place in a very fluid situation. The degree of scientific uncertainly about the infection and decisions being made as part of the civil contingency to deal with a public emergency, influenced how immunisation policy was shaped. The initial scope and phasing of the programme required on-going modification.
- Close liaison with Scottish Government was essential and a specific mechanism was developed for this. The Scottish Government H1N1 Programme Lead provided a link on project progress through each stage. This ensured the programme interfaced with key Government processes such as vaccine procurement, GP contracting, issuing CMO and Chief Executives letters.
- Procurement and logistics were more complex than for other programmes with the initial limited stocks leading to the need to prioritise who received the vaccine first.
- At first planning needed to ensure that the programme could cover the total population if required (including groups not usually reached by standard vaccination programmes). This meant that the range of service providers and models of delivery was extensive. It led to the need for a more complex programme structure for service delivery with groups covering occupational health, school aged children and primary care.
- Ensuring professionals knew about vaccination was only part of a broader suite of pandemic influenza related education training issues being addressed by NHS Education Scotland. This work was therefore transferred to a group which formed part of NES's programme structures.
- The interface between HPS and NHS boards had to be particularly strong with Government requiring assurance that the programme was being implemented evenly and effectively throughout the country. NHS boards needed frequent updates on the changing circumstances and direction of the programme. NHS boards were instructed by Scottish Government to appoint strategic and operational leads for the programme. A range of specific communication systems were developed to facilitate joint national and local working.

The Initial Programme structures are presented in Figure 2 below. These were modified and new Working Group leads appointed when appropriate: Dr Brian Robson (Data Management) Ms Shirley Fraser (Information Resource). Their remits are presented in the individual sections reporting on their activities in Appendix 1.

Figure 2: H1N1 Vaccination Programme Governance Structure



Programme Working Groups

The Coordination Group chaired by the project Sponsor, managed the project. It was accountable to the H1N1 Steering Group. The Coordination Group provided direction to the H1N1 Vaccination Programme Working Groups and monitored the outputs from the groups.

Five H1N1 Vaccination Programme Working Groups were integrated in the programme structure. They were:

1. Service Delivery

Based on the experience of seasonal flu immunisation, from the early stages it was clear that the engagement of the primary care sector was essential. It was decided therefore that a primary care professional should lead this group supported by HPS. Professor Lewis Ritchie of the University of Aberdeen agreed to undertake this challenging task. The Occupational Health Sub-Group was led by a representative of the NHS Occupational Physicians Group, the School Group by a School Health Service Nurse Consultant and the Primary Care Group by a Community Health Partnership GP lead. Wide-ranging input went into these

groups including from the Scottish GP Sub-Committee of the BMA. As the programme developed, a liaison group with NHS board Midwife leads was established, meeting regularly via a teleconference.

The four UK Health Departments decided that general practices should be the main providers of immunisation to the clinical at-risk groups (including pregnant women) and subsequently to children in the under 5 age group. Contractual arrangements were put in place. These took some time and NHS boards were asked to put in place contingency measures should these prove to be unsuccessful. Plans also required to be put in place to ensure potential coverage of the whole population. For the health and social care workforce, NHS boards were asked to build on current mechanisms mainly based on occupational health services. Taking these factors into consideration, service delivery was broken down into three areas: schools (children aged 5-17 years who are pupils), health and social care workforce and primary care (all other remaining sections of the population).

Given the scale and urgency of the problem, there was a need for locally determined, innovative models of service delivery. However there was also a requirement to balance this with centralised governmental, decision making at a Scottish and UK level and considerations of equity, coordination and assurance. Given that pregnant women are a group who are not routinely immunised but are at specific risk from the infection, how to achieve this balance was a question which featured prominently as the programme evolved.

2. Procurement and Logistics

This group was led by HPS jointly with NSS National Procurement with input from NHS boards and Scottish Government.

All work related to the contracting and procurement of vaccine for use in the national programme was undertaken by the UK Government Department of Health (DH) which had in place contractual arrangements known as Advance Purchase Agreements (APA) with two vaccine manufacturer's (GlaxoSmithKline and Baxter Healthcare Ltd) to ensure that the UK would receive an agreed amount of pandemic influenza vaccine in the event that the World Health Organisation (WHO) declared a pandemic. The APAs were activated and contracts signed with GSK and Baxters in June 2009. As part of these arrangements Scotland received an 8.45% share (based on Barnett Formula) of all vaccine deliveries into the UK.

The vaccine manufacturers made deliveries of vaccine on a weekly basis to the DH vaccine distributor. Following allocation of vaccine stock across the UK orders were processed for deliveries into NHS boards in Scotland. Stock was delivered on a weekly basis into the NHS board vaccine holding centres (VHC) that currently manage the distribution of childhood vaccines across primary care. Following receipt of stocks from DH vaccine distributor into the VHC the responsibility for storage and distribution to GP practices and other destinations was with the NHS board.

3. Data Management

This group was led by NSS e-Health with input from ISD, HPS, Scottish Government and NHS boards. Work was integrated with other activities being taken forward in relation to national and primary care data systems.

Evidence based reviews of the effectiveness of vaccination programmes highlight the importance of information systems. Core to this is the establishment of an accurate population register to identify the target population. This should have the capacity to provide 'real time' feedback on uptake rates so that action can be taken to improve these. For the clinical at-risk population, two options were available: centralised registers operated by the NHS boards or practice list registers operated by GPs. Priority was given to the latter although information systems required modifying, particularly in order to resolve issues concerning the identification of pregnant women and the recording of their immunisation status. On a number of occasions, the scope for integrating the various information systems to reconcile the data held on them was reviewed. However this proved to be impracticable.

The introduction of standardised, automated UK reporting into the 1,024 Scottish general practices was a major task. Core to this was working with the three main software suppliers for the GP information systems: GPASS, EMISS and INPS (the first of these, operated by the Scottish NHS, is currently being discontinued.) A number of significant data management challenges were addressed in the course of this work and there remain some data quality issues associated with the immunisation of pregnant women on which work is ongoing.

4. Epidemiology & Surveillance

The group was led by HPS with input from ISD, Scottish Government, NHS boards and academics. This facilitated integration of this work with other HPS activities especially the concurrent surveillance of pandemic flu related illness and death and the seasonal flu vaccination programme.

As the pandemic evolved into the containment phase, a Scottish surveillance strategy for the infection was put in place which was meshed with those in other parts of the UK. This built on the systems in place for seasonal flu, principally based on reporting from GPs and virological laboratories. Monitoring GP uptake rates was part of the strategy and mechanisms were developed specifically for the programme. This was accompanied by NHS board reporting on health and social care workforce rates which required the development of specific local mechanisms.

Most of the specialist epidemiological expertise was directed at ensuring 'real time' uptake monitoring was occurring. The priority now is to review the data available to assess the impact of the programme. Some of the initial findings are summarised in the Conclusions section of this report. Many of the findings remain provisional. If we are truly to understand the epidemiology of the infection and the impact on it of immunisation in Scotland, we need to supplement the final findings from routine reporting with specific studies. HPS has prioritised assessing the effectiveness of the programme in protecting pregnant women, the health and social care workforce and socio-economically disadvantaged groups.

5. Information & Resources

Given their experience in developing professional materials for other vaccination programmes, this group was led by NHS Health Scotland with input from H1N1 operational leads, NES, NHS 24, Care, Immunisation Coordinators, Service Delivery Group chair, HPS and Scottish Government and specific programme manager support from Health Scotland.

Communications related to immunisation are divided into public and service. Scottish Government in partnership with the UK Department of Health, was responsible for delivering the public-facing communications which needed to be integrated with other aspects of the response to the pandemic. The main purpose of this group therefore was to ensure that the information materials developed were relevant to the vaccination programme in Scotland.

The effectiveness of both types of communication depended on an understanding of how the public perceived the risk of the infection and the benefits and risks of immunisation. The UK Health Departments monitored public attitudes through regular polling. In Scotland, NHS 24 regularly fed back on calls to their service and 'hits' on their website.

The IRG formally ceased its business on 12 November 2009 with the proviso that it could be reconstituted if the programme required this.

H1N1 Working Groups were accountable to the H1N1 Coordination Group and provided verbal and written updates at scheduled weekly meetings. Each working group and the coordination group agreed Terms of Reference and members were selected with a variety of suitable skills.

Key outputs from each group are outlined in Appendix 1.

Liaison with NHS Boards

NHS boards are responsible for meeting the health needs of their resident populations. HPS is responsible, in partnership with others, protecting the Scottish public from infectious and other health hazards. The planning, development and implementation of the vaccination programme therefore entailed effective joint working among these organisations and other national NHS agencies. Special NHS boards and the Scottish Prison Service were also engaged because of their need to immunise their workforce. The framework for this collaboration was set out in SGHD letters. Each Board was required to have a strategic and operational lead.

HPS therefore chaired a Board Liaison Group composed of the operational leads from the territorial and special NHS boards, a representative from Scottish Government, and other group leads/deputies i.e. service delivery, data management as appropriate. The group was accountable to the Coordination Group. Regular progress reports were received and a weekly teleconference was held.

To ensure that the provision of the programme was equitable across Scotland and to facilitate its effective delivery, a number of guidance documents were produced. These particularly covered groups in the population who were at higher risk or harder to reach, in line with

the Scottish Government's commitment to tackling health inequalities. In addition all NHS board plans were reviewed centrally, gaps identified and fed back to NHS boards. Steps were taken to facilitate the sharing of good practice among NHS boards.

A key challenge for NHS boards was the immunisation of groups who do not routinely receive this service, especially pregnant women and the social care workforce. Different models of delivery developed as the programme was rolled out.

Key outputs from the liaison group are outlined in Appendix 1.

Liaison with Scottish Government

As indicated, input from Scottish Government officials to the Coordination Group and working groups was essential. The Scottish Government Health Directorates were responsible for setting national policy in line with Ministerial decisions and communicating it within Scotland. They briefed Ministers, monitored NHS board performance and were involved in negotiating primary care contracts. They provided input into the development of the marketing campaign in Scotland. They linked with other parts of Government involved in the civil contingencies response and received scientific advice from the JCVI and SAGE. They liaised with the UK Department of Health on the development of evidence based guidance on immunisation, which formed a chapter of the 'Green Book' issued to GPs and other professionals.

Key outputs from the liaison with Scottish Government, and in particular the Chief Medical Officer and Public Health Directorate, are outlined in Appendix 1.

Programme Management Processes

HPS adopted the NHS Corporate Programme Office project management methodology, based upon PRINCE2®. It comprised of the following phases - Proposal, Initiation, Implementation, Closure and Review.

A Project Initiation Document relating to the proposed H1N1 vaccination programme was thus developed and subsequently approved by the H1N1 Steering Group on 26 August 2009. Thereafter the Programme Coordination Group provided monthly project reports for review and discussion at each meeting.

A High Level Plan was created as a result of individual working groups scoping out the various activities relating to their work areas. Additionally a Pre-Implementation Plan for both Phase 1 and 2 was completed which served as a monitoring tool for task scheduling and monitoring slippage. As there were a number of variables and unknowns at the onset of the programme, the working groups operated on a three month cycle of planning projections.

In addition, local NHS boards were asked to prepare local implementation plans and share them with Health Protection Scotland to assess readiness for both workforce vaccination and for vaccination of the clinical at risk groups.

The Programme Manager produced monthly reports to communicate and update progress to the H1N1 Steering Group, SGHD, initially HPS linked the work on immunisation with its other pandemic activities through it's Influenza Response Coordinating Team. H1N1 Working Group Leads contributed to the monthly reporting cycle for their respective areas. These reports were consolidated into a central project update on a regular basis

Due to the many 'unknowns' about the programme, the short time-lag between decisions and implementation, logistical challenges and the iterative nature of the programme, a change control mechanism was deemed not applicable. A dedicated H1N1 project folder was created and all relevant documentation stored in the appropriate folder relating to the project lifecycle. Emails relating to key decisions will also be stored within this structure to ensure a full audit trail

Resources

The Programme Manager (Immunisations) HPS was responsible for the coordination and management of the project on a day-to-day basis through the use of project plans, monitoring of risks and issues, managing resources, adherence to governance, producing project status reports and recommending corrective action when necessary. The Programme Manager provided frequent updates to SGHD, Project Sponsor and Coordination Group and was a member of all the H1N1 Working Groups.

HPS provided secretariat and project support to all these groups with the exception of the Steering Group and the Information and Resources Group.

At the start of the programme, the Immunisation team at HPS produced a resources brief to outline the support needed for the programme including an adequate balanced skill mix. Specifically, a Service Planning Manager was secured on a short term basis to work directly with NHS boards in preparation for implementation. Additionally, one senior epidemiologist was transferred internally onto the programme and an increase in administration support was secured at a later stage of proceedings.

