Public Health England

Department of Health

NHS England

Flu Plan

Winter 2015/16

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Published March 2015
PHE publications gateway number: 2014833
NHS England gateway number: 03316

Contents

Foreword

Flu is a key factor in NHS winter pressures. It impacts on both those who become ill, the NHS services that provide direct care, and on the wider health and social care system that supports people in at-risk groups. Flu occurs every winter in the UK. The Flu Plan aims to reduce the impact of flu in the population through a series of complementary measures. These measures help to reduce illness in the community and unplanned hospital admissions, and therefore pressure on health services generally and A&E in particular. The plan is therefore a critical element of the system-wide approach for delivering robust and resilient health and care services throughout the year.

The national flu immunisation programme is a key part of the plan. In 2014/15 the flu vaccine only provided limited protection against infection caused by one particular strain of flu A, H3N2. This was because of a mismatch between the A(H3N2) strain selected for the vaccine and the main A(H3N2) strain that circulated. Throughout the last decade, there has generally been a good match between the strains of flu in the vaccine and those that subsequently circulated. Flu vaccination remains the best way to protect people from flu. It is crucial the problem that occurred in the winter 2014/15 does not discourage people in at-risk groups from having flu vaccination this coming flu season.

The national flu immunisation programme is being extended to children in a phased roll-out. As well as all two to four year olds, in 2015/16 all children of school years 1 and 2 age will be eligible for flu vaccination. Vaccination will also continue to be offered to primary school-aged children in the areas that participated in primary school pilots in 2014/15. Vaccinating children each year, means that not only are the children protected, but also that transmission across the population is expected to be reduced, lessening the overall burden of flu. Implementing this programme is therefore an important contribution to increasing resilience across the system through the winter period. Results from the first year of the primary school pilots in 2013/14 were encouraging, with reduced numbers of GP attendances for influenza-like illness and reduced emergency department respiratory attendances in all age groups in pilot areas, compared to non-pilot areas.

We anticipate that the children’s programme, once fully implemented, will avert many cases of severe flu and flu-related deaths in older adults and people in clinical risk groups. But we should continue to work hard to ensure that we are communicating the benefits of the vaccine among all recommended groups, making vaccination as easily accessible as possible, including for frontline health and social care workers.

In addition to immunisation, influenza antivirals and a range of other measures aimed at reducing transmission of flu and other respiratory virus infections (such as good hand and respiratory hygiene) are vital elements in the battle to reduce the impact of flu each year.

This is the fifth Flu Plan to be published. It supports a co-ordinated and evidence-based approach to planning for the demands of flu across England. It has the support of the Chief Medical Officer (CMO), Chief Pharmaceutical Officer (CPhO) and the director of nursing.

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 co-ordinated 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 co-ordination and the preparation for the flu season and signposting to further guidance and information.

The Flu Plan includes details about the extension of the flu vaccination programme to children, which is being implemented gradually due to the scale of the programme.

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
- the enhanced service specifications for seasonal flu and the childhood flu vaccination programmes[3]
- the CMO/CPhO letter on antivirals issued to GPs and other prescribers during the flu season advising that antivirals may be prescribed

Roles and responsibilities in 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 across the system. 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 and authorisation of their use
- authorises campaigns such as 'Catch it, Kill it, Bin it'

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
- monitoring the enhanced services that GP practices provide for flu vaccination to ensure that services comply with the specifications
- building close working relationships with directors of public health 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
- managing and co-ordinating the response to local incidents and outbreaks of flu
- public communications to promote uptake of flu vaccination and other aspects of combating flu such as hand hygiene

- supporting directors of public health 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 advocacy with key stakeholders and challenge to local arrangements 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

Local authorities can also assist by:

- promoting uptake of flu vaccination among eligible groups, for example older people in residential or nursing care, either directly or through local providers
- promoting uptake of flu vaccination among those staff providing care for people in residential or nursing care, either directly or through local providers

Clinical commissioning groups (CCGs) are responsible for:

- 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:

