



Public Health
England



Department
of Health

NHS
England

Flu Plan

Winter 2014/15

About Public Health England

Public Health England's mission is to protect and improve the nation's health and to address inequalities through working with national and local government, the NHS, industry and the voluntary and community sector. PHE is an operationally autonomous executive agency of the Department of Health.

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Foreword

Flu is an unpredictable but recurring pressure that the NHS and the public faces each winter although for most healthy people, it is an unpleasant but usually self-limiting disease with recovery generally within a week.

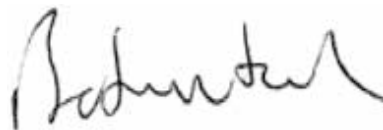
Last season was a mild flu season but it is important that we are not complacent and continue to be as prepared as possible for the next high incidence flu season, whenever that may be. There are still improvements we can make to prevent and manage flu in the future. Chief amongst these are to increase the uptake of vaccine especially among those in clinical risk groups, pregnant women and healthcare workers with direct patient contact and social care workers. However, older people, the very young, 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. The extension of the flu vaccination programme to children will lower the public health impact of flu by directly averting a large number of cases of flu in children and through lowering flu transmission in the community.

This is the fourth *Flu plan* to be published. It supports a coordinated and evidence-based approach to planning for the demands of flu across England including plans to extend the programme to children. The Annual Flu Letter is being issued at the same time. Both these documents have the support of the Chief Medical Officer (CMO), Chief Pharmaceutical Officer (CPhO) and Public Health England and the Department of Health's Director General, Public Health.

We commend the *Flu plan* to you, and hope that you find it useful in preparing for this coming winter.



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Introduction

This *Flu plan* sets out a coordinated and evidence-based approach to planning for and responding to the demands of flu across England, taking account of lessons learnt during previous flu seasons. It will aid the development of robust and flexible operational plans by local organisations and emergency planners within the NHS and local government. It provides the public and healthcare professionals with an overview of the coordination and the preparation for the flu season and signposting to further guidance and information.

This year the *Flu plan* also includes details about the extension of the flu vaccination programme to children in 2014/15. Due to the scale of the extension nationally it is being implemented gradually, with geographical piloting in the early years that will provide learning to inform subsequent roll-out.

The *Flu plan* is supported by the following:

- Annual Flu Letter issued alongside the *Flu plan*¹
- influenza chapter in *Immunisation against infectious disease* (the Green Book, chapter 19)² which is updated regularly, sometimes during a flu season
- two service specifications between NHS England and the Secretary of State for Health for the 'routine' seasonal flu programme (No.13) and for the extension of the programme to children (No. 13A)³

¹ www.gov.uk/government/organisations/public-health-england/series/immunisation

² www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

³ www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2014-to-2015

Reform of the NHS and public health system

The Health and Social Care Act 2012 created a new set of responsibilities for the delivery of public health services. In England, although the local leadership for improving and protecting the public's health sits with local government, the reforms provided specific roles for NHS England and Public Health England (PHE) for the commissioning and system leadership of the national immunisation programmes. NHS England has responsibility for commissioning the programme and GPs, midwives, other healthcare professionals and immunisation system leaders, managers and coordinators play a vital role in delivery. NHS England ensures 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 all the eligible groups. Local authorities, through the auspices of the Director of Public Health (DPH), provide independent scrutiny and challenge of the arrangements of NHS England, PHE and providers.⁴

Each of the partners has its own responsibilities for which it is accountable.

In outline these are:

The **Department of Health** (DH) is responsible for:

- policy decisions on the response to the flu season
- holding NHS England and PHE to account through their respective framework agreements, the Mandate, and the Section 7A agreements
- oversight of the supply of antiviral medicines.

NHS England is responsible for:

- commissioning the flu vaccination programme under the terms of the Section 7A agreements
- assuring that the NHS is prepared for the forthcoming flu season
- building close working relationships with Directors of Public Health (DsPH) to ensure that local population needs are understood and addressed by providers of flu vaccination services.

Public Health England is responsible for:

- planning and implementation of the national approach
- monitoring and reporting of key indicators related to flu, including flu activity and vaccine uptake
- procurement and distribution of flu vaccine for children
- oversight of vaccine supply and the strategic reserve

- advising NHS England on the commissioning of the flu vaccination programme
- supporting DsPH in local authorities in their role as local leaders of health and ensuring that they have all relevant expert input, surveillance and population data needed to carry out this role effectively

Local authorities, through their Director of Public Health, have responsibility for:

- providing appropriate challenge to local arrangements and advocacy with key stakeholders to ensure access to flu vaccination and to improve its uptake by eligible populations
- providing independent scrutiny and challenge to the arrangements of NHS England, PHE and local authority employers of frontline social care staff and other providers of health and social care
- providing leadership, together with local resilience partners to respond appropriately to local incidents and outbreaks of flu infection

Clinical commissioning groups (CCGs) are responsible for:

- a duty of quality assurance and improvement which extends to primary medical care services delivered by GP practices including flu vaccination and antiviral medicines

GP practices and other providers are responsible for:

- ordering the correct amount and type of vaccine for their eligible patients, taking into account new groups identified for vaccination and the ambition for uptake
- ordering vaccine for children from PHE central supplies through the ImmForm website
- ensuring that all those eligible for the flu vaccine are invited personally to receive their vaccine
- encouraging and facilitating flu vaccination of their own staff
- ensuring that antiviral medicines are prescribed for appropriate patients, once the CMO/CPhO letter has been distributed alerting them that antiviral medicines can be prescribed

All employers of individuals working as providers of NHS services are responsible for:

- management and oversight of the flu vaccination campaign for their frontline staff
- support to providers to ensure access to flu vaccination and to maximise uptake amongst those eligible to receive it

⁴ See *Immunisation and Screening National Delivery Framework & Local Operating Model* at www.england.nhs.uk/wp-content/uploads/2013/05/del-frame-local-op-model-130524.pdf

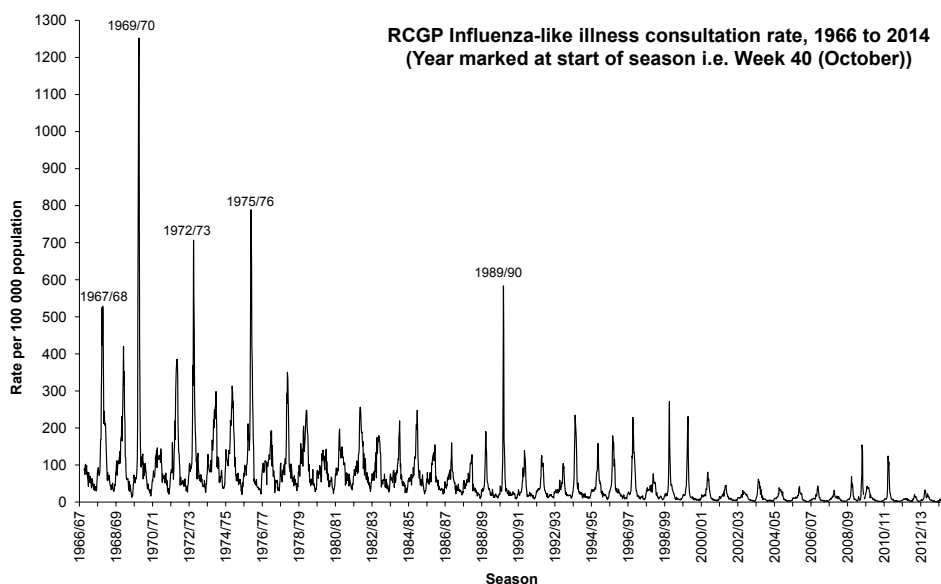
Influenza and the flu virus

Influenza (often referred to as flu) is an acute viral infection of the respiratory tract (nose, mouth, throat, bronchial tubes and lungs) characterised by a fever, chills, headache, muscle and joint pain, and fatigue. For otherwise healthy individuals, flu is an unpleasant but usually self-limiting disease with recovery within two to seven days. Flu is easily transmitted and even people with mild or no symptoms can still infect others. 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 disease, cardiac disease or immunosuppression, as well as pregnant women. These groups are at greater risk of complications from flu such as bronchitis or pneumonia or in some rare cases, cardiac problems, meningitis and/or encephalitis. The influenza chapter in the Green Book contains more details of the epidemiology of flu.

