Department of Health & Social Care

Government Response to the House of Commons Science and Technology Committee Report on Flu Vaccination in England:

Ninth Report of Session 2017-19

Published January 2019

CP 3

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Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

January 2019

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This publication is available at www.gov.uk/government/publications

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ISBN 978-1-5286-0946-3

CCS 1218242148 01/19

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the APS Group on behalf of the Controller of Her Majesty's Stationery Office

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Introduction

On 18 October 2018, the House of Commons Science and Technology Committee published its report Flu vaccination in England[1]. The report followed an evidence session held by the Science and Technology Committee on 7 March 2018 which took evidence from Professor Paul Cosford, Director for Health Protection and Medical Director, Public Health England; Professor Stephen Powis, National Medical Director, NHS England; Professor Jonathan Van-Tam**,** Deputy Chief Medical Officer for England; Professor Andrew Pollard**,** Chair, Joint Committee on Vaccination and Immunisation; and Dr Sue Crossland**,** Vice-President, Society for Acute Medicine.

Written evidence was provided by the British Medical Association, Seek Group, and following the evidence session on 7 March 2018, Public Health England (PHE) and NHS England provided written information at the request of the Committee.

This paper sets out the Government's response to the conclusions and recommendations made in the Science and Technology Committee's report.

[1] Flu vaccination in England: Ninth report of Session 2017-19

Overview

Flu vaccination is the best protection against the serious effects of flu, and the UK has one of the most comprehensive flu vaccination programmes in the world. The Government is rolling out a programme to vaccinate children between the ages of 2 and 11 years, in addition to vaccinating individuals who are most at risk.

Morbidity and mortality due to flu is a major cause of harm to individuals. Flu also contributes to NHS winter pressures by putting pressure on GPs, hospitals and the care sector, as evidenced in winter 2017/18 where almost 3500 admissions to intensive care were due to flu. The overall number of flu-related admissions to hospital was particularly high last year, with most of these amongst the elderly and vulnerable.

The national flu immunisation programme aims to provide protection to those who are most at risk from the complications of flu and, in the case of children, to reduce the risk of transmission to their families and the wider community. Since 2013/14 we have made good progress in rolling out a programme to children, with an additional cohort added each year. In 2018/19 the flu vaccination will be offered to all children aged 2-9 years. The programme is delivered as part of the NHS public health functions agreement, commonly referred to as Section 7A, between the Department of Health and Social Care and NHS England, supported by Public Health England.

In 2018/19, under the seasonal flu immunisation programme, immunisation is recommended for:

- Those aged 65 years and over
- Those aged six months to under 65 years in clinical risk groups
- Pregnant women
- Children aged 2 and 3 years
- Children in reception and school years 1-5
- Carers
- Health and social care workers, to help protect themselves and patients from infection

Health and social care worker vaccination is a key priority, so in September 2018, NHS England and NHS Improvement wrote to all Chief Executives of NHS Trusts and Foundation Trusts to advise on how they can increase the number of frontline staff who are vaccinated.

As well as focusing on ensuring those at risk are protected, and increasing vaccine uptake rates, the Government has taken advice from the Joint Committee on Vaccination and Immunisation (JCVI) on the most effective vaccines that should be offered. In 2018/19, following advice from JCVI, NHS England recommended that all people aged 65 and over should receive the newly available adjuvanted trivalent influenza vaccine (aTIV). This vaccine is far more effective in this age group and would typically be expected to reduce GP consultations by 30,000, hospitalisations by over 2,000, and prevent over 700 deaths from flu in England annually.

We have also recommended that those in the younger at-risk groups should receive a quadrivalent influenza vaccine (QIV) which protects against four strains.

As noted by the Committee, the Department of Health and Social Care (DHSC), Public Health England (PHE) and NHS England work together in the delivery and evaluation of the seasonal flu immunisation programme. This response incorporates the views of PHE and NHS England who have the lead responsibility in relation to some of the Committee's recommendations.

