



Equality Analysis

*Extension of the flu immunisation programme
to all children aged 2 to less than 17 years old:
Update July 2015*

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Introduction

The general equality duty that is set out in the Equality Act 2010 requires public authorities, in the exercise of their functions, to have due regard to the need to:

- Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- Advance equality of opportunity between people who share a protected characteristic and those who do not.
- Foster good relations between people who share a protected characteristic and those who do not.

The general equality duty does not specify how public authorities should analyse the effect of their existing and new policies and practices on equality, but doing so is an important part of complying with the general equality duty. It is up to each organisation to choose the most effective approach for them. This standard template is designed to help Department of Health staff members to comply with the general duty.

Equality analysis

Title: Equality Analysis: Extension of the flu immunisation programme to all children aged 2 to less than 17 years old: Update July 2015

What are the intended outcomes of this work?

The objective is to offer flu vaccination to all children aged 2 to under 17 years, resulting in reduction in transmission of influenza, with reduced levels of influenza-related morbidity and mortality throughout the population.

In February 2011, the Secretary of State for Health asked the Joint Committee on Vaccination and Immunisation (JCVI) to review the seasonal influenza vaccination programme and provide advice and recommendations on possible extensions of the programme to include the routine vaccination of age groups of the healthy population. The existing programme provides vaccination annually for those aged 65 years and over and those in the defined influenza clinical risk groups, including all pregnant women (this programme has been running for many years, though its remit has been expanded intermittently).

In July 2012, JCVI recommended that all children aged 2 to less than 17 years should be offered the flu vaccination. The JCVI recommendation to the Secretary of State for Health is based upon analysis that suggested that any vaccination campaign including school age children is highly likely to be cost effective, particularly over the longer-term. JCVI further recommended that the rationale for this programme was best served by the use of the live attenuated influenza vaccine (LAIV) vaccine nasal spray. This vaccine was preferred above the inactivated injectable vaccines for several reasons:

- higher efficacy in children, particularly after a single dose
- potential to have broader coverage against strains that have drifted from those in the vaccine
- higher acceptability with parents and carers as it is a nasal spray rather than an injectable
- 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 vaccines.

The modelling that underpins this recommendation showed that vaccinating children would reduce transmission of the influenza virus in children, and thus protect the whole community. This will reduce the spread of flu to unvaccinated children and to those in other age groups, including those in clinical risk groups for whom flu can be extremely serious and even life-threatening. The modelling further indicated that even with low levels of coverage in school children, groups that are not eligible or able to benefit from the direct protection of vaccination, will still accrue substantial benefits through indirect or herd protection.

It should be noted that when a recommendation of the JCVI meets certain conditions, which are fulfilled in this case, the Secretary of State is obliged (under the Health Protection (Vaccination) Regulations 2009) to make arrangements to ensure, as far as is reasonably practicable, that the recommendation is implemented. Section 3a of the NHS Constitution states that “You have the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation [JCVI] recommends that you should receive under an NHS-provided national immunisation programme”.

This right applies where, following a request from the Secretary of State for Health, the JCVI makes a recommendation to introduce a new national immunisation programme, or to make a change to an existing national immunisation programme. Where the JCVI makes a recommendation of this sort, SofS is obliged to make arrangements in England to ensure (so far as is reasonably practicable) that the national immunisation programme is implemented so that the people who meet the criteria in the recommendation have access to the vaccine via the NHS. In practice this means that, if a person falls into a group that the JCVI recommends is offered a particular vaccine, that person has the right, after allowing for a reasonable period of time to implement the programme, to be vaccinated against that disease free of charge on the NHS.

The Department of Health, based on the recommendation received from the JCVI in July 2012, took a decision to implement a national programme to vaccinate all children from the ages of two to less than seventeen years against influenza, using a live attenuated influenza vaccine. The scale of the implementation, however, was recognised as unprecedented and so a phased roll-out including a series of pilots was planned.

There is currently only one LAIV vaccine available, Fluenz Tetra®. It has a good safety profile in children aged two years and older and has an established history of use in the United States for over ten years. It is authorised for use in children aged two to less than eighteen years. The decision to include pre-school children in the target group was based on the high morbidity from flu in young children; but limited to those aged over two years because there is no equivalent effective vaccine available for children aged less than two

years.

This update reflects all the evidence available following the 2013/14 winter flu season. A further update reflecting the 2014/15 winter flu season will be published later in 2015.

Who will be affected?

Children aged 2 - under 17 years and their parents / carers. NHS and other provider staff carrying out the vaccinations such as school nurses, health care assistants, GPs, practice nurses, pharmacists and some school staff.

Phased roll-out

Because the scale of this programme is large, implementation is being phased, with roll out to the youngest cohorts first, and extension upwards through the age cohorts thereafter. In 2013/14, the vaccination was offered to pre-school children (those aged 2 and 3 years on 1st September 2013) including those children in this age-group at high risk who would have been eligible under the risk group recommendation. During 2013 there were also seven pilot programmes to test the delivery models for primary school aged children to determine the best way to deliver the extended programme in future years. Children outside of the eligible age range were not offered any flu vaccination unless in a clinical risk group.

All children who are eligible for vaccination should be offered the vaccination. Building on the evidence from the pilots, the following requirements will be in place for 2015/16: 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. As a minimum, we would expect uptake levels between 40-60% to be achieved. Uptake levels should be consistent across all localities and sectors of the population.

Pre-school children are currently vaccinated in General Practice. This is likely to continue. Immunisation services for school-aged children are being commissioned locally by NHS England. Delivery for school-aged children is mainly through schools, for example through school nursing teams or specialist immunisations teams, although in some areas primary care providers, such as community pharmacies and general practice, are being used.

Childhood flu immunisation: roll-out schedule

Year	Status	Pre-school age	Primary school age	Secondary school age
2013/14	Completed	2-3 year olds	Pilots in 7 areas	-
2014/15	Completed	2-4 year olds	Pilots in expanded areas	Pilots for children in year 7 & 8 (aged around 11 and 13 years) in 12

				areas
2015/16	Confirmed	2-4 year olds	5-6 year olds, plus primary school-aged children in areas that previously participated in the pilots	-
2016/17	Provisional	2-4 year olds	5-7 year olds, plus primary school-aged children in areas that previously participated in the pilots	-
2017/18	Provisional	2-4 year olds	5-10 year olds	-
2018/19	No formal decision has been made			

Notes:

Plans for 2016/17 onwards are provisional.

Secondary school pilots in 2014/15 were for one year only. To enable valuable learning to ensure the best approaches to working with this age group are identified, with sufficient resources to enable proper evaluation. (In 2015/16 all available capacity will be targeted on bringing 5 and 6 year olds in to the programme).

Plans for 2016/17 onwards are indicative at this stage, and will be kept under review year-on-year.

Vaccination is not compulsory in the UK, and the planning of the childhood flu programme is based on this premise. Anyone who does not wish to be vaccinated can refuse to take part in the programme.