NHS boards in partnership with Directors of Finance were requested to capture actual and opportunity costs in delivering Phases 1 and 2.

LESSONS LEARNED

Introduction

In accordance with NSS Corporate Programme Office project management methodology, a structured assessment exercise was undertaken to determine lessons learned from the H1N1 vaccination programme. The assessment was an opportunity for stakeholders to comment on the programme, share experiences, draw from good practice and identify practical and strategic issues that need to be considered from the programme.

Methodology

The lessons learned assessment was developed in conjunction with the programme operational groups. The assessment tool was distributed to these groups, the NHS board leads and the H1N1 steering group for completion. Participants were asked for their views on;

- what worked well;
- what didn't work well; and
- what should be improved.

These questions were asked for six areas of the national programme:

- Governance and Management;
- Epidemiology and surveillance;
- Data Management;
- Service Delivery;
- Procurement and Logistics; and
- Public and Professional Communication and Workforce Development.

Board leads were not asked for their views on their own local issues. It is expected that each Board will undertake its own lessons learned exercise.

Thirty-four NHS board leads and members of the steering group, working groups and coordination group responded. Over 1500 comments were received. None were discarded but similar points made by different participants have been amalgamated for brevity. Collation was carried out by a member of HPS staff who was not directly involved in the programme or HPS's emergency response. The number of original comments received was tallied and tabulated in a matrix of what worked well.

Lessons Learned

There was a high degree of consistency in responses, indicating that the issues encountered in the programme were common to most participants. Table 1 summarises the number of comments received in the six programme areas. It varies across each due to the numbers of lessons learned questions asked in each area; high numbers of questions have elicited high numbers of comments. An exception to this is the data management section where a relatively low number of comments have been received. This is because the bulk of the comments received in this area came from a group response submitted by the Data Management Group rather tan from individual members. A group response was also provided by the Service Delivery Group however, a substantial number of further comments were provided in this area by the other participants.

Table 1: Summary of the number of original comments captured in the H1N1 Immunisation Lessons Learned Assessment

Programme Area	What worked well?	What work well?	What should be improved?
National Programme Governance and Management (12 Questions)	167	191	119
Epidemiology and surveillance (5 Questions)	37	40	27
Data Management (14 Questions)	25	66	33
Service Delivery (12 Questions)	120	140	64
Procurement and Logistics (8 Questions)	93	118	33
Public and Professional Communication and Workforce Development (8 Questions)	87	112	52
TOTALS	529	667	328
	1524		

Key themes from each of the assessed programme areas were identified based on their frequency of occurrence in responses. These were presented at the meeting of the Coordination and Boards Groups and further refined in light of comments received at these meetings. The issue which participants identified as causing most problems was the delay in vaccine supply from the manufacturers. This impacted on the achievement of all subsequent programme objectives. The next most frequent cause for concern was the accurate identification of pregnant women for vaccination.

The following is a summary of the key themes arising from respondents' views.

National Programme Governance and Management

What worked well:

- Programme administration arrangements, including teleconferencing, meeting arrangements, production of minutes and reports and communication links with the operational leads all worked well given the complexity of the programme objectives.

- High level programme plans were useful, ensuring consistency of delivery. Had there been no framework then NHS boards may not have started vaccinating on time.

What didn't work well:

- In comparison to other vaccination programmes, the development of H1N1 immunisation policy did not have as full an engagement of all stakeholders. It was appreciated that this was mainly due to the need to have UK-wide policies in place quickly and to the initial lack of clarity over which population groups would most benefit from vaccination.
- The delay in agreement between the Scottish Government and GPs over the extent of GPs' role in immunisation created uncertainty initially.
- Local anecdotal feedback indicated that the use of the term 'fast-tracking' for the licensing of the vaccine appeared to create anxiety over vaccine safety among the public.

What should be improved

- Further development of common templates for planning future vaccination programmes.
- National agreements with GPs over the nature and extent of their role in any future vaccination programme should be clarified as early as possible.

Epidemiology and Surveillance

What worked well

- Surveillance and reporting worked well for the programme with information being shared effectively among programme stakeholders.

What didn't work well

- There were problems with the quality of the data making it difficult to target practices where uptake was low.
- Guidance on anticipating vaccine administration errors could have been provided earlier.

What should be improved

- A more clearly defined epidemiological dataset should be available before the start of a future vaccination programme with a plan on how this is collected from GP systems.
- There was difficulty in distinguishing between the function of the Epidemiology and Data Management Groups.These should be more clearly defined for future vaccination programmes.

Data Management

What worked well

- Arrangements for sharing data from general practices worked well.

What didn't work well

- Delays and problems with the data extraction software meant that accurate uptake reporting could not commence until after the programme had started.
- Identifying pregnant women was problematic, despite the establishment of good communication links with midwifery teams.

What should be improved

- Further work is needed to define models of good practice for identifying pregnant women. Arrangements in the other three countries of the UK should be appraised.
- There should be extensive consultation among programme operational groups, end-users and extraction software suppliers in the early stages of future vaccination programmes.

Service Delivery

What worked well

- Locally developed models of service delivery on the whole worked well.
- NHS boards had well established pandemic plans in place ahead of the H1N1 incident.

What didn't work well

- Delays in producing the Direct Enhanced Service (DES) agreement caused uncertainty.
- The national command and control arrangements led many NHS boards to perceive that the implementation of the programme was micro-managed by HPS and the Scottish Government, particularly in the early stages.

What should be improved

- If at all possible, a Directly Enhanced Service agreement should be put in place with GPs in advance of a future pandemic.
- National and local responsibilities should be more clearly defined with, as far as possible, command and control arrangements clarified ahead of a future pandemic.

Procurement and Logistics

What worked well

- Input and support from the Procurement and Logistics Group; in particular, having a central point of contact at HPS to deal with procurement and logistics issues and provide updates on vaccine supply status was helpful.
- Storage and distribution arrangements worked well locally.

What didn't work well

- While the procurement process worked well, there were significant delays in commencing vaccine supply and initial uncertainty over the amount of vaccine to be supplied. Only short-term forecasts of vaccine supply could be produced in the early stages because of the limited information the vaccine manufacturers were able to provide.
- Multi-dose vials meant that providing opportunistic vaccination was problematic and led to wastage of vaccine in some areas.

What should be improved

- Greater clarity is needed at UK level around vaccine supply arrangements to allow NHS boards to plan vaccinations especially in the initial stages of a programme.

Public and Professional Communication and Workforce Development

What worked well

- National training materials were of a high standard and could be readily disseminated among staff.
- The microsite was a useful single source of information for H1N1 immunisation, but needed to be updated more frequently.

What didn't work well

- There were delays in receipt of public information material, which were sometimes significant. Partly this was due to their centralised development at a UK-wide level. Vaccination went ahead without this material in some cases.
- GPs felt at times overloaded with information material, including duplicate information from different sources.
- The need for openness and transparency by UK and Scottish Governments in dealing with the media at times presented problems. Information could appear in the media ahead of NHS boards and local services receiving it or having in place the capability to respond to public demand.

What should be improved

- Improved coordination of UK and Scottish communication is desirable to ensure that appropriate material is delivered to the correct recipients on time while acknowledging that 'emergency' vaccination programmes such as H1N1 should not be delayed as a result of a lack of information materials.
- Equality Impact Assessments should be carried out in advance of vaccination programmes to identify population groups who may need specific information tailored to their needs.
- Earlier availability of Scottish and UK communication for NHS boards is desirable, particularly when the information relates to changes in immunisation policy.

Summary

Responses were limited to the national coordination of the programme not its full implementation locally. As has been pointed out, the degree of local decision-making about the timing and nature of the delivery of the programme was sometimes limited. Despite this, NHS boards worked often under great pressure to deliver the programme on time and were flexible in changing models of provision when necessary e.g. the immunisation of pregnant women.

Relatively more comments focussed on what didn't work well. This is a common feature of lessons learned exercises, where participants tend to focus on areas that caused difficulty and should be avoided in future programmes. Moreover they did not greatly exceed what worked well suggesting that the programme on the whole performed satisfactorily. Similarly the number of suggestions for improvement is relatively low, suggesting that there are not many specific programme areas that should be corrected for future programmes.

CONCLUSIONS

Public Health Goals

The public health aims of the H1N1 vaccination programme were to:

- protect those who are at most risk of serious illness or death should they develop influenza;
- reduce the transmission of the H1N1 virus within health and social care premises;
- indirectly protect those who may have a suboptimal response or are too young to be immunised;
- avoid disruption to essential care services

The effectiveness of influenza vaccine depends primarily on the age and immunocompetence of the recipient and the degree of similarity between the viruses in the vaccine and those in circulation. Among adults influenza immunisation is usually very effective (70-90%) in reducing influenza morbidity. In those who were immunised as part of the H1N1 vaccination programme, preliminary UK evidence (including findings from Scotland) indicates that vaccination was very effective in preventing infection. Pandemic influenza vaccine effectiveness was estimated as 95% (95% Confidence Interval 76%, 100%) i.e. those receiving it were 95% less likely to be infected compared to those who did not[2].

The effectiveness of a public health programme depends not only on the benefits from its interventions but also on its ability to reach the people who need it at the right time and in the right way. The main aim of the programme was to reduce serious illness and death in those most at risk from influenza A(H1N1) infection. The impact of the seasonal flu immunisation has been estimated by assessing its effect on seasonal increases in morbidity and mortality above a predicted baseline. To help assess the overall impact of the H1N1 vaccination programme on morbidity and mortality, it would be useful to be able compare its impact with baseline estimates of the impact of the annual seasonal flu vaccination programme in Scotland. However estimates of this impact are currently not routinely available in Scotland.

As previously indicated, decisions on the public health management of the pandemic were largely made on relatively limited scientific evidence and were based on estimates of the 'reasonable worst case' scenario so that planning could err on the side of caution. In September 2009, the 'reasonable worst case' scenario was set out in guidance on planning assumptions. This indicated that the pandemic could have a cumulative 30% clinical attack rate in its next wave with up to 15% of clinical cases having complications, up to 1% being hospitalised and up to 0.1% of clinical cases dying[3]. These estimates of the disease were based on the modelling of data, including those on immunity from and the incidence of the infection. Decisions on the likely effectiveness of the vaccination programme also took into consideration the findings from modelling these and other data.

A discussion on the impact of the programme should therefore recognise that the decision to implement it was based on its likely effectiveness in reducing the then 'worse case scenario' of the pandemic's risks to health.

Evidence from a study carried out during the pandemic shows that around one child in every three was infected with influenza A(H1N1) in the first wave of infection in regions in England with the incidence of the infection being ten times more than that estimated from clinical surveillance[4]. It would therefore appear that many influenza A(H1N1) infected patients did not consult healthcare services, possibly due to mild or asymptomatic infection. For these reasons, the initial estimates from modelling probably underestimated the true infection rate but as the disease was relatively mild, overestimated the number of clinical cases with complications. Based on the official mid-range estimate for incidence of influenza A(H1N1), the overall estimated case fatality rate to November 2009 in the UK was 26 (range 11-66) per 100 000 population of all ages[5], considerably lower than the 'worst case scenario'.

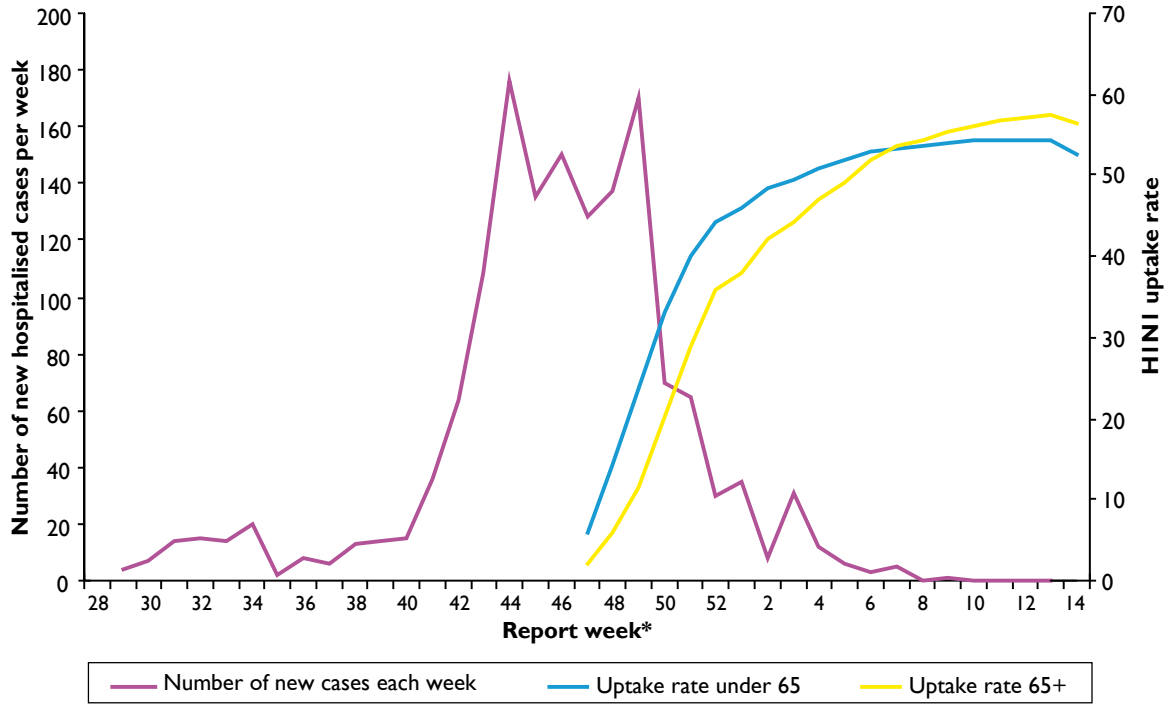
One indicator of the programme's actual effectiveness in Scotland is its impact on the hospitalisation rate due to influenza A(H1N1) infection in the target population for the intervention. Figure 3 presents the number of hospitalisations due to influenza A(H1N1) infection in Scotland and the uptake rates in under and over 65s clinical at risk groups per week between July 2009 and March 2010.

