Seasonal flu plan

Winter 2012/13
The purpose of this document is to set out a co-ordinated and evidence-based approach to planning for and responding to the demands of seasonal flu across England. It will provide healthcare professionals with comprehensive information on best practice to prepare for flu in 2012/13.
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Foreword

Each year, the Department of Health (DH) and the National Health Service (NHS) prepare for the unpredictability of flu. For most healthy people, flu is an unpleasant but usually self-limiting disease with recovery generally 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.

Flu is an unpredictable but recurring pressure that the NHS faces during the winter. Last season was a mild winter, and we were fortunate that very few people were affected by flu so it had less impact on the NHS than previous years. However, there are still improvements we can make in the NHS and the DH for managing flu in the future. Some of these include increasing the uptake of vaccine especially among those in clinical risk groups, pregnant women and healthcare workers with direct patient contact and social care workers.

This is the second seasonal flu plan to be published that supports our coordinated and evidence-based approach to planning for the demands of flu across England.

I commend it to you, and hope that you find it useful in preparing for next winter.

PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER
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 flu across England. It takes account of the experiences and lessons learnt during previous flu seasons. 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 flu and signposts where further guidance and information can be found.

The *Seasonal flu plan* is not intended to be comprehensive or exhaustive guidance..Nor does it take precedence over other standard operating procedures such as the Annual Flu Letter\(^1\) from the Chief Medical Officer (CMO), Director of Nursing and Chief Pharmaceutical Officer (CPhO) to the NHS and the influenza chapter in *Immunisation against infectious disease* (the Green Book),\(^2\) 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* was published on 17 November 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 from responding to routine seasonal flu.

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\(^1\) [http://immunisation.dh.gov.uk/category/letters/](http://immunisation.dh.gov.uk/category/letters/)

NHS reforms

This plan covers winter 2012/13 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, flu vaccination will be delivered through the NHS. The NHS Commissioning Board (NHSCB) would have responsibility for commissioning the programme and with GPs expected to continue to play an important role. In future years, the NHSCB will 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.
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. These people may still infect others with flu. 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 flu vaccine. It also monitors changes in flu viruses to assess their potential to cause a pandemic.

How flu spreads

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 that, 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 2011/12. The data show that flu viruses circulate each winter season, but the degree of activity varies substantially.
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 (i.e. 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, laboratory confirmations of flu and flu vaccine uptake.

During the flu season, the HPA receives and follows up reports of deaths in patients in hospital 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

Strategic objectives

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

- vaccinating at least 75% of those at greatest risk with the flu vaccine before the virus starts to circulate
- monitoring flu activity, severity of the disease, vaccine uptake and impact on the NHS
- offering antiviral medicines to patients in at-risk groups as well as those patients who the prescriber believes may suffer serious complications if not treated, in line with NICE guidance, once the CMO/CPhO letter has been sent to prescribers informing them that they are now able to prescribe antiviral medicines\(^4\)
- 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 DH and NHS response to flu each winter should be appropriate to the known risks. That is why, for example, the flu vaccination programme is based on an assessment of the cost effectiveness of the use of vaccine for specific risk groups. These groups are 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 DH’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.

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

\(^4\) www.nice.org.uk/TA168
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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 flu programme

The cycle for preparing for and responding to flu is set out below.

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 so it is necessary to formulate each season’s flu vaccine to match 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.

WHO releases details of its recommendations for the 2012/13 northern hemisphere flu vaccine. It is recommended that vaccines for use in the 2012-13 influenza season (northern hemisphere winter) should include protection against the following strains:

- A/California/7/2009 (H1N1)pdm09;
- A/Victoria/361/2011 (H3N2); and
- B/Wisconsin/1/2010.

- Final vaccine orders placed with suppliers.

Manufacture of trivalent 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.
April–June: Assurance

- A letter from the CMO, Director of Nursing and the CPhO (referred to as the 'Annual Flu Letter') is sent to the NHS setting out key information for the autumn’s immunisation programme. The information in the letter includes:
  - the groups to be immunised
  - a GP practice checklist
  - advice on increasing uptake among pregnant women and healthcare workers
  - the available vaccines and data collection arrangements.