All those who are eligible for Fluenz Tetra will be offered it for the reasons outlined above. However, only those who are in clinical risk groups (who were already eligible to receive vaccine prior to the child flu programme) are currently able to opt for an inactivated injectable vaccine as an alternative to LAIV (two doses will be required in many cases). Those who do not fall into such categories, and who choose not to receive LAIV will not be provided with an alternative, for the reasons discussed in the section below on “Addressing the impact on equalities”, though they will benefit from the protection gained from the wider target-group vaccination.

In terms of groups with protected characteristics, the policy is going to have an impact on persons within a particular age group (children aged 2 – under 17), who will gain personal protection from the vaccine. For other age groups, the aim of the full programme is to reduce the transmission of influenza, thereby reducing the spread of flu to unvaccinated children and to those in other age groups, including those in clinical risk groups for whom flu can be extremely serious and even life-threatening. Even though the highest rate of serious

illness in healthy children is in infants and toddlers under two years of age, these children will not be directly protected with LAIV, and so will only benefit from reduced exposure from older children when the schools programme is rolled out.

Fluenz Tetra contains a wide range of ingredients, including porcine (pork) gelatin (as do many other pharmaceutical products). There is currently no equivalent vaccine that can be used as an alternative. Inactivated flu vaccines have been shown to be less effective than Fluenz (a live vaccine) in preventing flu in children, so cannot be regarded as equivalent. This is discussed further in the section below considering the possibility of offering an alternative vaccine. Nevertheless the question of whether an inactivated vaccine should be offered as an alternative has been explored. Most inactivated vaccines do not contain porcine products, but all inactivated vaccines are made using animal products, some of which are of porcine origin. So while the end product may not contain porcine products, they may have been used during the manufacturing process and therefore the manufacturer cannot always guarantee that traces of the animal product are not present in the final vaccine.

There is potential for this vaccination programme to be less acceptable to persons belonging to certain faith groups or those possessing certain beliefs which prevent them from using products with porcine (pork) ingredients, as compared with those not belonging to such groups or possessing such beliefs. As described above, those who refuse the LAIV vaccine for whatever reason will not be offered an alternative vaccine, unless they are already eligible to receive a flu vaccination under the existing programme. Unvaccinated children will not be directly protected with vaccine, but will benefit from reduced exposure when the schools programme is rolled out.

These issues are addressed further below.

Evidence *The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the assessment.*

What evidence have you considered? *List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.*

This update to the Equality Analysis considers all the evidence available up to and including the 2013/14 flu immunisation programme. A further update will be made when all the evidence from the 2014/15 flu immunisation programme is available, with annual updates in future years in line with the annual cycle of the seasonal flu immunisation programme.

In order to evaluate the impact of this programme fully, evidence is required from a variety of sources:

- **Clinical and scientific evidence** – evidence of the safety and efficacy of the vaccine; and modelling that underpins the premise of the programme (to interrupt transmission of influenza). This has been gathered over a number of years from a variety of sources, often linked to the clinical testing and licensing of vaccine. The Green Book, a document published by PHE (an Executive Agency of the Department

of Health) provides details to the NHS and the public about all vaccines, based on this evidence. This includes some information as to the impact on people in certain protected groups, i.e. those disabled persons and persons in the over-65 age group who are identified as being in a clinical risk group eligible for vaccination.

The link to the chapter on flu is provided below:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/427809/Green_Book_Chapter_19_v9_0_May_2015_.PDF

- **Uptake of the vaccine:** Uptake rates of the vaccine, if available in sufficient detail, can provide valuable evidence demonstrating variation in uptake rates between different models of delivery (for example schools based programmes vs primary care), geographical areas, or different population groups, including faith groups.
- **Disease surveillance data:** this evidence is expected to be the key indicator as to whether the programme is achieving its objective of reducing transmission of flu throughout the whole population. Modelling predicts that transmission will be reduced with a schools programme that achieves overall uptake rates as low as 30%. Disease surveillance will be used in order to test this model, and provide real data to evaluate the relationship between uptake rates and interruption of transmission. Data collection systems are being developed in preparation for wider roll-out of the programme in forthcoming seasons. Surveillance systems that will be utilised and further developed to evaluate the impact of the programme over forthcoming seasons include:
 - Excess mortality monitoring
 - Surveillance of flu related intensive care and hospital admissions
 - Surveillance of influenza like illness in primary care
 - Virological surveillance in primary and secondary care

As this data becomes available, it will be used to consider whether the extension of the programme to children is having a differential impact on protected groups (for example, those of a particular faith), in terms of a higher rate of flu-like illness. It is unlikely such data will be available in the early years of the programme as the numbers will be small, but the data that is available will be interrogated as far as possible and will be incorporated into future equality analyses. It is already known that a higher burden of flu is associated with deprivation and/or ethnic minority backgrounds¹.

- **Qualitative evidence and stakeholder engagement:** Qualitative evidence and feedback from a variety of sources is required in order to understand the factors that are leading to the levels of uptake seen, and how the population groups affected perceive the programme. This will be gathered through specially commissioned research, feedback from pilot sites and interested groups and attitudinal research and surveys which will be available during the course of the year.

The evidence will grow over time as surveillance and data systems tailored to the child flu immunisation programme come on stream, and as the scale of the programme grows

¹ Zhao et al. Epid Infection 2015 1. Ethnicity, deprivation and mortality due to 2009 pandemic influenza A(H1N1) in England during the 2009/2010 pandemic and the first post-pandemic season.

enabling more sophisticated analysis to be undertaken:

Timeframe and extent	Timetable for data availability	Evidence available or expected
Before programme starts	September 2013	Theoretical modelling and existing clinical guidance; Early discussion with faith leaders and other stakeholders; learning from other immunisation programmes
2013-14 flu immunisation season: Offer to all 2 and 3 year olds via GP; Primary school aged children in 7 pilot areas	Summer 2014	Uptake rates by age and model of delivery (school-based, primary care/pharmacy, GP) Qualitative evidence from narrative evaluation of pilots and other feedback Initial evidence from disease surveillance, although sample size too small to drill down to protected groups Ongoing discussion and engagement with faith groups at local and national level
2014-15 flu immunisation season Offer to all 2-4 year olds via GP; Expanded pilots for primary school aged children; Pilots for some secondary school aged children	Summer 2015	Uptake rates across all ages and models of delivery Disease surveillance overall, and broken down by population group including faith groups if data is sufficient. This will compare: <ul style="list-style-type: none"> - rates of illness in pilot to non-pilot areas in targeted and non-targeted age groups to determine the population impact of vaccinating school age children - Rates of illness in targeted and non-targeted age groups before and after the introduction of the vaccine programme to determine the impact of vaccinating pre-school age children - Qualitative data from attitudinal research, surveys and in-depth interviews with parents, with a particular emphasis on those with concerns relating to porcine gelatin

		<p>content</p> <p>- Ongoing engagement at local and national level with faith groups and vulnerable communities in deprived areas</p>
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Disability

JCVI has recommended that all 2 – under 17 year olds inclusive are offered the vaccine. The programme is being phased in over a number of years, and once fully implemented, it will therefore be a right of all 2 - under 17 year olds to receive flu vaccine regardless of disability status. The vaccine will be free to all children in this age group and information about the vaccine will also be freely available. Offering the vaccine through schools and via general practice will minimise the risk of differential coverage based on a child's disability.

