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Seasonal flu plan

Winter 2011/12

DH INFORMATION READER BOX

Policy	Estates Commissioning IM & T Finance Social Care / Partnership Working
HR / Workforce Management Planning / Clinical	
Document Purpose	Policy
Gateway Reference	16004
Title	Seasonal Flu Plan
Author	Seasonal Flu Team
Publication Date	25 May 2011
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Local Authority CEs, PCT Chairs, GPs, Chief Pharmacists, PCT pharmaceutical advisers, PCT Directors of Public Health, Immunisation & Flu Co-ordinators, Lead nurses at PCTs, GP practice nurses,
Circulation List	Local Authority CEs, PCT PEC Chairs, NHS Trust Board Chairs, All pharmacists, Chairs of Infection Control committees, Consultants in Communicable Disease Control, Accident and Emergency Departments, Monitor, British Medical Association, Royal College of General Practitioners, Royal Pharmaceutical Society, Pharmaceutical Services Negotiating Committee, National Pharmacy Association, Company Chemists Association.
Description	The purpose of this Seasonal Flu Plan is to set out a coordinated and evidence based approach to planning for and responding to the demands of seasonal flu across England. It will provide the public and healthcare professionals with an overview of coordination of preparation for seasonal flu and signposts where further guidance and information can be found.
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	By 25 May 2011
Contact Details	Seasonal Flu Programme Immunisation Branch 505 Wellington House 133-155 Waterloo Road, London SE1 8UG 020 7210 4850 http://www.info.doh.gov.uk/contactus.nsf/memo?openform
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First published May 2011

Published to DH website, in electronic PDF format only.

www.dh.gov.uk/publications

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Foreword

Each year, the Department of Health (DH) and the NHS prepare for the unpredictability of seasonal flu. For most healthy people, seasonal flu is an unpleasant but usually self-limiting disease with recovery usually within a week. However, older people, pregnant women and those with underlying disease, particularly chronic respiratory or cardiac disease, or those who are immunosuppressed, are at particular risk of severe illness if they catch flu. Last winter, the risk of serious illness or death from seasonal flu was estimated to be more than 15 times higher for people in clinical risk groups than healthy people.

Flu is an unpredictable pressure that the NHS faces during the winter and the NHS coped well last year. However, the consequences of the surge in demand for vaccine as well as the number of patients requiring treatment in hospital for flu were felt across the primary and secondary care systems; there were also issues for the vaccine industry. There are improvements we can make in the NHS and the DH for managing flu in the future and the publication, for the first time, of this *Seasonal flu plan* is a step in that process of improving our resilience. I am, therefore, setting out a coordinated and evidence-based approach to planning for us to be better prepared for the demands of seasonal flu across England.

Andrew Lansley CBE

Secretary of State for Health

Introduction

The purpose of this *Seasonal flu plan* is to set out a coordinated and evidence-based approach to planning for and responding to the demands of seasonal flu across England. It takes account of the experiences and lessons learnt during the 2010/11 flu season. It is intended to assist in the development of robust and flexible operational plans by local organisations and emergency planners within the NHS and across other sectors in England. It will provide the public and healthcare professionals with an overview of the coordination of the preparation for seasonal flu and signposts where further guidance and information can be found.

The *Seasonal flu plan* is not intended to be comprehensive or exhaustive guidance, or to take precedence over other standard operating procedures such as the annual flu letter¹ from the Chief Medical Officer (CMO) to the NHS and the *Immunisation against infectious disease* (the Green Book) Influenza chapter², which is updated ahead of flu seasons. The plan will be kept under review and updated as necessary. Healthcare professionals are advised to review the guidance regularly since it has proved necessary on previous occasions to update advice before and during the flu season, and given the nature of influenza viruses, this is likely to happen again.

Separately, the *UK Influenza Pandemic Preparedness Strategy 2011* is currently out for consultation until 17 June 2011. An influenza pandemic occurs when a new influenza virus emerges to which most people do not have immunity. The *Pandemic Preparedness Strategy* sets out the planning required in order to be ready for this, which is significantly different to responding to routine seasonal flu.

¹ www.dh.gov.uk/en/Publichealth/Immunisation/Officialimmunisationletters/index.htm#jumpTo1

² www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

NHS reforms

This plan covers winter 2011/12 and arrangements will be updated as necessary to reflect NHS system reform. The robustness of the NHS response to flu will be maintained or enhanced in the future system. Alongside the NHS reforms will be the creation of Public Health England (PHE) which will incorporate, amongst other things, the functions of the HPA. Immunisation programmes are in future expected to be funded from the public health budget. In the consultation on funding and commissioning routes for public health, which accompanied the White Paper, *Healthy Lives, Healthy People*, we proposed that, as at present, seasonal flu vaccination will be delivered through the NHS. The NHS Commissioning Board would have responsibility for commissioning the programme and most flu vaccines would continue to be administered by GPs. In future years, the NHSCB would want to assure itself that robust plans are in place locally to identify all eligible patients, sufficient vaccine has been ordered by practices to meet their needs, and that high vaccination uptake levels are reached in the clinical risk groups. We will publish our response to the consultation following careful analysis of comments on our proposals.

Influenza and the flu virus

Influenza (often referred to as flu) is an acute viral infection of the respiratory tract (nose, mouth, throat, bronchial tubes and lungs). There are three types of flu virus: A, B and C, with A and B responsible for most clinical illness.

Following infection, flu has a usual incubation period of one to three days. The disease is characterised by the sudden onset of fever, chills, headache, muscle and joint pain and fatigue. Other symptoms include a cough, sore throat, nasal congestion and diarrhoea may occur. For otherwise healthy individuals, flu is an unpleasant but usually self-limiting disease with recovery usually within two to seven days. A proportion of people infected may have very mild illness or no symptoms at all. However, for those that become sick, the illness may be complicated by bronchitis or pneumonia (either from the virus itself or a secondary bacterial infection) and, in children, otitis media (ear infection). In some rare cases, infection can cause cardiac problems, meningitis and/or encephalitis (inflammation of the brain). The risk of serious illness from influenza is higher amongst children under six months of age, older people and those with underlying health conditions such as respiratory or cardiac disease or immunosuppression.

The genetic make up of the flu virus is unstable and new variations (strains) often emerge. Minor changes ('drifts') occur from season to season. Major changes ('shifts') occur periodically, resulting in the emergence of a new subtype of the virus that can cause widespread epidemics or even a pandemic if populations have little or no immunity to that strain. The World Health Organization (WHO) monitors changes in flu viruses in order to make recommendations on the most appropriate three strains to include in seasonal flu vaccine. It also monitors changes in flu viruses to assess their potential to cause a pandemic.

