Fluenz Tetra Safety Surveillance 2020-2021 Study summary

Children (or their parents/guardians) are eligible to participate in this surveillance if they have received the nasal seasonal flu vaccine, Fluenz Tetra, as part of their routine care in accordance with guidance from the Department of Health.

After vaccination, the parent or guardian of children vaccinated in GP surgeries will be given an Information Sheet by immunisation staff, explaining the purpose of the surveillance, and a 'Safety Report Card' (SRC). For children who receive the vaccination in school, the Information Sheet and SRC will be given to the child immediately after vaccination alongside any other information that they would routinely receive from the school nurse to take home.

If their child has any side effects after vaccination, parents are requested to complete and return the SRC (by freepost) to the marketing authorisation holder in the UK, AstraZeneca or report the side effects online via an online reporting portal. The SRC/online survey asks simple questions about symptoms experienced by the child following vaccination and whether the child has any medical conditions or takes medication.

As this is post-marketing surveillance, not a clinical trial, the child will not need to have any additional clinical assessments and their care will be unaffected by the decision to take part. The child will not be given any experimental treatment or medication as part of this surveillance.

Participation in the surveillance study is voluntary. The person reporting a side effect is asked to sign the SRC to show that they have read and understood the Information Sheet. If reporting online, these confirmations will be captured electronically using check boxes. The individual reporting the side effect is also asked to provide contact details for themselves and the child's GP in case the research team need to ask further questions about the symptoms experienced. Children aged 16 and 17 years may complete the SRC/online survey themselves.

Follow up information may be requested from GPs, subject to participant consent. The details from the cards will be entered into the company's safety database. Patient identifiers (names, addresses) will be visible only to authorised personnel in the UK. If data are shared with departments of AstraZeneca or regulatory agencies based in other countries, then patient identifiers are removed. AstraZeneca and DSRU Education and Research will analyse and assess the information collected. DSRU Education and Research will have access to the information in an anonymised format only and no contact details will be shared with DSRU Education and Research. If serious suspected adverse reactions are reported in this surveillance, this information will be reported (again, with patient identifiers removed) to the drug regulators (European Medicines Agency).

Immunisation providers in the school and GP setting will receive a fee to cover set-up and research costs. Participating sites will be asked to prepare each SRC with the vaccination date, the batch number administered and the study site number before handing out to the vaccinee or representative. GP sites will be asked to complete a data capture form on a weekly basis to provide details of the numbers of children given an SRC for each different age group and batch number. School immunisation teams will be asked to complete a data capture form for each school. Timely completion of data capture forms is essential to allow real-time calculation of the number of reported adverse drug reactions (ADRs) relative to the number of cards issued. The study team will investigate whether there are any differences between reporting of adverse drug reactions between different age groups or for different batch numbers and will compare the pattern of ADRs with those reported in previous years.