Fluenz Tetra is the vaccine of choice but some children have particular conditions that means they can't receive Fluenz Tetra (for example: clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies; and high dose corticosteroids). In these cases, an inactivated influenza vaccine (of which there are various types and suppliers) is offered as an alternative to LAIV (two doses will be required in many cases), although response to vaccination may be sub-optimal. These children may therefore benefit more from reduced exposure when the schools programme is rolled out.

Fluenz Tetra and some inactivated influenza vaccines are contra-indicated in children with severe egg-allergies; such children will be eligible for vaccination with an appropriate vaccine only if they are also in an existing clinical risk group. Some children with learning disabilities have been found to react badly (emotionally) to the nasal spray vaccine, and as such children are in a clinical risk group, medical staff may offer suitable injectables.

A suitable inactivated influenza vaccine will therefore be available for use in those eligible children in at risk groups when LAIV is contraindicated or cannot be given.

Further information about clinical risk groups and other details about live and inactivated vaccines and government programmes can be read in the Green Book, a document published by PHE (an Executive Agency of the Department of Health) that provides details to the NHS and the public about all vaccines (see link above).

Local commissioners are responsible for ensuring that contra-indicated children are offered an appropriate vaccine. This may be part of a schools-based programme, or offered by the GP.

Age

In 2011, the Secretary of State for Health asked JCVI to consider and make recommendations on possible extensions to the influenza vaccination programme to include

the routine vaccination of a range of age groups of the healthy population. JCVI reviewed an unpublished study² from the Health Protection Agency (HPA) and London School of Hygiene and Tropical Medicine (LSHTM) on the impact and cost effectiveness of the current influenza vaccination programme and a range of possible extensions to the programme to low risk groups (i.e. to include people without clinical risk factors for influenza in various age groups).

The study suggested that, despite the high cost, extending the influenza vaccination programme to low risk children is highly likely to be cost effective and well below the cost effectiveness threshold requirement for an intervention to be recommended when indirect protection to the whole population is taken into account, particularly over the longer-term.

Extending vaccination to low risk children aged five to less than 17 years was the most cost effective option evaluated. Vaccinating low risk children aged six months to less than 17 years is also likely to be cost effective, although the additional benefit from vaccinating the six months to less than five years age group is relatively small compared with that arising from vaccinating children aged five to less than 17 years.

JCVI noted that there is evidence that the authorised live attenuated intranasal influenza vaccine (LAIV, Fluenz) is more effective compared with inactivated influenza vaccines in children aged six to 17 years (mean age 11 years)³ as well as in younger children. However, it is not suitable for children aged less than two years. Offering the vaccine to all children aged 2 – under 17 year olds therefore maximises effectiveness of the programme whilst remaining in accordance with the recommended vaccine's licensing regulations. Those under two years of age should benefit from indirect protection from reduced exposure.

There would be relatively little further benefit from extending the vaccination programme to adult age groups of the low risk population and that is unlikely to be cost effective.

This programme is being introduced on the basis of scientific and clinical evidence indicating that it will significantly reduce the number of deaths and hospitalisations among both the target population (2 – under 17) **and** the wider population (all other ages) by reducing transmission of influenza. The scientific evidence supporting this is listed and explained in detail in the JCVI statement, available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224775/JCVI-statement-on-the-annual-influenza-vaccination-programme-25-July-2012.pdf

In 2013/14 the vaccine was offered to children aged 2-3 in General Practice, and to children of primary school age in 7 pilot areas.

The pilot scheme and wider disease surveillance will allow DH and PHE to gather further

² Cromer *et al.* Estimating the burden of influenza by risk group. *Unpublished.*

Baguelin *et al.* Reconstructing past influenza epidemics from consultation, virological surveillance data and a contact survey. *Unpublished.*

Baguelin *et al.* The cost effectiveness of vaccination against seasonal influenza in England. *Unpublished.*

³ Fleming *et al.* (2006) Comparison of the efficacy and safety of live attenuated cold-adapted influenza vaccine, trivalent, with trivalent inactivated influenza virus vaccine in children and adolescents with asthma. *Pediatr. Infect. Dis. J.* 25, 860-869.

evidence on how this policy impacts upon both the target age group and on other high-risk age groups, e.g. those aged 65 and over.

Evidence from 2013/14

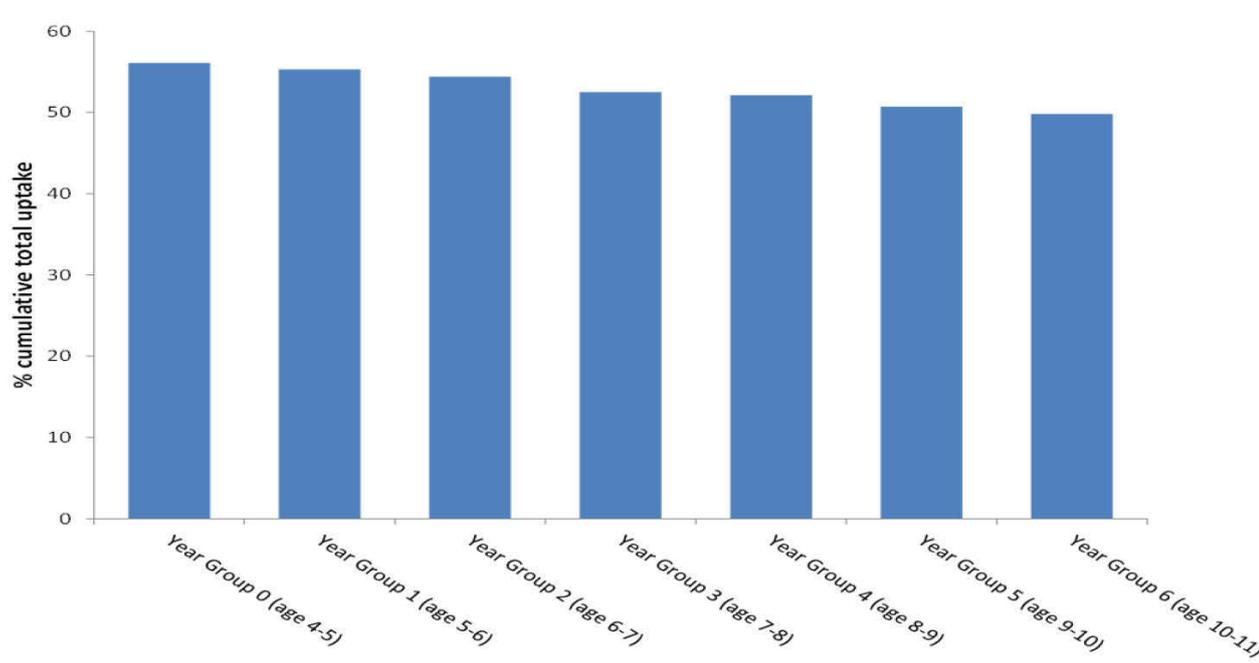
Clinical Evidence: No further clinical evidence relating to age came to light in 2013/14.

