Health Protection Scotland

NHS National Services Scotland

Scottish Vaccine Update

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MenACWY vaccination programme

On a UK level there has been an increase in the incidence of meningococcal group W disease over the past few years. In response to this increase the Joint Committee on Vaccination and Immunisation (JCVI) agreed that the current increase in meningococcal W cases constituted an outbreak situation and recommended a vaccination programme aimed at protecting adolescents by immunisation with the MenACWY vaccine. This was felt to be the best option to generate population protection and should provide some protection to other age groups.

This MenACWY vaccination programme is being delivered through general practice for individuals in the eligible cohort who have left school and the school based programme for individuals in S3-S6 will commence early in 2016. More information is available here.

The importance of encouraging uptake is highlighted by the continuing increase in MenW cases reported in Scotland. In the five years 2009-2013 cases of MenW were relatively rare in Scotland ranging from one to four cases per year (mean 2.2). This increased to five cases in 2014 and 15 in the first 43 weeks of this year, accounting for 25% of all meningococcal cases reported to date in 2015.

Pertussis vaccination in pregnant women remains important

In 2012, Scotland, like the rest of the UK, experienced a large national outbreak of pertussis with 1926 laboratory confirmed cases that year, 140 of which were in infants under one year of age. In October 2012, the maternal pertussis vaccination programme was introduced which has had a significant impact in reducing infant cases with 19 and 20 infant cases (aged less than one year) in 2013 and 2014 respectively. The Scottish Government CMO letters on pertussis vaccination in pregnancy are available here and here.

In the first part of 2015 the number of laboratory reports of *Bordetella pertussis* was comparable to the corresponding period in 2014. In the latter part of the year the incidence of pertussis has increased, so that in the first 44 weeks of 2015 there have been 778 laboratory confirmed cases compared to 430 for the same period in 2014, an increase of 348 (81%).

The increase has been observed across all age groups. However of particular concern is the increase in cases under one year of age. In the first 44 weeks of 2015, there have been 38 infant cases compared to a total of 20 and 19 in the whole of 2014 and 2013 respectively. 19 of the 38 infant cases reported to date in 2015, have been infants aged two months or under. These infants rely on maternal immunisation for their protection, since routine infant vaccination against pertussis is not scheduled until ages two, three and four months.

In view of the ongoing raised levels of pertussis activity it is very important that women are immunised between weeks 28 and 32 of pregnancy to maximise the likelihood that the baby will be protected from birth through the transfer of the mother's antibodies in the womb. Although women may be immunised up to week 38 of pregnancy, later immunisation is not ideal as the baby is less likely to be protected by their mother's immunity. At this stage of pregnancy, vaccination would potentially only directly protect the mother against disease and thereby

just reduce the risk of exposure to her infant. All pregnant women should continue to be given the opportunity to be vaccinated, by using every contact to remind them of the importance of vaccination and by sign-posting them to vaccination services in their local area. All babies should continue to receive their primary vaccinations, scheduled at two, three and four months, in a timely manner.

Live attenuated influenza vaccine (LAIV) for the UK childhood flu programme

Background

Live attenuated influenza vaccine (LAIV) has been used in the UK since 2013 to protect children against infection with influenza. The vaccine is the preferred product for children in flu "at-risk" groups aged from 2 to 17 years (inclusive), except for a very small number of contraindicated children, and is used as part of the routine children's programme delivered in schools and general practices.

The vaccine was chosen for children because of its good safety profile, superior performance compared with inactivated flu vaccines and ease of administration. LAIV is manufactured by AstraZeneca/Medimmune and has been sold in many countries for over 10 years. Only one LAIV vaccine is available, marketed as Fluenz Tetra® for the UK and EU market, and FluMist® Quadrivalent for the US market. Fluenz Tetra® and FluMist® Quadrivalent are the same product but in different packaging.

