FluSNIFF toddler – Guidance for investigators on vaccine and placebo supply and ordering.

Version 2.0 19th August 2025

1. Fluenz Live Attenuated Influenza Vaccine

- Vaccine for the trial will be provided to GPs by UKHSA free of charge, and will be available to order via ImmForm in the same way as seasonal supply for the 2025/26 children's flu programme.
- Investigators should order supply of Fluenz for both NHS programme and the FluSNIFF trial via ImmForm in the usual way once the UKHSA opens ordering in September. We will notify you of this date as soon as UKHSA make this publicly available (will be same as for whole NHS).
- As practices can place weekly orders and receive weekly deliveries (on their scheduled delivery days), investigators are asked to ensure they are not over-ordering and to balance total practice stock across NHS and trial requirements.
- GP sites participating in the trial will have additional vaccine allocated to them, however, if investigators find they have reached their ordering cap on ImmForm and require additional vaccine, please email sitesupport@umed.io and the Sponsor will pass this information to the UKHSA vaccine supply team to ensure the right number of vaccines can be ordered.
- Sites that are part of a multi-branch practice should ensure that they order vaccine for the trial directly to their site and not transfer vaccine between sites.

Please note this specific information provided by UKHSA regarding LAIV for the GP programme (Vaccine update: issue 361, July 2025 - GOV.UK):

Ordering controls will be in place for general practices, to enable UKHSA to balance supply with demand. These controls will work by allocating an amount of LAIV based on the number of registered eligible patients and will be tailored to each practice.

UKHSA expects to be able to accommodate the following, however at this time, this information remains subject to change:

- each GP practice will initially be allocated sufficient LAIV to vaccinate at least 45% of its eligible patients (all 2 and 3 year olds, plus children in clinical risk groups from age 4 to less than 18 years) when ordering commences
- increases to these allocations will be made in response to demand and vaccine availability
- requests for extra vaccine will be considered on a case-by-case basis throughout the ordering period – requests for additional vaccine should be

sent to the helpdesk (helpdesk@immform.org.uk) and should be sent in good time before your order cut-off (out-of-schedule deliveries will be by exception only)

This vaccine has a short shelf life. Try to hold no more than 2 weeks' stock at a time and re-order regularly to reduce local wastage through expiry before use.

Multi-branch practices and LAIV allocations

GP practices or groups that operate over multiple sites but are part of the same organisation will have a joint allocation (as in previous years), even where each site has a unique ImmForm account. This means that it is possible for one site to potentially order all of the available vaccine for the group, unless there is local agreement on how the allocated volume is shared. UKHSA recommend that this agreement is in place before ordering opens to reduce the risk of supply interruption. The information above allows practices to estimate the amount of vaccine they will be initially allocated, and how it should be split between all sites.

Placebo

The placebo for this study is 0.9% saline, drawn from routine NHS stock (vials or ampoules) available at your site. The total dose is 0.2 ml — 0.1 ml per nostril.

Essentially the same volume and technique as the LAIV (Fluenz) spray will be used. However, there are differences in the appearance of the administration device, and it is important that the training document and video on maintaining the blind is followed to exactly during all vaccine or placebo administration:

- preparing tray with vaccine or placebo out of site of parent/carer
- parent/carer facing sideways away from staff member administering doses with head turned further away, child on their knee facing staff member.
- 0.1 ml 0.9% saline placebo per nostril but note sites to use standard 1ml syringe and NHS stock CE marked atomiser (supplied by sponsor, no others allowed). There is no stop plastic on 2ml syringe (as on the LAIV vaccine). It does not matter if small variations in volume occur per nostril as long as 0.2 mls is total given and some is given to each nostril.

No ordering via ImmForm is required. Saline should be stored in accordance with standard NHS storage instructions. Unlike LAIV, no trial-specific accountability or documentation is required for placebo stock. However, preparation and administration should follow site SOPs and the study's blinding guidance to ensure the parent/guardian remains unaware of whether vaccine or placebo has been administered.