Uptake rates:

Data from 2013/14 indicates that the flu vaccine uptake rate was 42.6% for two year olds and 39.5% for three year olds. The overall uptake rate for children (4-11 years of age) in the primary school pilot areas was 52.5%.

The graph below provides data on the uptake levels across children aged 4 – 11 who were vaccinated as part of the pilot programme in schools. Uptake rates were higher for children being offered vaccinations in schools than for the pre-school children offered vaccination by GPs. There is no *evidence* as to the reasons for this, but it is assumed that school based programmes are more convenient for families, with no need to make a special trip to the GP or other location to take up the offer of vaccination. Within the school aged cohorts, there was a reduction in uptake rate as the age of children increased.

Cumulative vaccine uptake in 7 pilots by school year, England, 2013-14



Disease surveillance: – Surveillance data from 2013/14 showed consistently lower rates of GP consultations for flu-like illness, and lower rates of confirmed cases of flu across the whole population in pilot areas vs non-pilot areas (see table below). While these differences were not statistically significant due to the small sample sizes, they provide a first indication

that the programme is having the impact expected – by vaccinating children, the whole population is protected⁴.

Disease indicator	Pilot	Non-pilot area	Risk ratio (95% CI)
ILI GP consultations	17.7/100 000 (16/90,403)	64.5/100 000 (538/833,704)	0.34 (0.07 – 1.72)
ILI swab positivity	8.5% (15/176)	16.2% (265/1,634)	0.53 (0.28 – 1.01)
ED syndromic surveillance	5.5% (2,804/51,413)	8.7% (83,224/954,225)	0.60 (0.30 – 1.19)
DataMart swab positivity	6.8% (129/1,885)	6.9% (1,432/20,820)	0.99 (0.35 – 2.80)
Lab confirmed hospitalisations	5.5/100 000	7.0/100 000	0.76 (0.33-1.75)

Race and Religion or belief

JCVI have recommended that all 2 - under 17 year olds inclusive are offered the vaccine. Under the NHS constitution, it is therefore a right of all 2 - under 17 year olds to receive flu vaccine regardless of race, religion or belief. The vaccine will be free to all children in this age group and information about the vaccine will also be widely available.

Communications are key to increasing uptake, particularly in groups who are known locally to mistrust vaccination campaigns, or who do not participate in health services generally. PHE is responsible for communications regarding immunisation programmes and will develop strategies to increase uptake in all groups, using acceptability testing and surveys to inform them.

Information for parents about flu vaccine in different languages, can be provided either hard copy (leaflets) or by translation services via NHS providers and the local NHS teams, who have a duty to ensure that people have equal access to information and services. This should reduce any negative impact on non-English speakers by ensuring they are aware of the vaccination programme, and in doing so should help to ensure that information about the

⁴ Pebody et al. Uptake and impact of a new live attenuated influenza vaccine programme in England: early results of a pilot in primary school age children, 2013/14 influenza season. Surveillance and Outbreak Reports. <http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20823>

vaccine is available to persons of all races, ethnicities and nationalities. In 2014/15, PHE revised their leaflets for parents to make it clear that the vaccine contained porcine gelatin. The consent form was also revised to make clear that the vaccine contained porcine gelatin.

The only specific consideration identified at this point for children with the protected characteristic of **religion or belief** concerns the porcine gelatin content included in the vaccine, and its acceptance by people of faiths that prohibit the eating of pork (Islamic and Jewish). In preparation for implementation of this programme there was engagement with leaders of both Jewish and Muslim faiths. (See later section on Engagement and involvement). This resulted in broad support from leaders of the Jewish faith. For the Muslim faith, the position was less clear cut but with the majority opinion of Muslim scholars being that the vaccine was not suitable for Muslims.

There are other beliefs that may result in refusal, for example people who are vegetarians or vegan.

In 2013/14 the policy was that no alternative would be offered if there was an objection to Fluenz on the grounds of religion or belief. This decision was guided by a number of factors summarised below:

- The recommendation by JCVI and introduction of the programme was based on the LAIV vaccine being the vaccine of choice; children who could not receive this vaccine (for example healthy children aged six months to two years) were excluded from the eligible group because they could not receive LAIV.
- The alternative, inactivated vaccine is not as clinically effective, and in particular would not produce the same 'herd immunity' effects at relatively low uptake rates as are expected with Fluenz. This would undermine the central purpose of the programme – to interrupt transmission of flu through the population.
- Fluenz is a nasal spray; the alternative is an injectable. Offering two different kinds of vaccine would have added complexity in delivery to a programme that was still in first pilot stage.

The possibility of offering an alternative vaccine to those who object to the porcine content of Fluenz for religious or belief reasons has been considered again in 2014/15 (see heading "consideration of the possibility of offering an alternative vaccine" under the section on "Addressing the Impact on Equalities", below, for further discussion of this).

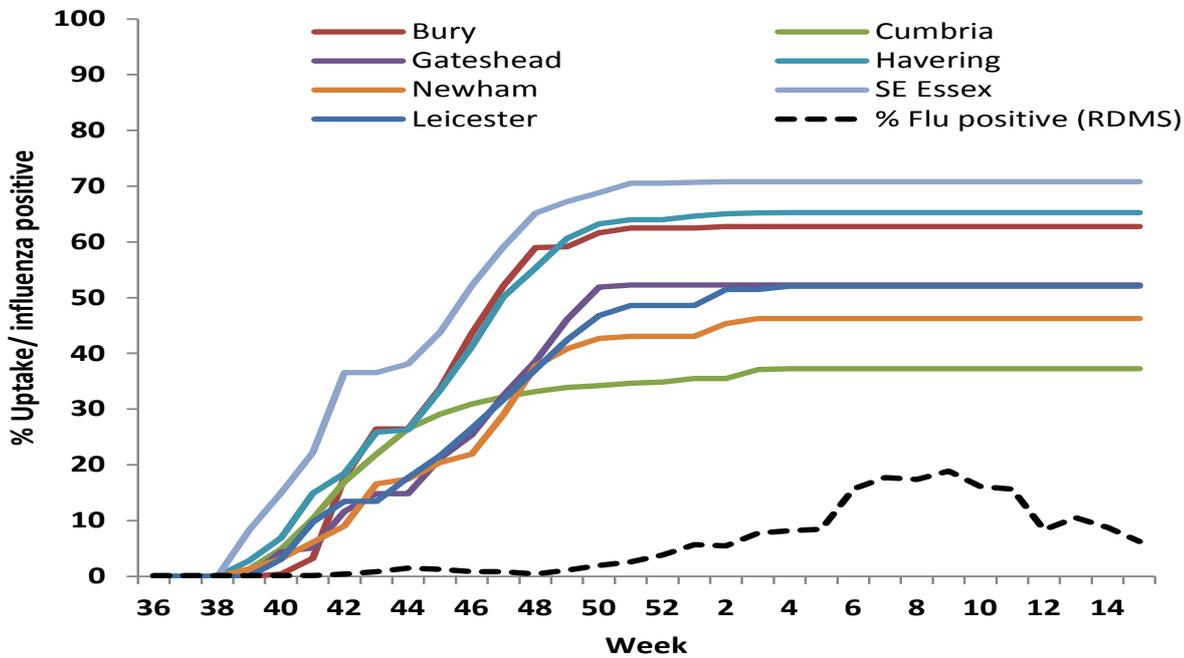
Experience from the 2013/14 pilot programme