NHS boards were asked to commence the programme from 21 October with initial priority being given to healthcare staff working in A&E, general medicine, intensive care, paediatrics and obstetrics, and following consultation with clinicians, patients in the clinical at risk groups in these specialities. The first supplies of vaccine were issued to general practices from week commencing Monday 26 October 2009 with initial priority being given to children aged less than 5 years in the clinical at-risk categories.

The immunisation campaign for the clinical at risk groups in the community commenced in practice from 3rd November (after the peak in the hospitalisation numbers) although because of problems with vaccine availability there was restricted delivery for a few weeks.

First reports of uptake rates were received in week 46 (15 November). Reported uptake rates in at risk patients in the under 65 age group increased rapidly but did not exceed 50% until week 51 (commencing 21st December). By this time the number of hospital admissions of confirmed cases per week had fallen by 80%. It is unlikely that this was mainly due to the vaccination programme.

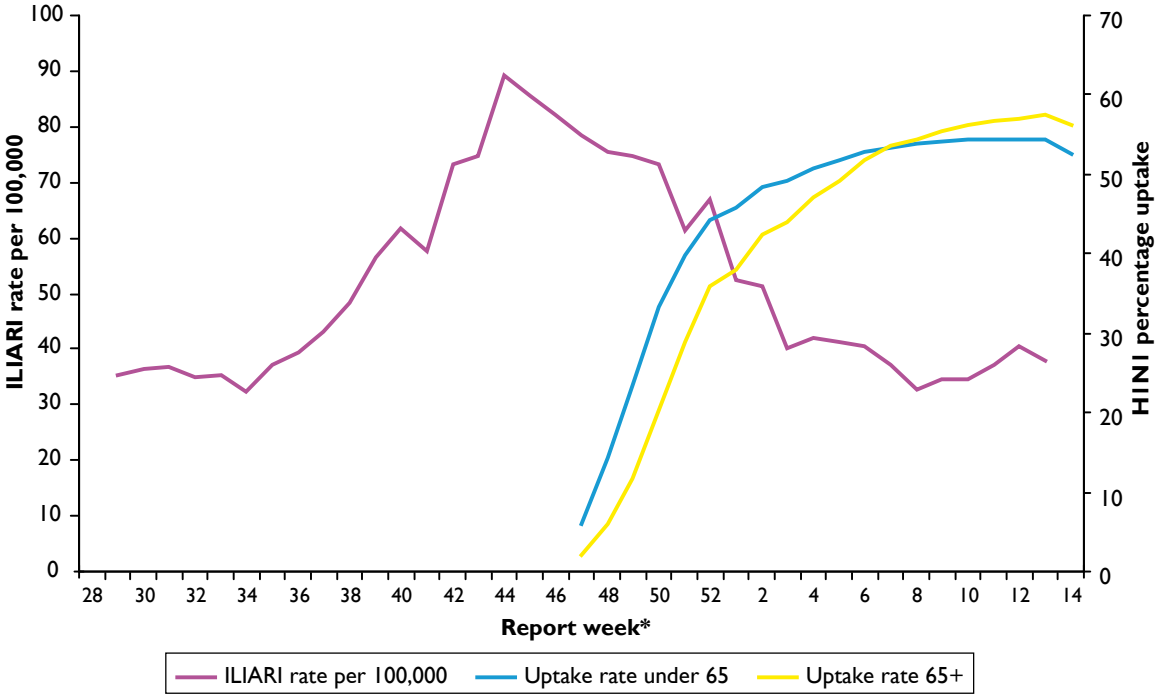
Figure 3: Number of hospitalisations per week and H1N1 uptake rate of under 65 and 65+ in a clinical at risk group.



* Appendix 2 gives the date for each report week.

The weekly rate of GP consultation due to influenza-like illness and acute respiratory infections closely matched the indicators of virus circulating in the Scottish population (as shown by the proportion of a sample of patients consulting who tested positive for influenza A(H1N1) (see Figure 1). Figure 4 shows the consultation rate and the uptake rates in the under and over 65 year olds by week in Scotland. A similar pattern to hospitalisation numbers is observed, with consultation rates having peaked and started to fall before the vaccination programme commenced.

Figure 4: ILIARI rate per 100,000 and H1N1 uptake rates of under 65 and 65+ in clinical at risk groups



* Appendix 2 gives the date for each report week.

Table 2 presents uptake rates by Board area for the clinical at risk groups. Table 3 presents them children aged 5 years who are not in an at-risk category. Table 4 presents the uptake in health and social care staff by age.

As at week ending 6 April 2009, the estimated overall cumulative uptake rate for H1N1 vaccine among individuals in clinical at risk groups among those aged under 5 years is 65.7%; in those aged 5-64 years it is 51.9% and in those aged 65 years, 56.2 %. The estimated overall cumulative uptake in those aged under 5 years old, who are not in the at-risk groups, is 44.6% (see Table 3). These figures are based on data from 95% of GP practices in Scotland. The figures remain estimates.

Currently there are different approaches to calculating and presenting uptake rates in the component countries of the UK and the rates are therefore not directly comparable. All are preliminary. All the countries published estimated uptake rates separately in different communications in late February. These were:

England (preliminary data to 28th February):

- Clinical at risk groups of all ages, including pregnant women: 37.1%;
- Healthy children aged under 5 years: 20.4%;
- Frontline Healthcare workers: 39.9%.

Wales (GP audit data to 19 February)

- All children (healthy and at risk): 21%;

- Clinical at-risk groups 5-64 years (including pregnant women): 42%;
- Clinical at-risk groups 65 years and above: 42%.

Northern Ireland (published on 23rd February)

- Clinical at-risk groups 0-64 years (including pregnant women): 81%;
- Clinical at-risk groups 65 years and above: 69%;
- Frontline health and social care workers: 48%;
- Pregnant women (at end November 2009): 58%.

Scotland (data week ending 21st February)

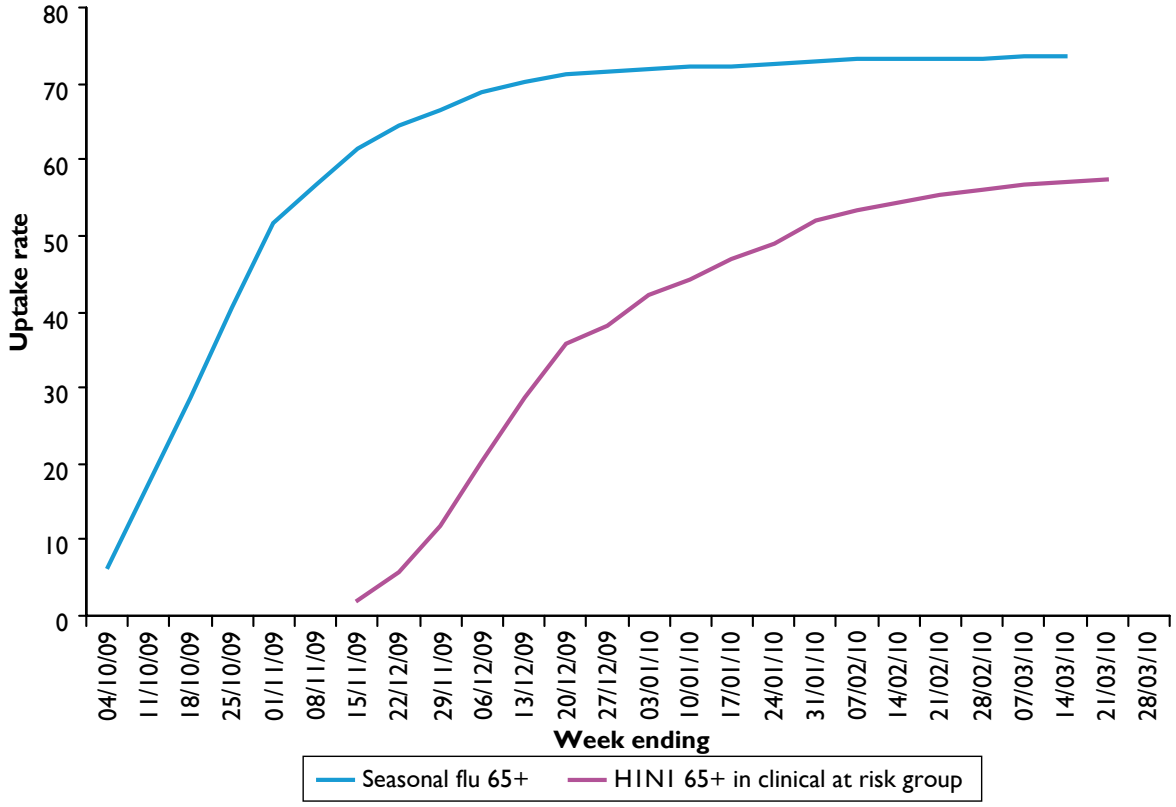
- Clinical at-risk groups 0-64 years (including pregnant women): 54.1%;
- Clinical at-risk groups 65 years and above: 55.4%;
- Frontline healthcare workers: 53.2%;
- Frontline social care workers: 31%;
- Pregnant women (newly delivered at end March 2010): 64.6%*.

The weekly uptake estimate for pregnant women as determined by GP data peaked at 48.1% for the week ending 14 February and has declined to 40.4% for the week ending 4 April. This decline was not unexpected and may reflect a lower level of uptake among newly pregnant women during a period when influenza A(H1N1) is less high profile than during the winter months. These figures were subject to a number of data problems and therefore to obtain a more accurate uptake data rate, two audits were undertaken in maternity units to estimate uptake among women at the point of delivery. The audit conducted in 12 maternity units from 11-17 January calculated an uptake rate of 61.5% for those women where vaccination status was known and when repeated in 9 maternity units on 22-28 March, uptake was 64.6%.*

As can be seen from Figure 5, the uptake of H1N1 immunisation in the over 65s at risk group is markedly lower than the uptake for seasonal flu in all over 65s (healthy and at-risk): 56.2% compared to 73.5%. This may be due to the difference in the target populations (with the healthy over 65s more able to access the service) or operational reasons with the H1N1 vaccination programme for this age group being phased in from early December in many areas compared to a September/October start for the seasonal flu campaign.

* The estimated uptake rate among all pregnant women in Scotland is more difficult to ascertain.* Immunisation was delivered by a mixed model of General Practice and Maternity Services resulting in different sources of information and varying data management systems. In relation to estimating uptake rates in pregnant women there are a number of complicating factors including coding, database and software problems associated with the reporting of uptake rates in pregnancy. In addition, this is a 'dynamic', continually changing cohort with approximately 1,100 newly pregnant and delivered women in Scotland per week.

Figure 5: Uptake rate for seasonal flu in all over 65 years and H1N1 vaccine for 65+ in a clinical at risk group



The pandemic flu immunisation campaign was in operation since 21 October 2009 for frontline health and social care staff. To 8 February 2010 the estimated uptake for one dose of vaccine was 55.2% and 32.1% in health and social care staff, respectively. The uptake of seasonal influenza vaccine was approximately 15% in the health care workforce by the end of the 2008/2009 influenza season (traditionally 31 March) although again the target populations are different with H1N1 immunisation being offered only to frontline workers.