The letter also sets out the assurance arrangements and seeks confirmation from PCT and SHA clusters that adequate local plans are in place.

- Any recommendations to change risk groups after vaccine orders have been placed would follow the advice of JCVI taking into account availability of the vaccine. However, due to the long lead in times for vaccine production and programme planning it is unlikely that any changes emerging from the February or June JCVI meetings, which significantly increased the number of people in at-risk groups, could be implemented 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, could not be implemented 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 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 flu vaccine. The influenza chapter is updated each year following JCVI advice and published ahead of the vaccination programme. It is important that all those involved in the flu programme are familiar with this chapter. Alongside the Annual Flu Letter, this comprises all the essential information needed by healthcare professionals in the implementation of the flu 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 that 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 GPs to make sure that patients who are eligible to receive the flu vaccine are included on their list of patients to contact at the start of the flu season. This is particularly important for carers who cannot easily be identified through medical records.

**July–September: Preparation**

- The Director of Immunisation at DH will write to the NHS with updated 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 flu vaccination.
- Communications and guidance about vaccine uptake data collections will be issued.
- Trusts, GP practices and pharmacists should begin communications activities to promote early 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.

**September–February: Implementation**

- Deliveries of vaccine continue according to manufacturers’ production processes.
- GPs and other providers begin vaccinating eligible patients against flu as soon as vaccine is available.
- 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 September. The information will be collected via the web-based ImmForm system that collates data extracted from a large national sample of GP practices (approximately 66%). Monthly collections start in early November for all GP practices and from all trusts (for healthcare workers with direct patient contact) and continue to early February. 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
- healthcare workers with direct patient contact
with weekly data providing representative estimates of national uptake by GP patient groups and monthly collections providing national and local level estimates of vaccine uptake by GP patients and healthcare workers with direct patient contact.

- 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 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 CPhO and CMO issue advice on the use of antiviral medicines, based on advice from the HPA in light of flu surveillance data.

  Following National Institute for Health and Clinical Excellence (NICE) guidance, antiviral medicines should only be prescribed once DH has notified GPs 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, antiviral medicines 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
‘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 respiratory and hand hygiene campaign may be launched to remind individuals of the measures they can take to protect against infection. The triggers for this campaign will vary from year to year and the decision to launch this campaign is likely to be made in the course of the flu season.
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 or to what extent. 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.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Level of flu like illness</th>
<th>Description of flu season</th>
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<tbody>
<tr>
<td>1</td>
<td>Community and primary care indicators starting to show that flu and flu-like illness are being detected</td>
<td>Beginning of the flu season – low levels of flu and/or low severity of illness associated with the virus</td>
</tr>
<tr>
<td>2</td>
<td>Flu indicators starting to show that activity is rising</td>
<td>Normal levels of flu and/or normal to high severity of illness associated with the virus</td>
</tr>
<tr>
<td>3</td>
<td>Flu indicators exceeding historical norms</td>
<td>Epidemic levels of flu – rare for a flu season</td>
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<table>
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<tr>
<th>Stage 1</th>
<th>Activity that would be undertaken</th>
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<tbody>
<tr>
<td>• Review data on flu activity and severity from the southern hemisphere.</td>
<td></td>
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<tr>
<td>• GPs invite their eligible patients to be vaccinated, using call and reminder systems.</td>
<td></td>
</tr>
<tr>
<td>• Data on flu incidence and vaccine uptake rates in England issued at a national and, if available, regional/local levels.</td>
<td></td>
</tr>
<tr>
<td>• Data on ILIs, virological surveillance, vaccine uptake and NHS operational data published on Winterwatch.</td>
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</tr>
<tr>
<td>• HPA publishes weekly reports on flu incidence, vaccine uptake, morbidity and mortality.</td>
<td></td>
</tr>
<tr>
<td>• Director of Immunisation writes to the NHS if vaccine uptake is low.</td>
<td></td>
</tr>
<tr>
<td>• DH in contact with vaccine manufacturers on production and delivery schedules.</td>
<td></td>
</tr>
<tr>
<td>• DH in contact with antiviral medicine manufacturers on their preparedness plans.</td>
<td></td>
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<tr>
<td>• The respiratory and hand hygiene campaign may be launched.</td>
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<tr>
<th>Stage 2</th>
<th>Activity that would be undertaken</th>
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<tbody>
<tr>
<td>• GPs and other non-medical prescribers will be alerted to start prescribing antiviral medicines in line with the NICE guidance and following expert advice that the flu virus is circulating.</td>
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<tr>
<td>• 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.</td>
<td></td>
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<tr>
<td>• Local NHS responds to local circumstances according to local plans and needs.</td>
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<tr>
<td>• Review daily NHS operational data, e.g. critical care.</td>
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<tr>
<td>• 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.</td>
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<tr>
<td>• If countrywide vaccine shortages are considered likely, DH will alert GPs to the availability of the central strategic reserve and set out how they should access it. 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.</td>
<td></td>
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<tr>
<td>• Vaccine manufacturers contacted regarding the availability of additional supplies if needed.</td>
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</tr>
<tr>
<td>• In the event of shortages of antiviral medicines, and an evident public health need, DH would take steps to</td>
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</table>
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.