- educating patients, particularly those in at risk groups, about the appropriate response to the occurrence of flu-like illness and other illness that might be precipitated by flu
- 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 and ensuring that vaccine wastage is minimised
- storing vaccines in accordance with national guidance
- ensuring that all those eligible for the flu vaccine are invited personally to receive their vaccine
- ensuring vaccination is delivered by suitably trained, competent healthcare professionals who participate in recognised on-going training and development in line with national standards
- maintaining regular and accurate data collection using appropriate returns
- 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 or alternative infection control measures for their frontline staff
- support to providers to ensure access to flu vaccination and to maximise uptake among those eligible to receive it

Influenza and the flu virus

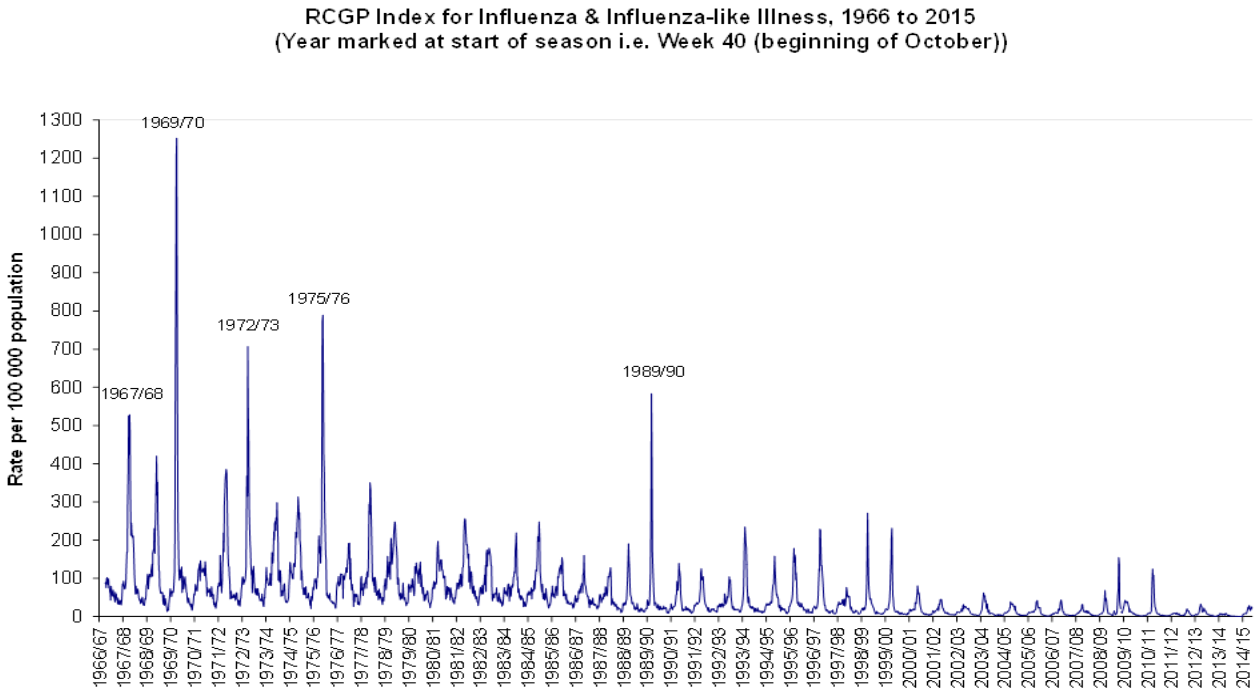
Influenza (often referred to as flu) is an acute viral infection of the respiratory tract (nose, mouth, throat, bronchial tubes and lungs) characterised by a fever, chills, headache, muscle and joint pain, and fatigue. For otherwise healthy individuals, flu is an unpleasant but usually self-limiting 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 among 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 clinical and epidemiological features 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 per 100,000 consultations in primary care in the population of England and Wales from 1966 to 2015. The data show that flu viruses circulate each winter season, but the degree of activity varies substantially.[4]