How it is spread

Flu is passed from person to person through droplets created when someone with the infection sneezes or coughs. Infection can also be spread by contact with surfaces on which the virus has become deposited. Flu can spread rapidly.

Most cases of flu in the UK tend to occur during an eight to ten week period during the winter. The timing, extent and severity of this 'seasonal' flu can all vary and are unpredictable. Flu A is the predominant virus causing outbreaks most years and is usually the cause of epidemics. Large epidemics occur intermittently. Flu B tends to cause less severe disease, although in children the severity of illness may be similar to that associated with flu A.

Impact of flu each winter on the population

The impact of flu on the population can vary from year to year and is influenced by changes in the virus which, in turn, influence the proportion of the population that may be susceptible to infection and the severity of the illness it causes. The proportion of the population susceptible to infection depends on how many people have been exposed to the same or similar strains in the past and consequently have some immunity, and how many have been vaccinated against the circulating strains.

Figure 1 shows the rate of influenza-like illness (ILI) per 100,000 consultations in primary care in the population of England and Wales from 1966 to 2010/2011. The data show that major epidemics with ILI consultation rates in excess of 500 per 100,000 persons were seen in the late 60s, early 70s and in 1989/90.

The last season the flu epidemic threshold was exceeded (defined as an ILI rate of over 200 GP consultations per 100,000 people) was in 1999/2000. The data show that flu viruses circulate each winter season, but the degree of activity varies substantially each year.

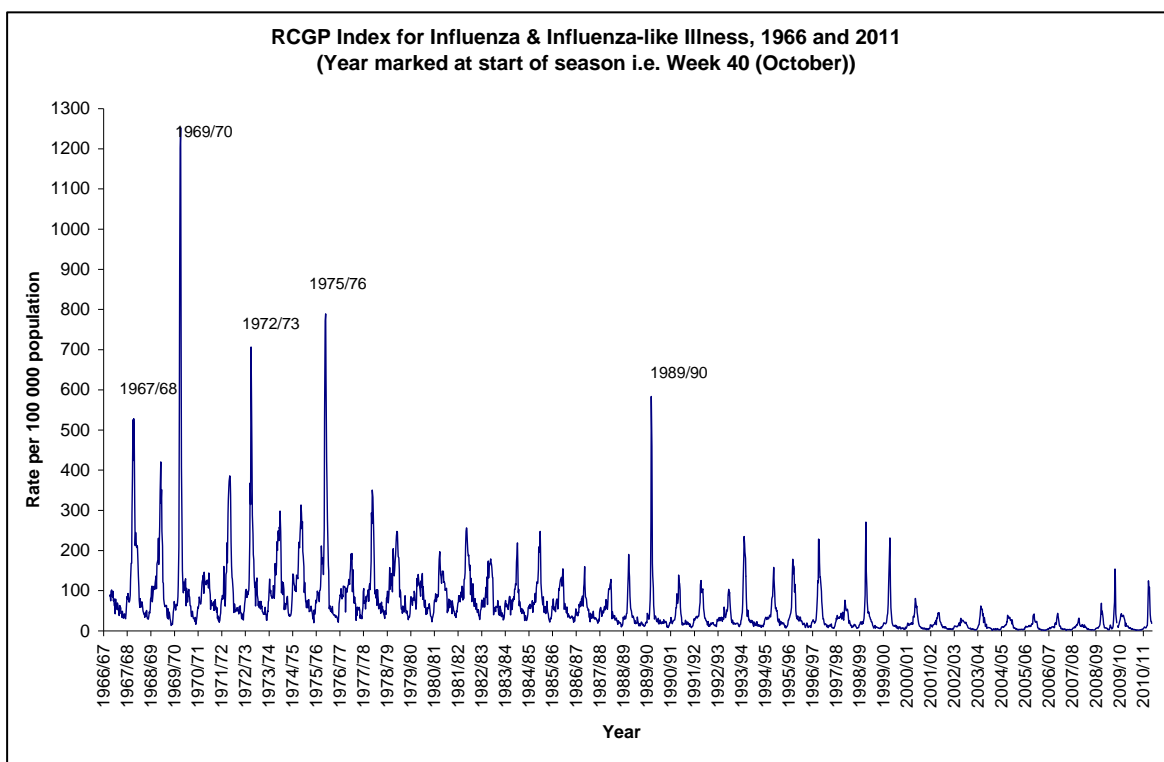


Figure 1 The rate of influenza-like illness (ILI) per 100,000 consultations in primary care in the population of England and Wales from 1966 to 2010/2011.

UK surveillance to assess the impact of flu includes:

- measuring the number of people consulting their GP with flu-like illnesses
- testing samples from people with ILI to determine whether they have flu or not, and which virus has caused the infection
- investigating the characteristics of people that have died from flu (ie their age and whether they had underlying health problems, whether they were vaccinated or received antiviral medicines).

There are a number of other viruses that may cause ILI but are not flu, such as respiratory syncytial virus (RSV), parainfluenza and rhinovirus: for this reason, ILI data alone may over-estimate the level of flu in the community. The HPA produces a weekly report during the flu season on numbers of GP consultations, rates of ILI by age group, and laboratory confirmations of flu.

During the flu season, the HPA receives and follows up reports from various sources (including clinicians, laboratory reports and death certificates) of deaths in patients in England where flu is suspected to have contributed. A confirmed case is defined as an individual dying with a laboratory confirmed flu infection, where flu contributed to the death. Although the fatal cases reported and confirmed to be associated with flu infection do not constitute all cases that occur, they provide a representative picture of the types of patients and underlying factors associated with severe disease. The figures presented are provisional and interim.³

³ The equivalent organisations in Scotland, Wales and Northern Ireland have established systems to gather and report information on influenza-related deaths. These systems, including the case definition, differ between countries. More details on the systems are available at www.wales.nhs.uk/news/18138; www.publichealth.hscni.net/publications; www.hps.scot.nhs.uk/

Strategic objectives

The objective of the seasonal flu programme is to minimise the health impact of seasonal flu through effective monitoring, prevention and treatment, including:

- vaccinating at least 75% of those at greatest risk with the seasonal flu vaccine before the virus starts to circulate
- monitoring flu activity, severity of the disease in risk groups, vaccine uptake and impact on the NHS
- offering antiviral medicines to patients in at-risk groups for the treatment of flu in line with NICE guidance⁴
- ensuring the NHS is well prepared.

Proportionality: planning for uncertainty

As described earlier, flu activity varies widely and is largely unpredictable. Therefore, planning for the flu season needs to prepare for a range of possibilities including the need to respond quickly to modify the plans. The Department and NHS response to seasonal flu each winter should be appropriate to the known risks. That is why, for example, the seasonal flu vaccination programme is based on an assessment of the cost effectiveness of the use of vaccine for specific risk groups. These are the groups that are then recommended for vaccination annually; current evidence does not support vaccination of the whole population as being cost effective.