Recommendations

Vaccine uptake

We heard that vaccine uptake rates were increasing year-on-year but there remains high geographical and demographic variation in uptake in some groups. We are reassured to hear about communication campaigns and other actions being taken to improve vaccine uptake in eligible groups. We recommend that the Government ensures that research into better understanding of the causes of unacceptable variation in vaccine uptake takes place. We call on the Government to continue to look at what actions work to increase flu uptake. Further, we call on the Government to invest in campaigns that are proven to be successful. (Paragraph 45)

The Government welcomes the Science and Technology Committee's report on flu vaccination in England. Vaccine uptake rates have remained relatively stable in people aged 65 years and older, those in clinically at-risk groups and pregnant women.

Since the Committee met in March 2018, PHE has published the final data on flu vaccine uptake rates for the winter season 2017/18. This indicated that vaccine uptake rates increased for all eligible groups compared to 2016/17.

Table 1: Flu vaccine uptake

Target group	2017/18 %	2016/17 %
Aged 65 years & over	72.6	70.5
Aged under 65 'at risk'	48.9	48.6
Pregnant women	47.2	44.9
Aged 2 years	42.8	38.9
Aged 3 years	44.2	41.5
Children in reception	(see notes)	33.9
Children vaccinated in school (combined)	59.5 Reception – School year 4	55.4 School year 1-3
Healthcare workers	68.7	63.2

Notes: In 2017/18 children in reception who were previously vaccinated at their GP practice were vaccinated in school

Vaccine coverage is closely monitored, with publication of weekly, and monthly reports. In addition, PHE publishes an annual report in the Spring with finalised data on vaccine uptake. We continually monitor vaccine uptake rates both at national and regional levels throughout the flu season.

We have taken steps to increase vaccine uptake rates by:

- Moving the vaccination of children aged 4 years, who are in reception, from GP practice to school. This resulted in an increase in vaccination in this age group from 33.9% in 2016/17, to 62.6% in 2017/18.

- Ensuring that flu vaccination for those aged 18 years and over is also available through community pharmacies to help increase access and patient choice. In 2017/18, it is estimated that over 1.2m eligible people had the flu vaccination through pharmacy services.

- Commissioning ~88% of maternity providers to offer flu vaccination to increase access for pregnant women.

Vaccination coverage varies across the country. PHE has been investigating factors associated with variation in flu vaccine uptake for the different components of the vaccine programme including children, pregnant women and the elderly. Deprivation and ethnicity are key predictors for most groups[2] [3]. Key factors also include access and systematic invitation for at-risk groups. It has reported this analysis to DHSC and NHS England to build into the delivery of the national programme.

NHS England local teams work in partnership with vaccination providers, Clinical Commissioning Groups, local authorities and other local stakeholders to plan and promote vaccination in a way that is responsive to local need and to deliver the national programme to the public. This takes into consideration local variation and plans for improved coverage.

PHE and NHS England also work closely to develop communication plans to support the public during the winter months.

In addition, PHE and NHS England jointly run the annual national Help Us Help You - Stay Well This Winter campaign which encourages eligible groups to get their flu vaccine each year. The campaign runs from October to December and includes television, radio, digital and social advertising supported by public relations activity which generates national news coverage of the importance of getting a flu vaccine.

This campaign includes targeted activity for: people aged 65 years and over, people with long term health conditions, pregnant women and parents of children aged two to three years. In addition, there is tailored activity for Black, Asian and Minority and Ethnic (BAME) groups where there is low uptake, and those with disabilities.

PHE works with an extensive range of partners including the NHS, local authorities, charities and pharmacies to provide campaign resources that can be tailored to specific audiences and local needs as required.

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[2]Tessier E, Warburton F, Tsang C, Rafeeq S, Boddington N, Sinnathamby M, Pebody R. Population-level factors predicting variation in influenza vaccine uptake among adults and young children in England, 2015/16 and 2016/17. Vaccine. 2018 May 31;36(23):3231-3238.

[3] Green HK, Andrews N, Letley L, Sunderland A, White J, Pebody R. Phased introduction of a universal childhood influenza vaccination programme in England: population-level factors predicting variation in national uptake during the first year, 2013/14. Vaccine. 2015 May 21;33(22):2620-8. d

Messaging encouraging people to take up the offer of the flu vaccine is also included within all winter communications activity, for example, within cold weather advice.

