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England

Focus On…Provision of vaccinations by non-registered healthcare workers

BACKGROUND

Vaccination is a key public health measure aimed at preventing and reducing morbidity and mortality across the population, particularly the protection of vulnerable cohorts.

Recent events such as the COVID 19 pandemic and subsequent mass vaccination programme witnessed the expansion of the workforce in the administration of vaccines with significant inclusion of non-registered healthcare care support workers (HCSWs) being involved.

The annual influenza programme heavily relies on non-registered HCSWs such as healthcare assistants (HCAs) to enable coverage and uptake.

UKHSA NATIONAL MINIMUM STANDARDS AND CORE CURRICULUM FOR VACCINATION TRAINING GUIDANCE

The UK Health Security Agency (UKHSA) have recently updated their guidance on the national minimum standards and core curriculum for vaccination training. There is particular reference to maintaining public confidence in vaccination programmes with concerns that public awareness and confidence in vaccines may waver, and that key to countering this and maintaining high levels of engagement is the identification of 'trust, advice, high level of knowledge and positive attitude' as being 'important determinants in achieving high vaccine uptake'.

UKHA's guidance outlines the requirements for vaccinating staff (vaccinators), including the role non-registered healthcare professionals should play in the provision of vaccinations. It specifies that non-registered HCSWs are unable to obtain the clinical consent for vaccination, with Registered Health Care Professionals (RHCPs) needing to obtain clinical consent, and the recommended training for those HCSWs who will administer vaccines:

'it is outside the scope of practice of a HCSW to undertake a clinical assessment for vaccination, take informed consent or work to Patient Group Directions (PGDs)'

'It is recommended that only experienced HCSWs take on a role in administering vaccines. It is expected that these HCSWs will have achieved education and training to Level Three of the Qualifications and Credit Framework (QCF) or equivalent and that they would be working at Level Three or above of the NHS Career Framework'

Given the implications, GPC England have contacted UKHSA, who have stated that this is not a change in policy, but a clearer articulation of wording. Although this may be the case, we appreciate that this 'clarification' around the role of HCSWs may have not be in line with existing interpretation and

could potentially significantly impact upon the way in which practices design and deliver mass vaccinations programmes.

CONSENT

It is a legal and ethical principle that prior to delivering personal care and treatment, including immunisation, valid consent must be obtained.

Those involved in obtaining consent for immunisation should keep up to date with the latest legal developments, legal rulings and their employing organisations' policies and procedures on consent.

Consent to care and treatment is regulated by the Care Quality Commission (CQC) under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 11.

What is required for consent to be considered valid?

In order for consent to be valid, patients must:

- have the capacity to make the decision;
- have been offered sufficient information to make an informed decision;
- be acting voluntarily and free from undue pressure; and
- be aware that they can refuse.

If an adult (over 18 years of age in England) has been assessed as lacking capacity, that is, they cannot make this decision or act for themselves, it may be possible to proceed with immunisation under the principle of acting in their "best interests".

Healthcare workers considering immunising under a "best interests" decision have a statutory duty to follow the Code of Practice and checklist set out in the Mental Capacity Act, 2005. It is good practice to check if an advanced decision or "living will" is in place as this may indicate the individual's wishes regarding vaccination.

How long is consent valid for?

Consent should be seen as a continuing process, rather than a one-off decision. Patients can change their mind about treatment at any time. Therefore, consent can be withdrawn or reinstated in line with the patient's wishes.

Before beginning any treatment, healthcare workers should check that the patient still consents. This is particularly important if:

- a significant length of time has passed since the patient agreed to the treatment;
- there is new information available;
- there have been any significant changes to the patient's condition; or
- the process of seeking consent had been delegated to a colleague.

It is important that patients are given continuing opportunities to ask further questions and to review their decisions and are kept informed about the progress of their treatment or care.