Impact of flu each winter on the population

The impact of flu on the population varies 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.

The graph below 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 2014. The data show that flu viruses circulate each winter season, but the degree of activity varies substantially.⁸



⁸ Data courtesy of influenza surveillance from the Centre for Infectious Disease Surveillance and Control (CIDSC) at PHE and the Royal College of General Practitioners. See www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Seasonalinfluenza

Strategic objectives

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

- actively offering the flu vaccination to 100% of all those in the eligible clinical risk groups, and vaccinating at least 75% of those aged 65 years and over, and healthcare workers with direct patient contact
- providing direct protection to children by extending the annual flu immunisation programme over a number of years so that eventually all children aged two to less than 17 years will be offered flu vaccination, and also interrupting the transmission of flu by these children to those unvaccinated children and adults, including those in clinical risk groups for whom flu can be extremely serious
- monitoring flu activity, severity of the disease, vaccine uptake and impact on the NHS
- enabling the prescribing of antiviral medicines to patients in at-risk groups and other eligible patients as set out in Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of drugs etc) Regulations 2004), commonly known as the Grey List or Selected List Scheme (SLS). These may only be prescribed once the CMO/CPhO letter has been sent to prescribers informing them that they are now able to prescribe antiviral medicines at NHS expense⁹
- providing public health information to prevent and protect against flu
- managing and implementing the public health response to incidents and outbreaks of flu
- ensuring the NHS is well prepared and has appropriate surge and resilience arrangements in place during the flu season

⁹ www.nice.org.uk/TA168

Elements of the flu programme

Flu surveillance

PHE has responsibility for flu surveillance and publishes a report weekly during the flu season which includes a range of indicators on flu that is in circulation including:

- the amount of influenza-like illness (ILI) in the community
- the prevalent strain(s) of flu circulating
- the proportions of clinical samples that are positive for flu or other specified viruses
- the number of flu-related hospital admissions
- the relative impact of flu on different groups of people, by age (including data on deaths where flu is the confirmed cause) based on data from intensive care units
- excess mortality monitoring
- the international situation

Flu vaccination

The flu vaccination programme is based on an assessment of the cost effectiveness of the use of vaccine for people in specific risk groups. 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.

Those over the age of 65, pregnant women and those in a clinical risk group have been offered vaccination annually for a number of years. Those living in long-stay residential care homes, people who are the main carer of someone whose welfare may be at risk if the carer falls ill, and all frontline health and social care workers should also be offered flu vaccination (see [Appendix C](#)).

In July 2012, JCVI recommended that the flu vaccination programme should be extended to healthy children aged two to less than 17 years. JCVI recognised that implementation of this programme would be challenging and advised that its introduction would require careful planning. In 2013/14 flu vaccination was offered for the first time to all two and three year olds, and a pilot programme in primary schools was run in seven geographical areas. In 2014/15 the flu immunisation programme for children will expand so that:

- all children aged two, three, and four years old (but less than five on 1 September 2014) will be offered flu vaccine;
- seven geographical pilots of primary school aged children started in 2013/14 will continue in England
- a minimum of twelve geographical pilots in secondary school aged children in years 7 and 8 in 2014/15¹⁰

Programme implementation from 2015/16 onwards will be based on learning from the pilots in both 2013/14 and 2014/15 and will focus on the timely, safe and successful roll out of the full programme.

Extension of the programme to healthy children

The JCVI recommendation to extend the flu vaccination programme to children is based upon analysis that suggested that any vaccination campaign including school-aged children is highly likely to be cost effective when the direct and indirect benefits to the individual and population are taken into account, particularly over the longer-term. JCVI further recommended a live attenuated influenza vaccine (LAIV) nasal spray. There is currently only one LAIV on the market and, this year, Fluenz Tetra® (a quadrivalent live attenuated intranasal influenza vaccine) will be supplied in place of Fluenz®. As Fluarix™ Tetra (a quadrivalent inactivated intramuscular influenza vaccine) will also be supplied, care must be taken not to confuse the two 'Tetra' brands, especially as Fluarix Tetra is not licensed for use in children less than three years.

JCVI recommended Fluenz Tetra® (the intranasal vaccine) as it has:

- higher efficacy in children, particularly after only a single dose;
- the potential to provide coverage against circulating strains that have drifted from those contained in the vaccine;
- higher acceptability with children, their parents and carers due to intranasal administration; and
- it may offer important longer-term immunological advantages to children by replicating natural exposure/infection to induce potentially better immune memory to influenza that may not arise from the annual use of inactivated flu vaccines

In addition to providing direct protection to children who are vaccinated, the full programme, by interrupting transmission of influenza, will reduce the spread of flu to unvaccinated children and adults, including those in clinical risk groups and for whom flu can be extremely serious.

Due to the scale of the programme, it is being phased in. In 2014/15 pre-school aged children (aged two to four years old) will be immunised in general practice, although some commissioners may choose to offer alternative vaccination routes in addition to general practice. Immunisation of school-aged children in pilot areas will be commissioned directly by NHS England. It is likely that most school-aged children in pilot areas will be immunised in schools, but NHS England will have options to commission services from a range of local healthcare providers, for example general practice or community pharmacies.

Although the patient information leaflet provided with Fluenz Tetra® suggests children should be given two doses of this vaccine if they have not had flu vaccine before, JCVI considers that a second dose only provides modest additional protection. Therefore, JCVI recommends that most children should be offered a single dose except for those children in clinical risk groups aged two to less than 9 years old who have not received flu vaccine

before who should be offered two doses of Fluenz Tetra® (given at least four weeks apart).

For children for whom Fluenz Tetra® is contraindicated, a suitable inactivated flu vaccine should be offered. If these children are aged six months to less than nine years and have not received flu vaccine before, two doses of the inactivated vaccine should be offered (given at least four weeks apart).

[Appendix D](#) gives further information about the extension of the flu vaccination programme to children. Learning from the 2013/14 geographical pilots in England can be found at [Appendix E](#).

Flu vaccine uptake data

Vaccine uptake information in 2014/15 will be reported by PHE for the following groups:

- people aged 65 and over
- people aged under 65 with specific clinical conditions
- all pregnant women
- all two, three and four year olds
- healthcare workers with direct patient contact
- carers

Flu vaccine uptake will be collected via the web-based ImmForm system for vaccinations given from the 1 September 2014 until the 31 January 2015.

The GP patient weekly and monthly vaccine uptake data will be extracted automatically onto ImmForm from over 80%¹¹ of GP practices.

The weekly GP patient vaccine uptake collection will commence the first week of September and will continue until early February. Weekly data provide representative estimates of national uptake by GP patient groups and are available for each CCG and NHS England Area Team.

The monthly GP patient vaccine uptake collection will start in November and continue until early February. The monthly collections provide national and local level estimates of vaccine uptake by GPs' patients for each CCG and NHS England Area Team. The final end of flu season data on GP patients will also be presented by local authority (aggregated by practices located in each local authority) to inform Public Health Outcomes Framework indicators 3.03xiv and 3.03xv.¹²

The monthly health care workers vaccine uptake collection will open in early November and continue to early February.

Pilot sites for the primary school aged children and secondary school aged children in years 7 and 8 will collect data for the period from September to the end of January.

An ImmForm survey user guide will be made available to access from the 'Immunisation and Vaccine Uptake Guidance' web pages of the GOV.UK website closer to the start of survey.¹³

The flu virus is constantly mutating and so it is necessary to formulate each season's flu vaccine for the flu vaccination programme to match the strains likely to be circulating the following winter. The World Health Organization (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.¹⁴

It is recommended that trivalent vaccines for use in the 2014/15 influenza season (northern hemisphere winter) contain the following:

- an A/California/7/2009 (H1N1)pdm09-like virus
- an A/Texas/50/2012 (H3N2)-like virus
- a B/Massachusetts/2/2012-like virus

It is recommended that quadrivalent vaccines contain the above three viruses and an additional B/Brisbane/60/2008-like virus.

Manufacturers begin vaccine production once WHO issues recommendations in February as to which strains to include. As manufacture of flu vaccine is complex and constrained by the length of time available between the WHO recommendations and the opportunity to vaccinate before the flu season, 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 [Appendix B](#).