The Stay Well This Winter flu vaccination campaign generates high levels of awareness amongst its target audiences, for example, 76% of pregnant women recognised the 2017/18 campaign.

Healthcare workers

Despite the 2017/18 season having the highest flu vaccination uptake ever in healthcare workers, significant variation remains. Some hospital trusts only achieved 30 to 40% uptake, whereas others achieved over 90%. All hospital trusts should give the same level of priority to vaccination programmes for staff.
We recommend that the Care Quality Commission should continue to assess how well trusts have performed this role and take action where fundamental standards relating to infection prevention and control have not been met. (Paragraph 55)

The Government welcomes the increase that we have seen in the vaccination of healthcare workers. The vaccination uptake rate in 2017/18 was 68.7%, compared to 63.2% in 2016/17, and 50.6% in 2015/16. We agree with the Committee that the current variation between Trusts in vaccinating healthcare workers is unacceptable.

In 2016/17, the NHS introduced a Commissioning for Quality and Innovation (CQUIN) to incentivise Trusts to increase vaccine uptake rates among healthcare workers. In addition, PHE is funding NHS Employers to run the flu fighter information campaign, to support NHS Trusts, and more recently the social care sector to increase vaccine uptake rates, sharing advice and support as well as good practice from Trusts with higher uptake rates. Where Trusts have high uptake rates, this has been driven by strong clinical leadership in this area.

For the 2018/19 season, NHS Improvement and NHS England have worked closely with national clinical leaders, including Royal College representatives and trade unions to review the evidence and to agree a package of measures with the aim of increasing uptake rates. These include:

- Recommending that all NHS and social care staff under 65 get the ‘quadrivalent’ vaccine which gives additional protection, and confirming that NHS England will fund free vaccine for social care workers again in 2018/19;

- Setting an aspiration for 100% of front line health care workers to be vaccinated;

- Introducing a best practice flu vaccination checklist against which each Trust Board will be asked to self-assess progress publicly in their Trust Board meetings before the end of 2018;

- Introducing an opt-out process whereby any front-line healthcare worker who decides not to be vaccinated will be expected, on an anonymous basis, to complete a form indicating their reason for not being vaccinated. This information will be used to identify further improvements to be made to the vaccination programme for next year. The number of staff being vaccinated and the number of staff offered vaccine and opting out will be reported to PHE monthly and published on the PHE website;

- For healthcare workers in higher risk areas Trusts will be required to collect information locally on whether members of staff in these areas have been vaccinated or not. Where staff have not been vaccinated, the local Trust clinical leadership have been asked to consider re-deploying un-vaccinated staff to work in other clinical areas if that is compatible with maintaining the safe operation of service; and

- Trusts will be required to report on progress publicly to their Board by the end of February 2019.

The letter issued by the NHS setting out the new measures is available on the NHS Employers website[4].

The Care Quality Commission (CQC) has a key role in ensuring that standards in relation to infection control are maintained. In Acute NHS Trusts the CQC, through its inspection framework and methodology, continues to assess providers against Regulation 12 of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Regulation 12 of the Fundamental Standards places a duty on providers to assess the risk and prevent the spread of infections. Inspectors will follow key lines of enquiry such as 'Are there reliable systems in place to prevent and protect people from a healthcare-associated infection?' to inform the 'Safe' rating of the provider. The safety rating will then inform the overall rating of the trust. Where regulations are breached CQC can, and does, use a range of enforcement action.

CQC also assesses Trusts under a 'well led' key question, where the Director of Infection Prevention and Control (IPC) may be interviewed by the inspection team on the systems to manage occupational health needs of staff in relation to IPC.

As part of its 'monitoring' function, CQC reports on a range of data. Going forward, CQC will be including the indicator 'staff vaccination rates' in intelligence reporting, under the 'well led' key question.

[4] https://www.nhsemployers.org/campaigns/flu-fighter/nhs-flu-fighter/free-resources/flu-letters

Healthcare workers

It is a professional duty for healthcare workers in hospitals to be vaccinated each year. We welcome recent advice to hospital trusts from NHS England and NHS Improvement on healthcare worker vaccination. The Government should undertake and conclude a review by the end of February 2019 to establish whether flu vaccination should be mandatory for certain categories of healthcare workers. (Paragraph 56)

The Government agrees with the Committee that it is a professional duty for all healthcare workers to be vaccinated each year to protect themselves from illness during the busy winter months, and to reduce the risk of transmission to patients.