The Joint Committee on Vaccination and Immunisation (JCVI) keeps the available evidence under review and modifies its advice should evidence suggest that the programme could be more effective.

For this reason, the *Seasonal flu plan* operates according to a series of stages, which enable individual elements of the Department's response to be escalated as appropriate.

Flexibility: managing the differing levels of severity, possible variation in age profile and intensity of activity

While DH leads the strategic response to flu each winter, the system needs to be sufficiently flexible to allow local adaptation of responses to take account of local variations in the spread and type of infection and impacts on local health services.

⁴ www.nice.org.uk/TA168

The impact of the virus on the population each year is variable – it is influenced by changes that may have taken place in the virus, the number of people susceptible to infection and the severity of the illness caused by a particular strain. These factors in turn affect the pressures the NHS experiences and where they are felt most.

Furthermore, these factors may vary between regions and local areas, requiring different approaches in different places. Local plans therefore need to be flexible to adapt as the flu season progresses.

For example, each hospital will have its own plans in place to free up critical care beds for those suffering severe effects from flu. But the decision to activate such a plan will be taken locally, based on the assessment of the situation including the support that neighbouring hospitals can provide.

In addition, the seasonal flu response will continue to be:

- evidence based
- built on established systems and business continuity
- coordinated at local and national levels and sharing information at an international level.

The annual cycle of the seasonal flu programme

The annual cycle for preparing for and responding to seasonal flu is set out below and includes new additions that have been made following experiences during the 2010/11 season.

January–March: Review and planning

- WHO announces the virus strains selected for the next season's flu vaccine for the northern hemisphere. The flu virus is constantly mutating and it is, therefore, necessary to formulate each season's flu vaccine so that it matches the strains likely to be circulating the following winter. WHO therefore monitors the epidemiology of flu viruses throughout the world in order to make recommendations about the strains to be included in flu vaccines for the coming winter.
- Final vaccine orders placed with suppliers.

Manufacture of trivalent seasonal flu vaccines is complex and conducted to a tight schedule, constrained by the length of time available between the WHO recommendations and the opportunity to vaccinate before the flu season.

Manufacturers can only start the process of creating the vaccine for use in the autumn once WHO has recommended the strains to be included in the vaccine. This happens in February, leaving a limited time for manufacture before the vaccination campaign starts usually in late September. Manufacturers may not be able to respond to unexpected demands for vaccine at short notice, or to allow for changes/mutations to the strains that may be identified later in the year. More detail on the vaccine manufacturing process is in annex B.

- A letter from the DH is sent to the NHS seeking assurance from PCTs that adequate local plans are in place for the flu immunisation programme to meet the national objectives, with contingency arrangements for unexpected demands on supplies or delays in delivery of vaccines from suppliers. The letter sets out the risk groups to be immunised and the WHO and EU recommended levels for vaccine uptake rates.

April–June: Assurance

- A second letter from DH is sent by the CMO and provides the detail of the flu vaccination programme for the following winter.
- DH has noted that there were some concerns over the impact of adding pregnant women to the risk groups after vaccine orders had been placed in 2010 although there should have still been sufficient vaccine available for GPs to provide for this new group. Any recommendations to change the groups would follow the advice of JCVI taking into account availability of the vaccine. Changes coming out of the February or June JCVI meetings, which significantly increased the number of people in at-risk groups, would not generally be implementable in time for the winter immediately following. Changes in the committee's advice following the October meetings, which increased the number of people in at-risk groups, would never be implementable for the following winter unless the advice changed the composition of the at-risk groups within the total number of vaccine doses already available.
- Local areas may start planning communications campaigns that will anticipate the start of the immunisation programme in September. Further information about any centrally-driven approach will be made available via the NHS Comms Link website, available to NHS Communicators.
- The Green Book, *Immunisation against infectious disease*, provides guidance for healthcare workers on administering the seasonal flu vaccine; the influenza chapter is updated each year following JCVI advice and published ahead of the vaccination programme.
- Vaccine supply – assurance is sought from manufacturers on the availability of vaccine. DH liaises with vaccine manufacturers to ascertain whether there are any manufacturing problems which might affect either the number of doses available or the dates of delivery. If there are factors that are sufficiently serious to significantly affect the immunisation programme, DH will issue guidance to the NHS suggesting arrangements to minimise the impact, for example advising GPs to prioritise particular clinical risk groups over other eligible groups.

Depending on the scale of any manufacturing, supply and/or regulatory authorisation difficulties, DH could take action to obtain additional supplies, assuming they were available.

- This is the time of year for patients who are eligible to receive the seasonal flu vaccine to make sure that their GP has included them on their list of eligible patients to contact at the start of the flu season. This is particularly important for carers who cannot be identified through medical records.

July–September: Preparation

- The Director of Immunisation at DH will write to the NHS with information on vaccine production and final administrative arrangements.
- Any centrally produced communications materials will be made available via NHS Choices, DH and NHS Comms Link websites for use by local areas. Practices may wish to use these materials as part of their campaigns to raise awareness of the availability of seasonal flu vaccination.
- Communications and guidance about vaccine uptake data collections will be issued.
- Trusts, GP practices and pharmacists should begin communications activities to promote uptake of the vaccine among eligible groups.
- GP practices should contact their eligible patients and invite them to attend for vaccination.
- Suppliers start to deliver vaccines to GP practices from September.

October–February: Implementation

- Deliveries of vaccine continue according to manufacturers' production processes.
- GPs begin vaccinating eligible patients against seasonal flu
- Weekly and monthly vaccination data collections from primary care, and monthly data collections from secondary care begin.

DH will monitor uptake on a weekly basis from the beginning of October. The information will be collected via the web-based ImmForm system that collates data extracted from a large national sample of GP practices (approximately 50%). The uptake information will show the coverage for the following groups:

- people aged 65 and over
- people aged under 65 with a clinical condition
- all pregnant women
- frontline healthcare workers

with weekly data providing representative estimates of national uptake by patient groups and monthly collections providing national and local level estimates of vaccine uptake by patients and frontline healthcare workers.

- From week 40 (early October) the HPA publishes weekly reports on flu incidence, vaccine uptake, morbidity and mortality.
- Information on flu and the vaccination programme will be issued each week on Winterwatch. The CMO will lead weekly press conferences as and when it is necessary. For example, this could be if the extent of flu is unexpected – more people than usual are ill, more people than usual are in hospital or more people are dying than would be expected. If media coverage is particularly intense and/or misinformed, the CMO may also want to hold press briefings to provide the facts and get appropriate messages to the public including how they can protect themselves and their families.
- DH publishes information on flu prevalence and vaccine uptake on Winterwatch.