<table>
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<tr>
<th>Stage 3</th>
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<tbody>
<tr>
<td>A national flu epidemic is declared</td>
</tr>
<tr>
<td>GPs alerted that a late surge in demand for the vaccine may occur.</td>
</tr>
<tr>
<td>Vaccine manufacturers contacted regarding availability of additional supplies.</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>DH may extend the vaccine uptake collections for additional weeks/months if vaccine uptake rates are still rising.</td>
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<tr>
<td>Weekly CMO press briefings will be considered.</td>
</tr>
<tr>
<td>Maintain or boost the respiratory and hand hygiene campaign</td>
</tr>
<tr>
<td>Proactive work with media to allay any public concerns.</td>
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<tr>
<td>Reiterate advice on signs and symptoms, and treatment at home.</td>
</tr>
<tr>
<td>Communicate regularly with clinical and professional networks, and stakeholder groups for patients at risk of severe illness.</td>
</tr>
<tr>
<td>Continue to review daily NHS operational data, e.g. critical care.</td>
</tr>
<tr>
<td>Alert the NHS when the flu season has peaked, to aid local planning.</td>
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</table>
Potential scenarios

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

<table>
<thead>
<tr>
<th>Event</th>
<th>Action</th>
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<tbody>
<tr>
<td>Delay in vaccine released from manufacturer.</td>
<td>DH writes to NHS informing them of delay so GP practices and other providers can reschedule vaccination clinics.</td>
</tr>
<tr>
<td>Production problems mean insufficient doses of vaccine are available nationally.</td>
<td>DH writes to NHS informing them of shortage and advising which risk groups to prioritise, following JCVI advice as appropriate.</td>
</tr>
<tr>
<td>Vaccine uptake remains below expected rate for the time of year. Virus adversely affects groups outside those recommended for vaccination.</td>
<td>CMO or Director of Immunisation writes to NHS recommending appropriate action to increase uptake.</td>
</tr>
<tr>
<td>The vaccine does not protect against the predominant circulating strain.</td>
<td>DH communicates the issue to GPs and the public. The 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 reminds prescribers that the regulations have been broadened to give them some discretion to prescribe antiviral medicines for patients who are not in one of the identified clinical at-risk groups, but who they consider may be at risk of developing serious complications from flu and could benefit from receiving treatment. It is expected that prescribers will be guided by the CMO in the use of this discretion.</td>
</tr>
<tr>
<td>Issue over safety of vaccine emerges.</td>
<td>DH considers launching the respiratory and hand hygiene campaign. 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. DH writes to NHS informing it of the consequences of the safety issue if it impacts on supplies and advising which risk groups to target, following JCVI advice as appropriate.</td>
</tr>
<tr>
<td>Production failure towards the end of the vaccination programme leads to localised vaccine shortages.</td>
<td>Central strategic reserve is released.</td>
</tr>
<tr>
<td>Vaccine shortage.</td>
<td>Central strategic reserve is released.</td>
</tr>
</tbody>
</table>

**Treatment**

| Antiviral medicines not available from pharmacies. | DH discusses stock levels with manufacturers and wholesalers to determine whether they can meet the increased demand. DH considers releasing the national stockpile to ease shortages, if appropriate. |

**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 |
| Media coverage | Increased media interest on particular issues. | CMO holds press briefing to communicate the facts and latest data to the media. |

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Preparing for uncertainty – plans to improve

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

By the end of the 2011/12 flu vaccination season, just over 50% of people under 65 years in clinical risk groups had been vaccinated against flu. The CMO has written to the NHS stating that the NHS should plan locally to reach or exceed 75% uptake for people under 65 years of age in clinical risk groups and for pregnant women, as recommended by the European Union (EU) by 2013/14.

