

# Quality criteria for an effective immunisation programme Published June 2025

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# Quality criteria for an effective immunisation programme

A consultation process has been carried out to ensure that the views of practitioners delivering immunisation in many different service areas have been represented.

#### The following organisations were asked for their comments:

- Centre for Pharmacy Postgraduate Education
- Chartered Society of Physiotherapists
- College of Paramedics
- Community Practitioners' and Health
  Visitors' Association
- Department of Health and Social Care, England
- Faculty of Public Health
- Institute of Health Visiting
- London School of Hygiene and Tropical Medicine
- NHS England Nursing Directorate
- NHS England Vaccinations Directorate
- Public Health Agency Northern Ireland
- Public Health Scotland
- Public Health Wales
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal Pharmaceutical Society
- School And Public Health Nurses Association
- Society of Occupational Medicine
- Surgeon General's Department, Defence Public Health
- UCL Great Ormond Street Institute of Child Health
- UKHSA Health Protection Operations Directorate The authors gratefully acknowledge the advice and recommendations that were received.



#### Introduction

#### Background

The national immunisation programme has been highly successful in achieving a marked reduction in the incidence and serious impact of vaccine preventable diseases (VPDs) across the life course. However, there are known and persistent inequities in access to vaccination, and in immunisation outcomes between and across populations. Reasons for these inequities are varied and complex and addressing them will require sustained action across a range of areas.

Whilst it is important to build on the valuable, focussed work undertaken within communities to address inequitable uptake of the COVID-19 vaccine, it is equally important to evaluate what is effective for each part of the national programme, maintaining an evidence-based approach.

The NHS Constitution for England states that individuals have the right to receive the vaccinations recommended for them by the Joint Committee on Vaccination and Immunisation (JCVI) under the NHS-provided national immunisation programme. The details are set out in Immunisation against Infectious Disease (the Green Book) and official communications to the NHS from the UKHSA and other NHS and government organisations. The JCVI Code of Practice requires that the Committee must, when formulating its evidence-based advice to government, include consideration of the cost-effectiveness of the proposed immunisation strategy.

The national immunisation programme is constantly evolving in response to the latest evidence, with fourteen new routine vaccination programmes introduced over the last fifteen years. Although disruption caused by the COVID-19 pandemic is likely to have caused some of the decreases in vaccine coverage seen in 2020-22, compared to earlier years, there has also been a gradual year on year decline in uptake for the routine childhood immunisation programme since 2013.

The National Audit Office published a report in 2019 highlighting that the drivers for the fall in uptake were multi-factorial and complex. Continued efforts are therefore required to maintain the success of the national programme, reduce geographical and other variation in vaccine uptake and ensure World Health Organization (WHO) targets are met.

The national immunisation programme is delivered in a variety of settings, by a large number of healthcare staff of different disciplines, to individuals of all ages across the life course. These practitioners face a growing number of challenges which include the increasing complexity of the immunisation schedule and an abundance of widely available vaccine related information, some of which may be inaccurate or misleading. Research has found that generally vaccine confidence is high among parents in England. Whilst understanding attitudes to vaccination is important, many of the factors that negatively impact upon uptake, including health inequities, are amenable to action by health care providers and other key stakeholders.

Delivering the programme involves the co-ordination of multiple organisations at national, regional and local level. It is therefore important to set out the key quality criteria to be used by all those involved, aiming to maximise vaccine uptake, reduce inequities and thereby protect the whole population from VPDs.



#### Purpose

This publication defines the key elements for the implementation and delivery of a safe, equitable, high quality, effective and efficient immunisation service which is responsive to the needs of vaccine recipients and/or their parent(s)/carer(s). It is intended for all those involved in the immunisation programme pathway, including commissioners, providers and advisors in England. Whilst the content may be equally applicable to the wider UK, it is recognised that there may be different processes and infrastructure in place in the devolved nations which may need to be taken into account in those areas.

Every aspect of the immunisation programme is considered – from ensuring that vaccines are handled properly, staff are trained, and vaccines are accessible – to the administration of all vaccines that are recommended by the JCVI to all eligible individuals. It is intended that these quality criteria can be applied in any setting in which vaccines are administered, for example, primary care, community health care, secondary care, schools, care homes, community pharmacies, prisons, occupational health, travel clinics, independent immunisation clinics and domiciliary and traveller sites.