Clinical Evidence: No further evidence in 2013/14

Uptake Rates

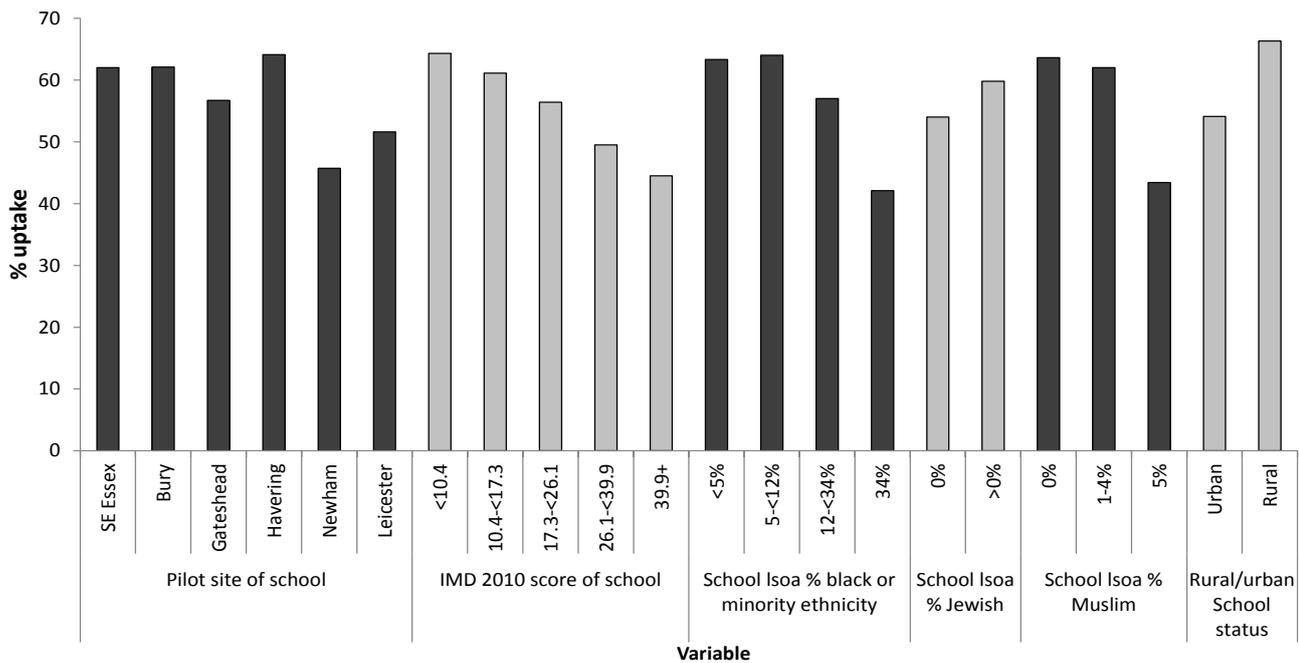
The graph below gives overall uptake levels in school aged children in the seven primary school pilots (all children offered vaccination). This shows that uptake varied considerably by geographic locality.

Roll-out of vaccination in primary school age children and flu activity in 7 pilot sites England, 2013-14



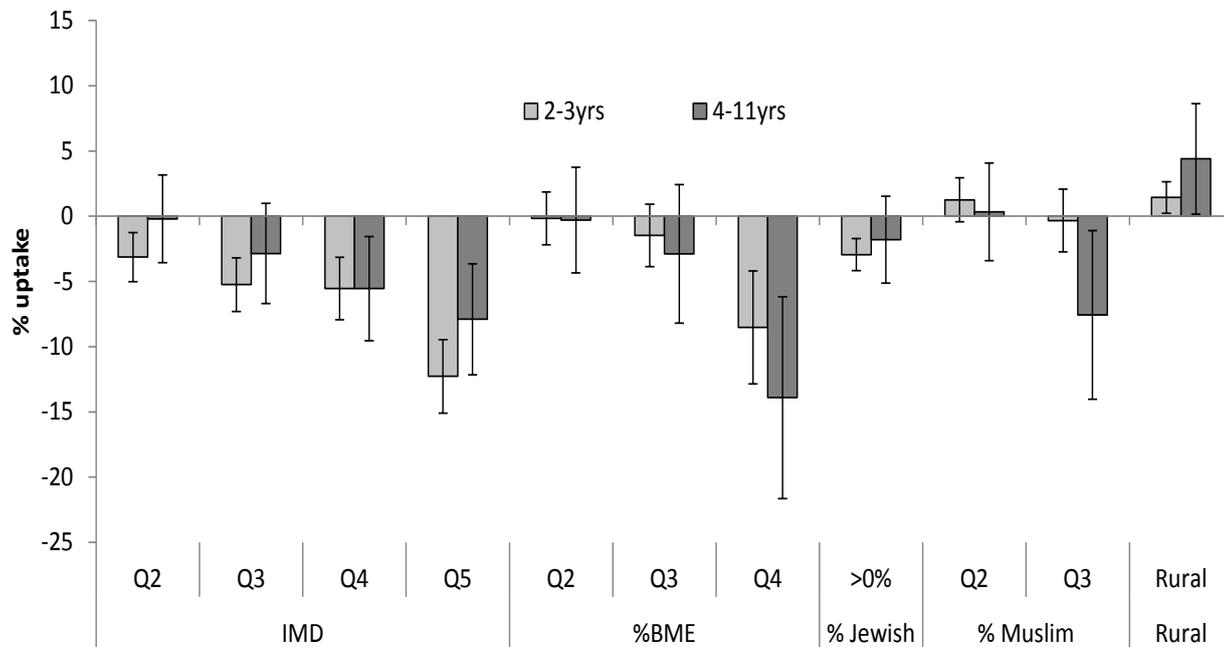
More detailed evidence relating to uptake rates by deprivation, ethnicity and religion from the 2013/14 programme was available at regional level only as shown in the graphs below.

Flu vaccine uptake in 4-11 year olds by region, deprivation, ethnicity and religion



For the 2-3 year olds programme, implemented right across England, lower uptake rates are associated with increasingly deprived areas, and areas with greater ethnic diversity. Religion was also important.

Adjusted linear regression relative % uptake change values with 95% ci for area-level predictors for 2-3 year olds and 4-11 year olds, England, 2013/14



Comparing key findings for 2-3 year olds with 4-11 year olds, the same pattern of reduced uptake level associated with deprivation and ethnicity is observed. In 4-11 year olds, a significant reduction in uptake in areas with Muslim populations, but not Jewish populations, was observed. The impact of Muslim faith on the uptake among children of primary school age remained significant after controlling for index of deprivation.

Disease surveillance

The pilots were too small and level of flu circulating too low to observe any difference in impact on levels of flu-like illness in individual population groups.