Up to 50% of confirmed flu infections are subclinical (i.e. asymptomatic). Unvaccinated, asymptomatic staff may pass on the virus to vulnerable patients and colleagues. Along with other interventions, flu immunisation is an important tool in helping to prevent respiratory infections in healthcare settings as highlighted in recent guidelines from the National Institute for Health and Care Excellence (NICE)[5].

Together with PHE, NHS England and NHS Improvement have evaluated mandatory staff flu vaccination for healthcare workers. A review of the evidence base by PHE in June 2018 highlighted the importance of ensuring easy access to vaccination. This was supported in the Guidelines published by NICE in August 2018 which concluded that there should be a multicomponent approach to staff flu vaccination, with a full participation strategy, where a range of approaches are used to maximise uptake, including mechanisms enabling staff to opt out. These guidelines have been adopted nationally this year.

Following discussions with national clinical leaders, Royal College representatives and trade unions, the NHS is going further, and has introduced a named opt-out for frontline healthcare workers in higher risk areas. This is a step-change in the Government's approach for this winter.

PHE will be measuring flu vaccination uptake among staff, to help understand the impact of new policies this winter, alongside NHS Employers collecting intelligence from across the NHS. This work will be completed after the end of the flu season 2018/19 when PHE will have collected and analysed vaccine uptake data from providers covering thousands of frontline NHS healthcare workers.

The Government will continue to review policies in this area, and focus on how we can reduce the variation of uptake between Trusts.

[5]Flu vaccination: increasing uptake NICE guideline [NG103]

Healthcare workers

We believe it is as much a professional duty for staff working in social care to be vaccinated as it is for frontline healthcare workers. We were surprised that no effective system of monitoring uptake of flu vaccination rates amongst staff working in social care settings has been established in England. While we accept there may be challenges in relation to information collection, we recommend that the Government should review this and determine how vaccination uptake data can be collected from care homes. An effective system of data collection should be established by the 2019/20 flu season. In its role regulating within the social care sector, the Care Quality Commission should take action where poor immunisation rates (or poor recording of uptake) could impact on standards of infection prevention and control. There should be an expectation of full coverage amongst staff working with individuals who are most at risk from serious illness from flu. (Paragraph 60)

We agree with the Committee about the importance of promoting the flu vaccination among social care workers, alongside those who work in the NHS. Health and social care vaccination is part of the employer's occupational health responsibility. Therefore, to increase uptake rates among social care staff, in 2017/18 NHS England made funding available so that staff working in this sector could access the flu vaccination through their GP or pharmacy. This funding will continue in 2018/19. PHE has also commissioned NHS Employers, as part of the flu fighters contract, to work closely with employers in social care to share good practice and advise on flu vaccination campaigns to help improve uptake.

Data Collection

The current systems we have are based on monitoring flu vaccine uptake among staff working within NHS organisations. The Government accepts that it is equally important to have uptake data for social care staff. The Government agrees with the Committee about the need to strengthen monitoring uptake data in the social care sector. However, establishing such a system will be challenging. PHE undertook a pilot data collection for staff working in a sample of 320 care homes in 2016/17. Key conclusions were that 70% of responding care homes do not have systems in place to collect data on staff flu vaccination. In addition, in this study undertaken by PHE, only 38% of the care homes in the study sample provided data on vaccine uptake despite considerable local follow-up. Key leadership groups in the care system have been approached to ensure that messaging is shared actively with residential facilities.

For the 2018/19 season, NHS England is working with social care provider representative bodies to undertake an end of season survey of flu vaccination uptake in frontline social care workers.

Role of the CQC

Care homes are assessed against the CQC's methodology, which is similar to the hospitals sector, and places a duty on providers to assess the risk and prevent the spread of infections.

In social care, inspectors use the key line of enquiry 'How well are people protected by the prevention and control of infection?' when inspecting.