DH will be advised by the HPA and other sources in respect of:

- the amount of flu-like illness (ILI) in the community
 - the most prevalent strain(s) of flu circulating
 - the proportions of clinical samples that are positive for flu or other viruses
 - the number of flu related hospital admissions, and
 - the relative impact of flu on different groups of people, by age and by clinical condition (including data on deaths where flu is the confirmed cause).
- The Chief Pharmaceutical Officer (CPhO) issues advice on the use of antiviral medicines, based on advice from the HPA in light of flu surveillance data.

Following NICE guidance, antiviral medicines should only be prescribed once DH has notified general medical practitioners and other prescribers that it is clinically appropriate to do so.

- The government holds large stocks of antiviral medicines in case of a flu pandemic. In the event of the commercial sector supply chain for antiviral medicines running low, antivirals from the national pandemic flu stockpile may be made available to suppliers as a contingency subject to arrangements about replenishment.

In this system, government stocks of antiviral medicines would be supplied to the manufacturers who would distribute to community and hospital pharmacies using their normal supply chain mechanisms. Government stocks would be replaced

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'like for like' by suppliers at the end of the flu season. This system would only be activated if there was overwhelming demonstrable public health need.

- The NHS implements winter pressures coordination arrangements.

A winter preparedness exercise will take place with the NHS before next winter.

- Respiratory and hand hygiene campaign launched as necessary.

Flexibility: a staged flu response

At some point during the autumn or winter, the levels of flu circulating in the community will rise, the incidence of flu-like illnesses will increase and GP practices and hospital services may come under increased pressure. It is not possible to predict when this will happen. DH will use such information to assess the overall impact of flu on the population and on health services and, if needed, initiate a public health response to address the situation. When this occurs, the response phase of implementation will come into effect. Not all elements may come into effect at the same time, or in a particular order, or in all localities. Local plans must be sufficiently flexible to be able to respond to local situations.

While DH leads the national strategic response to flu each winter, the system needs to be sufficiently flexible to allow local adaptation of responses to take account of local variations in the spread and type of infection and local health services.

In this section, the flu response is set out in stages of activity that would take place depending on various factors, including the levels of flu that are circulating, pressure on NHS services, and epidemiological evidence on the nature and severity of illness the virus is causing, and among whom.

While the stages are illustrative of when levels of escalation in the flu response could be expected, other factors will sometimes determine an alteration to the timing of an activity. For example, based on a range of indicators collected each week during the flu season by the HPA and others, DH informs GPs that flu is circulating at levels that would justify the use of antiviral medicines. The 2010/11 flu season highlighted the problem of applying a single indicator when it became evident that significant numbers of people with flu were being admitted to critical care, despite low overall levels of flu activity being recorded in primary care. These flexibilities are necessary to allow the NHS to respond to the circumstances in any given flu season. See section on NHS Winter Planning on page 27.

Stage	Level of flu like illness	Description of flu season
1	Community and primary care indicators starting to show that flu and flu-like illness are being detected	Beginning of the flu season – low levels of flu and/or low severity of illness associated with the virus
2	Flu indicators starting to show that activity is rising	Normal levels of seasonal flu and/or normal to high severity of illness associated with the virus
3	Flu indicators exceeding historical norms	Epidemic levels of flu – rare for a flu season

	Activity that would be undertaken
Stage 1	<ul style="list-style-type: none"> • Review data on flu activity and severity from the southern hemisphere. • GPs invite their eligible patients to be vaccinated, using call and reminder systems. • Data on flu incidence and vaccine uptake rates in England issued at a national and, if available, regional/local levels. • Data on ILIs, virological surveillance, vaccine uptake and NHS operational data published on Winterwatch. • HPA publishes weekly reports on flu incidence, vaccine uptake, morbidity and mortality. • Director of Immunisation writes to the NHS if vaccine uptake is low. • DH in contact with vaccine manufacturers on production and delivery schedules. • DH in contact with antiviral medicine manufacturers on their preparedness plans.
Stage 2	<ul style="list-style-type: none"> • GPs will be alerted to start prescribing antiviral medicines in line with the National Institute for Health and Clinical Excellence (NICE) guidance and following expert advice that the flu virus is circulating. • The respiratory and hand hygiene campaign launched as necessary. • If evidence emerges that a particular age group or people with a certain clinical conditions are being disproportionately affected by the flu virus, the CMO may issue specific advice to both the public and health professionals to increase efforts to vaccinate that particular group, if practicable and seeking expert advice from JCVI if necessary. • Local NHS responds to local circumstances according to local plans and needs. • Review daily NHS operational data, eg critical care. • CMO may provide a media briefing to provide clear, factual information on flu. This may include information for the public about what to do if they become unwell and advice on accessing services. <p>If vaccine shortages are considered likely across the country, DH will alert GPs to the availability of the central strategic reserve and set out how they should access this stock. It is likely this will be through the on-line Immform system. Depending on the level of shortages, restrictions may be placed on the number of doses a GP can order.</p>

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	<ul style="list-style-type: none"> • Vaccine manufacturers contacted regarding the availability of additional supplies if needed. • In the event of shortages of antiviral medicines, and an evident public health need, DH would take steps to support arrangements for supplies by using its pandemic flu stocks as buffers in the supply chain. In this system, government stocks of antiviral medicines would be supplied to the manufacturers who would distribute to community and hospital pharmacies using their normal supply chain mechanisms. • DH will work closely with antiviral medicines manufacturers, wholesalers and pharmacies to minimise disruptions of supply to patients. • DH will work closely with antibiotic manufacturers, wholesalers and pharmacies to minimise disruptions of supply to patients.
<p>Stage 3</p>	<ul style="list-style-type: none"> • A national flu epidemic is declared • GPs alerted that a late surge in demand for the vaccine may occur. • Vaccine manufacturers contacted regarding availability of additional supplies. • JCVI will review the available data and amend guidance on vaccination if necessary and if sufficient supplies of vaccine are available and can be delivered and administered in time. • Weekly CMO press briefings will be considered. • Maintain or boost the respiratory and hand hygiene campaign • Proactive work with media to allay any public concerns. • Reiterate advice on signs and symptoms, and treatment at home. • Communicate regularly with clinical and professional networks, and stakeholder groups for patients at risk of severe illness. • Continue to review daily NHS operational data, eg critical care. • Alert the NHS when the flu season has peaked, to aid local planning.

Potential scenarios

The table below gives examples of factors affecting the Department and NHS flu response during the flu season, and describes the actions that DH and the NHS could take in response. It should be noted that this table is indicative - it cannot cover all potential eventualities and the consequential actions.

