Department of Health | Public Health England | NHS England

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NHS England Area Directors
Accountable Officer of Clinical Commissioning Groups
General Practitioners
Screening and Immunisation Leads
Directors of Public Health
Local Authority Chief Executives

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Dear Colleague,

The flu immunisation programme 2013/14

This letter is the first of two letters about the flu immunisation programme for the 2013/14 winter. This one relates to planning for the existing flu programme. A second letter will follow with details about the extension of the flu immunisation programme to children in 2013/14.

This annual flu letter has the support of the Department of Health's Chief Medical Officer, Chief Pharmaceutical Officer and Director of Nursing.

The national immunisation programme in 2013-14

Following advice and recommendations by the Joint Committee on Vaccination and Immunisation (JCVI), and in line with our standing commitments on patient rights to implement such recommendations under the NHS Constitution, a series of changes to England's national immunisation programme will be introduced over the course of 2013/14. A table providing the full details of these changes is at ***Annex I*** but, in summary they are as follows:

- **MenC:** From June 2013, changes to the current schedule for administering the MenC conjugate vaccine. The second priming dose currently given at four months will be replaced by a booster dose given in adolescence. The initial change will be to cease giving the four month dose from 1 June 2013.
- **Rotavirus:** From July 2013, the introduction into the childhood immunisation schedule of a vaccine to protect babies against rotavirus.
- **Shingles:** From September 2013, the introduction of a shingles vaccine for people aged 70 years (routine cohort) and 79 years (catch-up cohort) to protect against herpes zoster.
- **Childhood Flu:** The existing flu immunisation programme will be extended over a number of years to include all children aged two to 16 inclusive. In autumn 2013, immunisation will be offered to a limited age range of pre-school-aged children. Full details will be published in a separate letter.

There are separate letters about each of the changes in England in relation to rotavirus, MenC and shingles. Further details about the flu immunisation programme for 2013/14 are contained in this letter.

The flu immunisation programme 2013/14

We would like to take this opportunity to thank those in the NHS and in social care for their hard work on the flu immunisation programme last winter. The purpose of this letter is to provide you with key information about the flu immunisation programme for winter 2013/14.

Last winter was another quiet flu season for England. However, some other countries experienced more severe flu, a reminder that flu can be dangerous and remains highly unpredictable. We must therefore guard against complacency and continue to improve vaccine uptake rates.

For ease of use, the information is set out in the attached annexes as follows:

Annex A Groups recommended to receive flu vaccine

Annex B GP practice checklist

Annex C Pregnant women

Annex D Health and social care workers

Annex E Improving uptake and data collections

Annex F Vaccine virus strains and available vaccines

Annex G Vaccine supply and strategic reserve

Annex H Contractual arrangements, service reviews and funding

Annex I Summary of planned changes to the immunisation schedule in 2013/14

Vaccine uptake aspirations 2013/14

Last year, the NHS was asked to plan to reach uptake of 70% for people aged under 65 years in clinical risk groups, as the second of a three year trajectory to reaching uptake of 75% by 2013/14. This is important because people in these groups are at increased risks from severe complications of flu. It is disappointing that overall vaccine uptake for the under 65 years in clinical risk groups has apparently stalled and has only been around 50% for several years now. Over 100 practices, however, managed to reach coverage of 75% or above in at-risk groups. Furthermore, GP practices and other providers need to be commended for the larger absolute number of patients vaccinated in 2012/13 compared to 2011/12 (see table below). This workload is not reflected in comparisons of percentages because more patients now fall into one of the risk groups.

Absolute numbers of patients vaccinated comparing 2011/12 with 2012/13

Target groups for vaccination	Number of patients vaccinated 2011/12	Number of patients vaccinated 2012/13
Aged 65 years and over	**6,764,364**	**6,881,636**
Aged under 65 years in a clinical risk group (excluding pregnant women without other risk factors and Carers)	**2,718,268**	**2,782,745**
All pregnant women*	**195,031**	**287,561**

*All pregnant women includes those NOT in a clinical risk group and those IN a clinical risk group.

In 2013/14 we are asking local areas to ensure that they offer flu vaccine to ***everyone*** at risk so we

- reach or exceed 75% uptake for people aged 65 years and over; and
- reach or exceed 75% uptake for people under 65 years in risk groups, including pregnant women

We need new ideas and new strategies to deliver these levels of achievement. GP practices should strive to achieve this by ensuring that 100% of all those who fall into a risk group eligible for the vaccine are offered it. NHS England will liaise with local partners to support practices with low uptake.