A review of the complete dataset on immunisation and specific studies to investigate uptake and effectiveness in certain target populations are required to elucidate the extent to which the programme achieved its public health goals. However there are indicators that the programme has been successful especially the high uptake rates in the under 5s in the clinical at-risk groups and frontline healthcare staff. Given the challenges faced, the programme does appear to have had relatively high levels of coverage.

Table 2: H1N1 Vaccination Programme Phase 1. Uptake in all clinical at risk groups by NHS board, - under 5, 5 to 64 and 65+ years. Reporting week - week ending 4 April 2010

		Under 5 years			5 to 64 years*			65 years and over		
NHS board	% practices responding with valid data	Number eligible	Number receiving vaccine	Uptake (%)	Number eligible	Number receiving vaccine	Uptake (%)	Number eligible	Number receiving vaccine	Uptake (%)
Ayrshire & Arran	94.9	484	291	60.1	42,431	22,804	53.7	38,143	19,838	52.0
Borders	96.0	119	97	81.5	12,749	8,161	64.0	12,302	8,542	69.4
Dumfries & Galloway	100.0	207	175	84.5	18,094	11,498	63.5	16,976	10,930	64.4
Fife	96.5	532	354	66.5	41,444	22,106	53.3	33,283	19,224	57.8
Forth Valley	96.5	462	332	71.9	34,485	19,218	55.7	26,184	16,450	62.8
Grampian	96.5	568	322	56.7	54,529	22,954	42.1	44,867	23,364	52.1
Greater Glasgow & Clyde	97.0	1,780	1,161	65.2	147,957	76,647	51.8	106,382	58,321	54.8
Highland	98.0	444	292	65.8	34,298	17,375	50.7	30,662	16,943	55.3
Lanarkshire	93.9	888	534	60.1	63,306	33,020	52.2	44,463	23,994	54.0
Lothian	96.8	1,037	721	69.5	88,894	46,179	51.9	64,186	36,775	57.3
Orkney	42.9	7	4	57.1	1,383	648	46.9	1,266	759	60.0
Shetland	100.0	61	49	80.3	2,667	1,567	58.8	1,875	1,084	57.8
Tayside	87.0	406	261	64.3	36,172	18,298	50.6	35,729	20,289	56.8
Western Isles	100.0	52	34	65.4	3,145	1,633	51.9	3,022	1,521	50.3
Scotland	95.3	7,047	4,627	65.7	581,554	302,108	51.9	459,340	258,034	56.2

*5 - 64 years at risk includes pregnant women

Table 3: H1N1 Vaccination Programme Phase 2. Uptake in healthy under 5 years of age by NHS board. Reporting week - week ending 4 April 2010

NHS board	Number practices responding with valid data	% practices responding with valid data	Number <5 years healthy eligible[1]	<5 healthy Number received vaccine[1]	<5 healthy Percentage Uptake[1]
Ayrshire & Arran	59	100.0	17,813	11,497	64.5
Borders	24	96.0	5,393	2,747	50.9
Dumfries & Galloway	35	100.0	7,762	3,888	50.1
Fife	55	96.5	17,900	7,235	40.4
Forth Valley	57	100.0	15,533	5,272	33.9
Grampian	83	97.6	27,223	11,757	43.2
Greater Glasgow & Clyde	262	97.0	61,640	22,674	36.8
Highland	100	98.0	14,758	5,804	39.3
Lanarkshire	96	98.0	28,939	17,391	60.1
Lothian*	107	85.6	38,295	18,174	47.5
Orkney	6	42.9	733	371	50.6
Shetland	10	100.0	1,259	629	50.0
Tayside	60	87.0	16,972	5,979	35.2
Western Isles	12	100.0	1,268	461	36.4
Scotland	966	94.9	255,488	113,879	44.6

1. Around 25% of practices in Scotland indicated that they used SIRS as the primary system for recording vaccinations for healthy children under 5. On SIRS it is not possible to separately identify children in an at risk category therefore the cohort (the denominator) will include children at risk. For these practices the number of doses given (the numerator) will also include vaccinations given to children at risk **where this has been recorded on SIRS**. It is not possible to assess from the data the completeness of data transfer between GP systems and SIRS.

Table 4: Vaccination Programme phase 1.Uptake in front line health and social care staff.
Reporting week - week ending 31 March 2010

NHS board	Health care staff Uptake rate	Social care staff Uptake rate
Ayrshire & Arran	53.6	51.2
Borders	70.8	18.8
Dumfries & Galloway	90.8	49.3
Fife	58.0	31.9
Forth Valley	56.9	42.3
Greater Glasgow & Clyde	53.0	36.7
Grampian	69.5	17.7
Highland	62.4	32.9
Lanarkshire	51.9	33.8
Lothian	54.7	17.4
Orkney	51.9	34.8
Shetland	68.0	34.3
Tayside	42.0	32.1
Western Isles	37.9	16.5
National Services Scotland	47.8	N/A
Golden Jubilee	52.7	N/A
State Hospital	38.0	N/A
Scottish Ambulance Service	44.5	N/A
NHS 24	36.4	N/A
Others		
Prison service	37.3	N/A

Programme Management Objectives

These were to:

- Be accountable to the Scottish Government Health Directorates (SGHD) and the NHS National Services Scotland (NSS) Board for the effective implementation of the national H1N1 vaccination programme;
- Establish and coordinate a national programme of work ensuring readiness for implementation of the new vaccine as recommended by the JCVI and Scottish Government;
- Coordinate local NHS board implementation groups to ensure that the H1N1 vaccination programme is implemented especially through links with local Primary Care services.

The Coordination Group reviewed how well it achieved its objectives, a view was provided from Scottish Government and a review of the management processes was undertaken by the Corporate Programme Office for NSS.

Accountability

The overall view is that the Steering Group provided good oversight of the programme. Problems did arise in the initial stages when it took a few weeks for SGHD and HPS to establish roles and responsibilities. The initial governance structure, which was modelled on those used to introduce previous vaccines with a longer lead in period, did not work totally effectively. Once these were recognised appropriate modifications were made.

Programme Management

The fact that immunisation was part of the urgent UK-wide response to a public emergency made this programme far more challenging that others. Initial changes in vaccine delivery schedules and limited supply presented a challenge in the early part of the vaccination programme as did the time required to come to an agreement of a national contract with the GPs. The relatively short planning timeframe between notification of the Phase 1 priority groups on 13 August 2009 and commencement of the programme at the end of October 2009 created additional pressures. Further complexity was added by the need to clarify the definitions of priority groups in early September and the dosage for different age and risk groups as new data became available.

The Coordination Group provided a platform to discuss these challenging issues and feedback indicates that this resulted in clear direction being given to the Working Group Leads. The creation of a dedicated team within SGHD assisted overall programme leadership and management and ensured that the vaccination programme was fully linked in to the overall pandemic response.

The processes used and outputs delivered were continually reviewed and adapted in order to ensure the programme met its operational goals. Within the constraints and challenges presented, the vaccination programme was delivered on time and with some caveats, consistently throughout Scotland.

The identification of a pharmacy lead for vaccine logistics provided an additional resource to the SGHD vaccination team taking on some of the vaccine delivery negotiations and greatly facilitated the effective allocation and distribution of vaccines.

The CPO review highlighted a number of areas where the management processes could have been improved. The programme management were often caught up in the day-to-day activity of servicing the programme's many working groups and communications. This hindered the development of a more strategic view. To help avoid this, the review highlighted the need to further improve the scoping, planning, resource identification/allocation and definition of roles and responsibilities.

The structure for the programme included an Information and Resources Group chaired by NHS Health Scotland. Leadership on communication however was retained by the Scottish Government which established a communications framework which fitted in with the overall response to the pandemic. Feedback from the group indicates that at times, the respective roles of SGHD and HPS were not well demarcated.

Coordination of NHS Boards

Strong organisational relationships among SGHD, HPS and NHS boards were needed to take forward the programme. These were established. Feedback from the NHS boards ensured that Scottish Government contributions at a UK level were well grounded in knowledge of operational issues experienced by NHS boards. The creation of a lead role at HPS to liaise with NHS boards was felt to be a particularly successful approach.

At times, communications to the service, whilst useful when received, could have been made in a timelier manner. Given the need for transparency and openness, Government communications especially to the media were regular and frequent. However such 'real time' messaging led on occasion to expectations existing in the media and among members of the public before services were in a position to meet those expectations.

Some of the public communication materials, whilst of a high standard, could have been produced and distributed earlier; in particular those for pregnant women and speakers of other languages. Some constraints arose from the fact that these materials were developed and agreed across all four UK countries. However despite these, there were benefits in a UK approach in terms of cost, the coordination of the response to the pandemic and consistency of messages.

A recurrent issue in coordination with the NHS boards was the extent to which service delivery models and information systems should be purely locally defined or standardised across the country to ensure equity of access to immunisation. The scale of the task, the short timescales and the number of uncertainties made achieving this balance challenging. Even though the programme was part of the centrally coordinated response to a national emergency, on the whole an effective balance was achieved between delivering a flexible local response within clearly defined national parameters. Evidence of this is how the NHS boards responded quickly in the early stages of the programme to immunise children with special need due to major physical disabilities in whom a number of deaths and episodes of severe illness were being reported throughout the UK. NHS boards also rapidly developed mechanisms to immunise pregnant women and women in the immediate post-partum period when requested to do so.

One indicator of equity of access for immunisation is the degree of variation in NHS board uptake rates. Table 5 presents the range of estimated NHS board uptake rates for H1N1 immunisation. Because of the influence of different data quality issues, they should be interpreted with caution. This is especially the case for health and social care staff, where there were major variations in the recording of immunisation status in this group and the identification of denominator numbers. However the range for all target population is relatively wide demonstrating the scope for improving equity access.

Table 5: Range of Uptake rates for H1N1 Vaccination Programme in NHS boards

Target Population	H1N1 Vaccination Programme
	Range of NHS board Uptake Rates %
Under 5's at risk	56.7 – 84.5
Healthy under 5s	35.2 - 64.5
Under 65s at risk	42.8 – 64.8*
Over 65's at risk	50.3 – 69.4
Health care staff	36.4 – 90.8***
Social care staff	16.5 – 51.2

* Includes pregnancy; ** data on uptake extracted automatically from GPAS practices and on voluntary basis from other practices; *** Includes non-territorial boards

Overall Conclusions

1. The Effectiveness of the Programme

The direct impact of the programme on rates of illness and death in the target population is not known. Its effectiveness is likely to have been limited to some extent because the commencement date occurred after the peaks in hospitalisation numbers and consultation rates,A future benefit from the programme will be to protect against the risks to health from influenza A(H1N1). The influenza A(H1N1) is expected to continue to circulate at some level during the annual flu season and the vaccine will continue to protect individuals for some time. The vaccination programme therefore has protected the health of communities in Scotland and will continue to do so.

Uptake rates in the different clinical at-risk groups vary among NHS boards. Because of data quality problems, it has not been possible to obtain accurate uptakes rates especially for pregnant women. Further work is being taken forward to provide a more accurate measure, investigate the reasons for it and to provide the basis for appropriate corrective actions.

Data quality issues constrained the ability to provide timely information to NHS boards in the form of reliable in-programme uptake monitoring to improve the effectiveness of delivery. It also limits an evaluation of the programme's public health impact and value for money. If a further vaccination programme is required to be implemented urgently, its effectiveness and efficiency will to a large extent depend on resolving the data problems encountered with H1N1 immunisation. This could take place by strengthening immunisation information systems within the context of the eHealth Strategy. A business case is presently underway with Scottish Government for taking forward the integration of data from immunisation systems in Scotland, in order to provide person-centred immunisation information, irrespective of the venue and mechanism of receiving vaccines.

2. The Management of the Programme

The management of the programme had to be flexed to respond to changing circumstances and expectations. and lessons have been learned from that set of circumstances which will allow future programmes to be as responsive as possible to emergencies. However on the whole the programme was delivered on time throughout Scotland and met its objectives. Further insight could be obtained by comparing different approaches in the UK and other European countries and developing indicators of best practice.

For future emergency situations, it would be helpful if certain areas of governance could be defined more formally especially the responsibilities of NHS organisations and Scottish Government for planning and delivering vaccination programmes. In particular, the NHS boards' relationship to HPS needs spelling out more clearly especially the balance between a common Scotland-wide approach and a flexible response to local needs.

The project management methodology used by HPS for introducing the HPV and PCV vaccination programmes needs to be modified to accommodate any future emergency vaccination programmes.

The programme benefited from the engagement of NHS board strategic and operational leads and a wide range of primary care representatives especially from SGPC, the Scottish Practice Managers Network, Community Health Partnership leads and the Scottish Government Health and Wellbeing Primary Care Directorate.