For the immunisation of those aged 18 years and over, flu vaccine is procured directly by the provider from the manufacturer. In some areas, this includes community pharmacists who have been commissioned to provide flu vaccination services. It is recommended that immunisers ensure they:

- order vaccine from more than one supplier
- order sufficient vaccine before the start of the season at least to cover the uptake aspirations for all their registered eligible patients
- note that they now order vaccine for children from central supplies through ImmForm
- pay attention to ordering the most appropriate type of vaccine such as enough egg-free or low ovalbumin content vaccine for those patients who may require it

PHE liaises closely with manufacturers and the vaccines group within the Association of the British Pharmaceutical Industry (ABPI). This helps promote optimal communication between GP practices and manufacturers.

PHE provides some oversight to help facilitate a constant supply of vaccine, liaising 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 vaccination programme, PHE will issue guidance to the NHS suggesting arrangements to minimize the impact, for example advising GPs to prioritise particular clinical risk groups over other eligible groups.

In order to simplify the supply of Fluenz Tetra® and inactivated flu vaccine for GPs during the phased implementation of the children's programme PHE has centrally procured influenza vaccine for all children aged six months to less than 18 years of age. This is for both those children who are part of the childhood flu programme and those children aged six months to less than 18 years of age in clinical risk groups who are not part of the childhood flu programme (ie. both Fluenz Tetra® and inactivated flu vaccine for those children whom Fluenz Tetra® is contraindicated or not suitable).

Central strategic reserve

PHE will hold a central strategic reserve of inactivated flu vaccine for all cohorts other than children to use if necessary to mitigate the impact of shortages. This stock has been purchased from more than one manufacturer to reduce any risk of reliance on a single supplier, and to conform to European directives on government procurement. The stockpile is intended only as an 'insurance policy' and will only be issued when PHE and DH determine that it is required to fill national shortages that cannot be managed locally. A guidance document outlines the circumstances under which the reserve will be made available to the NHS by placing orders through ImmForm.¹⁵

NHS England assurance process

Assurance of the planning and delivery of the flu vaccination programme is vital to its success. Area Teams will provide assurance before the flu season that all GP practices and other providers are prepared for the upcoming season. Area Team leads will assure themselves that:

- the necessary structures are in place to assess the performance of providers against flu vaccination plans for 2013/14 in order to help planning for 2014/15
- robust flu vaccination plans are in place to meet or exceed the vaccine uptake ambitions for 2014/15. To support this process, a checklist is attached at [Appendix G](#) of the steps that GP practices and other providers can reasonably be expected to take to improve uptake of flu vaccine among their eligible patients
- sufficient amounts of vaccine have been ordered from manufacturers for those aged 18 and over and from central supplies for children less than 18
- sufficient supplies of certain flu vaccines have been ordered for patients who require particular flu vaccines due to their age or because of contraindications

- arrangements are in place to ensure the collection and provision of data on vaccinations to support the local and national monitoring of the delivery of the programme and flu vaccine uptake
- arrangements are in place to actively reduce any health inequalities; plans include provision of vaccinations for adults and children that do not readily engage with the health system in high risk settings such as care homes and special schools

Area Teams will be expected to report on the performance and outcome of the programme as part of the responsibilities that NHS England has agreed for the flu vaccination programme under a Section 7A agreement with the Secretary of State for Health.

NHS England through its Head of Public Health Commissioning and Screening and Immunisation Team should provide regular reports to local authority DsPH on performance of local screening and immunisation programmes as described through public health outcome indicators, key performance indicators and use of outcome indicators where available.

Local authority scrutiny

Local authorities have a responsibility to provide information and advice to relevant bodies within their areas to protect the population's health.¹⁶ Although not specified in the regulations this can reasonably be assumed to include immunisation.

Local authorities will provide independent scrutiny and challenge of the arrangements of NHS England, PHE and providers. This function may be carried out through agreed local mechanisms such as local programme boards for screening and immunisation programmes or using established health protection sub-committees of the health and wellbeing boards. They also have a duty to ensure that frontline social care workers are offered flu vaccination and are encouraged to take this up. They may also wish to offer an extended provision of flu vaccination to frontline staff working in institutions with vulnerable populations, such as special schools.

The Director of Public Health in the local authority is expected to provide appropriate challenge to arrangements and also to advocate within the local authority and with key stakeholders to improve access and uptake of flu vaccination. The DPH also needs to work with Area Teams to ensure strategic commissioning.

Antiviral medicines

Prescribing of antiviral medicines on the NHS is restricted through statutory prescribing restrictions set out in Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of drugs etc) Regulations 2004, commonly known as the Grey List or Selected List Scheme (SLS). Schedule 2 is replicated and published monthly in Part XVIII B of the Drug Tariff.¹⁷

Details of eligible and at risk patients and the circumstances when antiviral medicines can be prescribed are contained in the Drug Tariff. Antiviral medicines can only be prescribed at NHS expense when DH sends out an annual letter from CMO/CPhO, notifying prescribers that the surveillance indicators are at a level that indicate that influenza is

circulating in the community. The exceptions to this are outbreaks of suspected influenza in care/nursing homes which may occur out of season.

Once the CMO/CPhO letter has been sent to primary care, antiviral medicines can be prescribed for patients in the at-risk groups and for patients who are not in one of the identified clinical risk groups but who are at risk of developing medical complications from flu. In order to minimise the development of antiviral resistance, it is important that prescribers use antiviral medicines prudently, taking into account national guidance and prescribe in accordance with the Marketing Authorisations of the antiviral medicines. GPs should continue to monitor their use, especially in immunosuppressed individuals where resistance is more likely to be seen.

The statutory prescribing restrictions do not apply in secondary care. This means that if hospital clinicians believe that a person's symptoms are indicative that the person has influenza and would suffer complications if not treated, they are able to prescribe antiviral medicines. Hospital pharmacies should ensure that in such situations they are able to access antiviral medicines in a timely manner. A letter from the CMO/CPhO is not required to provide the trigger for prescribing antiviral medicines in the hospital setting.

DH will notify the manufacturers of antiviral medicines and wholesalers when the notification has been issued to prescribers that antiviral medicines can be prescribed for those eligible for antiviral medicines, to ensure that they are prepared for an increase in demand. Manufacturers will in turn need to ensure that there are enough antiviral medicines in the supply chain so that pharmacists are able to supply them when patients present to pharmacies with prescriptions. Prior to this and during the flu season, DH will be in regular contact with manufacturers and wholesalers to ensure that there are enough antiviral medicines in the supply chain to meet demand. DH will also communicate with pharmacy organisations immediately before the letter is issued and regularly thereafter if necessary to ensure that community pharmacies are able to access and supply antiviral medicines when they are presented with prescriptions.

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.

Winter planning

Flu is one of the factors that the health and social care system considers as part of winter preparedness. Each year the system plans for and responds to surges in demand, called winter pressures. Pressures associated with winter include:

- the impact of adverse weather, including cold temperatures which increase emergency hospital admissions for diseases such as cardiovascular and respiratory disease, and snow and ice which result in increased numbers of accidents and can significantly disrupt services
- 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.

The Cold Weather Plan recommends a series of steps to reduce the risks to health from cold weather for the NHS, local authorities, professionals working with people at risk, individuals, local communities and voluntary groups. The cold weather alert service comprises five levels (levels 0-4), from long-term planning for cold weather, through winter and severe cold weather action, to a major national emergency. Each alert level aims to trigger a series of appropriate actions for different organisations such as flu vaccination, public health communications and health and social care demand management. Local areas should tailor the suggested actions to their situation and ensure that they have the best fit with wider local arrangements.

¹⁰ More information will be available in a service specification to be published at:

www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2014-to-2015

¹¹ Vaccine uptake data is based on registered GP practice population. Data source: ImmForm reporting website www.immform.dh.gov.uk

¹² www.phoutcomes.info

¹³ www.gov.uk/government/collections/vaccine-uptake

¹⁴ www.who.int/influenza/vaccines/virus/recommendations/2014_15_north/en/

¹⁵ www.gov.uk/government/publications/accessing-the-flu-vaccine-strategic-reserve-in-england

¹⁶ Draft regulations laid before Parliament under section 272(6) of the National Health Service Act 2006 and section 240(6) of the Local Government and Public Involvement in Health Act 2007, for approval by resolution of each House of Parliament.

¹⁷ www.ppa.org.uk/ppa/edt_intro.htm

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.