NHS reforms

The new structure of the NHS and public health should enable innovative approaches to improving flu vaccine uptake. The creation of Public Health England (PHE) which incorporates amongst other functions those of the Health Protection Agency, will provide a centre of expert advice and monitoring of public health, including immunisation. NHS England now has responsibility for commissioning the flu programme and GPs continue to play a key role. NHS England area teams will ensure that robust plans are in place locally to identify all eligible patients, that sufficient vaccine has been ordered by practices to meet their needs, and that high vaccination uptake levels are reached in the clinical risk groups. Clinical Commissioning Groups (CCGs) will have a duty of quality improvement and this extends to primary medical services delivered by GP practices such as immunisation and screening services.

At a local level the Head of Public Health and Screening and Immunisation Lead in discussion with local authority Directors of Public Health (DsPH), CCGs, PHE Centres, providers, and other key stakeholders should agree local arrangements to develop multi-agency approaches to improving outcomes from screening and immunisation services. Local authority DsPH have a duty to ensure plans are in place to protect their population including through screening and immunisation. They will provide independent scrutiny and challenge of the plans of NHS England, PHE and providers. PHE will support DsPH in local authorities in their role as leaders of health locally through the provision of data and information on performance against standards. DsPH will need to assure themselves that the combined plans of all these

organisations will deliver effective screening and immunisation programmes to their local populations.

Vaccine ordering

The majority of flu vaccinations are given in primary care and general practice is key to the success of the flu vaccination programme. It remains the responsibility of GPs to order sufficient flu vaccine for eligible patients in 2013/14.

The groups of people recommended to be vaccinated against flu are set out in Annex A. GP practices are reminded that ordering from more than one supplier is recommended particularly in the light of last year's experience when disruption in the supply of vaccine from one manufacturer led to localised vaccine shortages. GP practices should also order appropriate vaccines for those with egg allergy.

Given that some flu vaccines are restricted from use in particular age groups, the Summary of Product Characteristics (SPC) for individual products should always be referred to when ordering and administering vaccines.

Further details about the extension to children of the flu immunisation programme for 2013/14 will be covered in a joint DH, NHS England, and PHE letter in the coming weeks. At this stage we recommend that practices purchase vaccine for their at risk groups as per usual, including for at risk children. Vaccine for the extension to healthy children will be purchased and supplied centrally.

The live attenuated influenza vaccine Fluenz® is the vaccine of choice for children in clinical risk groups aged 2-17 years as it has been shown to provide a higher level of protection for children than inactivated influenza vaccine. It is recommended that GP practices order this vaccine for children in clinical at-risk groups; however it is unsuitable for children under the age of 2 years and for those over the age of 2 years with contraindications such as severe immunodeficiency or egg allergy. GPs should ensure they have ordered sufficient supplies of suitable alternative vaccines for children who should not be given Fluenz®.

Programme assurance

Assurance of the planning and delivery of the flu immunisation programme is vital to its success. Area Team leads will assure that:

- the necessary structures are in place to assess the performance of providers against flu vaccination plans for 2012/13 in order to help planning for 2013/14.
- robust flu vaccination plans are in place to meet or exceed the vaccine uptake aspirations for 2013/14. To support this process, a checklist is attached at Annex B of the steps that GP practices can reasonably be expected to take to improve uptake of flu vaccine among their eligible patients.
- adequate amounts of vaccine have been ordered, noting that extra vaccine will be needed for higher levels of coverage, and anticipating that the target population will be greater.
- sufficient supplies of certain flu vaccines have been ordered for patients who require particular flu vaccines due to their age or because of contraindications.
- arrangements are in place to ensure the collection and provision of data on immunisations to support the local and national monitoring of the delivery of the programme and flu vaccine uptake (see Annex E).

Area teams will be expected to report on the performance and outcome of the programme as part of the responsibilities that NHS England has agreed for the seasonal flu programme under a Section 7A agreement with the Secretary of State for Health. See Annex H for further details about NHS England's assurance responsibilities.

Pregnant women

Pregnant women are particularly vulnerable to severe complications of flu, and last year saw marked improvement in uptake of flu vaccine in pregnant women. This is thanks to the maternity services, midwives and GP practices who worked hard to support the programme. Flu vaccination uptake may also have increased because pregnant women were being offered it at the same time as the pertussis vaccination which was introduced in October 2012. This is a temporary programme which will be kept under review by the JCVI.

Recent experience suggests that the best uptake of flu vaccine to pregnant women is found where maternity services both encourage and provide it. Maternity services are encouraged to provide flu vaccine as part of routine care for all pregnant women. Where a pregnant woman is vaccinated but not by her GP, it is important that the information is provided to the GP for timely update of her clinical record.

Health and social care workers

We would like to re-emphasise the importance of flu vaccination of health and social care workers with direct patient / client contact. Health and social care workers must protect their patients and this is an important way to help reduce the risk of patient infections. Indeed, the General Medical Council's 2013 good medical practice guidance for doctors includes under bullet 29 the following statement: "You should be immunised against common serious communicable diseases (unless otherwise contraindicated)"[1]. There is always pressure on the NHS and social care services during the winter. Vaccinating staff against flu is an important infection control measure as part of the annual winter planning process to ensure the NHS and social care are as resilient as possible.