Strategic objectives

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

- actively offering flu vaccination to 100% of all those in eligible groups
- vaccinating at least 75% of those aged 65 years and over
- vaccinating at least 75% of healthcare workers with direct patient contact
- improving uptake for those in clinical risk groups, particularly for those who are at the highest risk of mortality from flu but have the lowest rates of vaccine uptake, such as those with long-term liver and neurological disease, including people with learning disabilities
- for children, a minimum uptake of 40% has been shown to be achievable in pilots conducted to date. As a minimum we would expect uptake levels between 40% and 60% to be attained. Uptake levels should be consistent across all localities and sectors of the population
- providing direct protection to children by extending the annual flu immunisation programme and also cutting the transmission of flu across the population
- monitoring flu activity, severity of the disease, vaccine uptake and impact on the NHS
- prescribing of antiviral medicines in primary care for patients in at-risk groups and other eligible patients is governed by NHS regulations and in line with NICE guidance[5]. For details please see page 20 in the section on antiviral medicines. Antiviral medicines may only be prescribed in primary care, once the CMO/CPhO letter has been sent to prescribers informing them that they are now able to prescribe antiviral medicines at NHS expense
- 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

Elements of the flu programme

National flu vaccination programme

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 aged 65 and over, 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).

Flu vaccination of frontline health and social care workers

Frontline health and social care workers have a duty of care to protect their patients and service users from infection. Doctors are reminded of the General Medical Council's (GMC) guidance on Good Medical Practice (2013), which advises immunisation 'against common serious communicable diseases (unless otherwise contraindicated)' in order to protect both patients and colleagues (see paragraph 29)[6]. Chapter 12 of the Green Book provides information about the staff groups that can be considered as providing frontline care.

Flu immunisation should be offered by NHS organisations to all employees directly involved in delivering care. This is not an NHS service, but part of the wider infection control responsibilities of the organisation delivered through occupational health services. Social care providers and independent primary care providers such as GP, dental and optometry practices, and community pharmacists, should offer vaccination to staff.

Uptake has increased markedly in recent years, and in the 2014/15 season had reached nearly 55% overall at the end of January 2015. There continues to be considerable variation around the country and there remains scope for improvement.

Extension of the programme to children

In July 2012, JCVI recommended that the flu vaccination programme should be extended to healthy children aged two to their seventeenth birthday. JCVI recognised that implementation of this programme would be challenging and due to the scale of the programme it is being phased in. Vaccinating children each year means that not only are the children protected, but the expectation is that transmission across the population will be cut, reducing levels of flu overall and reducing the burden of flu across the population. Implementing this programme is therefore an important contribution to increasing resilience across the system through the winter period.

The children's programme began in 2013/14 with all two- and three-year-olds being offered vaccination through general practice and geographic pilots in primary school-aged children. In 2014/15 this offer was extended to four-year-olds through general practice, with pilots in primary and secondary school-aged children (in years 7 and 8).

Despite the low flu activity in 2013/14, early results, although statistically non-significant, suggest a positive impact on flu transmission of the pilot vaccination programmes in primary schools. Results were obtained from a range of surveillance indicators including GP consultations for influenza-like illness, swab positivity in primary care, laboratory confirmed hospitalisations and percentage of respiratory emergency department attendances[7]:

- the cumulative GP consultation rate for 'influenza-like illness' in all age groups over the 2013-14 season was higher in non-pilot (64.5/100,000) compared to pilot areas (17.7/100,00)
- the cumulative influenza positivity rate in all ages in primary care in pilot areas was 8.5% compared to 16.2% in non-pilot areas
- the cumulative proportion of emergency department respiratory attendances was 5.5% in pilot compared to 8.7% in non-pilot areas

Phase 2 – Primary school age-children: 2015/16 extension of the programme to children of school years 1 and 2 age

In 2015/16, all two-, three- and four-year-olds will continue to be eligible for flu vaccination through general practice. Vaccination will also continue to be offered to primary school aged-children in the areas that participated in the primary school pilots in 2014/15.

For the phase 2 extension of the flu vaccination programme in 2015/16, all children of school years 1 and 2 age will be eligible for flu vaccination. Local NHS England teams will commission this extension and delivery models will vary by area. Delivery is likely

to be mainly through schools, for example, through school nursing teams or specialist immunisation teams, or in some instances through primary care services such as community pharmacies and general practices. A number of elements of the programme will be dependent upon local commissioning arrangements. So, for instance, in some areas, four-year-olds who have started school could receive their vaccination from either primary care or a school-based provider.