Please also refer to:

- Please see the BMA Ethics Toolkit: Consent and refusal by adults with decision-making capacity
- Children under 16
- Treating 16 and 17-year-olds in England, Wales, and Northern Ireland
- Best interests decision making for adults who lack capacity toolkit

PATIENT GROUP DIRECTIONS (PGDs)

The Medicines and Healthcare Products Regulatory Agency (MHRA) advise that only competent, qualified and trained professionals can use Patient Group Directions (PGDs) for the supply and/or administration of vaccines.

NICE guidance on PGDs recommends that a comprehensive and appropriate training programme be provided for all people involved in using PGDs, and that training and re-training of healthcare professionals using PGDs should incorporate a post-training assessment of competency.

UKHSA template PGDs developed for the NHS in England state that the practitioner using the PGD "must have undertaken training appropriate to [the] PGD as required by local policy and in line with [these] National Minimum Standards and Core Curriculum for Vaccination Training" and "must be competent to undertake vaccination and to discuss issues related to vaccination".

PATIENT SPECIFIC DIRECTIONS (PSDs)

Non-registered healthcare professionals can only administer prescription only medicines where they have either been prescribed or there is a Patient Specific Direction (PSD) in place. The Human Medicines Regulations 2012 does not allow such individuals to administer prescription only medicines under a PGD.

When operating under a PSD, the responsibility for seeking informed consent to vaccination lies with the prescriber i.e. registered healthcare professional. This does not prevent a non-registered healthcare professional from administering vaccination and they can seek agreement to administer a vaccine ("consent to proceed") where consent has already been obtained previously.

CONSENT AND IMMUNISATION

The principles of consent with regards to immunisations are set out in Chapter 2 of the Greenbook.

In relation to Patient Specific Directions (PSDs), a RHCP should oversee the clinical assessment and consent process before delegating vaccine administration to a HCSW. The prescriber (registered health care professional) is accountable for the initial patient assessment, consent process, and the decision to delegate the administration. The HCSW is accountable for ensuring that the patient has not raised any new clinical concerns since the initial assessment. They must refer any new issues back to the prescriber/regulated healthcare professional.

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).

Consent for immunisation can be broken down into stages, which may be repeated should there be changes in information available, clinical context, new queries etc:

1. Clinical assessment and consent process by RHCPs:

> Clinically consenting and agreeing to have the vaccination as a recommended procedure i.e. reviewing the information provided, raising queries and having them answered, and consenting to the vaccination being performed

2. Delegation for administration of vaccine to other HCPs including HCSWs in the absence of any new changes or queries since initial assessment, which would require referral back to a RHCP to reassess

Consent for the actual physical administration of the vaccine ("consent to proceed")
i.e. rolling sleeve up, holding arm out for injection

Steps 1 and 2 do not need to occur contemporaneously and in a co-located manner, but those vaccinators undertaking Step 2 would need to confirm that the consent given in Step 1 was still valid, had been performed by a registered professional, and was appropriately documented in the patient notes prior to the vaccine administration.

Recording of consent: *UKHSA: 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.*

Professional guidance on consent

Health professionals should ensure they are working within their competence, scope of practice and refer to guidance issued by their regulatory and professional bodies.

- **The Nursing and Midwifery Council (2018).** The Code: Professional Standards of Practice and behaviour for nurses, midwives and nursing associates. https://www.nmc.org.uk/standards/code/
- **The General Medical Council** provides guidance for doctors on decision making and consent (2020). Accessed at https://www.gmc-uk.org/ethical-guidance/ethical-guidance- for-doctors/decision-making-and-consent
- **Health and Care Professions Council (2016).** Standards of conduct, performance and ethics. Accessed at: https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/
- **The General Pharmaceutical Council (2018)**. In practice: Guidance on consent. Accessed at: Guidance for pharmacy professionals | General Pharmaceutical Council

SEASONAL VACCINATIONS CONSENT

According to the latest UKHSA guidance:

'The principle of consent as a process 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.'

For this reason, it may be prudent for practices to ensure that a registered healthcare professional is available to respond to any questions should they arise during a vaccination clinic.

