Kernow Health CIC
1st Floor, Cudmore House
Oak Lane
Truro
Cornwall
TR1 3LP
School Immunisation Admin Tel: 01872 221105 /221106
Email: enquiries.kernowcic@nhs.net
Website: http://www.kernowhealthcic.org.uk

Dear Sir/Madam

Some concerns have been raised by some parents surrounding the school based nasal flu vaccination programme.

Flu immunisation is a key part of protecting the health of children each winter. The safety and effectiveness of the flu vaccine is of paramount concern to all healthcare workers administering the vaccines, as it is to parents and schools. The information contained in this letter is to help reassure all school staff, parents and children about the safety and effectiveness of nasal flu vaccines.

Background

The children's flu immunisation programme is based on expert advice and recommendations of the Joint Committee on Vaccination and Immunisation (JCVI). This independent expert advisory group provides guidance to Ministers and health departments in all four countries of the United Kingdom.

The nasal flu immunisation programme aims to directly protect children and substantially reduce flu-related illness, GP consultations, hospital admissions and deaths in the population.

The nasal influenza vaccine uses live attenuated (weakened) influenza viruses which help protect against influenza infection in those who receive it. Live attenuated influenza vaccine (LAIV) does not cause clinical influenza in those who are vaccinated. LAIV is offered to children because it has a good safety record, is painless and easier to administer to children than an injection and is effective in preventing flu in those who receive it. For these reasons, in the UK it is the recommended flu vaccine for eligible children aged from two to under 18 years.

Vaccine effectiveness

Concerns have been raised by some parents that the nasal flu vaccine is ineffective and that its recent discontinuation in the USA should also apply to the UK. In August 2016, JCVI reviewed scientific data from the 2015/16 flu season in the UK, Finland and Canada which, in contrast to the USA, showed evidence of good overall vaccine effectiveness. JCVI therefore continues to recommend using the nasal spray vaccine for preventing flu in children and strongly supports the continuation of the UK childhood influenza immunisation programme.

The full JCVI statement can be read here: https://www.gov.uk/government/publications/jcvi-statement-on-the-nasal-spray-flu-vaccine

In 2014/15, in pilot sites where the nasal flu vaccine was offered to all primary school aged children, rates of children seeing their GP for influenza like illness were 94% lower and rates of children being admitted to hospital with influenza were 93% lower than in non-pilot areas.

Vaccine safety

Before being granted a UK license, all medicines must have been assessed for their safety and effectiveness. The nasal flu vaccine, marketed in the UK as Fluenz Tetra, has had a UK license since 2013 and similar authorisation in the US (where it is marketed as FluMist Quadrivalent) since 2003. The vaccine used in both preparations is manufactured here in the UK and has been since 2003.

Medicines that are relatively newly licensed in this country, are subject to intense safety surveillance and are designated as “Black Triangle” after the symbol used in their accompanying literature (▼).This symbol is not intended to restrict use of medicines to certain physical locations such as health centres, but instead acts as a reminder to healthcare workers to report all suspected adverse reactions to the Medicines and Healthcare Products Regulatory Agency (MHRA). This forms part of the on-going surveillance of the safety of this and many other medicines in the UK.

Over the last 3 years in the UK, millions of children have been successfully and safely vaccinated with LAIV. Serious side effects are uncommon, but children may commonly develop blocked or runny nose, headache, tiredness and some loss of appetite. These effects may last a few days.

Viral shedding and exposure to vaccine viruses

Some parents have raised concerns that appear to relate to two **misunderstandings:**

1. As the flu vaccine is squirted out of the applicator as a fine mist, that the school’s rooms will be filled with flu vaccine virus which could infect others.
2. Children who receive the vaccine will actively ‘shed’ live flu virus for several days or even weeks after vaccination, thus putting others at risk of infection, particularly those with weakened immune systems.

The nasal influenza vaccine uses a weakened influenza virus which stimulates the immune system to produce a protective response against influenza, but does not cause influenza infection.

Administration of the vaccine via a nasal applicator delivers just 0.1ml (around 1/50th of a teaspoon) of fluid into each nostril. There is not a ‘mist’ of vaccine virus in the air when children are being vaccinated, almost all the fluid is immediately absorbed into the child’s nose and others in the room are not at risk of “catching” the vaccine virus. The room or school in which administration of nasal influenza vaccine has taken place does not require any special cleaning afterwards.

Although vaccinated children are known to shed virus a few days after vaccination, the vaccine virus that is shed is less able to spread from person to person than the natural infection. The amount of virus shed is normally below the levels needed to pass on infection to others and the virus does not survive for long outside of the body. This is in contrast to natural flu infection, which spreads easily during the flu season. It is important to realise that not all respiratory infections are due to the influenza virus. Even during the peak of flu activity, the majority of respiratory illnesses are caused by other infections.

Excluding children from school during the period when LAIV is being offered or in the following weeks is not necessary.

Some parents of children with immune suppression have been concerned about their child being exposed to vaccinated children in the two weeks following vaccination. As a precaution, children who are severely immunocompromised (for example have just had a bone marrow transplant) should avoid being in school when LAIV is being administered. These children are normally advised not to attend school anyway because of the definite and much higher risk of being in contact with other infections that spread in schools. If a parent is concerned that their child falls into this category, the child's specialist doctor will be able to advise them further and parents can also contact the school immunisation team for advice.

It is important that all children with immune problems should themselves be vaccinated, usually with an injected (inactivated) vaccine. Similarly, healthy children who have family contacts who are severely immunocompromised should be given inactivated influenza vaccine to reduce the chance they will pass on flu to the severely immunocompromised family contact.

Parental consent and information about the vaccine being offered

Responsibility for seeking consent before immunisation lies with the relevant healthcare professional. Before administering LAIV or any other vaccines to children, parents are provided with information about the risks of the illness their child is being offered protection against, along with information about the vaccine including side effects, safety, efficacy and the content of LAIV, such as it containing porcine gelatine.

The information is provided in leaflets which accompany the parental consent forms. This allows parents time to read about the vaccine, as well as a telephone number for them to contact health professionals if they want to discuss the immunisation being offered in more detail. This process is designed to allow the parent, or the person with parental responsibility, make an informed choice about whether their child receives the vaccine.

Parental consent for immunisation is provided via a form, signed by the parent(s) and returned to the school immunisation team. This form also asks parents to notify the immunisation team of any relevant health problems that may contraindicate immunisation, or may require the school immunisation team to seek further medical information before proceeding with immunisation.

Summary

LAIV has been used in this country and others for a number of years and has a good safety record. Whilst the effectiveness of LAIV has been lower than expected in the US, effectiveness in the UK has been good and after looking at all the available evidence, the expert committee advising UK health departments (JCVI) has recommended its continued use. The reasons for the results in the US are not clear.

Schools and parents should be reassured that those receiving LAIV and those who do not, but share common facilities, are not at risk of developing influenza infection following the use of LAIV in school. The very small number of severely immunocompromised children (e.g. after bone marrow transplant), who may possibly be at risk would not be attending school because of the much greater risk of being exposed to many different infections that circulate in school populations.

I hope this information provides you and your staff with sufficient reassurance about the safety and effectiveness of LAIV to allow us to continue to work collaboratively to protect the health of children at your school and our wider community.

If you have any further questions please contact us on 01872 221105 / 221106

Yours faithfully

Kernow Health CIC