

Advice on consent to immunisation

The following text has been provided to clarify which healthcare professionals can seek consent to vaccination and vaccine administration. It should be read in conjunction with chapter 5 of the Green Book and NHS SPS advice on Patient Group Directions and other legal mechanisms

For consent to immunisation to be valid, it must be given freely, voluntarily and without coercion by an appropriately informed person who has the mental capacity to consent to the administration of the vaccine in question. This will be the person themselves, someone with parental responsibility for a child (where that child does not have the capacity to consent for themselves), someone authorised to do so under a Lasting Power of Attorney (LPA) for health and welfare, or someone who has the authority to make treatment decisions as a court appointed deputy. People have the right to be involved in decisions relating to their treatment and care. The exchange of information between the healthcare professional and individual on both the risks and benefits of the vaccine to that individual, bearing in mind any relevant medical conditions, is key to ensuring informed consent.

Where the vaccine is being supplied or administered under a Patient Group Direction (PGD) or Written Instruction (WI) for occupational health purposes, it is the responsibility of the registered healthcare professional operating under the PGD or WI to ensure they have gained informed consent before vaccine supply or administration. Delegation under PGDs and WIs is not permitted.

Where a vaccine is prescribed, for example under a Patient Specific Direction, responsibility for seeking informed consent to vaccination as a prophylactic treatment lies with the prescriber (General Medical Council 2021, Nursing and Midwifery Council 2025).

Whilst it is outside the scope of healthcare support workers and other non-registrants to seek informed consent to prophylactic treatment with a vaccine, they should seek agreement to administer a vaccine for which informed consent has been gained by a specified registered healthcare professional. This applies to HCSWs working under a national protocol for influenza or COVID vaccines or where the vaccine has been prescribed, (please see below).

Consent is a process rather than a one-off event. Consent may be withdrawn at any time and consent obtained for 1 immunisation does not necessarily remain in place for all future

doses of a course of immunisation or other vaccines. Where consent has been obtained for a full course, however, it is not necessary to seek consent again for each subsequent vaccine unless new information has come to light. However, it is good practice to check that the individual is content to proceed before administering subsequent doses of any vaccine.

This principle may also be applied to the provision of regular seasonal vaccines, such as influenza, under a PSD. For example, where a patient becomes eligible to receive an influenza vaccine for the first time and the vaccine is prescribed, it is the responsibility of the prescriber to seek informed consent. In subsequent influenza seasons, where a patient has previously received influenza vaccine and the vaccine (of the same formulation that is unchanged except for the seasonally updated antigens), is again being supplied or administered under a PSD, the prescriber does not necessarily need to seek consent again, provided they are satisfied that the risks and benefits of influenza vaccination in the individual for whom they are prescribing are unchanged.

Consent for subsequent doses in a course, or for a regular seasonal vaccine, may need to be re-sought if evidence arises that suggests the initial course consented for may not provide as high a level of protection or may have a different safety profile than was initially communicated. This would include, for example, if the course was expected to lead to more significant or more common adverse events than outlined initially. Consent may also need to be re-sought if there is a change in medical indication, or the number of doses required, or in the type of vaccine for that individual is changed mid-course. For example, if the course will offer a significantly different level of protection by covering fewer diseases or strains.

People must be listened to, given the information they require to make decisions about immunisation and given sufficient time and support to understand that information. Information should be accessible and provided in a way the individual can understand, ideally before the immunisation appointment.

Information should include details of the process, the benefits of immunisation, and the risks, including known side effects and what to do if they occur. A specified healthcare professional with the necessary knowledge and understanding of the individual's medical indications to receive the vaccine, and of the vaccination being offered should provide this information, for example using the resources produced by the public health agencies, so that they can answer any questions about it to help the person consent to it. Where feasible, healthcare professionals seeking consent should find out what matters to individuals so that they can share relevant information about the benefits and risks of immunisation, including the risks of not proceeding with immunisation.

There is no requirement for consent to immunisation to be in writing, but it is good clinical practice to record that a discussion has taken place and consent has been obtained. The completion of a consent form is not a substitute for the provision of meaningful information sufficient to meet the individual's needs.

Consent is an affirmative act. Before proceeding with vaccination, the immuniser must check that consent has been given, or for adults unable to provide their own consent, satisfactory alternative arrangements are in place e.g. a best interests decision has been made.

Resources to support consent

Written or verbal information should be available in a format that can be easily understood by the individual who will be giving the consent. Where English is not the first language, translations and properly recognised interpreters should be used. The 4 UK countries provide a wide range of public facing information, including leaflets, posters, videos, information packs, factsheets, and websites to support all aspects of the immunisation programme. This information is based on the current scientific evidence and clinical advice.

Whilst this information is available in the form of leaflets and their use is strongly encouraged to help aid informed consent, where invitation to vaccination is made by text or email, then links to these authoritative leaflets can also be provided.

Resources for the 2026/27 flu season in England are available here: <u>Annual flu programme - GOV.UK</u>

References

General Medical Council (2021) <u>Good practice in proposing, prescribing, providing and managing medicines and devices - GMC</u>

NMC (2025) Useful information for prescribers - The Nursing and Midwifery Council