A Flu Communications Steering group for 2014/15 has been formed, and will include communication representatives from PHE national and regional press offices, NHS England, NHS Employers, and DH, to help develop a coordinated and strategic approach to flu communications. Meetings of the communications teams of these partners are also planned to review the 2013/14 delivery and refine the 2014/15 plan as required.

While communications will take place within an overarching flu communications framework, some elements of the communications campaign will be dictated by the severity of the flu season and subsequent impact on at risk groups. Therefore it will be important to maintain a flexible approach so that appropriate channels are chosen to maximise impact and ensure that messages to the public are clear, consistent and relevant to the target audiences.

Communications will also aim to raise awareness of the new elements of the flu programme, including the extension to new child cohorts. It is likely that much of the communications focus will be on reaching parents and carers of those aged 2-4 years, and there will be specific messaging aimed at the cohorts participating in the pilots.

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

Green Book

The Green Book, *Immunisation against infectious disease*, provides guidance for health professionals on administering the flu vaccine. The influenza chapter (chapter 19) is updated each year following review by JCVI 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 and this *Flu plan*, this comprises all the essential information needed by healthcare professionals in the implementation of the flu programme.

Annual Flu Letter

Every year an Annual Flu Letter¹⁸ sets out information about the forthcoming annual seasonal flu vaccination programme. The information in the letter includes:

- the groups to be immunised (including which children to offer vaccine to)
- a GP practice checklist
- advice on increasing vaccine uptake
- the available vaccines and data collection arrangements
- details about ordering vaccines for children

- the assurance arrangements
- information about prescribing and supply of antiviral medicines

Press briefings

The Chief Medical Officer and representatives from DH, NHS England and PHE as appropriate will lead press conferences as and when it is necessary. 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, press briefings may be held to provide the facts and get appropriate messages to the public, including how they can protect themselves and their families. If held, they will occur on Thursday afternoons to coincide with the release of the weekly influenza reports from PHE.

The briefings are an opportunity for:

- the CMO, and/or PHE and NHS England representatives to issue a specific public health message
- 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

PHE weekly influenza reports

These reports represent the most comprehensive and detailed assessment of the current situation. They will be of relevance to health and social care professionals, health planners, journalists and interested members of the public. The contents of the reports are listed above in the flu surveillance section.

Reports from previous seasons can be viewed at:

www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1287147913271

Invitations and information for patients

Proactive and personalised invitations from GPs and other health professionals to patients have a key role to play. 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, and use any available 'free' communications channels to promote the vaccination message (such as the electronic booking system or patient newsletters). PHE have produced a flu vaccination invitation template letter which can be found at:

www.gov.uk/government/publications/flu-vaccination-invitation-template-letter

Any centrally produced communications materials such as leaflets will be made available via NHS Choices, DH, PHE and NHS Comms Link websites for use by local areas.¹⁹ GP practices may wish to use these materials as part of their campaigns to raise awareness of the availability of flu vaccination. We will also be working very closely with partners including NHS England, NHS Employers, the LGA and the excellent network of health charities to ensure that key messages are transmitted effectively to their various audiences.

Respiratory and hand hygiene

Existing learning suggests that respiratory and hand hygiene messaging is most effective during an outbreak, when the public sees a clear need and value in behaviour change. We encourage GPs, other providers and healthcare professionals to use their own channels to convey respiratory and hand hygiene messages throughout the flu season through, for example by adding a respiratory and hand hygiene footnote to all patient letters, emails, electronic booking systems and so forth.

¹⁸ www.gov.uk/government/organisations/public-health-england/series/immunisation

¹⁹ Information about any centrally-driven approach will be available via the NHS Comms Link website, available to NHS Communications. See: <http://nhscommslink.ning.com>

The annual cycle of the flu programme

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

- **November – March:** Vaccine orders placed with suppliers for eligible patients aged 18 and over
- **February:** WHO announces the virus strains selected for the next season's flu vaccine for the northern hemisphere
- **April:** Variation to Section 7A Agreement No 13A on the extension of flu immunisation programme to children published
- **April:** Annual flu letter is sent to the NHS and local government setting out key information for the autumn's immunisation programme
- **April – June:** Liaison with manufacturers to assure the availability of vaccine
- **April – June:** Providers that are immunising children in schools to contact schools to begin planning for local vaccinations from September
- **April – June:** Assurance that all patients eligible for the vaccine are included on the list of patients to contact
- **July:** Centrally produced communications materials made available
- **June – July:** Publication of the revised influenza chapter of the Green Book
- **July – September:** providers who are immunising children in schools ensure consent forms are sent to parents
- **August:** Communications and guidance about vaccine uptake data collections issued
- **August:** NHS England Area Teams, NHS Employers, local government health and wellbeing teams, trusts, GP practices, pharmacies and local authorities begin communications activities to promote early uptake of the vaccine among eligible groups including health and social care staff
- **August – March:** DH in regular contact with manufacturers of antiviral medicines and wholesalers to ensure enough antiviral medicines in the supply chain
- **September – February:** Suppliers deliver vaccines to GP practices and PHE central stock. GPs and other providers begin vaccinating eligible patients and staff against flu as soon as vaccine is available
- **September:** Flu vaccine for children available to order through ImmForm.
- **September:** GP practices and other providers contact their eligible patients and invite them to attend for vaccination
- **September:** Occupational health providers make flu vaccination available to eligible health and social care staff

- **September – February:** Weekly GP patients and monthly vaccination data collections from primary care, and monthly data collections from secondary care begin
- **October:** From week 40 (early October) PHE publishes weekly reports on flu incidence, vaccine uptake, morbidity and mortality
- **October – February:** The CPhO and CMO may issue advice on the use of antiviral medicines, based on advice from PHE in light of flu surveillance data. Antiviral medicines from the national pandemic flu stockpile may be made available
- **October – February:** The NHS implements winter pressures coordination arrangements
- **October – February:** A respiratory and hand hygiene campaign may be considered
- **November – February:** Monthly GP patient flu uptake and the health care worker flu uptake collection commence for data submissions and closes early February.
- **End January:** date by which almost all supplies of Fluenz Tetra® will have expired.
- **March – May:** The CPhO and CMO may issue letter asking GPs and other prescribers to stop prescribing antiviral medicines, once PHE informs DH that surveillance data are indicating very little flu circulating in the community and other indicators such as the number of flu-related hospital admissions

Flexibility: a staged flu response

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.

Planning for the flu season therefore needs to prepare for a range of possibilities including the need to respond quickly to modify the plans ([Appendix J](#) identifies some potential scenarios). For this reason, the *Flu plan* operates according to a series of stages, which enable individual elements of the DH, NHS England, and PHE's response to be escalated as appropriate:

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

[Appendix I](#) lays out in greater detail the 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 which population.

Levels of circulating flu 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. While the DH, NHS England, and PHE lead 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.

Plans to improve vaccine uptake

Flu vaccination uptake rates

Flu vaccine uptake in the last three years was as follows:

	2013/14 (%)	2012/13 (%)	2011/12 (%)
Patients aged 65 years or older	73.2	73.4	74.0
Patients aged six months to under 65 years in risk groups (excluding pregnant women without other risk factors)	52.3	51.3	51.6
Pregnant women	39.8	40.3	27.4
Health care workers	54.8	45.6	44.6
Carers	44.8	46.3	45.2
Patients aged two years old (including those in risk groups)	42.6	N/A	N/A
Patients aged three years old (including those in risk groups)	39.6	N/A	N/A

Source: Source Public Health England: ImmForm reporting website: Data submitted by NHS trusts and area teams

NHS England Area Teams recognise the need to assess the quality of their local flu immunisation services and drive towards continuous improvement including progress to reaching and exceeding vaccine uptake aspirations. Area Teams will ensure that local plans are in place for GPs to order sufficient vaccine and use robust call and reminder systems to contact and make flu vaccination available to 100% of all eligible patients.

Area Teams and DsPH should build close working relationships to ensure that local population needs are understood and addressed by those providing flu vaccination. When requested, the Area Teams should provide reports to the health and wellbeing boards. The DPH is expected to provide appropriate challenge to local arrangements to improve flu vaccine uptake rates.

Community pharmacists are playing an increasing role in providing both non-NHS and NHS flu vaccination services. Pharmacists can also alert patients who are in at-risk groups, who probably visit pharmacies regularly to collect their medicines, of the importance of being vaccinated, where they do not administer the vaccines themselves. It is important to ensure that the administration of the flu vaccine is recorded in all cases and the information is returned promptly to the GP and/or CCG so that vaccinations given by other providers are included in the uptake figures. Where other providers are used to

vaccinate people, it is critical that there is easy and timely data transfer from other providers to GP practices to ensure that uptake rates for the national flu programme are accurately reflected.