Where a child is vaccinated but not by their GP, it is important that the vaccination information is provided to the practice for the timely update of clinical records.
The principle for the future extension of the programme beyond 2015/16 will be to extend upwards through the age cohorts. Plans are subject to the outcome of the Spending Review, and the annual agreement between the DH and NHS England regarding public health functions (Section 7A agreement).

JCVI recommended that a live attenuated influenza vaccine (LAIV), Fluenz Tetra®, administered as a nasal spray, is the vaccine of choice for children because of higher efficacy in children compared with other flu vaccines. The vaccine is licensed for those aged from 24 months to less than 18 years of age. JCVI recommended Fluenz Tetra 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
- 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

The early vaccine effectiveness data that have been published for the 2014/15 mid-season estimates relate to the overall flu vaccine programme, which is dominated by inactivated vaccine in adults. Vaccine effectiveness data specifically for LAIV in children are not yet available.

Fluenz Tetra is unsuitable for children with contraindications such as severe immunodeficiency, severe asthma or active wheeze. Following more evidence on the safety of Fluenz Tetra in egg allergic children, JCVI has amended its advice on offering it to children with egg allergy. For the full list of contraindications please see the Green Book, where the amended advice on egg allergy will be published shortly. Those children in clinical risk groups who are medically contraindicated to Fluenz Tetra should be offered a suitable inactivated flu vaccine. Flu vaccines for children are purchased centrally by PHE – the Annual Flu Letter contains details about how to order these vaccines.

Fluenz Tetra contains a highly processed form of gelatine (derived from pigs). Some faith groups do not accept the use of porcine gelatine in medical products. Current policy is that **only** those who are in clinical risk groups and have clinical contra-indications to Fluenz Tetra are able to receive an inactivated injectable vaccine as an alternative. The implications of this for the programme will continue to be monitored.

Flu vaccine effectiveness

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.[8] In the elderly, protection produced by the vaccine may be lower[9], although immunisation has been shown to reduce the incidence of severe disease including bronchopneumonia, hospital admissions and mortality.[10, 11]

PHE undertakes estimations of the protective effect of the flu vaccines in use during the flu season. The following should be noted:

- epidemiological estimation is carried out using data from consultations in general practice and standardised methodology. In order to obtain sufficiently robust estimates, only mid-season and end of season estimates are made.
- in order to provide an indication of how well the vaccines are protecting against the currently circulating strains of flu, these data are combined with virological characterisation data of circulating flu viruses
- significant mismatch between circulating strains and the vaccine strains occur infrequently. Detailed virological characterisation of the circulating viruses which is carried out throughout the season might give an early indication of the existence of a significant mismatch so that clinicians can be made aware

A PHE study found that the 2014/15 mid-season estimates of flu vaccine, which is used primarily in adults, provided low protection against flu infection due to one particular subtype, H3N2. This was because a drifted strain of flu A(H3N2) emerged in 2014/15 after the 14/15 A(H3N2) vaccine strain had been selected in February 2014. This resulted in a mismatch between the vaccine strain and the main A(H3N2) strain that circulated in the UK. The study was based on the results from 1,314 patients presenting in primary care across the UK and found that vaccine effectiveness in preventing laboratory confirmed influenza was estimated to be 3% overall (with an

upper 95% confidence interval of 35%)[12]. This compares to approximately 50% vaccine effectiveness that has typically been seen in the UK over recent years.

Trivalent live attenuated influenza vaccine has been shown to provide a higher level of protection for children than trivalent inactivated influenza vaccine[13]; a recent meta-analysis suggested an efficacy against confirmed disease of 83% (95% confidence interval 69-91).[14, 15, 16] Since 2014/15 the child flu programme has offered a quadrivalent LAIV rather than a trivalent vaccine. This should provide better protection against circulating influenza B strains because it contains two influenza B viruses (compared to one in trivalent vaccines). Vaccine effectiveness data for LAIV in 2014/15 is not yet available.

Vaccine supply

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.[17]

It is recommended that trivalent vaccines for use in the 2015/16 influenza season (northern hemisphere winter) contain the following:

- an A/California/7/2009 (H1N1)pdm09-like virus
- an A/Switzerland/9715293/2013 (H3N2)-like virus
- a B/Phuket/3073/2013-like virus

It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus.