In 2012/13 vaccine uptake in health and social care workers remained at a similar level to the previous year at 45.6%. This level of uptake is still below expectations and it is important that we see an increase this year. NHS Employers produce guidance and material to support Trusts in delivering their own healthcare worker campaigns and provide advice to those running vaccination campaigns at local level. The material can be accessed via the internet[2].

Publicity and information materials

An updated patient leaflet will be available from the immunisation page of the Gov.uk website before the start of the flu immunisation programme[3]. Hard copies of the leaflet can be ordered by GP surgeries through Prolog.

[1] www.gmc-uk.org/publications/index.asp
[2] http://www.nhsemployers.org/HEALTHYWORKPLACES/SEASONALFLUCAMPAIGN/Pages/seasonal-flu-campaign.aspx
[3] https://www.gov.uk/government/organisations/public-health-england/series/immunisation

The Green Book

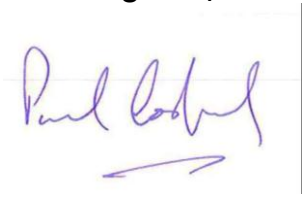
The Green Book, *Immunisation against Infectious Disease*[4], provides guidance for healthcare workers on administering the flu vaccine. PHE will publish an updated influenza chapter of the Green Book on the Gov.uk website ahead of the flu season. This will include detailed information about the way that the available flu vaccines should be administered.

The Seasonal Flu Plan

An updated plan for 2013/14 will be published soon on the Gov.uk website. We encourage you to read it and make use of the helpful advice it contains.

Yours sincerely

Dame Barbara Hakin
NHS England, Chief Operating Officer and Deputy Chief Executive



Dr Paul Cosford
Public Health England, Medical Director and Director of Health Protection

Dr Felicity Harvey
Department of Health, Director General, Public Health

For further information please contact: Angela Edwards, Seasonal Flu Lead, Public Health England at immunisation@phe.gov.uk

This letter and the updated flu plan for 2013/14 will also be available at: www.gov.uk/government/organisations/public-health-england/series/immunisation

[4] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

Annex A - Groups recommended to receive flu vaccine

Flu vaccine should be offered to the eligible groups set out in the table below, which continues overleaf.

Eligible groups	Further detail
All patients aged 65 years and over	"Sixty-five and over" is defined as those aged 65 years and over on 31 March 2014 (i.e. born on or before 31 March 1949).
Chronic respiratory disease aged six months or older	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease.
Chronic heart disease aged six months or older	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged six months or older	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged six months or older	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease aged six months or older	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised, due to neurological disease (e.g. polio syndrome sufferers). Clinicians should consider on an individual basis the clinical needs of patients including individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes aged six months or older	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic medicines, diet controlled diabetes.

Immunosuppression aged six months or older	Immunosuppression due to disease or treatment. Patients undergoing chemotherapy leading to immunosuppression. Asplenia or splenic dysfunction, HIV infection at all stages. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age) or for children under 20kg a dose of 1mg or more per kg per day. It is difficult to define at what level of immuno-suppression a patient could be considered to be at a greater risk of the serious consequences of flu and should be offered flu vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine. Consideration should also be given to the vaccination of household contacts of immunocompromised individuals, i.e. individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable. This may include carers (see below).
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).
People in long-stay residential or homes	Vaccination is recommended for 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.
Carers	Those who are in receipt of a carer's allowance, or those who are the main carer, or the carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.
Health and Social Care staff	Professional health and social care workers who are in direct contact with patients/clients should be vaccinated by their employer as part of an occupational health programme

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.

Annex B – GP practice checklist

The checklist below is based upon the findings from a study examining the factors associated with higher vaccine uptake in general practice[5]. The checklist highlights what works effectively and should be regarded as good practice. GP practices are encouraged to look at their own practice and review their systems in the light of the checklist below, which suggests that the following should be in place:

General

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

Registers and information

2. The GP practice has a register that can identify all pregnant women and patients in the under 65 years at risk groups or aged 65 years and over.[7]

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

4. The GP practice will submit accurate data on the number of its patients eligible to receive flu vaccine and the flu vaccinations given to its patients on ImmForm (www.immform.dh.gov.uk).

Meeting any public health targets in respect of such immunisations

5. The GP practice will/has ordered sufficient flu vaccine taking into account past and planned performance, expected demographic increase, and to ensure that everyone at risk is offered the flu vaccine. It is recommended that vaccine is ordered from more than one supplier.

Robust call and recall arrangements

6. Patients recommended to receive the flu vaccine will be contacted directly (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.