For the 2012/13 season the planning assumption for vaccine uptake for this group is 70%. Increasing uptake is important because of the increased risk that people in risk groups are at from the effects of flu. Achieving this level of uptake will be challenging and will require fresh thinking and new approaches to deliver a step change in outcomes. The performance of some GP practices and PCTs has demonstrated that it is possible to achieve uptake significantly higher that last year’s national average of 51.6%.

SHA clusters need 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. During the period of transition, as new commissioning arrangements are formed, commissioners may wish to consider the continuation of local innovative services where there is clear evidence of beneficial outcomes. 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) so that pharmacy provided vaccinations are included in the uptake figures.

In order to be confident that robust planning is in place, DH has asked SHA clusters for assurance from PCT clusters on their flu immunisation plans for 2012/13. Full details are contained in the Annual Flu Letter.

Ensuring a reliable and accessible supply of vaccine

Central strategic reserve

DH will continue to purchase a small central strategic reserve of trivalent 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.

DH has asked immunisers to ensure they have adequate supplies for the 2012/13 season, allowing for greater uptake than in previous years. GPs and other providers should order sufficient flu vaccine for their eligible patients. The stockpile is intended only as an ‘insurance policy’.

For 2012/13, the responsibility for ordering vaccines will continue to lie with GP practices. Practices will need to make their own arrangements with suppliers to ensure they have sufficient vaccine for the needs of their eligible patients. 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 is considered 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 flu vaccine

DH is reviewing whether the arrangements for procurement of 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 2012/13 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, is under review.

Increasing vaccination rates for healthcare workers with direct patient contact and social care workers

Patients may expect health and social care workers to be vaccinated against flu. This protects healthcare workers and it reduces the risk of them transmitting the flu virus to their vulnerable patients. Uptake of the flu vaccine in healthcare workers was higher in 2011/12 (44.7%) than the previous year (34.7%), 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 healthcare workers with direct patient contact 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.

An NHS staff vaccination communications campaign will again be run by NHS Employers in 2012/13. 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

Once the CMO/CPhO letter has been sent to prescribers informing them that they are now able to prescribe antiviral medicines, they can use their discretion to prescribe antiviral medicines for patients who are not in one of the identified clinical risk groups but who they consider may be at risk of developing serious complications from flu and could benefit from receiving the treatment. It is expected that GPs will be guided by the CMO in the use of this discretion.

At present, DH alerts GPs 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 CMO/CPhO. When notified by the DH, GPs and other prescribers can prescribe in accordance with NICE guidance. 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

Manufacturers, pharmaceutical wholesalers and community and hospital pharmacies do not routinely stock large quantities of antiviral medicines. The DH will continue to work with the relevant pharmaceutical manufacturers and wholesalers to ensure there are adequate supplies of antiviral medicines in the supply chain to meet expected demand.

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. This 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 has a variable impact, depending on the severity of the season, 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 will be published on Winterwatch (www.dh.gov.uk/winterwatch).
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
- hospital surveillance
- disease severity
- vaccination uptake
- the international situation.

Previous reports can be viewed at:

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

CMO will lead 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).

These 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 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 will be updated every Thursday afternoon during the flu season and can be viewed here: www.dh.gov.uk/winterwatch
Introduction of the respiratory and hand hygiene campaign

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 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.

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.

While a national campaign might play a role in raising awareness of the vaccine, research suggests that it cannot replace proactive and personalised invitations from GPs to patients. GP practices therefore need to plan carefully to ensure that they are making every effort to identify and contact eligible patients before the flu season starts.