The WHO recommendation includes changing the H3N2 component to include a vaccine strain to better match the drifted H3N2 strain seen in the Northern Hemisphere 2014/15 flu season.

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 all eligible populations apart from children, providers remain responsible for ordering vaccines directly from manufacturers. 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 across the UK 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 minimise the impact, for example advising GPs to prioritise particular clinical risk groups over other eligible groups.

All flu vaccines for children are purchased centrally by PHE. This includes vaccine for the national offer to all two- to four-year-old children in general practice and those children of school year 1 and 2 age, and for children in risk groups aged six months to under 18 years.

For children in risk groups under 18 years of age where Fluenz Tetra is contraindicated, suitable inactivated influenza vaccines will be provided centrally and should be offered. Fluenz Tetra and inactivated injectable vaccines can be ordered through the ImmForm website: www.immform.dh.gov.uk.

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.[18]

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 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 vaccine uptake data

Vaccine uptake information in 2015/16 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
- children of school years 1 and 2 age

Flu vaccine uptake will be collected via the web-based ImmForm system for vaccinations given from the 1 September 2015 until the 31 January 2016. The GP patient weekly and monthly vaccine uptake data will be extracted automatically onto ImmForm from over 90%[19] of GP practices.

The weekly GP patient vaccine uptake collection will start the first week of September and will continue until early February. Weekly data provides representative estimates of national uptake by GP patient groups and will be available for each CCG and local NHS England teams.

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 local NHS England teams. 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.[20]

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

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.[21]

Assurance of general practice

Local NHS England teams will monitor the enhanced services that GP practices provide for flu vaccination to ensure that services comply with the specifications for at risk patients and for those aged two, three and four years[22]. Local NHS England teams will need assurance that providers have robust implementation plans in place to meet or exceed the vaccine uptake aspirations for 2015/16 and that they have the ability to identify eligible 'at risk' patients and two-, three- and four-year-olds.

To support this process, a checklist is attached at Appendix E of the steps that GP practices can reasonably be expected to take to improve uptake of flu vaccine among their eligible patients.

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. Local authorities will provide independent 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-groups of the health and wellbeing boards. They can also assist by promoting flu vaccination among frontline social care workers, offering flu vaccination through occupational health services for those staff who are directly employed and encouraging external providers to also offer flu vaccination for staff. 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 director of public health also needs to work with local NHS England teams to ensure strategic commissioning.

Antiviral medicines

Influenza antivirals form part of the programme for protection of people who are at increased risk of severe illness due to flu. NICE has reviewed its guidance on the use of flu antivirals in seasonal influenza and it remains unchanged[23]. Influenza antivirals may only be prescribed in primary care when influenza is circulating in the community and the CMO/CPhO letter has been sent out. Prescribing in secondary care and in the event of outbreaks of flu is described separately.

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 XVIIIB of the Drug Tariff.[24]

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 in primary care 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 2014/15 when flu vaccine effectiveness was limited, the early use of antivirals to treat and help prevent serious cases of flu in vulnerable patients was particularly important and remains so every flu season.

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.

Prescribing in secondary care

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.

Prescribing in outbreaks

PHE has published recommendations for the antiviral treatment and prophylaxis of influenza drawing on guidance already issued by the National Institute for Health and Care Excellence (NICE), DH and WHO[25]. This guidance should be used in secondary care for any patient where influenza is suspected or confirmed at any time, in primary care it should only be used once DH issues notice that influenza is circulating and that antiviral agents can be used. However, antivirals may be used in primary care outside the periods where national surveillance indicates that influenza virus is circulating in the community, in certain situations, for example, for the treatment of laboratory confirmed influenza outbreaks in 'at-risk' people who live in long-term care homes.

Liaison with manufacturers and pharmacy organisations

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. Before 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 so community pharmacies can be pre-warned that they may receive prescriptions for antiviral medicines in the near future, 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
- 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[26]. 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.

Communications

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 is to be formed for 2015/16 and will include communication representatives from PHE national and regional press offices, NHS England, NHS Employers, DH, and the Department for Education, to help develop a co-ordinated and strategic approach to flu communications. A communications strategy will be developed to support this Flu Plan and to provide communications colleagues in partner organisations with information and resources ahead of the 2015/16 winter flu season for use at national and local level. Meetings of the partners' communications teams are also planned to review the 2014/15 delivery, including the impact of publicity surrounding the low vaccine effectiveness, and refine the 2015/16 communications strategy as required.