3. The Coordination of the Vaccination Programme with Other Aspects of the Pandemic Response

Immunisation was only one of the health interventions employed in the UK to mitigate the impact of influenza A(H1N1) infection, the other main measures being healthcare preparedness, antiviral treatment, infection control, public education on hygiene and in certain circumstances, outbreak management. Decisions on the programme were therefore synchronised with those related to these other interventions.

The need for and the roll out of interventions were considered by UK scientific advisory committees and by Government within the civil contingencies framework. The need to maintain confidentiality until Ministerial decisions were announced at times led to information about what to do appearing with a relatively short lag period before implementation. This was partly inevitable given the short planning timescales to which all parties were working to develop UK-wide positions, often on limited and changing data.

All NHS boards had prepared pandemic plans. However, prior to the programme not all contained plans to implement a wide ranging vaccination programme. Future planning should address this by building on the common templates developed in this programme.

4. Generic NHS Preparedness and Service Delivery

At a national level, a large amount of effort was put into resolving problems with data quality and completeness. The issues arising from this are described in the report from the Data Management Working Group. Two areas have a wider resonance than H1N1 immunisation:

- Current developments in GP data systems within Scotland especially the transfer from GPASS to other software suppliers.

One of these suppliers INPS has only recently made available its software to underpin the vaccination programme, many months after its start. Currently there are only a limited number of software suppliers for primary care computing systems operating in the UK. This may lead to problems with resilience and the specific software requirements of Scotland – not only in relation to immunisation matters but also for other service imperatives.

- Computerised records of pregnant women receiving antenatal care.

This programme coincided with a major transitional phase of antenatal care in Scotland, which is being progressively transferred from general practice to maternity services. Delivery of antenatal care is undertaken in a number of different ways by NHS boards, depending on local circumstances, including geography (urban v rural/remote). Most women now receive such care from midwives with data on their care being contained in a 'hand-held' personal record. Almost half of the territorial NHS boards have no centralised register of such women and where they do, there are issues of maintaining their accuracy. This is a very dynamic cohort with as noted earlier, approximately 1,100 newly pregnant women and deliveries per week in Scotland. In addition, these IT systems are 'stand alone' – although they contain CHI numbers, they are not presently linked to other databases. In consequence, systematic and timely notification of pregnancy status by maternity services to GPs is pivotal. GPs may therefore have different counts of those patients on their list who are pregnant and receiving antenatal care when compared to Board antenatal services. This has led to problems identifying all pregnant women and accurately assessing uptake in this important group.

RECOMMENDATIONS

Further Action on Vaccination Against Influenza A(H1N1) Infection

1. NHS boards should complete and where appropriate, publish their own lessons learned from the H1N1 vaccination programme.

2. Scottish Government and HPS should hold a workshop with the key stakeholders involved in the programme to share lessons learned and discuss how to take forward the recommendations in this and other relevant reports.

3. Scottish Government Health Directorates should collaborate with their UK counterparts in evaluating the contribution of the vaccination programme to the overall pandemic response.

4. HPS should lead research to elucidate how well the programme achieved its public health goals especially those related to pregnant women, frontline healthcare staff and socio-economically disadvantaged groups.

5. HPS should ensure that all outstanding actions, risk and issues associated with the H1N1 vaccination programme are recorded and handed over to the team responsible for coordinating the seasonal flu immunisation campaign and appropriate actions taken. In particular the data quality and management problems related to the immunisation of pregnant women should be resolved as soon as possible.

6. HPS and partners should continue to seek a more accurate estimate of uptake especially in pregnant women and further review variations in uptake and the reasons for them to identify any relevant remedial actions needed and feed these back to its stakeholders.

7. NHS boards should continue to monitor the accessibility of current models of delivery for immunising pregnant women and when appropriate, take any necessary steps to modify these.

8. Scottish Government should collaborate with NHS boards in estimating the overall cost of the programme including opportunity costs.

9. Scottish Government Health Directorates and HPS should collaborate with their UK counterparts to compare uptake rates and other benchmarks of performance.

Other Routine Vaccination Programmes

10. Scottish Government and HPS should develop indicators to improve assessment of the overall effectiveness of the seasonal flu vaccination programme in preventing excess mortality and morbidity (previously recommended in the re[port on managing the seasonal flu programme[6,7]).

11. HPS and NHS boards should ensure that the experience gained from the H1N1 vaccination programme is incorporated into their management of the seasonal flu programme especially the immunisation of health and social care staff.

12. Scottish Government should formalise the governance arrangements for the implementation of national vaccination programmes especially the relationship between itself and HPS and between HPS and NHS boards.

13. NHS boards should liaise with HPS and their local practices to continue the development of 'real time' monitoring of practice based immunisation uptake rates during the seasonal flu vaccination campaign with a view to enhancing uptake particularly in those most at risk.

14. NHS boards should establish a forum which brings together GPs, nurses, community pharmacists, and public health practitioners engaged in the seasonal flu campaign to facilitate the sharing of best practice locally[7].

15. NHS boards should build on the experience of the H1N1 vaccination programme and more actively seek to share best public health practice in coordinating vaccination programmes and where appropriate, offer mutual aid to each other.

16. Scottish Government should commission work to take forward the integration of data from healthcare information systems in Scotland, in order to provide person-centred immunisation information, irrespective of the venue and mechanism of receiving vaccines. (Previously recommended in the Meningococcal C Immunisation Programme Report[8] and the Review of the Expert Group on MMR[9]).

Emergency Vaccination Programmes

17. Scottish Government should review the possibilities for expediting UK-wide, governmental decision-making on emergency vaccination programmes covering aspects such as policy, communications to the public and service and local implementation.

18. Scottish Government should review the coordination of public and service communications during a major response to an outbreak or epidemic.

19. Scottish Government and its counterparts in other UK countries should explore the scope for pre-contract agreements with primary care contractors to facilitate the delivery of vaccination programmes during an emergency response.

20. Scottish Government and its partners should incorporate any relevant lessons learned and recommendations from the vaccination programme into their broader planning for dealing with civil contingencies and that as recommended by Audit Scotland[10], monitoring arrangements are in place to ensure their effective implementation.

21. HPS should modify its current project management approach for coordinating national vaccination programmes to make it more fit for purpose for an emergency response. This should include the early identification of stakeholders.

22. NHS boards should review their own systems which were employed for the planning and implementation of the H1N1 vaccination programme (including potential service delivery models for the remainder of the population who were in the end, not offered immunisation) and incorporate relevant lessons learnt into the further development of pandemic and other plans e.g. smallpox.

23. NHS boards should draw up as part of their emergency plans, templates for delivering mass vaccination campaigns based on their experience with the H1N1 vaccination programme. These should include the outcomes of Equality Impact Assessments to identify population groups who may have specific needs and the best means of reaching them.

24. NHS boards and NHS Education Scotland should build on the progress made in workforce development and the building of additional capacity needed to implement the H1N1 vaccination programme.

NHS Services Other Than Vaccination

25. Scottish Government e-Health and NISG should review the experience with the suppliers of software for GP computing systems during the H1N1 vaccination programme, assess its ongoing implications and take remedial action should this be required.

26. Scottish Government and ISD should review the current status of data systems used in antenatal care and close any gaps required to support the planning and delivery of such care.

27. Scottish Government and ISD should review the current status of data systems used in NHS occupational health services and whether there is scope for the development of common data sets and reporting.

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Appendix 1

Reports From National Working Groups

Service Delivery

Objectives

a) Ensure a Service Delivery Plan for the mass vaccination programme is in place in advance of the commencement of the programme that clearly sets out models of delivery, role of stakeholder agencies, the timetabling/scheduling of the vaccine and the resource constraints.

b) Assist nationally in the overall preparedness of the resources required to implement the H1N1 vaccine within prioritisation groups.

c) Ensure partnerships are in place with the relevant stakeholders in advance of the introduction of the vaccine e.g. SGHD / NSS HPS / Health Scotland / NSS ISD / NSS NSD / NHS boards / education sector (public and private) / local authorities.

d) Assess and assure preparedness / readiness within NHS boards through the formal project management reporting mechanism and informal assessments carried out through 1-1 dialogue.

e) Address Inequalities in Health through defining any 'difficult to reach' groups who are at increased risk of H1N1 infection; interventions for reaching these groups; defining the content and method of communications with these groups and developing an evaluation methodology to assess the effectiveness of such interventions and communications.

f) Establish an infrastructure that will support the introduction of the H1N1 vaccination in various prioritisation groups.

Processes

The work on service delivery was coordinated by the Service Delivery Group (SDG). Three work-streams each led by a sub-group were established: occupational health, primary care and school aged children. This group was chaired by Professor Lewis Ritchie, Centre of Academic Primary Care, University of Aberdeen.

Service Delivery Group

The work of the SDG brought together the various work streams with all leads attending the biweekly meetings (Epidemiology & Surveillance, Data Management, Procurement & Logistics, Information and Resources, NHS boards). In addition during the course of SDG, NHS 24 and the Seasonal Flu Programme were assimilated to report their progress, with a view to facilitating a systematic and coordinated approach. A weekly reporting log update was inaugurated for all workstreams complementary to SDG, maintained by HPS, to underpin

coordinated working and reporting. Specific improvements were made to documentation regarding notes of meeting and action points – also documentation sign off.

SDG had an inclusive participating membership with the reporting of progress by main stakeholders, including NES, NHS 24, Seasonal Flu programme. As advised by the Service Delivery Group, SGHD also engaged with Third Sector and Educational Sector via relevant communications/newsletters.

On behalf of the Service Delivery Group, the Chair produced a series of briefing papers on evolving delivery models mapping to changed policy, data completeness and interpretation – including intermediate analysis and uptake reporting, for consideration by the Coordination Group.

All recommendations and documentation regarding service delivery were transmitted to the Coordination Group for ratification/approval. Additional supplementary activities to promote this aim are listed as an Annex to this paper.

At the inception of the implementation phase of the programme (end October 2009) the SDG moved into stand-by mode and its responsibilities were transferred to the Coordination Group, which met on a weekly basis, in order to ensure speedy resolution of service issues, and to avoid duplication of effort. The terms of reference of the Coordination Group were modified to take this into account and ratified by the H1N1 Steering Group at its November meeting. The Chair continued to represent SDG interests on the Coordination Group. The SDG met on one further occasion – 25 November to consider the service delivery requirements of the Phase 2 Programme.

Occupational Health (covering Health and Social Care workers)

This Subgroup was established under the chairmanship of Dr Eugene Waclawski, Consultant Occupational Physician, NHS Greater Glasgow and Clyde. Occupational PID documentation was prepared and two workshops were convened.

School-aged (Primary/Secondary)

This stream was established under the co-leadership of Scott Hanley and Rina Duff, NHS GGC. Sue Rust, NHS Lothian deputised as appropriate. PID documentation was prepared building on recent HPV Vaccination Programme experience. In the event this programme did not materialise because the overall school age children cohort were not part of the policy for vaccination. At-risk schoolchildren were vaccinated by GPs.

Primary Care (covering infants, <65 at risk groups – including pregnancy, ≥65 at risk/elderly, working age healthy adults)

This stream was established under the co-leadership of Dr Sheena MacDonald, Primary Care Lead, NHS Borders and Marion Macleod, Practice Manager, NES. This subgroup met on two occasions and operated virtually. In addition, a further subgroup on pregnancy was established with leadership input from Jane Walker and Ann Holmes, SGHD and from Shirley

Fraser, NHS Health. The subgroup met in a workshop to deal with specific delivery and support issues relating to pregnant women.

Outputs

Service Delivery Group

1. Overall, SDG recommended 184 separate action points in relation to the programme – all were subsequently reviewed and completed.

2. All NHS boards received a template for their own Service Delivery Plans, for submission to HPS, including a set of guiding principles and a specific format. NHS boards were asked to prepare contingency plans for all aspects of the programme, including pregnant women. These plans were submitted to HPS by agreed dates and subject to a HPS scrutiny/ratification process which included external peer review. The HPS Boards Project Manager liaised on a one-to-one basis and also through weekly Board Leads teleconferences. NHS boards readiness were scrutinised by SDG, then by the Coordination Group and ultimately by the H1N1 Steering Group.

3. A specific action point for SGHD was a request for robust financial information to be sought from NHS boards on the costs/opportunity costs of the programme. This was acted upon and submitted.

4. With regard to Health Inequalities, specific guidance/guiding principles were provided for the programme by SDG and each Board was asked to identify an Equity/Diversity Lead to scrutinise the impact of the programme locally in each Board, to avoid any adverse discrimination. This guidance was also sent to Directors of Nursing. SDG came to the view that it would not be possible, under its own auspices, to conduct a rigorous evaluation of the effectiveness of the programme and communicated that to the Coordination Group.