In 2011, DH commissioned research on seasonal influenza vaccination practice in primary care. Some of the key findings have been incorporated into the GP practice checklist (Annex E).
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 flu vaccination programme is to offer protection to those who are most at risk of serious illness or death should they develop influenza. It is therefore important that eligible individuals are offered the flu vaccination as early as possible in the Autumn. 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’ 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. 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.

Antiviral medicines are available on the NHS for certain groups of patients, including those in one of the identified at-risk categories as outlined in Annex C.

Once the CMO/CPO letter has been disseminated to prescribers informing them that they are now able to prescribe antiviral medicines, they can use their discretion to prescribe antiviral medicines for patients who are not in one of the identified clinical

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risk groups, but who they consider may be at risk of developing serious complications from flu and could benefit from receiving the treatment. It is expected that GPs will be guided by the CMO in the use of this discretion.

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 a few 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. Eight 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 flu vaccination programme.

The flu vaccine production ‘window’ is limited. WHO makes recommendations on the composition of the northern hemisphere 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 flu vaccination

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

- people aged 65 years or over (including those becoming age 65 years by 31 March 2013)
- all pregnant women (including those women who become pregnant during the flu season)
- 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.
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.

Also recommended to be vaccinated as part of occupational health:

- healthcare workers with direct patient contact and social care workers.

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

Annex D

Health and social care worker vaccination programme

Importance of vaccinating healthcare workers with direct patient contact and social 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 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 healthcare workers with direct patient contact against influenza has been shown to significantly lower 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 health and social care 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.

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

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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 flu, and can lead by example to drive up rates of vaccination among frontline staff.

NHS Employers will again be running a communications campaign to encourage healthcare workers to get vaccinated. NHS Employers will be producing a range of materials and practical advice to promote vaccination. These can be be accessed (when available) at the following web address:

http://www.nhsemployers.org/HealthyWorkplaces/seasonalflucampaign/Pages/seasonal-flu-campaign.aspx

Provision of the vaccine for health and social care 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


\(^{13}\) www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_0799

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.

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 – GP Practice checklist

(NB: A shortened version of this checklist is appended to the 2012/13 Annual Flu Letter to assist GP practices with their planning)

General
1. The GP practice has a named individual who is responsible for the flu vaccination programme.

2. Ensure all practice staff are fully informed of the arrangements for the campaign as set out in the Annual Flu Letter sent in the spring.

Registers and information
3. The GP practice has a register that can identify all patients in the under 65 years at risk groups, those aged 65 years and over, and pregnant women.¹⁵

4. The GP practice will update the patient registers throughout the flu season paying particular attention to the inclusion of women who become pregnant during the flu season.

5. The GP practice will submit accurate data on its patients eligible for flu vaccination and the flu vaccinations given to them on ImmForm.

6. 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).

Meeting any public health targets in respect of such immunisations
7. The GP practice will/has ordered sufficient flu vaccine to achieve the 2012/13 uptake levels.

Robust call and recall arrangements
8. Each patient who is recommended to receive the flu vaccine will be sent a letter, inviting them to a flu vaccination clinic or to make an appointment.

¹⁵ Immunisation of carers and pregnant women are not covered by the national DES and will be subject to local agreement
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9. The GP practice will write/telephone patients who do not respond to the letter or fail to attend scheduled clinics or appointments (some practices also now have texting systems in place and this could also be used).

Maximising uptake in the interests of at-risk patients
10. The flu vaccination campaign will start as soon as practicable after receipt of the vaccine so that the maximum number of patients are vaccinated as early as possible (i.e. by the end of October), to ensure they are protected before flu starts to circulate.

11. The GP practice will collaborate with local community midwives to offer and provide flu vaccination to pregnant women.

12. 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.

13. The GP practice will offer flu vaccination in clinics and opportunistically. Consider increasing access arrangements at the surgery, e.g. evening and Saturday morning clinics for flu vaccine in addition to routine.

14. Regularly review those on the flu vaccine list who have not yet received the vaccine.

15. 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.

16. The GP practice will offer the flu vaccination to all its practice staff and will submit data on vaccinations given to the national uptake survey.

Communication with patients
17. 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 flu vaccine.

18. Respond to any objections the patient may have to receiving the vaccine and point out the increased risk that flu poses to them and the benefits of having the vaccine.