	Event	Action
Vaccination	Delay in vaccine released from manufacturer.	DH writes to NHS informing them of delay so GP practices and other providers can reschedule vaccination clinics.
	Production problems mean insufficient doses of vaccine are available nationally.	DH writes to NHS informing them of shortage and advising which risk groups to target, following JCVI advice as appropriate.
	Localised vaccine shortages (eg due to unexpectedly high uptake rates or local storage problems).	Redistribution of stocks locally. Central strategic reserve is released.
	Vaccine uptake remains below expected rate for the time of year. Virus adversely affects groups outside those recommended for vaccination.	CMO or Director of Immunisation writes to NHS recommending appropriate action to increase uptake.
	The vaccine does not protect against the predominant circulating strain.	DH communicates the issue to GPs and the public. The seasonal flu vaccination programme is maintained to ensure that older people and those in clinical risk groups are protected against the two other strains of flu covered by the vaccine. DH alerts the NHS that they may have higher numbers of flu cases to manage, and remind GPs that the regulations have been broadened to give GPs more flexibility to prescribe antiviral medicines. This applies to patients who are not in one of the clinical

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		<p>risk groups, but who GPs consider may be at risk of developing serious complications from flu.</p> <p>DH considers launching the Respiratory and Hand Hygiene campaign.</p>
	Issue over safety of vaccine emerges.	<p>The Medicines and Healthcare products Regulatory Agency (MHRA) considers the available evidence and recommends course of action. Depending on balance of risks and benefits, MHRA may amend prescribing advice to minimise any risks. Action may be taken by the European Medicines Agency (EMA). The DH and/or MHRA will give advice on implications of safety issue.</p> <p>DH writes to NHS informing consequences of safety issue if it impacts on supplies and advising which risk groups to target, following JCVI advice as appropriate.</p>
	Production failure towards the end of the vaccination programme leads to localised vaccine shortages.	Central strategic reserve is released.
	Vaccine shortage.	Central strategic reserve is released.
Treatment	Antiviral medicines not available from pharmacies.	<p>DH contacts pharmacy organisations to determine the cause of supply issue.</p> <p>DH discusses stock levels with manufacturers and wholesalers to determine whether they can meet the increased demand.</p> <p>DH considers releasing the national stockpile to ease shortages, if appropriate.</p>

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NHS operations	Extra cases put increased pressure on care locally.	Local action in line with local plans, under existing contractual arrangements.
	Extra cases put excessive pressure on care regionally or nationally.	Strategic Health Authorities (SHAs), DH and the NHS Chief Executive keep under review the need to trigger 'Strategic command arrangements for the NHS during major incident', as per the guidance. ⁵
Media coverage	Increased media interest on particular issues.	CMO holds press briefing to communicate the facts and latest data to the media.

⁵ www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081507

Preparing for uncertainty – plans to improve

Following the experiences of the 2010/11 flu season, DH is working to improve the response plans for seasonal flu in the following areas:

Improving vaccine uptake among people aged under 65 in clinical risk groups

By the end of the 2010 flu vaccination season, about 50% of people under 65 years in clinical risk groups had been vaccinated against seasonal flu. The CMO has written to the NHS stating the need for the NHS to plan locally to reach or exceed 75% uptake for people under age 65 in clinical risk groups as recommended by the European Union (EU), and for pregnant women.

Significantly improving uptake in the clinical risk groups will be challenging. A reasonable trajectory for increases in uptake in clinical risk groups and pregnant women might be to reach 60% in 2011/12, and 70% in 2012/13, so that an uptake of 75% can be reached or exceeded in 2013/14.

The letter also asks SHAs to assure themselves that local plans are in place for GPs to order sufficient vaccine and use robust call and reminder systems to contact their eligible patients.

Community pharmacies are increasingly providing both NHS and non-NHS flu immunisation services. This is both convenient for, and liked by the public. Pharmacies can also alert patients who are in at-risk groups of the need for vaccination, where they do not administer the vaccines themselves. It is important to ensure that the provision of flu vaccine is recorded in all cases and the information is returned promptly to the GP and/or PCT (or equivalent data centre in the future).

DH will continue to discuss with pharmacy organisations how best to involve pharmacists in the provision of flu immunisation in ways that are welcomed by the public and that offer a safe environment for the provision of the service, acknowledging the need for submission of relevant information.

In order to be confident that robust planning is in place, DH has asked SHAs for assurance from PCTs on their seasonal flu immunisation plans for 2011, including plans for the vaccination of frontline health and social care workers.

Ensuring a reliable and accessible supply of vaccine

Central strategic reserve

Following the localised vaccine shortages experienced in the 2010 vaccination season, DH will purchase a small central strategic reserve of trivalent seasonal flu vaccine to use if necessary to mitigate the impact of shortages. This stock will be purchased ideally from more than one manufacturer to reduce any risk of reliance on a single supplier, and to conform with European directives on government procurement.

For 2011, the responsibility for ordering vaccines will continue to lie with general practices. Practices will need to make their own arrangements with suppliers to ensure they have sufficient vaccine for the needs of their eligible patients. If isolated local shortages of flu vaccine occur, then they need to be managed locally, with local management addressing such shortages through the redistribution of existing stocks. The central strategic reserve will only be issued when DH determines that it is required to fill national shortages that cannot be managed locally.

It is anticipated that in a normal flu season the strategic reserve will not need to be released. This reserve will be considered as an appropriate insurance against shortages that may occur in a more severe flu season when there has been exceptional demand in excess of estimations for practice requirements.

Central procurement of seasonal flu vaccine

In light of the shortages of seasonal flu vaccine during the 2010 flu vaccination season, DH is reviewing whether the arrangements for procurement of seasonal flu vaccine should be changed for future years. Due to the timescales required to implement changes to current GP procurement arrangements, ordering of vaccine for 2011 will remain unchanged, with the responsibility remaining with general practices. The option of central procurement of flu vaccine, with DH procuring all flu vaccine required by primary care and distributing it free of charge to GPs, will be the subject of a consultation.

Increasing vaccination rates for frontline health and social care workers

Patients may expect frontline health and social care workers to be vaccinated against seasonal flu. This protects healthcare workers and it reduces the risk of them transmitting the flu virus to vulnerable patients. Uptake of the seasonal flu vaccine in frontline healthcare workers was higher at the end of the 2010/11 vaccination programme (34.7%) than at the end of the 2009/10 vaccination programme (24.7%), but this is still too low. National and international experience shows that considerably higher coverage can be achieved and more work needs to be directed towards better protection of this group.