While communications will take place within an overarching flu communications strategy, 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 used to maximise impact and ensure that messages 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 children of school Year 1 and 2 age. This will also mean effective communications at national and local level with education partners and schools (eg local authorities and academy chains) and schools (eg head teachers and governors).

The following communication mechanisms and resources 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 regularly, sometimes during a flu season. 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.

NICE guidance on influenza antivirals

The NICE guidelines “Amantadine, oseltamivir and zanamivir for the treatment of influenza” published in 2009 set out the circumstances under which Oseltamivir and zanamivir are recommended for the treatment of flu in adults and children. Amantadine is not recommended for the treatment of flu.

Annual Flu Letter

Every year an Annual Flu Letter[27] sets out information about the forthcoming annual seasonal flu vaccination programme. The information in the letter includes:

- groups to be immunised (including which children should be offered the vaccine)
- available vaccines and ordering vaccines for children
- data collection arrangements
- advice on increasing vaccine uptake
- the enhanced service specification and assurance arrangements
- a GP practice checklist
- information about prescribing and supply of antiviral medicines

PHE weekly national 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 in the flu surveillance section. The reports can be found at: www.gov.uk/government/publications/weekly-national-flu-reports.

PHE guidance on the use of influenza antivirals for outbreaks

PHE has published recommendations for the antiviral treatment and prophylaxis of influenza drawing on guidance already issued by the NICE, DH and the WHO[28]. This guidance should be used in secondary care for any patient where influenza is suspected or confirmed at any time, in primary care it should only be used once DH issues notice that influenza is circulating and that antiviral agents can be used.

However, antivirals may be used in primary care outside the periods where national surveillance indicates that influenza virus is circulating in the community, in certain situations, for example, for the treatment of laboratory confirmed influenza outbreaks in ‘at-risk’ people who live in long-term care homes.

Press briefings

The CMO 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

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). Template letters will be available for GP practices to use to invite at risk patients and those aged two to four years for flu vaccination.

Ahead of the flu season, NHS branded patient information materials will be reviewed and developed, tailored for different eligible groups. These materials, along with the template letters, will be available at: www.gov.uk/government/collections/annual-flu-programme and free copies of the leaflets will be available to order through the Prolog Publications Orderline: www.orderline.dh.gov.uk/ecom_dh/public/home.jsf.

Any centrally produced communications materials such as leaflets will also be made available on NHS Choices, DH and PHE websites. Any additional resources for NHS

communicators will be made available via NHS Comms Link for regional and local use.[29]

We will also be working very closely with partners including NHS Employers, the Local Government Association, the Department for Education, professional health bodies and the network of health charities to ensure that key messages are transmitted effectively through their networks.

The ‘Flu Fighters’ campaign

NHS Employers has run a ‘Flu Fighters’ campaign to support flu vaccination of healthcare workers in previous years, and their resources have been available to order from their website at: www.nhsemployers.org/campaigns/flu-fighter.

National marketing campaign

The 2014/15 marketing campaign (‘It’s free because you need it’) is being evaluated and the lessons will inform any campaign plans for 2015/16. Further information will be issued in due course.

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, for example by adding a respiratory and hand hygiene footnote to all patient letters, emails, electronic booking systems and so forth.

The respiratory and hand hygiene campaign ‘Catch it, Kill it, Bin it’ may be launched during the flu season.

The annual cycle of the flu programme

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

Preparations

- **November to March:** Vaccine orders placed with suppliers for eligible patients aged 18 and over
- **December:** Section 7A service specifications for delivery of the flu immunisation programme published
- **February to September**: Manufacture of vaccine
- **February:** Enhanced service specifications for flu immunisation programme published
- **February:** WHO announces the virus strains selected for the next season's flu vaccine for the northern hemisphere
- **February/March:** Annual flu letter is sent to the NHS and local government setting out key information for the autumn's immunisation programme
- **March to June:** Publication of the revised influenza chapter of the Green Book (although this can be revised at any time, sometimes during a flu season)
- **April to June:** Liaison with manufacturers to assure the availability of vaccine
- **April to June:** Assurance that primary care providers have the ability to identify all eligible patients
- **June:** Revised flu information leaflets and GP template letters made available
- **August/September:** Communications and guidance about vaccine uptake data collections issued
- **August/September:** Local NHS England 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 to March:** DH in regular contact with manufacturers of antiviral medicines and wholesalers to ensure enough antiviral medicines in the supply chain