5. On-going support for the introduction of the H1N1 population vaccination in various prioritisation groups was achieved by an inclusive SDG membership, the preparation of specific PIDS for identified priority groups, the specification of Board delivery plans and their subsequent scrutiny with resolution of specific outstanding issues through one-to-one dialogue by the HPS Board Project Manager.

6. PGD guidance for Phases 1 and 2 directed to Health Professionals and Immunisation providers was prepared by Procurement and Logistics Lead, scrutinised by SDG, and disseminated to the service.

7. Partnership with Seasonal Flu working groups to avoid duplication of effort and encourage a synergistic approach to co- administration of vaccine in appropriate

prioritisation groups was done by assimilating Seasonal Flu Group progress into the working of SDG and the participation of Seasonal Flu colleagues in the weekly reporting log of all workstreams, as inaugurated by SDG.

8. Consent Issues - HPS on the encouragement of SDG, liaised with the Central Legal Office regarding the status/requirements for consent/written consent for pregnant women and eligible frontline health care and social care workers for data transfer to their GPs. Guidance was produced and disseminated.

Occupational Health

1. Specimen occupational health service consent documentation was prepared and disseminated to the service.
2. Occupational Q&As were prepared and disseminated, analogous to the Primary Care Q&As.
3. specific plans were sought re occupational vaccination in the Scottish Prison Service and in Offshore Oil/Gas Industry settings.

School-aged (Primary/Secondary)

1. Documentation was prepared and scrutinised on the weaknesses/strengths of delivering the programme to clinically at-risk children of school age in GP or school settings.

Primary Care

1. PID documentation was prepared on the strengths/weaknesses of primary care v Board-based delivery models.
2. Specific advisory materials on pregnancy, including pregnancy Q&As were prepared and uploaded under one pregnancy umbrella on the HPS microsite for ease of access.
3. Specific Primary Care Q&As were produced, disseminated and updated on the HPS microsite.

Vaccine Procurement and Logistics

Objectives

a) Provide advice regarding the pharmaceutical aspects of the programme and ensuring the development of systems and processes to ensure the safe prescription, supply and administration of H1N1 vaccine in all care settings.

b) Provide pharmaceutical advice on development of Patient Group Directions (PGDs) for vaccine administration.

c) Ensure that pharmaco-logistics of procurement, storage and distribution of H1N1 vaccine comply with legislation, professional standards and manufacturer requirements at national level, involving liaison with established national procurement processes to ensure Scotland's share of UK allocation of vaccine in assured.

d) Work with NHS board implementation teams to ensure local systems are in place to order, store and distribute vaccine in effective and efficient manner.

Processes

At the outset of the programme the vaccine procurement and logistics workstream was established. This workstream was chaired by William Malcolm, Pharmaceutical Adviser, Health Protection Scotland. The activity, outputs and outcomes of the vaccine procurement and logistics workstream were reported via the Service Delivery Group infrastructure.

To support the planning and implementation of the pharmaceutical aspects of the programme there was a requirement for dedicated pharmaceutical advice. This was delivered through an agreement that 0.4 WTE Pharmacist and 0.4 WTE Pharmacy Technician time would be available through a short term secondment of an appropriately qualified pharmacy technician and a qualified pharmacist from within NHS National Services Scotland. They took forward:

- A system to confirm NHS boards' share of available vaccine through regular (daily at outset of programme) liaison between procurement and logistics workstream and DH vaccine distributor This ensured that Scotland's share of all deliveries of vaccine into the UK were assured and that the information on vaccine supply was communicated quickly and clearly to NHS boards.
- An appraisal of the options for allocation of the available vaccine across the NHS boards when at the outset of the programme there were insufficient quantities available to supply all GP practices with at least a single box of vaccine. This required led to a model where each NHS board received a proportionate share (based on resident population) of each vaccine delivery. As a result, it was agreed that in the face of initially limited supplies that Scotland's share of each delivery of vaccine will be allocated to NHS boards on a central basis.

- In liaison with SG/DH, central allocation of stock on a weekly basis and efficient communication to NHS boards was very labour intensive. As soon as the schedule of deliveries was confirmed all NHS board immunisation planning leads and VHC Staff were informed of the quantity available and expected delivery date. To further ensure NHS board planning leads had early access to the updated information W Malcolm joined the weekly teleconference with NHS boards to update on the supply position. The process remained in place until mid January 2010 when the vaccine supply position eased.
- Operationalising the agreement that all GP practices should receive a share of initially limited vaccine supplies (on a pro-rata basis determined by NHS boards). This meant that, at the outset, individual practices could be sent less than one full pack of vaccine every week. This required splitting of original packs in line with a protocol developed by the UK Quality Assurace Committee. This required significant liaison between the vaccine procurement and logistics workstream and pharmacy staff within VHC.
- Through regular liaison with pharmacy staff in VHC, assurances from NHS boards that they had the capacity to store and distribute the estimated quantities of vaccine whilst observing the requirements to ensure maintenance of the cold chain. This was achieved through meetings and regular communication with a pre-existing network of pharmacy staff in VHC known as the Vaccine Operational Group. These meetings were a mixture of face to face meetings and teleconference. The Vaccine Operational Group expressed the view that teleconference was very successful.
- New arrangements were developed for the supply of vaccine to these NHS boards that do not normally receive nationally procured vaccines e.g. special NHS boards and the Scottish Prison Service. In relation to the Prison Service this required collaboration with two commercial medicines distributors to ensure appropriate arrangements were in place.
- Central allocation of appropriate quantities of a range of syringes, needles and sharps bins required for the administration of H1N1 vaccine. These had been procured as part of longer term national pandemic influenza planning and were held in a national stockpile within Scotland.
- Liaison with SG to arrange for a national procurement of a sufficient quantity of appropriately sized sharps bins The size of the sharps bins procured under pandemic preparedness arrangements were regarded as too large for use in a progarmme delivered in GP practices.
- Support for immunisers to understand the nature of the product. The programme was delivered using a syringe with an integrated needle (Flu+™ device) that was chosen to minimise the wastage of vaccine. This was accepted as an important feature in the context of limited supplies of multidose vials but was a departure from usual practice in Scotland.
- Liaison with DH to ensure that all consignments of vaccine were accompanied by a supply of self adhesive labels that contained the details of the vaccine batch number

and expiry date. These labels are useful to support immunisers to record these details in the patients record.

- Establish a process whereby VHC would communicate the details of deliveries received to SG to allow SG to have confidence that invoices received from DH were appropriate. H1N1 vaccines were centrally funded by SG and were provided free of charge to NHS boards. This required an extension to the system successfully introduced during HPV immunisation progarmme whereby following receipt of a delivery of H1N1 vaccine the VHC would forward details to SG.
- Input into the pharmaceutical aspects of the development and maintenance of the web based training materials used to support immunisers to deliver the progarmme.

Outputs

1. Guidance for NHS boards and the establishment of a small national reserve stock of Celvapan® There were particular challenges with supplies of Celvapan® vaccine which was in even more limited supply compared to Pandemrix®. This required the vaccine procurement and logistics workstream to produce and lead discussion on the options for the deployment of the available stocks of Celvapan®.

2. Guidance on the mechanisms for legally administering vaccines guidance was prepared and issued for NHS board planners.. Vaccines are Prescription Only Medicines and the preferred way for patients to receive medicines is for registered prescribers to prescribe for individual patients on a one to one basis. In the context of this programme it was recognised that it may be more appropriate for an individual to receive a vaccine directly from a healthcare professional who was not an authorised prescriber. Unless the healthcare professional is covered specifically by an exemption in the Medicines Act 1968, there are two ways of achieving this: either by Patient Specific Direction (PSD) or Patient Group Direction (PGD).

3. National PGDs were produced.to support NHS boards and to minimise duplication of effort within boards. The vaccine procurement and logistics workstream led on the production and dissemination of two national PGD for administration of Pandemrix® and Celvapan®. National PGDs could not be completed before the vaccines were licensed and national policy for their use was available. This resulted in only a very short time between the necessary information becoming available to allow PGDs to be produced, distributed to NHS boards and approved for use in each NHS board area. To support NHS boards to respond quickly to the requirement to approve PGD for administration of H1N1 vaccine they were sent national PGDs signed by a doctor and pharmacist –so allowing these to be adopted without any further amendment. But NHS boards also received unsigned versions which could be adapted locally if required. This approach allowed maximum flexibility and proved useful in responding to the short time between issue of PGD and start of programme. The approach to issuing signed PGDs was especially useful within special NHS boards. With changes to the recommended dosage and schedule for Pandemrix® vaccine the PGD was updated and reissued to NHS boards.

4. Guidance for residential care services on issues related to immunisation of people in this setting with H1N1 vaccine: The vaccine procurement and logistics workstream supported the Care Commission in the development of this.

5. Clear advice for immunisers on the process for decontamination of the surface of the bung of the vaccine vial with alcohol wipes prior to drawing up of doses. The workstream undertook liaison between DH, SG and infection control team within HPS to develop this.

6. Interim guidance on the use of influenza A(H1N1) vaccine in individuals taking medicines that suppress the immune system was produced in response to requests from NHS boards on which groups of individuals should be regarded as being immunosuppressed as a result of treatment. It was produced in collaboration with SG specialty advisers in immunology, rheumatology and oncology; Senior Medical Officer, Primary and Community Care Directorate of SG and with Immunisation advisers at Health Protection Agency.

Data Management

Objectives

a) To recommend the optimum approach for IT support for the H1N1 vaccination programme which in effect evolved throughout the course of the programme; significant changes included late alterations to number of doses and uncertainty in methods of vaccine delivery.

b) To define the data set required to support the evolving programme, covering phase 1 (<65s at risk, pregnancy, >65s at risk and OH groups), and Phase 2 (<5 year olds).

c) To define the requirements for effective system(s) for managing and monitoring H1N1 vaccine administration.

d) To progress delivery of the necessary systems to support the H1N1 vaccination programme. This included specifying functionality that would be sufficiently flexible to accommodate uncertainties in mode of delivery and scope of the programme and management of system supplier(s) and reporting progress towards delivery of these systems.

e) To consider, and advise on, the implications of information governance matters with respect of data and systems.

f) To consider and advise on impact upon the data and systems of changes introduced by other elements of the programme, for example changes in scope or prioritization by JCVI.

g) To provide a vehicle for identifying and escalating issues related to data and systems that could impact delivery of the H1N1 Programme.

h) To provide end users with advice on using the various systems' functionality and more generally to inform and advise on external communications in relation to data and IT elements of H1N1 programme.

Processes

This group was initially chaired by Dr Adam Bryson, lately Medical Director, NHS NSS and latterly chaired by Dr Brian Robson, Medical Director of eHealth, NHS NSS.

- Group were accountable to H1N1 Coordination Group & provided verbal and written updates at scheduled weekly meetings.
- Group included a met fortnightly with wide range of stakeholder members and met fortnightly.
- Network of key NHS boards contacts was set-up to provide assistance with communication of IT Supplier software releases, Information Governance and Data Quality issues.
- IT Technical liaison provided by NISG and Scottish Government between H1N1 Programme, DoH and all the Scottish IT Suppliers.
- Terms of Reference for Group was created and revised, when applicable, during the programme with associated review of membership.
- Meeting notes & rolling actions progressed have been documented and submitted to micro site for Operational Leads to access (in excess of 150 actions progressed to completion).
- Provided input to weekly working group report – circulated to Operational Leads.
- Active input to weekly Coordination Group and ad hoc to Service Delivery group and Operational Leads meetings.
- Regular discussion and collaboration with Service Delivery Group and E&S Group.

Outputs

1. GP systems were developed as the first option for data management of the programme

   – All GP systems were able to provide practices with the necessary support to identify and vaccinate relevant patients.

- Two of the GP IT Suppliers (GPASS and EMIS) were able to deliver software to meet the reporting requirements at an early stage of the programme. However, two (Ascribe and INPS) were not.
- Scotland had little control over the commercial GP IT Suppliers – no mechanisms to provide this were in place.

2. Pregnancy (subset of specific outputs separate from GP systems)

- Limitations of GP systems.
- Creation of database of pregnant women and written invites. There was no creation of a central database for pregnant women. NHS boards were requested to ensure all pregnant women had received an invite for vaccination. In some boards this was via General Practice. In others, boards wrote to pregnant women using information provided by maternity services. Subsequent ongoing invites and encouragement were made.

3. SIRS was developed in preparation for the initial remit to delivery whole population immunisation and as insurance against the potential eventuality that GPs did not or could not deliver the vaccination programme.