Qualitative Evidence:

Local intelligence from the pilot areas in Leicester, Bury and Newham indicated that the porcine gelatin content of Fluenz had adversely affected uptake rates. It was largely felt that the information about the porcine gelatin content was not clear enough and parents had not been able to make an informed choice.

In Scotland injectable vaccine was offered as an alternative in 2013/14 and this continued in 2014/15, as in Northern Ireland. Data from Scotland showed that the offer of an alternative vaccine did not lead to higher uptake levels. Data suggests that uptake for the alternative vaccine was extremely low.

Anecdotally it is suggested that other factors such as communicating with non-English speaking families are relevant.

The implications of this evidence for the programme will continue to be monitored and considered carefully in light of evidence gathered through the pilots and research. The approach for 2014/15, developed in the light of these findings, is set out in the section 'Action planning for improvement'.

Pregnancy and maternity

The flu vaccine is already offered to all pregnant women as part of the seasonal flu immunisation campaign that targets people in specific risk groups.

Carers

The flu vaccine is already offered to carers.

Other identified groups

As part of the long-standing seasonal flu vaccination campaign, the flu vaccine is already offered to all those aged 65 and over and those under 65 who fall into the following clinical risk groups: chronic respiratory disease, chronic heart disease, chronic kidney disease, chronic liver disease, diabetes, immunosuppression and certain neurological conditions. This is due to the personal protection from flu required by these individuals, for whom flu can be serious and life-threatening. Further details on groups recommended to be offered flu vaccination can be viewed in the annual flu letter 2015/16 at: [Annual Flu Plan and Letter for 2015/16](#).

The pilot scheme and wider disease surveillance should allow DH and PHE to gather further evidence on uptake across a range of groups (currently by age and clinical risk group, though likely to expand to include sex and ethnicity). Specific research will be carried out should cases of differential impact on other identified groups come to the Department's attention through either national lobby groups or through local experience in the NHS.

Engagement and involvement

How have you engaged stakeholders in gathering evidence or testing the evidence available?

The programme as a whole

Recommendations for new immunisation programmes are based on evidence from HPA (now PHE) and London School of Hygiene and Tropical Medicine (LSHTM) reviewed by JCVI members representing a broad range of stakeholders.

Faith groups

Various work has been undertaken over the years to gain acceptance by a broad spectrum of Muslim and Jewish faith groups for porcine gelatin content in medicines (and other excipients,

for example bovine gelatin and their acceptance by Hindus). Clearly it is of crucial importance for global health organisations, for example the WHO, in ensuring the success of many global Public Health Programmes that use products containing animal products.

Broad acceptance has been gained from the Jewish faith, as outlined in the following statement from Rabbi Abraham Adler, BPharm MRPharm S, Kashrus and Medicines Information Service

To whom it may concern

Re: Porcine and other animal derived ingredients in non oral medication.

It should be noted that according to Jewish laws, there is no problems with porcine or other animal derived ingredients in non oral products. This includes vaccines, injections, suppositories, creams and ointments.

PHE regularly updates statements of this type with UK and global experts. In preparation for launch of this programme, direct correspondence took place between Dr Penelope Toff from PHE and Rabbi Abraham Adler from the Kashrus and Medicines Information Service in September 2013. Direct correspondence took place between Dr Mary Ramsay and Dr Shuja Shafi (Secretary General of the Muslim Council of Britain) and Dr Yusuf Ghumra (British Islamic Medical Association) in September 2013. This correspondence was to enable leaders of key Muslim and Jewish communities to understand the use of Fluenz and the purpose of the programme. It was a direct request for support and to improve understanding by asking the leaders to provide guidance for their group members regarding the acceptability of the existence of porcine gelatine in Fluenz.

Some key statements, including from Rabbi Adler, above, are available on the PHE website (<https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response>).

How have you engaged stakeholders in testing the policy or programme proposals?

The programme implementation was developed through discussions at the Flu Project Board which consisted of a range of stakeholder representatives, professional organisations (RCN, the School and Public Health Nurses Association (SAPHNA), Unite the Union, NHS England, PHE, DH, NHS Employers, Department for Education, and colleagues from the Devolved Administrations). A workshop was also held in December 2012 to discuss the programme which involved frontline health workers and regional representatives from NHS England and PHE.

Consultation with faith groups at national level began prior to the implementation of the programme, in 2013, and is ongoing. This includes consultation with the Muslim community. The current position is that the majority of Muslim scholars in England regard Fluenz as forbidden. However, at a meeting (December 2014) organised by the Muslim Council of Britain, Muslim and Jewish leaders recognised the need to consider the issue of acceptability further and we await their deliberations. In addition, these faith leaders understood the rationale for not providing an alternate vaccine, and are willing to assist with the communications around this topic.

As implementation continues, engagement at regional and local level is taking place to ensure that all parents are able to make an informed decision about whether to take up the offer of the vaccine. In 2013/14, feedback suggested that the principal difficulty was that information regarding the porcine content of the vaccine was not clear enough, leading to a concern that parents were not able to make an informed decision about whether to give consent for vaccination.

Further engagement will be undertaken to understand the impact of the policy on stakeholders as the programme is rolled out.

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

2013/14

As noted above in the section entitled “How have you engaged stakeholders in gathering evidence”, direct correspondence took place between PHE and representatives from the Kashrus and Medicines Information Service, the Muslim Council of Britain and the British Islamic Medical Association in September 2013. This correspondence was to enable leaders of key Muslim and Jewish communities to understand the use of Fluenz and the purpose of the programme and to request their support by asking the leaders to provide guidance for their group members regarding the acceptability of the existence of porcine gelatin in Fluenz.

Subsequently, Rabbi Abraham Adler from the Kashrus and Medicines Information Service provided direct support to the programme.

Following communication with UK Muslim leaders on the WHO letter on the acceptability of porcine gelatin in Fluenz, it was thought better to allow people to make their own decisions, or follow guidance of local Muslim leaders.

At regional and local level, NHS England and PHE officials, and the service providers, have worked with local communities and faith leaders as local implementation is planned, to ensure that the programme is fully understood and local faith leaders have all the information they need in order to advise their communities.

2014/15

Engagement activity grew considerably in preparation for the 2014/15 season. This included both national and local activities. These are outlined in ‘Addressing the Impact on Equalities’, and will be discussed further in the next update of this document which will incorporate all findings from the 2014/15 season.

The implications of this for the programme will continue to be monitored and considered carefully in light of evidence gathered through the pilots and research.

Summary of Analysis *Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.*

The evidence gathered from the 2013-14 flu season can be summarised as:

Clinical evidence: There was no new clinical evidence relevant to the implementation of the programme with respect to protected groups.

Uptake rates:

Age: Uptake rates were higher for school-aged children offered vaccination in a school based setting, than for younger children offered vaccination by their GP. It is assumed this relates to ease of access, as a GP visit requires more action from a parent than consenting to vaccination in the school setting.

Deprivation: Low uptake is associated with a higher index of deprivation score.

Race: Low uptake is associated with a more diverse community.