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HEALTHCARE SUPPORT WORKERS AND THEIR ROLE IN VACCINATION

Whilst it is outside the scope of healthcare support workers to seek informed clinical 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.

However, vaccine administration by HCSWs must be undertaken only within defined boundaries of competence, under appropriate supervision of a RHCP, where a suitable legal mechanism is in place.

HCSWs may undertake	HCSWs must not
• Vaccine administration, where a suitable legal mechanism is in place, a RHCP is available and the HCSW is trained, competent, and supervised • Suitable vaccines may include influenza, shingles, pneumococcal, and COVID-19 vaccines • Check if patient well on the day, and consent to the technical process of vaccination. (If patient feels unwell on day guidance to be sought from RHCP) • Clinical assessment of vaccine suitability is the responsibility of the prescriber, who would then document this via the PSD mechanism. • Supportive roles in vaccination delivery, including: - Preparation of vaccination areas and equipment. - Monitoring and maintaining the cold chain. - Ordering, receiving, and stock control of vaccines. - Supporting patient flow and observation post-vaccination. • Communication and support, including reassurance, basic information provision, and escalation of patient queries to a RHCP	• Undertake a clinical assessment of vaccine suitability. (This is a RHCP responsibility) • Work under a Patient Group Direction (PGD). • Prescribe or authorise vaccine administration. • Administer injected vaccines to: - Individuals with complex medical or vaccination histories (unless specifically assessed and authorised by a RHCP). - Individuals requiring travel vaccinations (which require a travel health risk assessment by a RHCP). • Respond independently to clinical questions or concerns about vaccination

Extra Responsibilities (dependent on duties within practice.)

- Audits
- Stock Checking
- Infection Control
- Disposal of sharp bins

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SUMMARY TABLE HEALTHCARE SUPPORT WORKERS' ROLE

Activity	Permitted for HCSW?	Conditions / Notes
Clinical assessment for vaccination	❌	RHCP responsibility
Obtaining the technical aspect of consent	☑	Only if trained, competent, and supervised
Work under a PGD	❌	HCSWs cannot use PGDs
Administer vaccine under PSD	☑	Only if trained, competent, and supervised
Administer injected vaccine to infants/preschoolers	❌	Outside scope of HCSWs
Administer vaccine to adults with complex medical histories	⚠	Only if assessed appropriate by RHCP, and where a valid PSD exists.
Administer travel vaccines	❌	RHCP must complete travel risk assessment
Cold chain management	☑	Must complete relevant training
Record keeping / data entry	☑	Under supervision and as directed
Responding to vaccine queries	⚠	Escalate to RHCP
Vaccine ordering and stock control	☑	In line with organisational procedures

Credit: NHSE HSCW Operational Guidance Publication reference: Northeast & North Cumbria Primary Care Training Hub 3/11/2025

HEALTHCARE SUPPORT WORKERS TRAINING AND COMPETENCE

UKHSA: Staff with a role in vaccination

All staff should have received appropriate training prior to undertaking a role in vaccination, whether administering, providing information and advice or any other role that supports the delivery of a vaccine programme. These standards should help staff to request and gain access to this training.

Individuals who have received training for a specific vaccine or vaccines and are now further expanding their vaccination role will require further training. It should not be assumed that an individual who has undertaken training and been assessed as competent to deliver one or more specific vaccine programmes has all the knowledge and skills necessary to provide other vaccinations without additional training, supervised practice, and assessment of competence, or that it is appropriate for them to do so.

When new vaccine programmes or significant changes to existing programmes are introduced, staff should be provided with additional training on these and should also use the competency tool (UKHSA guidance).

SUMMARY:

- HSCWs need to be educated and trained to Level 3 of the Qualifications and Credit Framework (QCF) or equivalent.
- Working at Level 3 or above of the NHS Career Framework.
- Training must include the same topic areas as Registered Healthcare Professionals, tailored to the HCSW's role and responsibilities.
- HCSWs must undertake a vaccination training course and attend / complete annual updates.
- HCSWs must not administer vaccines until assessed as competent by a qualified RHCP.
- Competence must be recorded, signed, and retained in the individual's training file.
- Vaccination must take place under a Patient Specified Direction (PSD).
- Annual updates and ongoing supervision are required to maintain competency.
- HCSWs are up to date with all mandatory training such as BLS and anaphylaxis training.
- Adequate clinical governance and risk management structures need to be in place to support.