7. The GP practice will follow-up with patients who do not respond or fail to attend scheduled clinics or appointments.

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[5] Dexter, L. et al (2012) Strategies to increase influenza vaccination rates: outcomes of a nationwide cross-sectional survey of UK general practice. http://bmjopen.bmj.com/content/2/3/e000851.full

[7] Immunisation of carers and pregnant women are not covered by the national DES and will be subject to local agreement

Maximising uptake in the interests of at-risk patients

8. Flu vaccination will start as soon as practicable after receipt of the vaccine so that the maximum number of patients are vaccinated as early as possible prior to the flu season (i.e. by the end of October), to ensure they are protected before flu starts to circulate.

9. The GP practice will collaborate with midwives to offer and provide flu vaccination to pregnant women and to identify, offer and provide to newly pregnant women as the flu season progresses.

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

Annex C – Pregnant women

Rationale and target groups

There is good evidence that pregnant women are at increased risk from complications if they contract flu.[6,7] In addition, there is evidence that flu during pregnancy may be associated with premature birth and smaller birth size and weight[8,9] and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with influenza infection during pregnancy.[10] Furthermore, a number of studies show that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.[11,12,13,14]

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.[15]

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

When to stop offering the vaccine to pregnant women

Flu vaccination is usually carried out between October and January and it would be unusual to carry on vaccinating after that date. However, clinicians should apply clinical judgement to assess the needs of an individual patient, taking into account the level of flu-like illness in their community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.

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[6] Neuzil KM, Reed GW, Mitchel EF *et al.* (1998) Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. *Am J Epidemiol.* **148**: 1094-102

[7] Pebody R *et al.* (2010) Pandemic influenza A (H1N1) 2009 and mortality in the United Kingdom: risk factors for death, April 2009 to March 2010. *Eurosurveillance* **15**(20): 19571.

[8] Pierce M, Kurinczuk JJ, Spark P *et al.* (2011) Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study. *BMJ.* **342**:d3214.

[9] McNeil SA, Dodds LA, Fell DB *et al.* (2011) Effect of respiratory hospitalization during pregnancy on infant outcomes. *Am J Obstet Gynecol.* **204**: (6 Suppl 1) S54-7.

[10] Omer SB, Goodman D, Steinhoff MC *et al.* (2011) Maternal influenza immunization and reduced likelihood of prematurity and small for gestational age births: a retrospective cohort study. *PLoS Med.* **8**: (5) e1000441.

[11] Benowitz I, Esposito DB, Gracey KD *et al*. (2010) Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants. *Clin Infect Dis.* **51**: 1355-61.

[12] Eick AA, Uyeki TM, Klimov A *et al*. (2010) Maternal influenza vaccination and effect on influenza virus infection in young infants. *Arch Pediatr Adolesc Med*. **165**: 104-11.

[13] Zaman K, Roy E, Arifeen SE *et al*. (2008) Effectiveness of maternal influenza immunisation in mothers and infants. *N Engl J Med.* **359**: 1555-64.

[14] Poehling KA, Szilagyi PG, Staat MA *et al.* (2011) Impact of maternal immunization on influenza hospitalizations in infants. *Am J Obstet Gynecol.* **204**: (6 Suppl 1) S141-8.

[15] Tamma PD, Ault KA, del Rio C, Steinhoff MC *et al*. (2009) Safety of influenza vaccination during pregnancy. *Am. J. Obstet. Gynecol*. **201**(6): 547-52.

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

Area teams will explore ways of linking midwifery services with GP practices so midwives can raise awareness of the flu vaccine among pregnant women and could administer the flu vaccine at ante-natal visits through Patient Group Directions. If arrangements are put in place where midwives administer the flu vaccine, it is important that the patient's GP practice is informed so their records can be updated accordingly, and included in vaccine uptake data collections.

Annex D – Health and social care workers

Flu outbreaks can arise in health and social care settings with both staff and their patients/clients being affected when flu is circulating in the community. Employers are responsible for ensuring that arrangements are in place for the vaccination of their health and social care workers with direct patient contact. It is important that health and social care workers protect themselves by having the flu vaccine, and, in doing so, they reduce the risk of spreading flu to their patients, clients, colleagues and family members. Uptake of the flu vaccine in healthcare workers with direct patient contact was 45.6% in 2012/13. Although this represents an increase in uptake over the last few seasons, there is still room for further improvement.

Vaccination of healthcare workers against flu significantly lowers rates of flu-like illness, hospitalisation and mortality in older people in healthcare settings.[16,17,18,19] Vaccination of staff in social care settings may provide similar benefits. Flu immunisation of healthcare workers with direct patient contact and social care staff is likely to reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity that may not respond well to immunisation.

Vaccination of health and social care workers also helps reduce the level of sickness absences and will contribute to keeping the NHS and care services running. This is particularly important in the face of winter pressures.

It is the responsibility of the NHS and social care bodies to ensure, as 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. Trusts/ employers should ensure that health and social care staff directly involved in delivering care are encouraged to be immunised and that processes are in place to facilitate this.