In order to be confident that robust planning is in place, Area Teams report on the performance and outcome of the programme as part of the responsibilities that NHS England has agreed for the flu vaccination programme under a Section 7A agreement with the Secretary of State for Health.

People aged 65 and over

For a number of years now the vaccine uptake rates for those aged 65 and over have been close to the European Union target of 75%. This represents a tremendous achievement especially given that the numbers in this group are growing due to an ageing population. Therefore, GP practices and other providers have vaccinated larger absolute numbers even though the rate has remained similar. Given the increased risk for older people of severe complications from flu, they remain an important target group. Implementation of the childhood flu programme will further reduce the risk of transmission.

People aged under 65 in clinical risk groups

Despite continued efforts, for a number of years around only half of patients in clinical risk groups have been vaccinated. Increasing uptake is important because of the increased risk that people in clinical risk groups are at from the effects of flu. For at-risk patients, including pregnant women, we know that increasing vaccine uptake is challenging and the true uptake rate is hard to establish because of difficulties in determining the denominator. This year, therefore, we are asking that GP practices and other providers prioritise the improvement of vaccine uptake in those with chronic liver disease and neurological disease, including those with learning disabilities, who are at the highest risk of mortality from flu but have the lowest rate of vaccine uptake. There is also a role for doctors and specialist nurses in secondary care, health visitors, pharmacists and other caregivers to raise awareness of flu vaccine as part of the care pathway for people in clinical risk groups.

Children in at-risk groups

Vaccine uptake is particularly low in children under 16 years of age with clinical conditions that put them at most risk of complications or hospitalisation from flu. The new programme to provide flu vaccine to all children aged two to under 17 years will take time to implement. In the meantime, it is important that children and parents of children in clinical risk groups understand the importance of children being vaccinated against flu and the protection it offers them, particularly children with neurological disease including learning disabilities. There is a role for paediatricians and specialist nurses in secondary care, school nurses, health visitors, pharmacists and other caregivers to raise awareness of flu vaccine as part of the care pathway for children in at risk groups (it may be useful to consider reminder systems in hospital notes and child health records).

GPs and practice staff managing the flu programme should make sure that all children in clinical risk groups have the opportunity to receive flu vaccine. In order to simplify the supply of Fluenz Tetra® and inactivated flu vaccine for GPs during the phased implementation of the children's programme PHE will centrally supply influenza vaccine for all children aged six months to less than 18 years of age. This is for both those children who are part of the childhood flu programme and those children in clinical risk groups who are not yet part of the childhood flu programme (ie. both Fluenz Tetra® and inactivated flu vaccine for those children for whom Fluenz Tetra® is contraindicated or not suitable). GPs will need to ensure appropriate arrangements are made for children who have difficulty attending their GP surgery. It may be more effective to arrange vaccination in other settings, such as at home or where appropriate within the special school services.

As a number of geographical pilots will be run in 2014/15 for primary and secondary school children, GPs should be aware that at risk children might be offered flu vaccination as part of these pilots. Area Teams will contact GPs to make sure they are aware of local arrangements.

Pregnant women

Pregnant women are particularly vulnerable to severe complications of flu. All pregnant women are recommended to receive the flu vaccine irrespective of their stage of pregnancy. If a woman becomes pregnant after the usual vaccinating period of October to January, it is still worth considering offering the vaccine if flu is still circulating in the community. Women should be offered the vaccine every time they are pregnant as the flu virus constantly mutates and therefore the strains included in the vaccine are reviewed annually.

Vaccine uptake in pregnant women in 2013/14 was 39.8% which is a similar level to the year before. Flu vaccination for pregnant women may be offered in general practice or through midwifery services. Maternity services are encouraged to provide the vaccine as part of routine care for all pregnant women. Where they are unable to offer this service, midwives should be trained and be sufficiently confident to discuss the benefits of having the flu vaccination and to sign-post the woman back to their GP. Where a pregnant woman is vaccinated but not by her GP, it is important that the vaccination information is provided to the practice for the timely update of the clinical records. See [Appendix H](#) for more information.

Healthcare workers with direct patient contact and social care workers

Frontline health and social care workers have a duty of care to protect their patients and service users from infection. This includes getting vaccinated against flu. The impact of flu on frail and vulnerable patients in communities, care homes, and in hospitals can be fatal.

The Secretary of State for Health and the CMO are keen to see increased uptake of vaccine by healthcare and social care workers, and in 2013/14 there was a very encouraging and marked improvement in the flu vaccination of frontline healthcare workers of 54.8% compared to 45.6% the year before. However, the overall level of uptake is still below the 75% aspiration and we know there is scope for improvement because 43 of 271

trusts were able to achieve the 75% coverage target. Those that did not meet the target this winter will need to demonstrate they have robust plans in place to meet it in 2014/15.

NHS organisations and local authorities need to ensure that appropriate measures are in place for offering flu vaccination to their health and social care workers with direct patient contact. This service is organised locally by these employers, 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. However, GP practices need to encourage and facilitate flu vaccination of their own staff through occupational health.

NHS Employers run a national staff-facing campaign to encourage healthcare workers to get vaccinated. The campaign provides support to teams running their local staff flu vaccinations campaigns, ensures consistency of message, shares best practice and harnesses clinical and professional leadership at both national and local levels. Further information and contact details can be found on the NHS Employers flu fighter website.²⁰

Carers

People in receipt of a carer's allowance, or who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill, should be offered flu vaccination. This includes carers who are children. Practices should remind at risk patients that if they have someone who cares for them, this person is also eligible for the flu vaccine. For more information including posters that can be downloaded and displayed in general practices and other locations visit the Carers Trust website.²¹

Healthy children

The flu vaccine uptake rate of 42.6% for two year olds and 39.6% for three year olds in the first year of the roll-out in 2013/14 is very encouraging and may increase as this element of the national programme becomes more routine.

Areas that are piloting vaccination of school-aged children are testing the efficiency and effectiveness of a range of delivery models. As part of the assessment of effectiveness, they will also assess the acceptability of delivery models to parents and children, in part by assessing their effect on uptake, with a view to refining eventual models to maximise uptake. Therefore, at this stage, uptake levels are not seen as a measure of performance, though uptake levels in the 2013/14 primary school pilots were very encouraging. The provisional uptake rate in the seven geographical pilots of school-aged children (between ages four to 10) was 53% in 2013/14. More detailed information is available in [Appendix E](#).

The implementation of the primary and secondary school pilots should include work to reduce health inequalities, with specific inclusion of children within special schools.

Commissioning services for those with particular needs

In addition to those patients who can attend a surgery or clinic to receive a vaccination, Area Teams need to plan to offer vaccination to those who require home visits; those who are in long-term care; those who are not registered with a general practice; those children that do not attend the main stream private and state schools and those adults and children

that do not readily engage with the health system. Commissioners may wish to consider the continuation of local innovative services, such as vaccination by pharmacists and in high risk settings such as care homes and special schools, where there is clear evidence of improved easy access and beneficial outcomes.

²⁰ www.nhsemployers.org/flu

²¹ www.carers.org/news/carers-encouraged-claim-free-flu-jab-winter

Appendix 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
- seek advice from a pharmacist about the best remedy for their symptoms
- consider taking the appropriate dose of paracetamol/ibuprofen-based painkillers or cold remedies to lower their temperature and relieve their symptoms
- avoid visiting GP surgeries and hospitals where they may infect other more vulnerable people

Vaccination

The main 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. With the childhood programme the aim is to provide direct protection to children who are vaccinated and, by interrupting transmission of influenza, reduce the spread of flu to unvaccinated adults and children, including those in clinical risk groups and for whom flu can be extremely serious. It is 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. Since 2013, a quadrivalent vaccine has also been available.

A recent meta-analysis, which included studies when the influenza virus strains in the vaccine were drifted or mismatched with those in circulation, suggested an overall efficacy against confirmed disease of 59% (95% confidence interval 51-67) in adults aged 18 to 65 years.²² In the elderly, protection produced by the vaccine may be lower²³, although immunisation has been shown to reduce the incidence of severe disease including bronchopneumonia, hospital admissions and mortality.^{24,25}

Trivalent live attenuated influenza vaccine has been shown to provide a higher level of protection for children than trivalent inactivated influenza vaccine²⁶; a recent meta-analysis suggested an efficacy against confirmed disease of 83% (95% confidence interval 69-91).^{27,28,29}

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 [Appendix C](#).