- Data fields extended to include 2 dose H1N1 schedule (subsequently amended to 1 dose for healthy under 5s) was delivered on schedule.
- Extended SIRS database to whole population - delivered on schedule,
- Additional treatment centre field included to permit usual vaccine schedule to continue and run alternative models for H1N1 (i.e. centralised) was delivered on schedule,
- Provided centralised, cost effective, selective call/recall for healthy under 5s for either GP or centralised clinics - delivered on schedule. NB the mixed model identified several issues that would be refined in subsequent functionality; only some GPs chose to use call/recall because of need for advanced planning of clinics through January by end of December,
- Provided individualised data output to ISD for centralised data analysis - delivered on schedule,
- Created a data import data facility to reconcile health records from other sources, primarily occupational health but also potentially for other sources. eg. GP to avoid duplicate invites and obtain more accurate uptake rates - delivered but being refined in light of data matching progress.
- The use of SIRS data export to update other systems, eg. GP systems after end of March 2010. The expectation is this will be delivered on paper or electronic file.
- Provided functionality for school based H1N1 vaccination - delivered on schedule, but subsequently not required.

- Reviewed SIRS functionality and refine it so that it could be suitable for any new one off generic vaccines, if required – work currently in progress.
- Consider further ways of utilising SIRS functionality and data alongside other NHS systems – work is currently in progress.

4. Occupational Health (OH) systems

- There was no specific engagement with OH software providers for changes to COHORT or OPAS systems at a national level. NHS boards utilised different systems for the management of the Health and Social care workforce (COHORT, OPAS or other).
- Implemented weekly manual reporting processes of vaccination uptake from all boards for the Occupational Health & Social care workforce.

5. HPS (including IM&T)

- HPS received & processed practice automated weekly data files and collated data for export to ISD.
- Contingency website reporting system was provided for recording of manual data stats for those practices with no automated data extract.
- HPS PIPeR Seasonal Flu system was extended to allow automatic import of weekly data files from c700 GP practices (INPS rollout is still WIP).
- End to end processes implemented to allow analyses and reporting of H1N1 Vaccination Uptake rates.

6. ISD functionality

- In Phase 1, ISD received weekly aggregated data file, derived from automatic extractions from GP systems. The data arrived from each practice to HPS and was compiled into one file weekly before being passed to ISD for analysis. Automated procedures were established to generate a standard set of analyses which were then fed back to HPS for incorporation in their HPS weekly situation reports (delivered each week on schedule). Monthly manual data from GP systems that did not have an automatic extraction was analysed in a similar way.
- In phase 2, data was extracted from SIRS (in addition to weekly automated extraction from GP systems) as noted above and analysed by ISD before being reported weekly to HPS in standard reports for inclusion in situation reports produced by HPS (delivered each week on schedule).

Information and Resources

Objectives

To provide guidance and direction [to the H1N1 vaccination programme, Scottish Government and to NHS Health Scotland] on communications activities that are developed to support the implementation of the H1N1 vaccination programme in Scotland and in so doing, subscribe to the governance processes established by Health Protection Scotland.

a) On request of the Scottish Government, to provide a consultation role in relation to the public facing materials produced by the UK government to ensure that these materials take account of the Scottish context.

b) If publication of the public materials is required in Scotland, to use the expertise of NHS Health Scotland and to offer advice to NHS Health Scotland on the dissemination routes.

c) Provide advice on the content, production and dissemination of professional communication materials and other communication materials that support the delivery of the vaccination programme in primary and secondary care.

d) Link with the other subgroups to ensure public and professional communication materials take account of relevant issues raised therein.

e) Provide a steer to all NHS Scotland agencies and NHS boards on the facilitation of local implementation of communications activities through active liaison with local stakeholders.

Processes

This group was chaired by Wendy Peacock deputy Shirley Fraser, both of NHS Health Scotland.

- As the programme development proceeded and the decision to centrally manage the production and dissemination of public materials and to have professional materials online, fulfilment of these aims was restricted to the consultation role.
- Accountability to the H1N1 Coordination Group with verbal and written updates at scheduled weekly meetings.
- Input made to weekly Board telecon meetings to ensure any communication issues identified at source and required action taken.
- Membership of the group reflected both those with communication skills as well as those representing end user audience.
- Meetings were held on an as needs basis with updates provided electronically.

- Flexibility around interpretation of the Terms of Reference reflecting the changing role of the group (as laid out in the Project Initiation Plan).
- High level risks to programme activities identified at outset and continuously updated (which became the basis of the Risk Log).
- Notes of meetings and summary of actions documented for direct action by IRG and/or passed onto other groups as required.
- Risk Log continuously updated and remedial action taken as appropriate – where not possible, high risk issues fed into Coordination Group.
- Active input to Service Delivery Group and ad hoc input to Data Management Group and Epidemiology and Surveillance Group to ensure read across in terms of communication issues.
- Regular off-line discussion and collaboration with SG delivery team on public facing materials.

The IRG formally ceased its business on 12 November 2009 with the proviso that it could be reconstituted if the programme required this.

Outputs

1. Project Initiation Plan outlining remit, key risks and project activities with associated milestones.
2. Initial communications framework provided for SG H1N1 team.
3. Contribution to NHS board leads event at Beardmore Hotel.
4. Draft detailed work plan (subsequently dropped given decision to develop materials on UK wide basis).
5. Outline communications strategy (which subsequently was further developed as SG communications strategy).
6. Draft protocol for the handling of media enquiries.
7. Options for Scotland production and dissemination of materials.
8. Option for patient vaccination record card (drafted and refined for consideration at UK level).
9. Inventory of communications materials (produced by all key partners).
10. Development of professional facing web pages on Health Scotland site linking into SG, HPS and NHS 24 websites.
11. Options paper for the identification and vaccination of pregnant women (as part of the work of the Service Delivery Group).

Not directly part of the IRG activities but part of communication outputs:

1. Training slides for vaccinators produced by NES.
2. Key questions and answers (and algorithms) developed by NHS 24.
3. Specific webpages developed by NHS 24.
4. Questions and answers for professionals developed by HPS.

Epidemiology & Surveillance

Objectives

a) Evaluate the impact of the H1N1 vaccine in the Scottish population by implementing a fit for purpose monitoring and surveillance programme.

b) Monitor the H1N1 vaccine uptake of the various priority groups in Scotland and determine the characteristics of those who do not take up the vaccine.

c) Measure vaccine effectiveness of H1N1 infections through collaboration with the Data Management Group and the Health Protection Agency (HPA) in the UK and European Centre for Disease Control (ECDC).

d) Monitor the rate of adverse events and other untoward consequences associated with the programme.

e) Collaborate with other HPS Emergency Coordination Response Teams to ensure effective and consistent working, particularly within Epidemiology and Surveillance and Guidance /Expert Advice.

Processes

This group was chaired by Katy Sinka, Senior Epidemiologist, Health Protection Scotland.

The epidemiology and surveillance group met on four occasions at key points during the vaccination programme to:

- review progress and assess emerging data for each the public health surveillance elements;
- liaise with researchers undertaking relevant projects on H1N1 vaccine effectiveness; potential adverse events and H1N1 disease in Scotland; and
- review whether any further action would be required to enable assessment of the overall programme impact.

- A fit for purpose monitoring and surveillance programme for H1N1 vaccination was developed following the standard model used for other vaccination programmes in Scotland. It included the following elements.
  - Vaccine Uptake
  - Vaccine Safety (including adverse events monitoring)
  - Vaccine Effectiveness
  - Programme Effectiveness
- Vaccine uptake required active management by the group to ensure delivery. The specific processes by which the data required to achieve this measure were obtained fell within the remit of the Data Management and Service Delivery Group as part of the overall data management and information flows used to deliver the vaccination programme. Key members of the epidemiology and surveillance group were active participants within these work groups during the planning and preparation for implementation. This ensured that the data flows that were being developed to manage the programme delivery would also be fit for timely, reliable reporting so that the progress of delivery of the programme could be monitored and that the overall impact of vaccination could be assessed.

  Unlike the monitoring of seasonal flu immunisation uptake rates, practices reported rates to ISD not HPS which received the collated data for analysis and presentation. Detailed scrutiny of vaccine uptake figures identified data quality issues which were fed back to the Data Management Group to progress technical solutions and the Service Delivery Group to undertake additional uptake monitoring in pregnant women. Data quality problems with GP systems extracts were communicated to English colleagues and the Department of Health and discussed in detail.

  Work to provide an accurate estimate of uptake rates continues. HPS is of the view that estimates of uptake rates in the over-65 year old at risk group and the health and social care workforce are relatively reliable. With regard to the under 65 year old at risk group, the estimates are relatively accurate for all clinical groups except pregnant women, Audits of uptake rates in pregnant women provide different estimates when derived from GP compared to maternity services data. There a number of known faults in the GP system and work is on-going to resolve these.

  Vaccine uptake rates were presented in weekly HPS Influenza Report initially submitted to Scottish Government for comment then published on the HPS website.

  HPS will continue to monitor vaccine uptake on a monthly basis using existing mechanisms over the Spring and Summer. It will report final uptake rates at the end of March and end of September, with the latter date marking the transition from spring summer of H1N1 pandemic into the seasonal flu season when H1N1 becomes part of normal seasonal flu activity
- Vaccine Effectiveness assesses how well a vaccine prevents infection in those who have received it. With regard to H1N1 immunisation in Scotland, this was assessed

using an existing process employed for the Seasonal flu immunisation. This work is part funded by the European Centre for Disease Prevention and Control and involves close liaison with HPA. It uses data from the influenza sentinel surveillance scheme in Scotland which covers 101 practices of which 90 contribute to swabbing patients with influenza-like illness. This area of work was taken forward by the HPS Respiratory Team. In addition a specific research study, VIPER -Vaccine effectiveness in pandemic influenza, involving a collaboration between HPS and the University of Aberdeen is being finalised.

- Vaccine safety and pharmacovigilance were undertaken on a UK-wide basis by the Medicines and Healthcare Resources Agency (MHRA). MHRA developed a specific surveillance system for the programme and laisied closely with counterpart agencies across Europe. HPS maintained regular contact with the Agency receiving when appropriate, confidential reports.

  HPS received updates from the UK-wide clinical Guillain-Barré Syndrome/Fisher syndrome surveillance system implemented immediately prior to the programme. In addition contact was made with two academic groups undertaking studies which relate to the safety of H1N1 immunisation:

  - Dundee University Swine Flu vaccination safety study
  - Nottingham University study of Influenza A(H1N1) in pregnancy.

- Expert advice on vaccine administration errors was frequently sought during the early stags of delivery of the programme due to the complex and evolving vaccination schedules. Responses and advice given were based on trials data, where available. An ongoing dialogue with HPA who were managing similar enquiries for England was established to create a log of such queries which could be shared with operational leads.

  HPS will continue to monitor safety reports from MHRA and EMEA beyond March 2010.

- Programme effectiveness sets out to determine how well the H1N1 immunisation campaign has met its overall public health objectives. This will be assessed over the coming months by retrospective analysis of available data. In particular HPS and key stakeholders will:

  - Review the impact and delivery of the immunisation of pregnant women in Scotland.
  - Assess the impact of the immunisation of the health and social care workforce especially with regard to absenteeism.
  - Assess the impact of H1N1 infection and immunisation on the socio economic distribution of related morbidity and mortality in Scotland.

Liaison was established with two academic groups studying the epidemiology of H1N1 disease in Scotland:

- The Seroepidemiology of H1N1 infection in adults – University of Edinburgh.
- Prevalence of Influenza A(H1N1) in Professionals and Pregnancy (PIPPIN).

- A number of briefing papers and reports were prepared by the Epidemiology and Surveillance Group. These were circulated to the H1N1 Coordination Group and to operational leads where appropriate. Most were also published on the HPS microsite.

Outputs

1. Weekly Reports
   - Uptake figures for occupational/workforce vaccination.
   - Uptake figures for clinical at risk groups.
   - Review of MHRA adverse events report.
2. Audits
   - Two audits of vaccine uptake in recently delivered women.
3. Supporting documents
   - Strategy for public health surveillance of H1N1 vaccination.
   - Proposal for production and publication of vaccine uptake figures.
   - Options paper for 'the data gap' in uptake reports from non automated practices in Scotland.
   - An assessment of issues concerning pregnant women denominators.
   - An assessment of overall data quality issues for uptake data for pregnant women.
   - An assessment of the reliability of uptake estimates in over 65 year olds.
   - Briefing papers exploring the reconciliation of the H1N1 uptake data.
   - Ongoing uptake reporting during the Spring and Summer 2010.
   - A report of an audit of vaccine uptake in women who gave delivered in maternity services.