Flu vaccination campaign

- **September/October**: Flu vaccine for children available to order through ImmForm
- **October**: PHE flu marketing campaign launched (if applicable)
- **September to February:** Suppliers deliver vaccines to GP practices, community pharmacies, and PHE central stock. GPs, community pharmacists and other providers begin vaccinating eligible patients and staff against flu as soon as vaccine is available
- **September to February:** Weekly GP patients and monthly vaccination uptake 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 to 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 to February:** The NHS implements winter pressures co-ordination arrangements
- **October to February:** A respiratory and hand hygiene campaign may be considered
- **November to February:** Monthly GP patient flu uptake and the healthcare worker flu uptake collection commence for data submissions and closes early February.
- **January/February:** date by which all supplies of Fluenz Tetra will have expired.
- **March to 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

Extension of the programme to children of school years 1 & 2 age

This extension of the programme will be commissioned locally and delivery mechanisms will vary. Key milestones will be determined locally with the overall objective:

- **September/October:** Children of school Years 1 and 2 age start to be offered flu vaccination

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 H 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 G 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 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

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 should 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. GP practices and other providers should 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.

Some local NHS England teams are commissioning pharmacists to provide flu vaccination for at-risk groups, as the majority of these people visit their community pharmacies regularly to collect repeat prescriptions. 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 extension of the flu vaccination programme to children 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).

Some children in clinical risk groups may be offered Fluenz Tetra alongside their peers as part of local provision for children either of school Years 1 and 2 age or in the primary school-aged geographic pilots. If a child in an at-risk group does not receive flu vaccination through this route, then they should be offered it in general practice. For instance, a child may miss out because of being absent from school on the day the vaccination was offered or because the child is contraindicated to Fluenz Tetra and the local service provider does not offer inactivated flu vaccines.

Where a child is vaccinated but not by their GP, it is important that the vaccination information is provided to the practice for the timely update of clinical records.

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.

Flu vaccination for pregnant women may be offered in general practice, through midwifery services, or through community pharmacies where relevant. 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 or community pharmacy. Where a pregnant woman is vaccinated but not by her GP, it is important that the vaccination information is provided to the practice as soon as possible for the timely update of the clinical records. See Appendix F 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.

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 for those organisations with one. 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 runs 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.[30]

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, community pharmacies and other locations, visit the Carers Trust website for professionals.[31]

Children

For the children's flu vaccination programme there must be a 100% offer of immunisation to eligible children. Providers and commissioners will be required, if asked, to demonstrate that such an offer has been made. A minimum uptake of 40% has been shown to be achievable in pilots conducted to date. We would expect uptake levels between 40-60% to be attained. Uptake levels should be consistent across all localities and sectors of the population.

Commissioning services for those with particular needs

In addition to those patients who can attend a surgery or clinic to receive a vaccination, local NHS England 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.

Appendix A. 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 and use community pharmacists as first port of call for early symptoms

Antiviral medicines

Antiviral medicines can 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 out 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.

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 before the supply of the 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 Medicines and Healthcare products Regulatory Agency (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

1. In 2015/16, flu vaccinations will be offered at NHS expense to the following groups:

    - people aged 65 years or over (including those becoming age 65 years by 31 March 2016)
    - people aged from 6 months to less than 65 years of age 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 five
        - chronic liver disease
        - chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability
        - diabetes
        - splenic dysfunction
        - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
    - all pregnant women (including those women who become pregnant during the flu season)
    - all those aged two, three, and four years (but not five years or older) on 31 August 2015 (ie date of birth on or after 1 September 2010 and on or before 31 August 2013) through general practice[32]
    - all children of school years 1 and 2 age through locally commissioned arrangements[33]
    - primary school-aged children in areas that participated in primary school pilots in 2014/15
    - 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
    - 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