Stocks of FluMist® Quadrivalent will be provided as well as Fluenz Tetra® this season

In agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), AstraZeneca is supplying two batches of the US labelled FluMist® Quadrivalent to the UK market, in addition to the usual UK labelled Fluenz Tetra® stock. FluMist® Quadrivalent is fully licensed for use in the UK (in accordance with the Fluenz Tetra® licence). This action has been taken due to a shortage of Fluenz Tetra® supply to meet the timelines for the 2015/2016 vaccination programme in the UK. There will be sufficient FluMist® Quadrivalent stock to fulfil the requirements of the childhood influenza vaccination programme.

An explanatory letter from AstraZeneca is available here

Fluenz Tetra® and FluMist® Quadrivalent are pharmaceutically identical and FluMist® Quadrivalent is fully licensed for use in the UK (in accordance with the Fluenz Tetra® licence). Some differences exist between the packaging of Fluenz Tetra® and FluMist® Quadrivalent. In addition, there are differences between the US Prescribing Information (USPI), and the UK Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC). In agreement with the MHRA, all FluMist® Quadrivalent packs will be therefore supplied with a UK Patient Information Leaflet (PIL) for Fluenz Tetra®, the USPI should not be used. The Summary of Product Characteristics (SmPC) and PIL are also available electronically here

As these are the same vaccines, both are indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. In the US LAIV is licensed up to the age of 49 years. In the UK LAIV is only licensed for those aged from 24 months to less than 18 years of age.

Expiry date

To ensure timely supply, changes in the supply schedule were required. This has resulted in a mismatch between the actual expiry date and that printed on the packaging and labelling. The two batches of FluMist® Quadrivalent being supplied (FL2113 & FL2118) must not be used after the 24th February 2016. This does not affect the safety, quality or efficacy of the batches.

Batches of UK labelled Fluenz Tetra® may be used up to the expiry date stated on the carton and nasal applicator.

FluMist® Quadrivalent availability

Only a small amount ot FluMist® Quadrivalent will be distributed in Scotland, once existing stocks of Fluenz Tetra® have been delivered to NHS board vaccine holding centres.

Children already consented to receive Fluenz Tetra® do not need to be re-consented to receive FluMist® Quadrivalent

This is because Fluenz Tetra® and FluMist® Quadrivalent are pharmaceutically identical live attenuated influenza vaccines (LAIV) and are therefore interchangeable.

PGD for LAIV

The initial template PGD produced by Health Protection Scotland mentioned only Fluenz Tetra® by name. Therefore the PGD template will be amended to a live attenuated influenza vaccine PGD which mentions both Fluenz Tetra® and FluMist® Quadrivalent by name. NHS boards will issue updated PGDs to frontline staff.

Administration of FluMist® Quadrivalent

FluMist® Quadrivalent should be administered in exactly the same way as Fluenz Tetra®.

Recording use of FluMist® Quadrivalent on the clinical system

Where a child has been vaccinated using Fluenz Tetra® vaccine there is no change to the coding requirements. There is no specific Read code for FluMist® Quadrivalent, but this vaccine can be recorded using the usual approach on the GP system (either “Influenza vaccine (Live attenuated)” or “Fluenz Tetra®”).

Agrippal® trivalent inactivated influenza vaccine

A question has arisen about the suitability of the content of Agrippal® trivalent flu vaccine for the 2015/16 flu season. The recommended strains for the 2015/16 season are:

- A/California/7/2009 (H1N1)pdm09-like virus
- A/Switzerland/9715293/2013 (H3N2)-like virus
- B/Phuket/3073/2013-like virus

It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus.

Agrippal® contains the following strains:

- A/California/7/2009 (H1N1)pdm09 – like strain
- A/Switzerland/9715293/2013 (H3N2) –like strain
- B/Brisbane/9/2014

The B/Brisbane/9/2014 strain in Agrippal® is not of the same lineage as the B/Brisbane/60/2008 like virus recommended as the fourth component of a quadrivalent flu vaccine for 2015/16. Instead the B/Brisbane/9/2014 strain in Agrippal® is of the same lineage as the B/Phuket/3073/2013-like virus and is therefore compliant with European Medicines Agency recommendations for trivalent flu vaccines for the 2015/16 season.

Green Book Updates

Shingles – further updated to include strengthened information on contraindications for Zostavax® in patients with immunosuppression. Updated chapter at https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a

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