Midlands Partnership NHS Foundation trust has been made aware of a number of letters to schools expressing concerns about the safety and effectiveness of the children's flu vaccine nasal spray. These concerns appear to relate to a number of misconceptions about the vaccine, many of which are addressed in the leaflet you can access through the link below. Some of the specific misconceptions are also addressed in this letter.

The nasal influenza vaccine contains a live attenuated (weakened) influenza virus which helps protect against influenza infection in those who receive it. Live attenuated influenza vaccine (LAIV) does not cause clinical influenza in those immunised and it is offered to children because it works well, has a good safety record and is easier to administer than an injectable vaccine.

Millions of doses of LAIV have now been given in the UK and it has an excellent safety profile. LAIV is used in a number of other countries worldwide including the USA.

Unvaccinated contacts are not at risk of becoming seriously ill with the weakened flu vaccine virus, either through being in the same room where flu vaccine has been given, or by being in contact with a recently vaccinated individual. Therefore, there is no need for any child or staff member to be excluded from school during the period when LAIV is being offered or in the following weeks. The tiny number of children who are extremely immunocompromised (for example those who have just had a bone marrow transplant), are already advised not to attend school because of the definite and much higher risk of contact with other infections that spread in schools.

Polysorbate 80 is a common food additive, for example it is used in ice cream. It is used in several vaccines as an emulsifier (to hold other ingredients together). Compared to its use in foods, there is very little polysorbate 80 in vaccines.

Exposure to vaccine virus during administration

The vaccine is administered using a nasal applicator which delivers just 0.1ml (around 1/50th of a teaspoon) of fluid into each nostril. No 'mist' of vaccine virus escapes into the air and therefore other people in the room should not be 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 in theory, healthcare workers could be exposed to the vaccine virus if it was accidentally released outside of the child's nose, during the extensive use of the vaccine over many years in the UK and the USA, no

transmission of the vaccine virus to healthcare workers has been reported to date.

Vaccine effectiveness

The effectiveness of the vaccine will vary from year to year, depending on the match between the strains of flu in circulation and those contained in the vaccine. Since the introduction of the LAIV programme for children in the UK in 2013, the vaccine effectiveness for laboratory confirmed infection has been good. During 2014/15, pilots were carried out in selected areas of England in which all primary school aged children were offered LAIV. These areas saw a 93% reduction in hospital admissions due to confirmed influenza and a 94% reduction in GP consultations for influenza-like illness in primary school children.

Shedding of vaccine virus

Although vaccinated children do shed vaccine virus for a few days after vaccination, the virus is less able to spread from person-to-person than the natural infection. The amount of virus shed is normally below that needed to spread 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. In schools where vaccine is being offered therefore, the overall risk of contact with influenza viruses is massively reduced by having most children vaccinated.

Despite this overall low risk of transmission, parents of children with immune problems may be concerned about their child being exposed to recently vaccinated children who may be shedding virus. In the USA, where there has been extensive use of LAIV for many years, serious illness amongst immunocompromised contacts who are naturally exposed to vaccine virus has never been observed. Expert doctors at Great Ormond Street Hospital, who deal with many children with very serious immune problems, do not recommend keeping such children off school purely because of vaccination. It is important that all children with immune problems, and their siblings and family contacts, should themselves be vaccinated, usually with an injected (inactivated) vaccine.

A tiny number of children who are extremely severely immunocompromised e.g. immediately after a bone marrow transplant, would not be attending school anyway because the risk from all the other infections that children pass to each other at school would be too great.

Black Triangle medicines (▼)

The LAIV (Fluenz® Tetra) used to have a black triangle symbol from 2013/14 through to 2018/19. It no longer requires this symbol. Before being granted a UK licence, all medicines (including vaccines) undergo a rigorous assessment of evidence relating to their safety, quality and efficacy. Following the introduction of a newly licensed medicine into the UK, it is given a black triangle (▼) symbol, usually for five years. This symbol is used as a reminder to healthcare professionals and the public to report all suspected side-effects to the Medicines and Healthcare Products Regulatory Agency (MHRA). It does not restrict the use of the medicine to healthcare premises. Vaccine safety is carefully and continuously monitored by the MHRA even when a vaccine no longer carries the black triangle symbol.

Consent to immunisation

The NHS and Public Health England information leaflet for parents (link below) covers topics such as side effects of LAIV, lists children to whom the vaccine should not be given and contains information about its porcine gelatine content. It also provides a link to the NHS website for further information and sign-posts parents to their GP, school nurse or health visitor if they wish to discuss the immunisation further.

www.gov.uk/government/publications/flu-vaccination-leaflets-and-posters

Summary

LAIV has a good safety and effectiveness record. Unvaccinated contacts are not at risk of becoming seriously ill with the weakened flu vaccine virus, either through being in the same room where flu vaccine has been given or by being in contact with a recently vaccinated individual. Excluding children from school during the period when LAIV is being offered or in the following weeks is therefore not necessary.

Further information

Further information for head teachers can be found in the leaflet: Flu vaccination: advice for headteachers:

www.gov.uk/government/publications/flu-vaccination-in-schools