Regulation 12 of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires providers to assess the risk and prevent the spread of infections. This regulation underpins the key line of enquiry above. The CQC can prosecute for a breach of this regulation, or a breach of part of the regulation, if a failure to meet the regulation results in avoidable harm to a person using the service, or if a person using the service is exposed to significant risk of harm. Additionally, CQC may also take other regulatory action.

The *Code of Practice on the prevention and control of infections and related guidance* published by the DHSC emphasises the need to ensure, so far as is reasonably practicable, that care workers are free of and are protected from exposure to infections that can be caught at work. It emphasises that all staff are suitably educated in the prevention and control of infection associated with the provision of health and social care. Registered providers should ensure that policies and procedures are in place in relation to the prevention and control of infection such that:

- all staff can access occupational health services or appropriate occupational health advice;
- occupational health policies on the prevention and management of communicable infections in care workers are in place;
- decisions on offering immunisation should be made based on a local risk assessment as described in Immunisation against infectious disease ('The Green Book');
- employers should make vaccines available free of charge to employees if a risk assessment indicates that it is needed (COSHH Regulations 2002); and
- there is a record of relevant immunisations.

The CQC must take the Code into account when making decisions about registration and by any court during legal proceedings about registration. By following the Code, providers will be able to show how they meet this regulation, but they do not have to comply with the Code by law. A provider may be able to demonstrate that they meet this regulation in a different way from that described in the Code. When assessing risk providers should consider: the link between infection prevention and control, antimicrobial stewardship, how medicines are managed, and cleanliness.

Healthcare workers

We were shocked by survey results from Public Health England which showed that the best flu vaccination uptake in social care settings was around 25%. The poor response rate was also disappointing. We welcome the extension of the NHS programme to frontline social care workers. We call on the Government to look at ways in which uptake among social care staff could be improved and establish the same principle as now exists in the NHS—the aim of 100% coverage. (Paragraph 61)

The vaccination of social care workers is a priority for this Government. In 2017/18, NHS England announced a scheme to enable frontline social care workers in community and care home settings to have access to free vaccination from their GP or a community pharmacy. This scheme has been extended in 2018/19, and in addition hospice workers will be able to access the flu vaccination for the first time from their GP or a community pharmacy.

In recent years the NHS Employers 'flu fighter' campaign has been providing support to the social care sector, including the provision of resources to social care providers.

The Committee refers to the ad-hoc survey undertaken for the 2016/17 season which indicated vaccine uptake in the social care sector amongst the sample as 26%. Only a small proportion of invited care homes responded to this survey. Therefore, the uptake results quoted must be treated with caution.

The Government would like to obtain a clearer position of the vaccination uptake rates in the social care sector, however, as set out above, most care homes do not have the systems in place to gather information on vaccine uptake amongst staff. This would be equally challenging in the domiciliary care sector.

Vaccine procurement in England

There are different procurement processes for flu vaccination programmes in the UK. We see no reason why this arrangement should change. There has been geographical variation in previous flu seasons with regards to vaccine purchasing but we were reassured that action had been taken to address this variation in vaccine provision in the 2018/19 season. We welcome that GP practices were able to change their orders following a change in advice on flu vaccination. Co-operation in this way between GPs, Public Health England, NHS England and flu vaccination manufacturers should continue. (Paragraph 70)

As noted by the Committee, there are different arrangements in place for the procurement of the flu vaccine compared to some other routine vaccines. GPs and pharmacists are responsible for ordering the flu vaccines for adults directly from manufacturers, and are reimbursed by NHS England for these purchases. PHE centrally procure the flu vaccine for children under the age of 18 years.

In 2017/18, GPs and pharmacists could order either the trivalent or quadrivalent vaccine. Both vaccines included those strains recommended by the World Health Organisation, although when decisions are made on which vaccine to order, it is not known which strains will be in circulation.