Religion: Low uptake is associated with the Muslim faith for children of primary school age. This was not seen in the pre-school cohorts. Religion remained a significant factor after controlled for deprivation.

Disease surveillance:

Disease surveillance data is not available at the level of individual population groups. Overall data showed that there was a consistently lower rate of flu-like illness across a range of indicators in pilot areas compared to non-pilot areas. Although not statistically significant, this is an early sign that the programme is likely to achieve its intended objective of interrupting transmission of flu and protecting the whole population by immunising children.

Qualitative evidence:

Qualitative evidence from the pilot sites in 2013/14 indicates that good information is key, enabling people who may have questions and concerns to make a properly informed choice about whether or not to take up the offer of vaccination with LAIV. Excellent local engagement between healthcare providers and the local community, supported by PHE and NHS England is essential to foster good relations, in particular ensuring it is understood that everyone in the local population is expected to benefit, even if they do not receive the vaccine.

Conclusion

From data available in 2013/14, there is no evidence of Muslim communities experiencing higher levels of flu than the wider population. Data is not yet rich enough to clarify at what level of coverage interruption of transmission may occur (ie determining the validity of the 30% level estimated through modelling studies).

It is clear that lower uptake is seen in Muslim communities, but also those with a higher index of deprivation and more diverse ethnicity. This information has been used to better target effort in future years to ensure that all communities are given appropriate support to understand and benefit from the programme. Evidence is not yet available to demonstrate whether lower uptake rates in these communities are leading to an increased level of flu compared to communities with higher uptake rates.

Further evidence about the impact of the policy will continue to be gathered through the pilot scheme and wider disease surveillance by PHE and will be taken into account when designing the most effective and equitable approach to the next stage of national implementation from 2015/16 onwards (see “Action planning for improvement”, below).

Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

By definition, this vaccination programme could be seen to be discriminatory on grounds of age, as the primary determinant of eligibility is the age of the person to be vaccinated. From research carried out by the JCVI, the recommendation to vaccinate 2 - under 17 year old children maximises the accrual of both clinical benefit and cost-effectiveness. The restriction of the vaccination programme to a discrete age range can therefore be justified on the grounds of **clinical efficacy and cost-effectiveness, supported by extensive scientific evidence.**

The programme is intended to have a positive effect on people's rights of access to healthcare as it will have a population-wide effect, but it may have a differential discriminatory impact on personal protection to children with the protected characteristics of religion or belief or race or to people of other ages (who don't specifically need personal protection from flu due to a clinical condition). The differential impact on sections of the population with protected characteristics can be measured in terms of uptake rates among the children in that group, disease surveillance across the whole age range, together with the qualitative evidence from attitudinal research exploring experiences and perceptions in these groups. DH and PHE are committed to gathering and evaluating this evidence as soon as it becomes available.

Insofar as the programme has a differential discriminatory impact on children of different religions, beliefs or races, this differential impact can be justified on the basis that a key objective of the programme is to gain population-wide protection by preventing the transmission of flu and clinical indications are that Fluenz Tetra is the option which will be most effective at raising overall immunity levels. Any differential discriminatory impact will be mitigated by the steps that will be taken by PHE and NHS England to ensure that uptake of the vaccine is encouraged and increased across all groups in the targeted age range, including those with a protected characteristic and in areas of deprivation. Please see the section on "addressing the impact on equalities" below.

Advance equality of opportunity *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

The extension of the flu vaccination programme to include all children aged 2 - under 17 years will have a positive effect upon the health of children and the wider community. The vaccination will be available to all children free of charge. The policy is designed to be totally non-discriminatory except on grounds of age (see above), and to the extent that it does discriminate in fact between persons belonging to different religions and having different beliefs, this is consistent with equality principles as it is justified and proportionate on the basis that this is the most cost-effective programme and all population groups will be protected by the indirect protection generated by an effective programme, as explained above.

Promote good relations between groups *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*

As immunisation of healthy children will reduce the ability of children to act as “super spreaders” of the influenza virus to others in the population (ie, the presumption being that children, as a group, spread influenza more than any other group), including at risk groups such as those aged 65 or over, it will promote solidarity and good public health practice between generations, linking young and old in a common alliance against the spread of preventable disease.

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?*

As this is an extension of flu immunisation to a new target group, there was no specific information available at the start of the programme. Uptake of flu vaccination in 2-16 year olds with risk factors prior to the start of the new programme was low (38.7%). However, this is currently only delivered through GP practices and many of those in a clinical risk group are not aware that they are eligible (details of clinical risk groups can be found in the Green Book).

It will be the responsibility for local commissioners and health professionals to ensure that the programme is offered to *all* children aged 2-17.

Communications are key to increase uptake, particularly in groups who are known to find it difficult to access, or are resistant to, vaccination. PHE is responsible for communications regarding the immunisation programme and will develop strategies to increase uptake in all groups, using acceptability testing and surveys to inform them.

Evidence from the 2013/14 season is limited primarily to uptake rates, as described in earlier sections. Lower uptake rates among particular population groups do not necessarily mean that that group will experience a higher rate of flu, but this can only be assessed when sufficient data is available (ie the programme has been offered to sufficient cohorts of children to generate protection across the whole population).

The overall impact of the policy on groups with protected characteristics will continue to be assessed on the basis of evidence gathered through the pilot scheme and through on-going uptake and disease prevalence surveillance undertaken by PHE.

Addressing the impact on equalities *Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.*

The 2009 publication from NICE – *Reducing differences in the uptake of immunisation* (reviewed and confirmed in December 2012) – provides guidance for health care professionals. Including both commissioners and providers on how to improve vaccination rates, including addressing issues that may arise in different ethnic groups, socio-economic factors etc.

<http://publications.nice.org.uk/reducing-differences-in-the-uptake-of-immunisations-ph21>

Information about flu and flu vaccination is included in *Immunisation against infectious disease* (the ‘Green Book’), which has been published alongside a letter to the NHS about the programme, public information leaflets, posters, information on NHS Choices, training materials for health care professionals etc.

Reducing inequalities is an integral part of the local Public Health commissioning team's remit, and they are responsible for ensuring providers have strategies to reach all eligible children. There will be variable arrangements for reaching different groups.

Consideration of the possibility of offering an alternative vaccine

More specifically for this programme, given that some protected groups are unable to accept Fluenz Tetra for reasons linked to their religion or belief, the possibility of offering an alternative vaccine has been raised and considered.

The benefit of offering an alternative would be an offer to those unable to accept Fluenz Tetra, that would offer them personal protection against influenza.

A number of factors have fed into the consideration of an alternative vaccine. Other types of influenza vaccine are available that do not contain porcine gelatin (although porcine products may have been used in their manufacture as discussed in the introductory section above), but these do not provide an **equivalent** alternative. They are injectable vaccines, which some will find less acceptable than the nasal spray formulation for Fluenz Tetra. They are also less effective than LAIV.