2. The list above is not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease

that a patient may have, as well as the risk of serious illness from flu itself. Flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above

3. Also recommended to be vaccinated as part of an employer's occupational health obligation:

   - health and social care workers with direct patient/service user contact

4. The JCVI has also advised that morbidly obese people (defined as BMI 40+) could also benefit from a flu vaccination. This has not been included as part of the GP contract in the 2015/16 DES. Many in this patient group will already be eligible due to complications of obesity that place them in another risk category. Practices will need to use clinical judgement to decide whether to vaccinate this group of patients, but vaccinations for morbidly obese patients with no other recognised risk factor will not attract a payment under the DES in 2015/16. The inclusion of this patient group into the flu programme from 2016/17 is currently under consideration.

5.

Healthcare practitioners should refer to the Green Book influenza chapter for further detail about clinical risk groups included in the national flu immunisation programme. This is regularly updated, sometimes during the flu season, and can be found at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book. Further information on the service specification for delivery of the seasonal influenza immunisation programme and the seasonal influenza programme for children can be found at: www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016.

Appendix D. 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 long term healthcare settings.[34, 35, 36, 37]

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.[38] 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 increase rates of vaccination among frontline staff, which is an important part of infection control.

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 produces 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.[39]

Additionally, DH will continue to work with PHE, NHS England, NHS Trust Development Authority (NHS TDA) and Monitor to agree action to ensure trusts take the necessary action to increase uptake rates.

Provision of the vaccine for health and social care workers

The code of practice on the prevention and control of infections and related guidance[40] 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).[41] Employers should make vaccines available free of charge to employees if a risk assessment indicates that they are needed.[42] This includes GP practices that 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 Health Protection Agency confirmed that the infection was mainly spread by healthcare workers[43].

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, and ambulance crew
- 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.[44]

Appendix E. 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.[45] GP practices are encouraged to review their systems in the light of the checklist.

General

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

Registers and information

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.

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.

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,[46] ideally using the automated function, and on uptake among healthcare workers in primary care using the ImmForm data collection tool.

Meeting any public health targets in respect of such immunisations

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

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 will revise template letters for practices to use which will be available nearer the time from the GOV.UK website.[47]

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

Flu vaccination will start as soon as practicable after receipt of the vaccine in the practice so that the maximum number of patients are vaccinated as early as possible to ensure they are protected before flu starts to circulate.

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.

The GP practice will offer flu vaccination in clinics and opportunistically.

The GP practice and/or CCG will collaborate with other providers such as community or health and social care trusts, to identify and offer flu vaccination to residents in care homes, nursing homes and house-bound patients.

Appendix F. Pregnant women

Rationale and target groups

There is good evidence that pregnant women are at increased risk from complications if they contract flu.[48, 49] In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight[50, 51] and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy.[52] Furthermore, a number of studies shows that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.[53, 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 offer the vaccine to pregnant women

The ideal time for flu vaccination is before flu starts circulating. However, even after flu is in circulation vaccine should continue to be offered to groups such as newly pregnant women. Clincians 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 vaccination 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 exists including running flu vaccination clinics alongside the midwifery service, where cold storage facilities exist. Local NHS England teams will explore ways of commissioning midwifery services to provide flu vaccination or linking midwifery services with GP practices or community pharmacies where relevant. If arrangements are put in place where midwives or community pharmacies 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.

Appendix G. Stages of activity

Activity that would be undertaken in Stage 1	
Stage 1	• 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 influenza-like illnesses, 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 in Stage 2	
Stage 2	• 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 by PHE 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 in Stage 3	
Stage 3	• 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 by PHE 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 H. Potential scenarios

The table below gives examples of factors affecting the DH, PHE, NHS England and the 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.	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 or three other strains of flu covered by the vaccine. 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

	Event	Action
		CMO in the use of this discretion. 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. PHE considers launching the respiratory and hand hygiene campaign.
	Issue over safety of vaccine emerges.	The 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.

	Event	Action
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.	Local NHS England teams, PHE, DH and the NHS Chief Executive keep under review the need to trigger strategic command arrangements for the NHS, as per the 'NHS Commissioning Board Command and Control Framework'[lix].
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.

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