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

- clinicians, midwives and nurses, paramedics and ambulance drivers
- occupational therapists, physiotherapists and radiographers

[16] Potter J, Stott DJ, Roberts MA, Elder AG, O'Donnell B, Knight PV and Carman WF (1997) The influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *Journal of Infectious Diseases* **175**: 1-6.
[17] Carman WF, Elder AG, Wallace LA, McAulay K, Walker A, Murray GD, Stott DJ (2000) Effects of influenza vaccination of healthcare workers on mortality of elderly people in long term care: a randomised control trial. *The Lancet*; **355**: 93-7.
[18] Hayward AC, Harling R, Wetten S, Johnson AM, Munro S, Smedley J, Murad S and Watson JM (2006) Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *British Medical Journal* doi:10.1136/bmj.39010.581354.55 (published 1 December 2006)
[19] Lemaitre M, Meret T, Rothan-Tondeur M, Belmin J, Lejonc J, Luquel L, Piette F, Salom M, Verny M, Vetel J, Veyssier P and Carrat F (2009) Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster randomised trial. *Journal of American Geriatric Society* **57**:1580-6.

- primary care providers such as GPs, practice nurses, district nurses and health visitors
- social care staff working in care settings, and
- pharmacists, both those working in the community and in clinical settings.

Students and trainees in these disciplines and volunteers who are working with patients should also be included. This is not an exhaustive list and decisions to provide immunisation should be made on the basis of a local risk assessment as described in *Immunisation against infectious disease.*[20] Employers need to make vaccines available free of charge to employees if a risk assessment indicates that they are needed.[21]

Vaccine uptake data collection of healthcare workers

Approval for a mandatory collection will be sought from the Review of Central Returns (ROCR). Further details about where the guidance about specific immunisation programmes and uptake data collections will be published will be set out in Vaccine Update.[22]

PHE will be responsible for monthly collections of flu vaccine uptake data over four months during the 2013/14 flu season. Guidance will be provided to Trusts and through area teams to all those involved in the collection and reporting of these data. Data will be published on the PHE website.

Area Teams can use their own methods of collecting information from GP practices so as to best meet the needs of their area. The recommended method of collecting HCW data from GPs would be through the ImmForm data entry tool. It is important to note that this data entry tool is not a route for GP practices to submit data directly to the PHE and thus bypass Area Teams – it is the responsibility of the Area Team to submit the data collected via the data entry tool; this application is not monitored by PHE and no data are extracted from it by PHE. This data entry tool is one of many different options for Area Teams to collect staff flu vaccination data from GP practices and other organisations that carry out work on behalf of the NHS.

[20] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book
[21] http://www.hse.gov.uk/coshh/basics/assessment.htm
[22] https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update

Annex E – Improving vaccine uptake and data collection

In winter 2012/13 the estimated uptake of the flu vaccine among those aged 65 years and over was 73.4% - just short of the World Health Organisation target of 75%. Uptake among people aged under 65 with clinical conditions which put them more at risk from the effects of flu was 51.3%. Uptake among pregnant women was 40.3%.

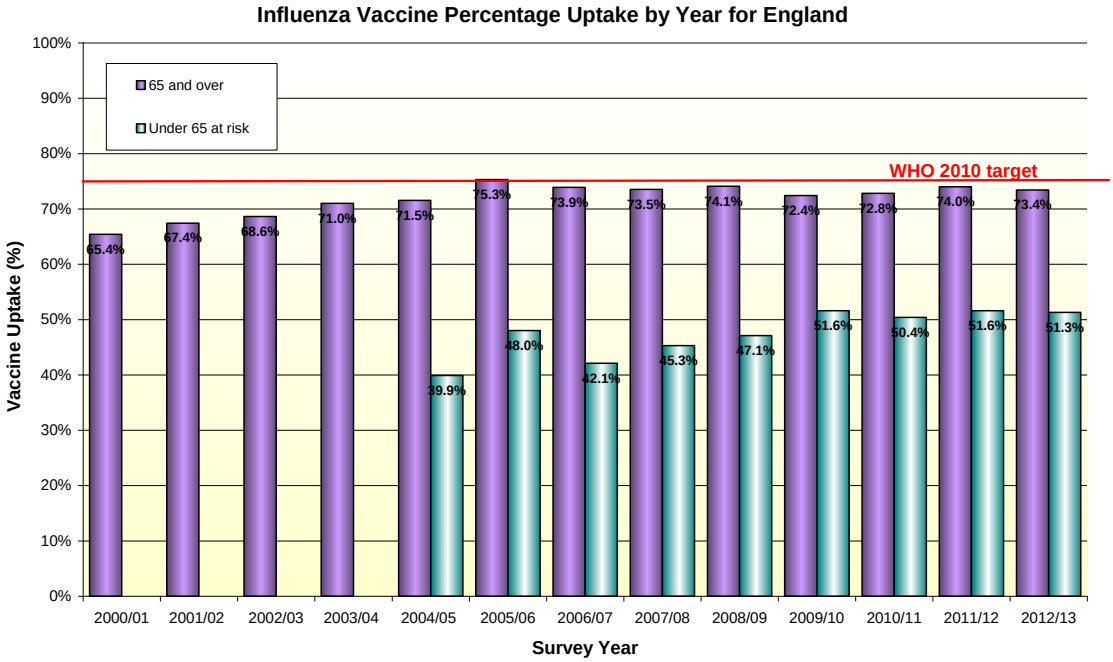

Figure 1: Seasonal influenza vaccine percentage uptake by year for England.