PRACTICE CHECKLIST

1. Familiarise with new UKHSA training and curriculum guidance
2. Review Green Book guidance especially Chapter 2 and 5
3. Ensure patient information and advice is available in a variety of formats
4. Ensure staff are familiar with their professional regulatory frameworks and standards of conduct (GMC, NIMC, GPHC, HCPC) particularly:
    a. Competence
    b. Consent
5. Map out vaccination clinic pathways and processes
    a. ensure RHCP clinical informed consent embedded at the start, or within process prior to administration
    b. Review PGD and PSD processes
6. Review of non-registered HSCWs' role
    a. ensure removed from clinical informed consent process
7. Ensure that consent and agreement can documented
    a. Verbally
    b. Writing
    c. Online forms
8. Ensure checking RHPC consent is clearly documented
    a. Who
    b. When
    c. How HSCWs can confirm, and check before proceeding
9. Ensure processes in place to identify changes in clinical context and queries and then escalate as appropriate
    a. Refer to a RHCP, or share guidance and reassess
10. Ensure training in place and available as per vaccination (including):
    a. Anaphylaxis
    b. Basic Life Support
11. Vaccination initial and refresher training in place with tailoring for the different roles and duties
12. Documentation of training and competence
13. Supervision framework and governance in place
14. Escalatory pathways for HCSWs

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Useful References

GMC Decision making and consent

https://www.gmc-uk.org/cdn/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf

UKHSA: National minimum standards and core curriculum for vaccination training for all healthcare staff with a role in delivering vaccination programmes

https://assets.publishing.service.gov.uk/media/6855b286b46781eacfd71dc9/UKHSA_National_Minimum_Standards_for_immunisation_training_2025.pdf

DHSC: Reference guide to consent for examination or treatment

https://assets.publishing.service.gov.uk/media/5a7abdcee5274a34770e6cdb/dh_103653__1_.pdf

Green Book Chapter 2: Consent

https://assets.publishing.service.gov.uk/media/6908d79fef26c341988b25f0/Green_Book_on_immunisation_Ch2_Consent_27_10_25.pdf

Green Book Chapter 5: Immunisation by nurses and other healthcare professionals

https://assets.publishing.service.gov.uk/media/5a7b4b7de5274a34770eaba9/Green-Book-Chapter-5.pdf

UKHSA Vaccine update: Vaccination newsletter for health professionals and immunisation practitioners.

https://www.gov.uk/government/collections/vaccine-update#2025

NHSE General practice vaccination and immunisation services: standards and core contractual requirements

https://www.england.nhs.uk/long-read/general-practice-vaccination-and-immunisation-services-standards-and-core-contractual-requirements/#2-vaccination-and-immunisation-standards

BMA Consent and refusal by adults with decision-making capacity toolkit:

https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/consent-and-refusal-by-adults-with-decision-making-capacity

BMA Children and young people under 16 toolkit:

https://www.bma.org.uk/media/swsfdkbw/children-and-young-people-under-16-toolkit.pdf

BMA Treating 16 and 17 year old in England and Wales and Northern Ireland toolkit:

https://www.bma.org.uk/media/royly4z3/treating-16-and-17-year-olds-in-england-wales-ni-toolkit.pdf

BMA Best interests decision making for adults who lack capacity toolkit:

https://www.bma.org.uk/media/tyufopmh/best-interests-toolkit-updated-2025.pdf

BMA Mental Capacity Act guidance England and Wales toolkit:

https://www.bma.org.uk/media/4z1l3khg/mental-capacity-act-guidance-england-and-wales-updated-feb-2025.pdf