For the 2018/19 season, based on the expert advice of the JCVI, the Government is offering patients the most effective vaccines currently available. A newly available adjuvanted trivalent influenza vaccine (aTIV) Fluad® is the recommended vaccine for everyone aged 65 years and older. This decision was made based on strong clinical evidence that this is the most effective vaccine for this group of vulnerable patients, because it provides a better immune response and therefore better protection against flu. NHS England issued guidance in February 2018, recommending which vaccines should be ordered, including the use of aTIV for those aged 65 years and older and quadrivalent vaccine for those aged under 65 years. We welcome the fact that the manufacturers extended the ordering deadline so that GPs and pharmacists could order the recommended vaccines for those aged 65 years and older, and those in at risk groups aged 18-64 years, based on expert clinical advice.

This year, the delivery of the aTIV was phased over a longer period than usual. There are sufficient stocks of the vaccine to meet demand and all of the vaccine has now been delivered, so patients will have access to the vaccine before the normal start of the flu season in late December.

Future developments in flu vaccination

We note the important role of the Joint Committee on Vaccination and Immunisation in keeping emerging evidence on vaccines under review and in providing advice. We urge the Government to take account of the future relationship with the European Medicines Agency and the impact this could have on flu vaccination in the UK as part of preparations for the UK leaving the European Union. The Government should set out in response to this Report how this relationship might be maintained in various outcomes of the Brexit negotiations. (Paragraph 76)

The Government is committed to the safe and effective regulation of medicines in the UK, ensuring patients and the public have fast access to new, innovative medicines, including flu vaccines.

The future regulatory system for medicines is subject to negotiation. The Political Declaration that accompanied the Withdrawal Agreement sets out the scope and terms of an ambitious future relationship between the UK and the EU. The declaration contains specific detail on our future economic relationship. This includes a new Free Trade Area with no tariffs, fees, quantitative restrictions or rules of origin checks – an unprecedented economic relationship that no other major economy has with the EU.

Furthermore, UK and EU negotiating teams have already agreed a time-limited implementation period, which has not yet been ratified, that will maintain access to each other's markets on current terms. This will provide certainty for businesses across the EU and UK and time to prepare for the future.

On 22 August the Government set out its plans, through a technical notice, for medicines regulation in the unlikely event of no-deal. In the unlikely event of a no-deal scenario, the Medicines and Healthcare products Regulatory Agency (MHRA) would be a stand-alone medicines regulator, taking any decisions and carrying out any functions which are currently taken or carried out at EU-level.

The Government also launched a no-deal consultation on medicines regulation, which closed on 1 November 2018. A formal response to all aspects is expected to be published in due course, but proposals would see existing, centrally-licensed flu vaccines being 'grandfathered' into UK licenses, with no interruption to their supply. All non-centrally licensed flu vaccines, including those whose approval was coordinated through the European regulatory network, already have UK national licenses.

Whatever the exit scenario, the Government will continue to ensure that UK patients are able to access the best and most innovative medicines and medical devices and that their safety is protected.

Future developments in flu vaccination

We call on the Government to ensure that it continues to support and invest in the development of important new medical products, including new and more effective vaccines (Paragraph 77).

The JCVI reviews the flu programme every year and keeps it under constant review by assessing new flu vaccines and the latest scientific evidence on influenza. JCVI also conducts horizon scanning every year, including writing to manufacturers about potential new vaccines in development and those close to licensure.

PHE works closely with JCVI and supports the work of the committee by annually providing comprehensive surveillance data assessing the UK flu programme, including the latest flu vaccine effectiveness data. This helps JCVI identify areas of concern and issue advice where appropriate. PHE also conducts impact and cost effectiveness modelling which is used to support JCVI advice on the introduction of new flu vaccines, adding new risk groups to be vaccinated and major recommendations such as the introduction of the childhood flu programme in 2013.

PHE also liaises with vaccine manufacturers to ensure new products are assessed and brought rapidly to the UK population. Recent examples of the latter include

JCVI's recent advice on the adjuvanted vaccine, the high dose vaccine (TIV HD) for the elderly, and the cell cultured quadrivalent influenza vaccine (QIVc). JCVI advice on the potential use of TIV HD and QIVc was given ahead of licensure to help with the planning for the 2019/2020 influenza season.

NHS England, PHE and the DHSC work together to ensure that all eligible groups in England consistently have access to the most appropriate flu vaccines for their age group, based on the advice of the JCVI.

CCS 1218242148

978-1-5286-0946-3