NHS organisations should ensure that appropriate measures are in place for offering flu vaccination to their frontline health and social care workers. These programmes are organised locally by NHS organisations, often through the occupational health service. GPs will only be involved in providing this part of the vaccination programme where this has been agreed locally.

DH will run an NHS staff vaccination communications campaign in partnership with external stakeholders in 2011-12. The campaign will be designed to support local teams, ensure consistency of message, share best practice and harness clinical and professional leadership at both national and local levels.

Improving the prescribing and supply of antiviral medicines

DH has changed the regulations to give GPs more flexibility to prescribe antiviral medicines. This applies to patients who are not in one of the clinical risk groups, but who GPs consider may be at risk of developing serious complications from flu, if they are not able to access antiviral medicines. It is expected that GPs will be guided by the CMO on when to use this flexibility.

At present, DH alerts general practitioners and other prescribers that the level of flu (as advised by the HPA) warrants the use of antiviral medicines on the NHS. This is done through a letter from the Chief Pharmaceutical Officer (CPhO). When notified by the DH, GPs and other prescribers can prescribe in accordance with NICE guidance. In the future, DH will also notify the manufacturers of antiviral medicines and wholesalers when the notification has been issued to prescribers, so they are prepared for an increase in demand.

In order to minimise the development of antiviral resistance, it is important that GPs prescribe antiviral medicines prudently, taking into account national guidance and prescribing in accordance with their marketing authorisations. GPs should continue to monitor their use, especially in immunosuppressed individuals where resistance is more likely to be seen.

Monitoring the supply chain and ensuring resilience of supply of antiviral medicines

Until the flu pandemic of 2009, antiviral medicines were not widely used in the NHS. Increased use of antiviral medicines, compared to previous years, was seen in the winter of 2010/11. As manufacturers, pharmaceutical wholesalers and community and hospital pharmacies do not routinely stock large quantities of antivirals, the increased demand resulted in greater pressure on the supply chain.

DH will improve communications with pharmaceutical manufacturers of antiviral medicines and wholesalers to provide greater information about expected demand for antiviral medicines. The regularity of contact between DH, manufacturers and

wholesalers will be influenced by the severity of the flu and the pressures on the supplies.

NHS winter planning

Flu is one of the factors that the NHS considers as part of winter preparedness. Each year the NHS plans for and responds to winter pressures. Last year, as in previous years, the NHS had plans in place that enabled it to cope well with winter pressures. Pressures associated with winter include:

- the impact of adverse weather, including snow and ice causing increased numbers of accidents
- flu, which this year included increased pressure from the number of people requiring critical care beds, and
- the impact of Norovirus on the acute sector, including the closure of beds in accordance with infection control processes.

Local planning allows the NHS to manage winter pressures effectively, by implementing local escalation plans where necessary, in response to local circumstances and needs. An example of local management of pressure could include, for instance, the cancellation of routine surgery to create additional capacity in critical care for those suffering from flu. Daily monitoring arrangements allow the NHS to monitor key indicators of pressure across the acute sector.

Information used to monitor pressure on the NHS was published for the first time last winter on Winterwatch (www.dh.gov.uk/winterwatch). A routine winter preparedness exercise will take place with the NHS before next winter, taking into account command and control arrangements and the impact of NHS system reform.

Communication

Clear and timely communication is vital to ensure that all parties involved in managing flu understand their roles and are equipped with the necessary information.

There will be different types of communication depending on the severity of the flu season and the nature of the audience. It will be important to maintain a flexible approach so that appropriate channels are chosen to maximise impact.

The following communication mechanisms are likely to play an important role in the coming flu seasons.

HPA weekly influenza reports

These reports represent the most comprehensive and detailed assessment of the current situation. They will be of relevance to healthcare professionals, health planners, journalists and interested members of the public.

During the flu season these reports will be published on the HPA website every Thursday afternoon. The reports will cover the following information:

- a narrative summary of the current situation
- weekly consultation rates (ILI) in national sentinel schemes
- community surveillance (e.g. calls to NHS Direct)
- microbiological surveillance
- disease severity
- vaccination uptake
- the international situation.

A sample report can be viewed at:

www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/SeasonalInfluenza/EpidemiologicalData/05influsWeeklyinfluenzareportsarchive/

CMO press briefing

During the 2009 H1N1 pandemic and during the flu season of 2010/11, CMO briefings were held weekly, according to need. In the future, the CMO will lead weekly press conferences as and when it is necessary, as set out on page 16. If held, they will occur on Thursday afternoons to coincide with the release of weekly flu data, such as the HPA report (see above).

If these are held, they would usually take place at Richmond House, Whitehall, London and be attended by the CMO, the Director of Immunisation, an HPA representative, and others as needed.

The briefings are an opportunity for:

- the CMO to issue a specific public health message and,
- for the media to have access to those dealing with the programme and for the media to obtain more detailed information to inform their reporting.

Winterwatch

Winterwatch was launched on the DH website during the 2010/11 season. It provides a less detailed summary of the flu position and is aimed primarily at members of the public. It also provides a vehicle for the CMO to offer public health advice on a number of winter health-related issues.

Winterwatch provides information on the following:

- vaccination uptake
- weekly consultation rates (ILI) from RCGP data
- data showing the impact of flu on the NHS, e.g. number of critical care beds in use, and
- a weekly message from the CMO.

Winterwatch was updated every Thursday afternoon during the 2010/11 flu season and can be viewed here: www.dh.gov.uk/winterwatch

Introduction of the respiratory and hand hygiene campaign once flu is circulating

DH has used its 'Catch it, Bin it, Kill it' campaign material to improve respiratory and hand hygiene behaviours with the aim of reducing the spread of flu and other respiratory viruses. It may also have a positive impact on reducing the spread of gastrointestinal illnesses such as norovirus.

It was deployed in early January 2011. It is important to time the launch of any such campaign so as to have an optimal impact on public behaviour and further work will be undertaken to improve our understanding of this.

The public response to the material will continue to be monitored so that the content and approach can be adapted if necessary.

Vaccine advertising campaign

DH will continue to review the best available evidence regarding flu vaccination advertising. Further information about centrally-driven plans will be made available via NHS Comms Link.

However, while a national campaign might play a role in increasing early uptake of the vaccine, research suggests that it cannot replace proactive and personalised invitations from GPs to patients. PCTs and GP practices therefore need to plan carefully to ensure that they are making every effort to identify and contact eligible patients.

Further information about the possibility of a national campaign will be made available in due course to allow local areas to create tailored plans for their areas that integrate well with any central activity.

Annex A

Prevention and treatment of flu

Treatment at home

People with suspected flu who are not in the at-risks groups should:

- stay at home
- rest
- drink plenty of fluids while they are recovering, and
- consider taking paracetamol/ibuprofen-based painkillers or cold remedies to lower their temperature and relieve their symptoms.