A recent meta-analysis suggest that LAIV is around 52.2% [31.6, 66.6] more effective than inactivated vaccine against moderate to severe influenza and around 45.0% [28.6, 57.5] more effective against milder illness (Ambrose et al, Vaccine 2014). In studies comparing the effectiveness of Fluenz® and inactivated influenza vaccines, there were between about one third to one half fewer influenza infections in groups of children given Fluenz® compared with those given inactivated influenza vaccines (Belshe et al., 2007; Ashkenazi et al., 2006; Fleming et al., 2006; Rhorer et al., 2009).⁵

In addition to the clinical difference between LAIV and other flu vaccines, there are other factors to be considered

- Impact on the complexity of the programme with possible increased costs, and resource implications. For example:
- Paying for the inactivated vaccine to be administered either by the existing provider or finding another suitable provider.
- It is envisaged that most children who are not at risk will not have had the flu vaccine before and will therefore need two doses of inactivated vaccine. This will require two appointments. For healthy children aged 2-4, the GP will only get paid for one appointment.

⁵ Ashkenazi, S, Vertruyen, A., Aristegui, J. et al. (2006) Superior relative efficacy of live attenuated influenza vaccine compared with inactivated influenza vaccine in young children with recurrent respiratory tract infections. *Pediatr Infect Dis J* 25(10): 870-9.

Belshe RB, Edwards KM, Vesikari T et al. (2007) Live attenuated versus inactivated influenza vaccine in infants and young children. *N Engl J Med* 356(7): 685-96.

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

Rhorer et al. (2009) Efficacy of live attenuated influenza vaccine in children: a meta-analysis of nine randomized clinical trials. *Vaccine*. 27, 1101-1110.

- There are no national contract arrangements for GPs to offer flu vaccine to healthy (non at risk) children over the age of 5.
 - Logistically the delivery will be complicated if providers are required to provide the inactivated vaccine alongside the nasal spray, as this will require staff with different skills to be available.
 - If providers are asked to give inactivated vaccines in school or non-primary care settings there are different costs of waste disposal (sharp bins) than for clinical waste bags that are used when Fluenz Tetra is administered.
- A greater element of choice as to which vaccine will be used, then a larger amount must be procured in order to meet that choice. This means significant amounts of public money would be spent on vaccine that might not be used and would have to be thrown away.
 - It could also have a behavioural impact on people from those communities who have decided that the porcine gelatin content in Fluenz Tetra is acceptable (which is likely to be the majority, based on the statements above and evidence and advice that Fluenz is a more effective vaccine), potentially causing some to then opt for a less effective alternative.
 - Evidence from Scotland suggests that offering an alternative vaccine will not necessarily lead to increased uptake in groups unable to accept Fluenz Tetra.
 - At this stage (ie data from the 2013/14 season) the evidence available is uptake rates, supplemented by feedback from the pilot areas. There is not yet any evidence to determine whether protected groups are experiencing increased rates of influenza compared to the wider population. The intention of the programme, to interrupt transmission, suggests that they will still be protected against flu by virtue of vaccination of others in their local community. This needs to be closely monitored through evaluation.

Offering an alternative vaccine at this stage runs the risk of reducing the effectiveness of the programme overall, when there is no evidence that protected groups are suffering discrimination in terms of their outcomes (ie likelihood of contracting influenza). DH therefore considers that it is proportionate not to offer an alternative vaccine at this stage.

However, DH and PHE are taking steps to ensure that any differential impact on persons sharing the protected characteristic of a particular faith or religious belief is minimised and kept under review, as outlined below. We will also assess uptake levels in areas of high deprivation.

Vaccination is not compulsory in the UK, and the planning of the childhood flu programme is based on this premise. A key learning point from the 2013/14 pilots is to provide good guidance and clear information about the programme to allow people to make choices, and excellent, tailored evaluation and surveillance methods are needed as the programme is implemented to understand both the public health impact of the programme, and the perceptions of faith communities. Actions for the 2014/15 season were as follows:

- Revision of the leaflets and consent forms to make clear the porcine content
- Data on ethnicity were complemented by qualitative analysis in some pilot areas with questionnaires and in-depth interviews with parents. JCVI review of the epidemiological

evidence as part of its annual review of the seasonal flu programme in June 2015.

- Good channels of communication have been established with Muslim groups:
- In October 2014, DH hosted a workshop, to explore these issues, and to discuss whether anything further should be included in the evaluation plans for following season. The event was very positive with stakeholders, recognising the value of open discussion. Key actions included
 - i) Clarification that a WHO statement suggesting that porcine gelatine was acceptable did not reflect the views of many British Muslims. This was subsequently withdrawn from PHE publications.
 - ii) DH also committed to on-going review of the existing Equality Impact Assessment (EIA) for the childhood programme which was drafted in November 2013.
- In December 2014, PHE attended a meeting with the Muslim Council of Britain to explore issues relating to the porcine content of Fluenz and other vaccines.

As the programme continues, evidence, including any evidence of differential impact or discrimination against those with a protected characteristic, will be kept under review.

Action planning for improvement *Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.*

A number of geographically based pilots were conducted with primary school children in 2013/14. As described in the section on Race, Religion or belief a number of issues were identified in relation to Fluenz Tetra. This has led to a range of actions which are outlined above.

This programme has an annual cycle, and while much has been learned from the first pilots in 2013/14, there will be an ongoing process of reviewing each season and incorporating lessons into the next year's programme, and taken into account when designing the future strategy for the programme in the longer term.

Please give an outline of your next steps based on the challenges and opportunities you have identified. *Include here any or all of the following, based on your assessment*

DH, PHE and NHS England will continue to engage with the pilot areas to facilitate pilot planning and ensure that all the necessary evaluation is possible so as to best inform national roll-out.

Engagement with faith leaders will continue on a national and regional/local basis.

DH, PHE and NHS England will further develop and refine the communications strategy, designed to raise public awareness about the extension of the vaccination programme to children. The communication strategy will consider uptake levels as the programme is rolled

out. A key lesson from working with Muslim communities in 2013/14 was that easy access to appropriate information to enable people to make informed choices was required. For the 2014/15 season, PHE revised their leaflets for parents about the childhood flu programme making it clear that the vaccine contained porcine gelatine. All health professionals working with the vaccines should also be aware of this, to provide advice and guidance and support parents in making an informed choice. In areas with significant Muslim communities local public health professionals will have the materials available to work with local faith leaders to explain the programme to the local community.

From 2014/15 a more comprehensive programme has been put in place to build the evidence base:

- The pilots will allow for continued exploration of the impact that different methods of delivery have on groups that the system finds hard to reach effectively. It would also allow investigation as to possible methods (eg communications) of enhancing uptake amongst such groups.
- Data on ethnicity will be complemented by qualitative analysis in some pilot areas with questionnaires and in-depth interviews with parents.
- JCVI reviewed the epidemiological evidence as part of its annual review of the seasonal flu programme in June 2015.

Once all the evaluation information for the 2014/15 season is available, this Equality Impact Assessment will be updated and policy reviewed to ensure the most effective and equitable approach to implementation in order to achieve the desired objectives.

For the record

Name of person who carried out this assessment:

Immunisation Branch: Helen Lovell and Zubeda Seedat

Date assessment completed: 14 July 2015

Name of responsible Director: Paul Macnaught

Date assessment was signed: 14 July 2015