As in previous years, flu vaccine uptake data collections will be managed using the ImmForm website (www.immform.dh.gov.uk). PHE will coordinate the data collection. PHE will issue details of the collection requirements by the end of July 2013 and guidance on the data collection process by early September 2013. The email contact for flu queries concerning data collection content or process should be directed to influenza@phe.gov.uk

Queries concerning ImmForm login details and passwords should be directed to helpdesk@immform.org.uk

Reducing the burden from data collections

Considerable efforts have been made to reduce the burden on GPs of data collections by increasing the number of automated returns that are extracted directly from GP IT systems. Over 80% of GP practices benefited from using automated IT data returns for flu vaccine uptake for the final 2012/13 survey. GP practices that are not able to submit automated returns should discuss their arrangements with their GP IT supplier. Health Care Worker uptake data can only be submitted manually.

Data collections for 2013/14

Monthly data collections will take place over four months during the 2013/14 flu immunisation programme. Subject to ROCR approval, the first data collection

will be for vaccines administered by the end of October 2013/14 (data collected in November), with the subsequent collections monthly thereafter, with the final data collection for all vaccines administered by the end of January 2014 (data collected in February). These collections will enable performance to be reviewed at area team level during the programme, with time to take action if needed, and for the uptake from the completed programme to be measured.

Data will be collected and reported monthly at national level, by Area Team and also byPCT (to allow comparison with historic data). Additionally, data at Local Authority level will be collected once at the end of the campaign.

During the data collection period, those working in the NHS with relevant access are able, through the ImmForm website, to:

- see their uptake by eligible groups;
- compare themselves with other anonymous general practices or areas;
- validate the data on point of entry and correct any errors before data submission;
- view data and export data into Excel, for further analysis;
- make use of automated data upload methods (depending on the IT systems used at practices);
- access previous years' data to compare with the current performance.

These tools can be used to facilitate the local and regional management of the flu vaccination programme.

Monitoring on a weekly basis

Weekly uptake data will be collected from a group of GP practices that have fully automated extract and upload facilities provided by their IT suppliers. This scheme was implemented successfully for the previous three vaccination seasons and provides high quality data from 80% of GP practices allowing national level monitoring of the vaccination programme. This data will be published in the PHE weekly flu report that is issued on their website throughout the flu season.

Guidance on the collection and provision of flu vaccine uptake data will be issued by PHE.

Annex F – Vaccine virus strains and available vaccines

Flu viruses change continuously and the World Health Organization (WHO) monitors the epidemiology of flu viruses throughout the world. Each year it makes recommendations about the strains to be included in vaccines for the forthcoming winter[23]. The WHO has announced the flu strains that should be included in the 2013/14 trivalent seasonal influenza vaccine. These are:

- An A/California/7/2009 (H1N1)pdm09-like virus.
- An A(H3N2) virus antigenically like the cell-propagated prototype virus A/Victoria/361/2011
- A B/Massachusetts/2/2012-like virus

The following table sets out the vaccines that will be available for the 2013/14 flu immunisation programme. This year for the first time a quadrivalent vaccine will be available – this contains an Influenza B/Brisbane/3/2007 (Yamagata) in addition.

[23] http://www.who.int/influenza/vaccines/virus/recommendations/2013_14_north/en/index.html