Once the CMO/CPhO letter has been disseminated to prescribers that enables them to prescribe antiviral medicines in accordance with the statutory prescribing restrictions set out in Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of drugs etc) Regulations 2004), commonly known as the Grey List or Selected List Scheme (SLS) and NICE guidance, prescribers are able to prescribe antiviral medicines for patients in the at-risk groups and for patients who are not in one of the identified clinical risk groups but who are at risk of developing medical complications from flu.

It should be noted that NICE guidance states that during localised outbreaks of influenza-like illness (outside the periods when national surveillance indicates that influenza virus is circulating generally in the community), antiviral medicines may be given to at-risk people living in long-term residential or nursing homes, whether or not they are vaccinated. However, this should be done only if there is a high level of certainty that the causative agent in a localised outbreak is influenza.

The CMO/CPhO letter, when published, will provide more details.

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 antiviral medicines, intravenous antibiotics will be used. The statutory Grey List restrictions for prescribing antiviral medicines in primary care do not apply to hospitals. 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 to 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.

²² Osterholm, MT, Kelley, NS, Sommer, A, and Belongia, EA (2012) Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. *Lancet Infect Dis.* **12**(1.1), 36-44.

²³ 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**: 581–9

²⁴ Wright PF, Thompson J, Vaughn WK et al. (1977) Trials of influenza A/New Jersey/76 virus vaccine in normal children: an overview of age-related antigenicity and reactogenicity. *J Infect Dis* **136** (suppl): S731–41.

²⁵ Mangtani P, Cumberland P, Hodgson CR et al. (2004) A cohort study of the effectiveness of influenza vaccine in older people, performed using the United Kingdom general practice research database. *J Infect Dis* **190**(1): 1–10.

²⁶ Belshe RB, Edwards KM, Vesikari T et al. (2007) Live attenuated versus inactivated influenza vaccine in infants and young children. *N Engl J Med* **356**(7): 685-96.
www.ncbi.nlm.nih.gov/sites/entrez/17301299

²⁷ Osterholm, MT, Kelley, NS, Sommer, A, and Belongia, EA (2012) Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis. *Lancet Infect Dis.* **12**(1.1): 36-44

²⁸ Ashkenazi S, Vertruyen A, Aristegui J et al. (2006) Superior relative efficacy of live attenuated influenza vaccine compared with inactivated influenza vaccine in young children with recurrent respiratory tract infections. *Pediatr Infect Dis J* **25**(10): 870-9.
www.ncbi.nlm.nih.gov/sites/entrez/17006279

²⁹ Fleming DM, Crovari P, Wahn U et al. (2006) Comparison of the efficacy and safety of live attenuated cold-adapted influenza vaccine, trivalent, with trivalent inactivated influenza virus vaccine in children and adolescents with asthma. *Pediatr Infect Dis J* **25**(10): 860-9.
www.ncbi.nlm.nih.gov/sites/entrez/17006278

Appendix B

Vaccine manufacture and supply

Flu vaccine manufacture and supply are undertaken on a global basis. Six 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. 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; and filling, packaging and labelling needs. 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 vaccination 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. 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.

Appendix C

Groups eligible for the flu vaccination

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

- people aged 65 years or over (including those becoming age 65 years by 31 March 2015)
- all pregnant women (including those women who become pregnant during the flu season)
- all those aged two, three, and four years old (but not five years or older) on 1 September 2014
- all school-aged children who are part of the pilot childhood programme
- 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 three, four or 5
 - chronic liver disease
 - chronic neurological disease, such as Parkinson's disease or motor neurone disease
 - diabetes
 - splenic dysfunction
 - 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, specifically 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:

- health and social care workers with direct patient/service user contact. Healthcare practitioners should refer to the Green Book influenza chapter for further guidance.³⁰

³⁰ www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

Appendix D

Extension of the flu programme to children

JCVI recommendation

In July 2012 JCVI published a statement³¹ setting out the basis and evidence for the extension of the flu immunisation programme to children. The JCVI recommendation to the Secretary of State for Health is based upon analysis that suggested that any vaccination campaign including school-aged children is highly likely to be cost effective when the direct and indirect benefits to the individual and the population are taken into account, particularly over the longer-term.

This has led to the following delivery statement in the 2014/15 Section 7A service specification³² between DH and NHS England:

“The best uptake of vaccination among 5-16 year olds is likely to be achieved through a school-based programme. However, it is recognised that the capacity of school health services (where appropriate locally working with specialist immunisation services) is not currently adequate to enable the programme to be offered to all children in this way. Work is being undertaken jointly by DH and NHS England, and with PHE, Health Education England and professional bodies to:

- *support the development of sustainable long-term solutions,*
- *ensure the availability of sufficient appropriately-trained staff, and*
- *work with local government to develop the associated commissioning arrangements for school nursing to deliver the programme.”*

The implementation of the programme will be phased in a way that achieves the expected public health gains quickly, but maintains high levels of safety and quality and does not put undue pressure on other programmes.

The programme in 2013/14 covered the following cohorts:

- a routine offer of vaccination to all those aged two and three year old (but not four years or older) on 1 September 2013;
- all primary school aged children in seven geographical pilot areas

The programme for 2014/15 expands 2013/14 delivery and is as follows:

- a routine offer of vaccination to all those aged two, three and four years old (but not five years or older) on 1 September 2014 (ie date of birth on or after 2 September 2009 and on or before 1 September 2012);

- seven geographical pilots of primary school aged children started in 2013/14 will continue;
- a minimum of 12 geographical pilots in secondary school aged children in Years 7 and 8 in 2014/15

In the interests of maintaining the highest level of safety, and in order to set a clear and manageable limit, the vaccine should not be offered to healthy children that turn two after 1 September.

Pre-school aged children (aged two to four years old) are currently immunised under an NHS England Enhanced Services contract with the General Practitioners Committee (GPC) of the British Medical Association (BMA). This is likely to continue for the foreseeable future, but will be based on ongoing discussions between DH, PHE, NHS England and the GPC.

It is likely that NHS England will commission the majority of immunisation for school-aged children in schools (including those in special schools). NHS England will, however, have options to commission services from a range of local healthcare providers, including in primary care or community pharmacies and those children of relevant ages outside the mainstream state and private school system. **Where children in clinical risk groups are in locations not covered by pilot areas, they should continue to be vaccinated in general practice.**

More information about the learning from the seven geographical pilots in 2013/14 can be found in [Appendix E](#) and a full evaluation report will be published at the GOV.UK website.³³

Use of the live attenuated influenza vaccine Fluenz Tetra®

None of the influenza vaccines should be given to those who have had:

- a confirmed anaphylactic reaction to a previous dose of the vaccine, or
- a confirmed anaphylactic reaction to any component of the vaccine (other than ovalbumin – see the Green Book influenza chapter for egg allergy and inactivated influenza vaccines)

Fluenz Tetra® is contraindicated in children and adolescents who are:

- clinically severely immunodeficient due to conditions or immunosuppressive therapy
- receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection.

Fluenz Tetra® is not recommended in children and adolescents who have active wheezing at the time of vaccination or severe asthma.

Fluenz Tetra® may not be suitable for children and adolescents with egg allergy.

The advice in contraindications and precautions sections in the Green Book influenza chapter should be referred to.³⁴

Porcine gelatine

Fluenz Tetra® contains a wide range of ingredients, including porcine gelatine (as do many other pharmaceutical products). There is currently no alternative vaccine of equivalent efficacy that does not include porcine gelatine. Although broad acceptance has been gained from faith groups for the use of porcine gelatine in non-oral medicines (see PHE's website www.gov.uk/government/news/vaccines-and-gelatine-phe-response), there is still some uncertainty amongst some groups. The implications of this for the programme will continue to be monitored and considered carefully in light of evidence gathered through the pilots.

Vaccination is not compulsory in the UK, anyone who does not wish to be vaccinated with Fluenz Tetra® can refuse vaccination. Current policy is that only those who are in clinical risk groups or have clinical contra-indications are offered an inactivated injectable vaccine as an alternative to Fluenz Tetra® (two doses will be required in many cases).