Vaccination

The purpose of the seasonal flu vaccination programme is to offer protection to those who are most at risk of serious illness or death should they develop influenza. Vaccines are produced each year, by a number of manufacturers, that provide protection against the three strains of influenza that the WHO considers may be most prevalent in the following winter.

These 'trivalent' seasonal flu vaccines give around 60 to 80% protection against infection with influenza virus strains with the higher protection when the strains are well matched with those in the vaccine, and according to the age and clinical conditions of individuals.⁶ The protection afforded by the vaccine lasts for at least one flu season but the protection over the longer term is uncertain. In the elderly, protection against infection may be less, but immunisation has been shown to reduce the incidence of bronchopneumonia, hospital admissions and deaths.

Antiviral medicines

Antiviral medicines prevent the influenza virus from replicating inside the body. They can lessen symptoms by a couple of days and reduce their severity, and help to reduce the likelihood of complications.

⁶ Fleming DM, Watson JM, Nicholas S *et al.* (1995) Study of the effectiveness of influenza vaccination in the elderly in the epidemic of 1989-90 using a general practice database. *Epidemiol Infect* **115**(3): 581-9.

Antiviral medicines are available on the NHS for certain groups of patients, including those in one of the at-risk categories as outlined in annex C. DH has changed the regulations to give GPs more flexibility to prescribe antiviral medicines. This applies to patients who are not in one of the clinical risk groups, but who GPs consider may be at risk of developing serious complications from flu, if they are not able to access antiviral medicines. It is expected that GPs will be guided by the CMO on when to use this flexibility.

Treatment in secondary care

In certain groups and individuals, flu can progress from a mild flu-like illness manifesting as fever, cough, sore throat, headache, malaise, and muscle and joint pains to one in which there is shortness of breath, chest pain or confusion, indicative of pneumonia, and/or a significant exacerbation of an underlying medical condition (such as heart, liver, lung or renal Insufficiency or diabetes mellitus). Patients presenting with these symptoms will usually need assessment and treatment in hospital.

If the infection is thought to be due to a bacterial infection secondary to flu, then as well as using antivirals, intravenous antibiotics will be used. Depending on the severity of the disease and any other co-morbidities, then some form of ventilation in a level 2 or level 3 critical care facility may be required.

A pneumonia that is caused directly by the flu virus (as was the case in a number of hospitalised cases of H1N1 (2009) flu) is usually considered more serious, requiring a prolonged admission to a level 3 critical care facility where specialist ventilatory techniques may be needed.

For some critically ill patients, a more invasive and complex intervention called Extra-Corporeal Membrane Oxygenation (ECMO) is required. ECMO involves removing blood from the patient, adding oxygen to the blood and then pumping it back into the patient in order allow the lungs to heal. This is a complex procedure which is only carried in certain specialist centres using highly trained specialist teams. It is high risk and is therefore only used as a matter of last resort in exceptional cases.

Annex B

Vaccine manufacture and supply

Flu vaccine manufacture and supply is undertaken on a global basis. Seven international companies manufacture flu vaccines for the UK. They all also supply other European countries and some manufacture vaccine for North America as well.

Manufacturers make an overall decision on their flu vaccine production quantities based on expected demand from all the countries that they supply. Such estimates will be based on a number of factors, such as current quantities supplied; anticipated changes in vaccine recommendations in different countries; and other commercial decisions regarding market share, etc. Based on this information, the manufacturers start their planning cycle, which includes reviewing existing production capacity and possible need for expansion; ordering sufficient pathogen-free eggs to meet production needs; filling, packaging and labelling needs, etc. This planning cycle starts 18 months before a seasonal flu vaccination programme.

The flu vaccine production 'window' is limited. WHO makes recommendations on the composition of the northern hemisphere seasonal flu vaccine in February. Their recommendations are based on the flu virus strains that they judge to be the most likely to circulate the following winter, and take into account data from the southern hemisphere flu season. Production of the vaccine usually runs from March to August/September, and packaging and labelling can continue until October. Once vaccine composition is agreed, then the manufacturers have to grow the vaccine viruses, formulate the vaccine, test, license, package and supply the vaccine within six months in order to ensure stocks are available for the beginning of the immunisation programme.

Following a thorough clean down of the production facility, most manufacturers then switch to flu vaccine production for the next southern hemisphere season. Hence, the flu vaccine production period is limited and complex, with little room for slippage in the process.

The UK arm of a vaccine manufacturer will take orders for flu vaccine from its customers (primarily GPs) from November to January for the following season, with the majority of orders being placed by December. The UK company, along with their sister companies in other countries, will then 'bid' for a share of vaccine supplies from their international headquarters. The process to finalise volume requirements for each country is completed at a national and European level between December and February/March. This completes a process on vaccine volumes that started with initial estimates made in the preceding May – that is 18 months prior to supply of vaccine.

Some manufacturers may plan to produce slightly greater quantities of vaccine than they have orders for. This allows for a number of eventualities such as: lower than anticipated vaccine yield; the potential of some vaccine batches to fail their release testing; late additional orders for vaccine, etc. The quantity of surplus stock will vary year on year, and the manufacturers will sell what stock they have to the countries where there is demand. It should be noted that flexibility is limited if the vaccine has already been packaged and labelled. The vaccine will only be available for use in those countries where it complies with the licence, so for example, vaccine labelled in a foreign language would need a licence variation to be granted by the MHRA in order for the vaccine to be licensed for use in the UK. Licence conditions vary between countries and the MHRA may not necessarily agree to a licence variation.

GPs can place orders with manufacturers after March. However, it is likely that they will have a limited choice of vaccine and there is a risk that there will be no further vaccine available to order.

Annex C

Groups eligible for the seasonal flu vaccination

Seasonal flu vaccinations are currently offered free of charge to the following at-risk groups:

- people aged 65 or over
- all pregnant women
- people with a serious medical condition such as
 - chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis;
 - chronic heart disease, such as heart failure;
 - chronic kidney disease at stage 3, 4 or 5;
 - chronic liver disease;
 - chronic neurological disease, such as Parkinson's disease or motor neurone disease;
 - diabetes; or
 - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment).
- people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence.
- people who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill.

Also recommended to be vaccinated as part of occupational health:

- frontline health and social care workers.

Healthcare practitioners should refer to the Green Book influenza chapter⁷ for further guidance.

The list above is not exhaustive and decisions should be based on a practitioner's clinical judgement. Consideration should also be given to the vaccination of household contacts of immunocompromised individuals, i.e. individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable.