Vaccines available for the 2013/14 flu immunisation programme

Supplier	Name of product	Vaccine Type	Age indications	Contact details
Abbott Healthcare	Influvac Desu®	Surface antigen, inactivated	From 6 months	0800 358 7468
	Imuvac®	Surface antigen, inactivated	From 6 months	
AstraZeneca UK Ltd	FLUENZ ▼	Live attenuated, nasal	From 24 months to less than 18 years of age	0845 139 0000
GlaxoSmithKline	Fluarix®	Split virion inactivated virus	From 6 months	0800 221 441
	Fluarix Tetra	Split virion inactivated virus	From 3 years	
Janssen-Cilag Ltd (formerly Crucell UK)	Viroflu®	Surface antigen, inactivated	From 6 months	0844 800 3907
	Inflexal®V	Surface antigen, inactivated	From 6 months	
MASTA	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From 6 months	0113 238 7552
	Fluarix®	Split virion inactivated virus	From 6 months	
	Optaflu ®	Surface antigen, inactivated, prepared in cell cultures	From 18 years	
	FLUENZ ▼	Live attenuated, nasal	From 24 months to less than 18 years of age	
Novartis Vaccines	Agrippal®	Surface antigen, inactivated	From 6 months	08457 451 500
	Fluvirin®*	Surface antigen, inactivated	From 4 years	
	Optaflu®▼	Surface antigen, inactivated, prepared in cell cultures	From 18 years	
Pfizer Vaccines	CSL Inactivated Influenza Vaccine	Split virion Inactivated virus	From 5 years	T: 0800 089 4033
	Enzira®	Split virion Inactivated virus	From 5 years	
Sanofi Pasteur MSD	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From 6 months	0800 085 5511
	Intanza® 9 microgram/strain	Split virion, inactivated virus	From 18 years - 59 years	
	Intanza®15 microgram/strain	Split virion, inactivated virus	From 60 years	

None of the influenza vaccines for the 2013/14 season contain thiomersal as an added preservative.
*This vaccine states in its Summary of Product Characteristics (SPC) that it contains traces of thiomersal that are left over from the manufacturing process.

Some flu vaccines are restricted for use in particular age groups. The Summary of Product Characteristics (SPC) for individual products **should always** be referred to when ordering vaccines for particular patients.

More detailed information on the characteristics of the available vaccines, including age indications and ovalbumin (egg) content can be found in the Seasonal Flu chapter of the Green Book. A revised chapter will be issued ahead of the flu season.

Annex G – Vaccine supply and the central strategic reserve

GPs remain responsible for ordering vaccine for all their eligible populations and final orders should now have been placed with manufacturers. It is recommended that orders are placed with more than one supplier in case of supplier delays or difficulties in delivery of the vaccine.

Further details about the extension to children of the flu immunisation programme for 2013/14 will be covered in a joint DH, NHS England, and PHE letter in the coming weeks. At this stage we recommend that you purchase vaccine for your at risk groups as per usual, including for at risk children. Vaccine for the extension to healthy children will be purchased and supplied centrally.

The live attenuated influenza vaccine Fluenz® is the vaccine of choice for children in clinical risk groups aged 2-17 years as it has been shown to provide a higher level of protection for children than inactivated influenza vaccine. It is recommended that GP practices order this vaccine for children in clinical at-risk groups, however it is unsuitable for children under the age of 2 and for some over the age of 2 with contraindications such as severe immunodeficiency or egg allergy and thus GPs should ensure they have ordered sufficient supplies of suitable alternative vaccines for children who should not be given Fluenz®. As currently, children aged under 9 years who have not received flu vaccine previously should be offered two doses of vaccine with at least four weeks between doses.

GP practices should be planning to contact patients in late September/early October as soon as their stocks of vaccine are in place.

Central strategic reserve
PHE will retain a small central strategic reserve of flu vaccine to mitigate the impact of any shortages should they occur.

It is anticipated that in a normal flu season the strategic reserve will not be accessed by primary care and that this small reserve will be considered as an insurance against shortages when an expected supply fails or in a more severe flu season when there has been exceptional demand for the vaccine.

This stock will only be issued if PHE and DH determine that it is necessary to bridge a gap for which there have not been sufficient local supplies.

A guidance document outlines the circumstances under which the reserve will be made available to the NHS by placing orders through ImmForm[24].

[24]http://webarchive.nationalarchives.gov.uk/20130105001007/http:/www.dh.gov.uk/health/2011/10/accessing-the-flu-vaccine-strategic-reserve-in-england/

Annex H – Contractual arrangements, service reviews and funding

NHS England has agreed responsibilities for the seasonal flu programme under a Section 7A agreement with the Secretary of State for Health ('Public Health Functions to be exercised by the NHS Commissioning Board')[25]. This describes in one place NHS England's public health responsibilities under that agreement as well as responsibilities arising from NHS England's duties to secure primary medical services for the population which includes securing flu services under the Primary Medical Services (Directed Enhanced Service) Directions (the 'DES').

The DES requires NHS England to operate, establish or revise an influenza and pneumococcal immunisation scheme under primary medical services contracts. The DES covers securing flu immunisation services for the majority of the at risk groups. However, previous additions to the groups recommended for immunisation (e.g. carers and pregnant women) sit outside the DES, giving NHS England additional flexibility in how to secure immunisation services for these groups. NHS England may enter into arrangements with primary medical services' contractors or any other local provider, for example community pharmacies, to provide a flu immunisation service for all risk groups under primary medical services contracts (GMS, PMS or APMS).

Under the contract transition arrangements, existing flu agreements under both DES and LES arrangements (including any consolidated 'DES-LES' type agreements) have been transferred to NHS England as the responsible commissioner for primary medical services, and allow for the continuation of local innovative services where there is clear evidence of beneficial outcomes.