³¹ www.gov.uk/government/publications/jcvi-statement-on-the-routine-annual-influenza-vaccination-programme

³² The 2014/15 Section 7A service specification can be found at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/256502/nhs_public_health_functions_agreement_2014-15.pdf

³³ www.gov.uk/government/organisations/public-health-england/series/immunisation

³⁴ www.gov.uk/government/publications/influenza-the-green-book-chapter-19

Appendix E

Learning from child flu immunisation pilots in 2013/14

The seven geographical pilots

In 2013/14 flu vaccination was offered for the first time to all two and three year olds in general practice, and a pilot programme in primary school aged children was run in seven geographical areas. The pilots were set up to assess issues such as workload, uptake and logistics of delivery in a variety of settings that reflect full-scale roll-out as closely as possible. Learning from the pilots is informing the national roll-out of the programme, including how best to work with local schools. Vaccine coverage monitoring and surveillance systems were also tested so that robust systems can be put in place to evaluate the impact of the programme in the longer term.

The pilots ran in Bury, Cumbria, South East Essex, Gateshead, Havering, Newham, and Leicester, East Leicestershire and Rutland and covered ethnic diversity and deprivation and a wide range of geographical locations, enabling delivery to be tested across a wide variety of different settings. The cohort size varied across pilot areas from just over 13,000 children in Gateshead to over 55,000 in Leicester, East Leicestershire and Rutland.

Six of the pilot areas delivered the programme using a school based programme. Of these, four areas used trust immunisation teams to deliver, one used the School Nursing Service and one used a private provider. All areas used qualified nurses to immunise under Patient Group Directions (PGDs). In addition South East Essex piloted the use of health care assistants (HCAs) immunising under a Patient Specific Direction. All but one of the areas immunised at risk children eligible for vaccination with Fluenz® as part of the programme. Additionally three of the pilots included provision of trivalent inactivated vaccine (TIV) for children with contraindications to vaccination with Fluenz®. In the other areas children with contraindications were referred to their GP. Four of the school based pilots provided 'mop up' sessions for children who had returned their forms late or who were absent on the day. These were either held within the school or in community clinics.

Due to the rural location and a relatively sparse population Cumbria chose a local pharmacy and general practice based model. Pharmacists and general practices were asked to offer immunisation with Fluenz® as a Direct Enhanced Service (DES).

Immunising primary school aged children with Fluenz® was generally well accepted by children, parents, schools and immunisation teams. Provisional uptake was 53% overall. There was considerable variation across the pilot sites from just over 35% for the community pharmacy based model to in excess of 60% in some sites (again, uptake figures are provisional). Newham, Bury and Leicester, East Leicestershire and Rutland reported that the porcine gelatine component of Fluenz® affected delivery of the programme in their areas and may have impacted on uptake although it is difficult to

differentiate non response due to porcine gelatine from other factors including language and literacy issues.

Further details of findings coming from the pilots will be published at the GOV.UK website.³⁵

³⁵ www.gov.uk/government/organisations/public-health-england/series/immunisation

Appendix F

Health and social care worker vaccination programme

Importance of vaccinating health and social care workers with direct patient/service user contact

Frontline health and social care workers have a duty of care to protect their patients and service users from infection. This includes getting vaccinated against flu.

Influenza outbreaks can arise in health and social care settings with both staff and their patients/service users 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, vaccination 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.^{36,37,38,39}

Vaccination of staff in social care settings may provide similar benefits. Influenza vaccination 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 vaccination.

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 these services increase.

Healthcare workers are a very influential group. Patients trust their nurses, doctors and other healthcare professionals and their opinions can affect the way patients act.

A vaccinated healthcare worker 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 about the vaccine.

A range of interventions can be employed to increase uptake.⁴⁰ 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.

The Secretary of State for Health and CMO and other senior professionals take a keen interest in seeing increased flu vaccine uptake in healthcare and social care workers.

NHS Employers produce guidance and material to support trusts in delivering their own healthcare worker flu vaccination campaigns and provide advice to those running vaccination campaigns at local level. These materials can be accessed via the internet.⁴¹

Additionally, DH will continue to work with PHE, NHS England, NHS TDA and Monitor to agree action to ensure trusts take the necessary action to increase uptake rates in the coming flu season.

Provision of the vaccine for health and social care workers

The updated code of practice on the prevention and control of infections and related guidance⁴² 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* (the Green Book).⁴³ Employers should make vaccines available free of charge to employees if a risk assessment indicates that they are needed.⁴⁴ This includes GP practices who need to have arrangements in place.

The flu vaccination 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/service user 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 former HPA confirmed that the infection was mainly spread by healthcare workers.

Trusts/employers must 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
- pharmacists, both those working in the community and in clinical settings

- staff working in direct support of clinical staff, often with direct patient care

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. For more information about groups to vaccinate see Appendix A of the ImmForm User guidance.⁴⁵

³⁶ Potter, J, Stott, DJ, Roberts, MA, Elder, AG, O'Donnell, B, Knight, PV and Carman, WF (1997). The influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *Journal of Infectious Diseases*; **175**:1-6.

³⁷ Carman, WF, Elder, AG, Wallace, LA, McAulay, K, Walker, A, Murray, GD, and Stott, DJ. (2000) Effects of influenza vaccination of healthcare workers on mortality of elderly people in long term care: a randomised control trial. *The Lancet*; **355**:93-7.

³⁸ Hayward, AC, Harling, R, Wetten, S, Johnson, AM, Munro, S, Smedley, J, Murad, S and Watson, JM. (2006) 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*; doi:10.1136/bmj.39010.581354.55 (published 1 December 2006).

³⁹ 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. (2009) Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster randomised trial. *Journal of American Geriatric Society*; **57**:1580-6.

⁴⁰ Can we achieve high uptakes of influenza vaccination of healthcare workers in hospitals? A cross-sectional survey of acute NHS trusts in England. *Epidemiol Infect.* 2013 May **15**:1-10. http://journals.cambridge.org/abstract_S095026881300112X

⁴¹ www.nhsemployers.org/flu

⁴² www.gov.uk/government/publications/the-health-and-social-care-act-2008-code-of-practice-on-the-prevention-and-control-of-infections-and-related-guidance

⁴³ www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

⁴⁴ www.hse.gov.uk/coshh/basics/assessment.htm

⁴⁵ www.gov.uk/government/uploads/system/uploads/attachment_data/file/259657/Seasonal_flu_HC_Ws_ImmForm_UserGuide_acc2_final.pdf

Appendix G

Increasing vaccine uptake among clinical risk groups: GP practice checklist

The GP practice checklist highlights good practice and is based upon the findings from a study examining the factors associated with higher vaccine uptake in general practice.⁴⁶ GP practices are encouraged to review their systems in the light of the checklist.

General

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

Registers and information

2. The GP practice has a register that can identify all pregnant women and patients in the under 65 years at risk groups, those aged 65 years and over, and those aged two to four years.
3. 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.
4. The GP practice will submit accurate data on the number of its patients eligible to receive flu vaccine and the flu vaccinations given to its patients on ImmForm,⁴⁷ ideally using the automated function, and on uptake amongst healthcare workers in primary care using the Immform data collection tool.

Meeting any public health targets in respect of such immunisations

5. The GP practice will/has ordered sufficient flu vaccine taking into account past and planned performance, expected demographic increase, and to ensure that everyone at risk is offered the flu vaccine. It is recommended that vaccine is ordered from more than one supplier and from PHE central supplies through the ImmForm website in respect of children.

Robust call and recall arrangements

6. Patients recommended to receive the flu vaccine will be directly contacted (for example through letter, e-mail, phone call, text or otherwise although such strategies are for GP practices to determine) inviting them to a flu vaccination clinic or to make an appointment. PHE has produced a flu vaccination invitation template letter which can be found at the GOV.UK website.⁴⁸
7. The GP practice will follow up with patients who do not respond or fail to attend scheduled clinics or appointments.

Maximising uptake in the interests of at-risk patients

8. Flu vaccination will start as soon as practicable after receipt of the vaccine so that the maximum number of patients are vaccinated as early as possible prior to the flu season (ie by the end of October), to ensure they are protected before flu starts to circulate.
9. The GP practice will collaborate with midwives to offer and provide flu vaccination to pregnant women and to identify, offer and provide to newly pregnant women as the flu season progresses.
10. The GP practice will offer flu vaccination in clinics and opportunistically.
11. The GP practice and/or CCG will collaborate with other providers such as Foundation Trusts, to identify and offer flu vaccination to residents in care homes, nursing homes and house-bound patients.