⁷ www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

Annex D

Healthcare worker vaccination programme

Importance of vaccinating frontline health care workers

Influenza outbreaks can arise in health and social care settings with both staff and their patients/clients being affected when influenza is circulating in the community. It is important that frontline health professionals protect themselves against flu by being vaccinated. As well as protecting themselves, it reduces the risk of them passing the virus to vulnerable patients, staff and to family members. Vaccination of frontline healthcare workers against influenza significantly lowers rates of influenza-like illness, hospitalisation and mortality in the elderly in healthcare settings.^{8 9 10 11} Vaccination of staff in social care settings may provide similar benefits. Influenza immunisation of frontline health and social care staff may reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity increasing their risks of flu and who may not respond well to immunisation.

Vaccination of these essential frontline workers also helps reduce the level of sickness absenteeism that can jeopardise the NHS and care services. This is essential in the winter when pressures on the NHS increase.

⁸ Potter, J., Stott, D.J., Roberts, M.A., Elder, A.G., O'Donnell, B., Knight, P.V. and Carman W.F. The influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *Journal of Infectious Diseases* 1997;**175**:1-6.

⁹ Carman, W.F., Elder, A.G., Wallace, L.A., McAulay, K., Walker, A., Murray, G.D. and Stott, D.J. Effects of influenza vaccination of healthcare workers on mortality of elderly people in long term care: a randomised control trial. *The Lancet* 2000; **355**:93-7

¹⁰ Hayward, A.C., Harling, R., Wetten, S., Johnson, A.M., Munro, S., Smedley, J., Murad, S. and Watson, J.M. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *British Medical Journal* 2006; doi:10.1136/bmj.39010.581354.55 (published 1 December 2006)

¹¹ Lemaitre, M., Meret, T., Rothan-Tondeur, M., Belmin, J., Lejonc, J., Luquel, L., Piette, F., Salom, M., Verny, M., Vetel, J., Veyssier, P. and Carrat, F. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster randomised trial. *Journal of American Geriatric Society* 2009; **57**:1580-6

Healthcare workers are a very influential group. Patients trust their nurses, doctors and health-care assistants and their opinions can affect the way patients act. A healthcare worker who opts to be vaccinated can talk from first hand experience with patients and reassure them of the benefits of being vaccinated. Healthcare workers need to understand the benefits of the vaccine and dispel the myths that may have developed around the vaccine.

Similarly, senior clinical staff can be influential in increasing staff awareness and understanding of the importance of staff vaccination against seasonal flu, and can lead by example to drive up rates of vaccination among frontline staff.

Provision of the vaccine for healthcare workers

The updated *Code of practice on the prevention and control of infections and related guidance*¹² reminds both NHS and social care bodies of their responsibilities. These are to ensure, so far as is reasonably practicable, that health and social care workers are free of, and are protected from exposure to infections that can be caught at work, and that all staff are suitably educated in the prevention and control of infections. This includes ensuring that occupational health policies and procedures in relation to the prevention and management of communicable diseases in healthcare workers, including immunisation, are in place.

Decisions on offering immunisation should be made on the basis of a local risk assessment as described in *Immunisation against infectious disease*.¹³ Employers should make vaccines available free of charge to employees if a risk assessment indicates that they are needed.¹⁴

The flu immunisation given to healthcare staff directly involved in patient care, and social care workers who are employed to provide personal care, acts as an adjunct to good infection prevention and control procedures. As well as reducing the risk to the patient/client of infection, the reduction of flu infection among staff, and reduced staff absenteeism, have also been documented. The importance of immunising healthcare workers was highlighted by the outbreak at the Royal Liverpool University Hospital where flu spread rapidly through several wards infecting both patients and staff in 2008. The HPA confirmed that the infection was mainly spread by healthcare workers.

¹² www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122604

¹³ www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_0799

¹⁴ <http://books.hse.gov.uk/hse/public/saleproduct.jsf;jsessionid=8308EB8C09997114490918A612B46189.plukweb1?catalogueCode=INDG342> (COSHH Regulations 2002)

Trusts/employers will wish to ensure that health and social care staff directly involved in delivering care are encouraged to be immunised and that processes are in place to facilitate this.

Examples of staff who may be directly involved in delivering care include:

- clinicians, midwives and nurses, paramedics and ambulance drivers
- occupational therapists, physiotherapists and radiographers
- primary care providers such as GPs, practice nurses, district nurses and health visitors
- social care staff working in care settings, and
- pharmacists, both those working in the community and in clinical settings.

Students and trainees in these disciplines and volunteers who are working with patients should also be included. This is not an exhaustive list and decisions to provide immunisation should be based on local assessment of likely risk and exposure to flu.

Annex E

Increasing vaccine uptake among clinical risk groups – a good practice guide

The following arrangements may enable GPs to increase the uptake of seasonal flu vaccine among their patients in clinical risk groups.

- Ensure all practice staff are fully informed of the arrangements for the campaign as set out in the annual CMO letter sent in the spring.
- Identify a named influenza champion in each practice to co-ordinate the programme, link with the PCT influenza co-ordinator and respond to patient queries.
- Share best practice with the PCT so that it can be disseminated to practices with lower uptake.
- Be able to identify the patients who fall into a clinical risk group.
- Have robust call and reminder systems in place.
- Have sufficient vaccine stock and appointment slots available to ensure all those eligible have the opportunity to receive the vaccine.
- Chase up patients who don't respond to invitations to attend for vaccination, ideally by phone (some practices also now have texting systems in place and this could also be used).
- Consider a domiciliary visit to the home of patients who do not respond to letters or phone calls or who are unable to get to the practice.
- Ensure that patients have up to date, accurate information available, e.g. attach a copy of the 'is your child at risk' leaflet to repeat prescriptions for at-risk children or attach other relevant leaflets to repeat prescriptions for other groups, for example, pregnant women; some practices also have a stamp that they use on repeat prescriptions reminding patients to have their seasonal flu vaccine.
- Respond to any objections the patient may have to receiving the vaccine and point out the increased risk that seasonal flu poses to them and the benefits of having the vaccine.

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- Make sure that systems are in place to ensure the GP practice receives and records details of anyone who receives the vaccine outside the practice (individuals in risk groups, pregnant women and others may get the vaccine from their employer, at-risk children/adults/pregnant women may be offered it in hospital/special school, community paediatrician clinic, secure children's units etc)
- Consider increasing access arrangements at the surgery, e.g. evening and Saturday morning clinics for seasonal flu vaccine in addition to routine clinics and appointment availability for the vaccine outside of these clinics.
- Put an alert on the computer records of those eligible to receive the vaccine and provide it opportunistically to those presenting at the surgery for other reasons when appropriate to do so.
- Regularly review those on the flu vaccine list who have not yet received the vaccine.