Coordination

Objectives

a) Be accountable to the Scottish Government Health & Wellbeing Directorate (SGHD) and the NHS National Services Scotland (NSS) Board for the effective implementation of the national H1N1 vaccination programme.

b) Establish and coordinate a national programme of work ensuring readiness for implementation of new vaccines and amendments to existing vaccination programmes as recommended by the JCVI.

c) Coordinate local NHS board implementation groups to ensure that new vaccines are successfully incorporated into the routine vaccination programme and links are in place with local Primary Care services.

Processes

The Coordination Group managed the project and was accountable to the H1N1 Steering Group (SGHD). In line with NSS guidance, HPS adopted the NHS Corporate Programme Office project management methodology, based upon PRINCE2®. It comprised of the following phases: Proposal, Initiation, Implementation, Closure and Review. The Coordination Group was chaired by Dr Martin Donaghy, Medical Director, Health Protection Scotland.

The group met weekly by teleconference and comprised of each of the H1N1 Working Group Leads, regional representation from three Immunisation Coordinators, Scottish Government liaison officers and key HPS personnel. The H1N1 Service Delivery Group stood down and its responsibilities were transferred to the Coordination Group in November. Additional members were invited to join the group to ensure a seamless transfer of outstanding work activities. Terms of Reference were amended at this stage to accommodate the handover.

- Review of vaccination programme development and implementation

  The group received a weekly update from Scottish Government on policy issues, from NHS boards on the status of planning and implementation of the programme and as they became available uptake rates. It considered any significant impacts of these on the different workstreams, decided how to amend the programme and consequently provided direction to the H1N1 Working Groups and the NHS boards. It was then down to these to incorporate the changes into the programme and to deliver these.

- Risk and issue management

  A process was established and the programme conformed to the existing NSS CPO methodology. All issues were documented in the Risk & Issues Logs which were held and maintained by the Programme Manager and reviewed weekly via the H1N1 Coordination Group.

Outstanding Rolling actions/Risks and Issues Log will be transferred to the Seasonal Flu Group after the final handover 31st March. In particular there remains ongoing work with service delivery models for pregnant women and data management for Phase 1 population.

- Reporting to the National Steering Group

  The group operated on exception reporting to the H1N1 Steering Group, identifying high impact risks and issues formally. It provided verbal and written updates at scheduled monthly meetings.

- Informing key stakeholders of developments

  Meetings and rolling actions progressed were documented and submitted to the micro site for Operational Leads to access. Briefings and guidance documents were disseminated to the relevant stakeholders by the Programme Management Support staff.

Outputs

1. Proposal Phase

   - National Project Team in place.
   - Establishment of governance infrastructure.
   - Establishment of H1N1 Working Groups to support implement.
   - Development and agreement of high-level approach.
   - Preliminary Scoping workshops held.
   - Working Group Scoping Workshops.
   - Initial risk assessment carried out.
   - Establish H1N1 Coordination Group.

2. Initiation Phase

   - Mode of delivery agreed.
   - Roles and responsibilities defined.
   - Method of approach agreed.
   - High-level milestone plan established.
   - Detailed Project Plans in place.
   - Communications Plan/Strategy in place.
   - Identification of key stakeholders (professional and public).

- Inequalities in Health / difficult to reach groups identified.
- Project meetings established.
- Risk and issue log established.
- Prioritisation groups confirmed.
- Liaison with DH/SGHD regarding vaccine procurement.
- Vaccine schedule drafted.
- Project Initiation Document (PID) signed-off.

3. Implementation Phase: Planning & Rollout Readiness

- Monitoring of high-level milestones.
- Monitoring of risks and issues (national and local).
- Progress reporting against readiness established.
- Vaccine schedule confirmed.
- Cold chain assurances in place.
- Establishment of Occupational Health Nurse/Primary Care Practice Nurse / School Nurse infrastructure.
- Communications strategy rolled out.
- IT systems and processes in place.
- Training provided to healthcare professionals.
- Local Implementation Plans within NHS boards.

4. Implementation Phase: National Rollout

- Implementation monitored nationally and locally.
- National mechanism in place to support NHS board issues / challenges during rollout.
- Progress reporting against implementation.
- Communications to public and key stakeholders.

5. Closure & Review Phase

- Overall evaluation of the H1N1 vaccination programme.
- Produce End Project Report which will be presented to the H1N1 Steering Group final meeting 20 April.
- Produce Lessons Learned Report.

NHS Board Liaison

Objectives

a) Coordinate local board implementation groups to ensure that the H1N1 vaccine is successfully incorporated into the routine vaccination programme and links are in place with Occupational Health and local Primary Care services for delivery.

b) Be responsible for the delivery of the local project and report on readiness to the H1N1 national programme on a regular basis through the project management framework and using the agreed templates.

c) Implement the vaccination programme using the resources and staff required.

d) Ensure that staff involved in delivering the vaccination programme have the necessary skills, competencies and support.

e) Develop local implementation plans for the delivery of the routine vaccination programme with local stakeholders and share local plans with Scottish Government and HPS.

Processes

The group comprised the operational leads from the territorial and special NHS boards and other members/deputies of their local implementation team, a representative from Scottish Government, and with other group leads/deputies i.e. service delivery, data management as appropriate. The group was chaired by Jill Carson, Senior Planning Officer, HPS. The group was accountable to the coordination group and provided verbal and written updates at the weekly meetings.

An initial one day meeting was held on 21 July to introduce the H1N1 vaccination programme and provide background information. This was followed by weekly teleconferences commencing on 28 July, these continued weekly until 12 January and then moved to fortnightly a total of 28 meetings (up to 2nd March). Meetings were held on a Tuesday afternoon, following the coordination group teleconferences in the morning, allowing timely dissemination of discussions and decisions from the coordination group to the board leads.

- Reviewing Plans: Prior to the start of the vaccination programme NHS boards were required to submit board plans for the vaccination of the health and social care workforce and one for population vaccination, outlining local plans including overarching planning, people (service delivery), people (priority groups & others), logistics, data, communication, equity and resources. These plans were reviewed at HPS by a small group comprising HPS, group chairs and board representatives and feedback provided to boards. Prior to the start of the programme all boards had an overall RAG rating for their board implementation plans of green.

- Monitoring Implementation: On a weekly basis, during the implementation of the programme, narrative questions based on issues that had arisen or discussions at the coordination or other H1N1 groups were issued to boards. The individual board responses were summarised in an overview and the summary issued to the group and the coordination group (copies of narrative summaries in Appendix). On an ad hoc basis if particular information was required i.e list of practices participating in a LES for Phase 2 for determination of uptake data, this was issued via the board leads group.
- Sharing Good Practice: The narrative report and discussions at the teleconferences allowed the sharing of good practices between boards.
- Reporting on progress: The Coordination Group was informed weekly on progress on key milestones.

Outputs

Action points raised from the teleconferences were recorded and actioned via a rolling action log which was reviewed at the start of each meeting over 230 actions were completed by the group.

The key output was the H1N1 vaccination programme was successfully implemented by all NHS boards to the phase 1 and phase 2 priority groups. Within this, this included:

1. NHS boards developed local implementation plans and implemented these plans.
2. As appropriate boards put in place a LES to cover phase 2 groups (and for one board social care workforce for phase 1).
3. NHS boards liaised with social care providers to identify workforce eligible for vaccination.
4. Developed local data management systems for the health and social care workforce as appropriate.
5. NHS boards ran clinics for the vaccination of health and social care workforce.
6. Supplied General Practices with vaccination details of individuals vaccinated outside General Practices.
7. NHS boards identified links with midwifery and equality and diversity leads.
8. Ensured appropriate training for staff delivering the programme.
9. Supported General Practices in the feedback of data issues.
10. Supported General Practices in the call of children for phase 2 of the programme.
11. Ran NHS board led clinics for the vaccination of phase 2 children including call, recall and data management.

12. Supported midwifery services in the vaccination of pregnant and post-partum women.
13. Ensured the vaccination of housebound patients (in particular those not on the case loads of district nurses).
14. Ensured the vaccination of in-patients in the at-risk groups as appropriate.
15. Developed local plans as appropriate for the identification and vaccination of children with complex needs and their carers.
16. Where appropriate developed and implemented local plans for the vaccination of poultry workers.
17. Liaised with General Practices and Community Health Partnerships over the vaccination programme.
18. Had local plans for the vaccination of hard to reach groups.
19. NHS boards provided regular status reports.

Scottish Government Health and Wellbeing Directorate

Objectives

a) With Health Protection Scotland, lead on the programme and ensure that NHS boards have the necessary arrangements and relationships in place to successfully deliver the programme.

b) Jointly with the NSS Board and through the receipt of regular reports and advice from the H1N1 Coordination Group, to monitor the performance of HPS in implementing the H1N1 Immunisation Project.

c) To be responsible, through existing performance management procedures, for ensuring that any significant departures from agreed local and national programme milestones are highlighted to individual NHS boards.

d) Liaise closely with the Department of Health (DH) to ensure that vaccine and any other UK procured consumables are available within Scotland to agreed timescales.

Processes

- Establishment of a dedicated H1N1 Vaccination Team within the SGHD Health Protection Team to lead the SGHD contribution and to prioritise H1N1 vaccination within the NHS and ensure mobilisation across NHS systems. Dona Milne acted as lead SGHD officer for this project.
- Regular negotiation with HPS lead and project manager to clarify roles and responsibilities of SGHD (strategic), HPS (tactical) and NHS boards (operational) in the early days of the programme.
- Creation of a Steering Group, chaired by an NHS Chief Executive and accountable to Scottish Government to oversee governance requirements for the programme.
- Include H1N1 vaccination as a standing item on the weekly teleconference with NHS Chief Executives.
- SGHD participation in all of the key groups within the vaccination programme, providing regular updates on scientific advice and policy developments from UK negotiations.
- Creation of an internal weekly SGHD vaccination meeting for the health protection team, medical officers, communications and primary care.
- Participation in weekly Four Nations Officials and Ministerial meetings on Pandemic Flu – vaccination was a key feature of all UK discussions and negotiations.

Outputs

1. Activation of Advanced Purchase Agreements for Pandemic Vaccine.
2. Vaccine delivery mechanisms negotiated and agreed with Department of Health and the vaccine and logistics pharmacy lead at HPS.
3. Clear governance arrangements established for the vaccination programme.
4. Good working relationships across the four countries which led to coordinated policy decisions and programme delivery across the four countries where appropriate, recognising that there were often delays in the transfer of scientific advice into government policy.
5. Provision of regular communication to the NHS and other programme providers via Chief Executive and CMO/CNO letters when there were scientific or policy changes.
6. Negotiation with SGPC, RCM, RCN and other professional bodies on delivery of the programme and communication of clear messages to key professionals.
7. Delivery of the overall communication activity for the vaccination programme including stakeholder and public communication materials as part of a UK programme of activity.

8. Continuation of a productive and transparent relationship with senior HPS staff on performance management and programme leadership, coordination and delivery.

9. Regular briefing to the Cabinet Secretary for Health and Wellbeing, the Cabinet Sub Committee for Pandemic Flu and the Scottish Government Resilience Team on vaccination programme priorities, delivery and uptake.

10. System established to gather financial monitoring information from NHS boards and to reimburse boards for vaccine doses administered outwith GP practices.

Appendix 2

Table 6:Week number and corresponding week ending data

Week number	Corresponding date and year
Week 28 week	ending 12 July 2009
Week 29 week	ending 19 July 2009
Week 30 week	ending 26 July 2009
Week 31 week	ending 2 Aug 2009
Week 32 week	ending 9 Aug 2009
Week 33 week	ending 16 Aug 2009
Week 34 week	ending 23 Aug 2009
Week 35 week	ending 30 Aug 2009
Week 36 week	ending 6 Sept 2009
Week 37 week	ending 13 Sept 2009
Week 38 week	ending 20 Sept 2009
Week 39 week	ending 27 Sept 2009
Week 40 week	ending 4 Oct 2009
Week 41 week	ending 11 Oct 2009
Week 42 week	ending 18 Oct 2009
Week 43 week	ending 25 Oct 2009
Week 44 week	ending 1 Nov 2009
Week 45 week	ending 8 Nov 2009
Week 46 week	ending 15 Nov 2009
Week 47 week	ending 22 Nov 2009
Week 48 week	ending 29 Nov 2009
Week 49 week	ending 6 Dec 2009
Week 50 week	ending 13 Dec 2009
Week 51 week	ending 20 Dec 2009
Week 52 week	ending 27 Dec 2009
Week 53 week	ending 03 Jan 2010
Week 1 week	ending 10 Jan 2010
Week 2 week	ending 17 Jan 2010
Week 3 week	ending 24 Jan 2010
Week 4 week	ending 31 Jan 2010
Week 5 week	ending 7 Feb 2010
Week 6 week	ending 14 Feb 2010
Week 7 week	ending 21 Feb 2010
Week 8 week	ending 31 Mar 2010