⁴⁶ Dexter, L. et al. (2012) Strategies to increase influenza vaccination rates: outcomes of a nationwide cross-sectional survey of UK general practice.

<http://bmjopen.bmj.com/content/2/3/e000851.full>

⁴⁷ www.immform.dh.gov.uk

⁴⁸ www.gov.uk/government/publications/flu-vaccination-invitation-template-letter

Appendix H

Pregnant women

Rationale and target groups

There is good evidence that pregnant women are at increased risk from complications if they contract flu.^{49, 50} In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight^{51, 52} and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy.⁵³ Furthermore, a number of studies show that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.^{54,55,56,57}

A review of studies on the safety of flu vaccine in pregnancy concluded that inactivated flu vaccine can be safely and effectively administered during any trimester of pregnancy and that no study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza vaccine.⁵⁸

All pregnant women are recommended to receive the flu vaccine irrespective of their stage of pregnancy.

When to stop offering the vaccine to pregnant women

The ideal time for flu vaccination is between September and early November before flu starts circulating. However flu can circulate considerably later than this and it may therefore be necessary to continue offering the vaccine to groups such as newly pregnant women. Clinicians should apply clinical judgement to assess the needs of an individual patient, taking into account the level of flu-like illness in their community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.

Data review and data recording

Uptake of vaccine by pregnant women, along with other groups, will be monitored. GPs will need to check their patient database throughout the flu season in order to identify women who are not pregnant at the start of the immunisation programme but become pregnant during the winter. GPs should also review their records of pregnant women before the start of the immunisation programme to ensure that women who are no longer pregnant are not called for vaccination (unless they are in other clinical risk groups) and so that they can measure the uptake of flu vaccine by pregnant women accurately.

Midwifery services

Midwives need to be able to explain the benefits of flu vaccination to pregnant women and either refer them back to their GP practice for the vaccine or offer the vaccine in the midwifery service itself. A number of different models exist including running flu vaccination clinics alongside the midwifery service, where cold storage facilities exist. Area

Teams will explore ways of commissioning midwifery services to provide flu vaccination or linking midwifery services with GP practices. If arrangements are put in place where midwives administer the flu vaccine, it is important that the patient's GP practice is informed in a timely manner so their records can be updated accordingly, and included in vaccine uptake data collections.

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- ⁴⁹ Neuzil KM, Reed GW, Mitchel EF *et al.* (1998) Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. *Am J Epidemiol.* **148**:1094-102
- ⁵⁰ Pebody R *et al.* (2010) Pandemic influenza A (H1N1) 2009 and mortality in the United Kingdom: risk factors for death, April 2009 to March 2010. *Eurosurveillance* **15**(20):19571.
- ⁵¹ Pierce M, Kurinczuk JJ, Spark P *et al.* (2011) Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study. *BMJ.* **342**:d3214.
- ⁵² McNeil SA, Dodds LA, Fell DB *et al.* (2011) Effect of respiratory hospitalization during pregnancy on infant outcomes. *Am J Obstet Gynecol.* **204**:(6 Suppl 1) S54-7.
- ⁵³ Omer SB, Goodman D, Steinhoff MC *et al.* (2011) Maternal influenza immunization and reduced likelihood of prematurity and small for gestational age births: a retrospective cohort study. *PLoS Med.* **8**:(5) e1000441.
- ⁵⁴ Benowitz I, Esposito DB, Gracey KD *et al.* (2010) Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants. *Clin Infect Dis.* **51**:1355-61.
- ⁵⁵ Eick AA, Uyeki TM, Klimov A *et al.* (2010) Maternal influenza vaccination and effect on influenza virus infection in young infants. *Arch Pediatr Adolesc Med.* **165**:104-11.
- ⁵⁶ Zaman K, Roy E, Arifeen SE *et al.* (2008) Effectiveness of maternal influenza immunisation in mothers and infants. *N Engl J Med.* **359**:1555-64.
- ⁵⁷ Poehling KA, Szilagyi PG, Staat MA *et al.* (2011) Impact of maternal immunization on influenza hospitalizations in infants. *Am J Obstet Gynecol.* **204**:(6 Suppl 1)S141-8.
- ⁵⁸ Tamma PD, Ault KA, del Rio C, Steinhoff MC *et al.* (2009) Safety of influenza vaccination during pregnancy. *Am. J. Obstet. Gynecol.* **201**(6):547-52.

Appendix I

Stages of activity

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 • GPs make arrangements to vaccinate patients who cannot attend the surgery because of frailty, severe chronic illness or disability • GPs encourage and facilitate their own frontline staff to be vaccinated • other NHS, local authority and care home employers arrange for their frontline staff to be vaccinated • 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 • PHE publishes weekly reports on flu incidence, vaccine uptake, morbidity and mortality • NHS England writes to the NHS if vaccine uptake is low • PHE in contact with vaccine manufacturers on production and delivery schedules • DH in contact with antiviral medicine manufacturers on their preparedness plans • the respiratory and hand hygiene campaign may be launched

Activity that would be undertaken	
Stage 2	<ul style="list-style-type: none"> • GPs and other non-medical prescribers will be alerted through a CMO/CPhO letter, to start prescribing antiviral medicines in line with the NICE guidance and Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of drugs etc) Regulations 2004), commonly known as the Grey List or Selected List Scheme (SLS) and following expert advice that the flu virus is circulating • if evidence emerges that a particular age group or people with certain clinical conditions are being disproportionately affected by the flu virus, a joint letter on behalf of DH, NHS England, and PHE 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 or representatives of PHE or NHS England 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 • if countrywide vaccine shortages are considered likely, PHE 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 • 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, PHE 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

Activity that would be undertaken	
Stage 3	<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 and that there may be greater use of antiviral medicines • vaccine manufacturers contacted regarding availability of additional supplies • antiviral medicines 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 • PHE may extend the vaccine uptake collections for additional weeks/months if vaccine uptake rates are still rising • weekly press briefings will be considered. These will be led by CMO or representatives of PHE or NHS England • 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 • regular liaison with pharmacy organisations to keep abreast of any supply problems associated with antiviral medicines • continue to review daily NHS operational data, for example, critical care • alert the NHS when the flu season has peaked, to aid local planning

Appendix J

Potential scenarios

The table below gives examples of factors affecting the DH, PHE 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.

	Event	Action
Vaccination	Delay in vaccine released from manufacturer	PHE communicates with NHS, via NHS England, informing them of delay so GP practices and other providers can reschedule vaccination clinics
	Production problems mean insufficient doses of vaccine are available nationally	PHE communicates with NHS, via NHS England, informing them of shortage and advising which risk groups to prioritise, following JCVI advice as appropriate
	Vaccine uptake remains below expected rate for the time of year. Virus adversely affects groups outside those recommended for vaccination	Joint letter issued on behalf of DH, PHE, and NHS England to NHS recommending appropriate action to increase uptake
	The vaccine does not protect against the predominant circulating strain	<p>PHE, via NHS England, 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</p> <p>PHE alerts the NHS, via NHS England, 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</p> <p>DH contacts manufacturers of antiviral medicines to check levels of antiviral medicines available from manufacturers and discusses arrangements to get additional supplies should the need arise</p> <p>PHE considers launching the respiratory and hand hygiene campaign</p>

	Event	Action
	Issue over safety of vaccine emerges	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). PHE and/or MHRA will give advice on implications of safety issue PHE communicates with the NHS, via NHS England, 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
	Production failure towards the end of the vaccination programme leads to localised vaccine shortages	Central strategic reserve is released
	National vaccine shortage	Central strategic reserve is released
Treatment	Antiviral medicines not available from pharmacies	DH discusses stock levels with manufacturers and wholesalers to determine whether they can meet the increased demand CPhO has regular contact with pharmacy organisations to determine any problems that community pharmacies may be encountering obtaining supplies of antiviral medicines to inform discussions with manufacturers of antiviral medicines and wholesalers. PHE 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	NHS England Area Teams, PHE, 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 ⁵⁶
Media coverage	Increased media interest on particular issues	CMO and/ or representatives of PHE and NHS England hold press briefing to communicate the facts and latest data to the media

⁵⁶http://webarchive.nationalarchives.gov.uk/20120503221322/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081507