NHS England area teams are responsible for the on-going management of these existing arrangements, including assurance of any LES agreements whether directly managed by the area team or delegated to clinical commissioning groups (CCGs) as a consequence of NHS England actions to devolve local commissioning to CCGs in 2013/14.

Wherever any separate arrangements have been entered into for securing the immunisation of carers and pregnant women, NHS England will want to ensure these contain requirements similar to the DES.

Immunisation coordinators in NHS England area teams should note the requirements in the DES and use these to assess the services provided. For a full list of the national requirements to be placed on GP practices and other providers appointed to supply flu immunisation services, please refer to the DES directions, the latest version of which can be downloaded.[26]

[25]https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192974/13_Seasonal_flu__service_specification_VARIATION__130422.pdf

[26] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/127322/Primary-Medical-Services-Directed-Enhanced-Services-Directions-2013.pdf.pdf

NHS England area teams will recognise the need to assess the quality of their local flu immunisation services, drive towards continuous improvement including progress to reaching and exceeding uptake levels recommended by the WHO and the CMO, be responsive to patient needs, provide value for money and extend the reach of their immunisation programme to those who need it most. Patients who fail to attend for vaccination should be followed up and their needs reviewed. NHS England will assure any targets and/or other performance measures set up previously by PCTs under local agreements, including any LESs devolved to CCGs.

In addition to those patients who can attend a surgery or clinic to receive a vaccination, area teams of NHS England will want to assure themselves that appropriate plans are in place to offer vaccination to those who require home visits; those who are in long-term care; and those who are not registered with a GP practice.

The DES covers most, but not all, of the eligible groups that should receive flu vaccine. Previously PCTs had LES agreements in place to cover the additional eligible groups. It is now the responsibility of NHS England area teams to review their local arrangements to ensure they cover all the additional eligible groups (including all pregnant women) and that they carry similar requirements to the DES (as set out above), this includes any LES arrangements that may have been delegated to CCGs. This will ensure that NHS England can be assured, and provide assurance to Public Health England, that GPs have identified all those registered patients who fall into the relevant eligible categories for 2013/14.

Previously some PCTs have had a low response rate from GP practices for data returns on vaccine uptake among their eligible patients. Where local contracts under the DES have been set up according to the DES directions, the legal documents should incorporate the following direction:

> ‘a requirement that the contractor supply the Board with such information as it may reasonably request for the purposes of monitoring the contractor’s performance of its obligations under the plan’.[27]

NHS England area teams (or CCGs acting on their behalf) will wish to check to ensure that the contracts for the flu immunisation programme are drafted in such a way as to ensure that GPs and other providers are obliged to provide the relevant data returns.

Commissioners are reminded when commissioning services for vaccinations given in settings other than a GP practice (eg community pharmacies, antenatal clinics etc), that the details of the vaccinations are provided to the patient’s registered practice and are recorded on their electronic clinical record in a timely manner. This is important for clinical reasons (such as any adverse

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27 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/127322/Primary-Medical-Services-Directed-Enhanced-Services-Directions-2013.pdf.pdf

events) and also means that these vaccinations will be included in the vaccine uptake data collections.

A range of mechanisms can be used for the supply and administration of vaccines, including Patient Group Directions (PGDs), Patient Specific Directions (PSDs) or prescribing. Where PGDs are developed, they must comply with the legal requirements of the Human Medicines Regulations 2012. Recent amendments have enabled CCGs, LAs and the NHS Commissioning Board (now known as NHS England) to authorise PGDs from April 2013. These changes are consequential to the Health and Social Care Act 2012, which enable the continued use of PGDs in the new health system organisational structures.

The section in the Green Book on PGDs and PSDs for the immunisation of vaccines will be updated shortly.

A letter was distributed on 28 May 2013 by NHS England clarifying the responsibilities for PGDs for nationally commissioned immunisation programmes[28].

Previously some PCT clusters have commissioned pharmacists to deliver part of the flu vaccination programme. It is essential that NHS England Area Teams (or CCGs continuing such arrangements under primary medical service LES arrangements) ensure that robust arrangements are made for vaccination records to be collected and passed back to patients' GPs for timely entry on the electronic patient record and submission to ImmForm for the national data survey.

[28] http://www.england.nhs.uk/resources/d-com/pub-hlth-res/

Annex I - Summary of planned changes to the national immunisation schedule in 2013/14

Programme	June 2013	July 2013	August 2013	Sept 2013
MenC vaccine: remove one primary dose	√			
Rotavirus vaccine introduced		√		
MenC vaccine: adolescent dose introduced through schools				√*
Shingles vaccine: programme begins (including catch-up)				√
Flu vaccine for some pre-school aged children introduced				√

* This can take place at any point in the 2013/14 academic year. In practice, it is most likely to be administered in schools in the spring 2014 term.