The quality criteria detailed in this publication provide a useful framework for all staff involved in commissioning, designing, providing and auditing immunisation services. These staff are asked to apply these criteria when implementing and maintaining these services. They are not designed to be used for performance management but should facilitate the development of consistent and realistic standards for such management. This publication covers the following key areas: 1 addressing inequities 2 vaccine accessibility 3 effective communication about vaccines 4 assessment prior to immunisation 5 transport, storage and handling of vaccines 6 documentation 7 adverse event/incident reporting 8 training co-ordination 9

#### **Complementary guidance**

These quality criteria are published in parallel with the UKHSA's Immunisation Equity Strategy: technical guidance and National Minimum Standards and Core Curriculum for Immunisation Training, both have been revised and updated since having been previously published by Public Health England, (the predecessor of the UKHSA). These earlier versions are cited in the National Institute for Health and Care Excellence (NICE) guideline NG218 (May 2022) Vaccine Uptake in the General Population and NICE guideline NG103 (August 2018) Flu vaccination: increasing uptake.

NG218 makes recommendations across three key domains: (1) service organisation; (2) identifying eligibility, giving vaccinations and recording vaccination status; and (3) invitations, reminders and escalation of contact. NICE recommendations are made following careful consideration of the available evidence (which are published as evidence reviews). Where the content of this publication and this NICE guideline overlap, the recommendations from NG218 (and, where appropriate, NG103 or other NICE publications) have been explicitly highlighted throughout to facilitate cross-referencing. The NICE recommendations are indicated thus: [NG218: 1.1; QS145: 1.1] etcetera.

As well as the two guidelines, NG218 and NG103, NICE publishes: a baseline assessment tool and visual summaries in support of NG218; Quality Standard QS190 (January 2020) Flu vaccination: increasing uptake; Quality Standard QS145 (March 2017) Vaccine uptake in under 19s; and a vaccination standard (4) in Quality Standard QS22 (February 2023) Antenatal care).

Taken together, these UKHSA and NICE publications provide a comprehensive suite of resources to support the evaluation and improvement of immunisation services at all levels.

#### **1.** Addressing inequities

Addressing inequities is an overarching requirement for the provision of a quality service across all immunisation programmes.

Immunisation is one of the most clinically and cost-effective public health interventions. Childhood immunisation in particular helps to prevent disease and promote child health from infancy, creating opportunities for children to thrive and get the best start in life. Equity in immunisation is an important way to address wider health inequities. Ensuring that coverage is not only high overall, but also within underserved communities, is also essential for disease control and elimination strategies. There are recognised inequities in vaccine uptake by ethnicity, deprivation and geography and the burden of disease falls disproportionately on some communities.

Commissioners and providers of immunisation services need to understand the specific issues affecting groups and individuals within the population that they serve and to work with communities and local organisations to address these [NICE: 1.1.10 and Box 2].

All public bodies involved in immunisation are also required by law to act to address inequities in outcomes relating to protected characteristics.

The UKHSA Immunisation Inequity Strategy should be consulted and used alongside these quality criteria to address inequities and minimise their impact on immunisation services and uptake. See also 2.4.



#### 2.1 Vaccines should be readily accessible in the appropriate setting(s)

The setting(s) most likely to achieve highest uptake in the target group(s) should be selected. For example, whilst routine infant and pre-school vaccinations are predominantly delivered in primary care, for vaccines delivered to school-aged children, such as influenza vaccine, school-based programmes achieve higher uptake and more equitable outcomes.

For some vaccinations, multiple providers (based on local geography and demographics) may be required to maximise access. Although, conversely increasing the number of providers does not necessarily automatically result in increased uptake and programmes may be best delivered via core service with very targeted/outreach approaches to supplement these and then reach all of those eligible in an efficient and effective way. There is now extensive evidence about the effectiveness of vaccination delivery to different populations in different settings which can be used to inform service design to maximise accessibility [NG218: 1.1.1 and 1.1.2 and Evidence review D].

In order to address inequities and meet specific population needs, immunisation programmes should be tailored to ensure they meet the needs of all communities including underserved populations. The evidence-based World Health Organisation (WHO) 'Tailoring Immunisation Programmes' (TIP) approach was developed to help those commissioning and providing immunisation programmes to identify barriers to vaccination among local communities and develop solutions to encourage and support them to be vaccinated. To improve access it may be necessary to consider, among other things, delivery of vaccination at different times of the day (which may include evenings), on different days of the week (for instance at the weekend and including more than one day of the week in the appointment offer) or in alternative settings such as hospital inpatient wards/outpatient clinics, schools, domiciliary settings, antenatal clinics, pharmacies, prisons or care homes, or through mobile outreach clinics [NG218: 1.1.9 to 1.1.15 and Boxes 1 and 2]; see also 2.4). Consultation with service users [NG218: 1.1.11] and evaluation of different approaches are key.

Patient safety is paramount. All vaccination settings should meet the requirements set out in the Green Book chapter 8 in relation to the provision of safe care, particularly with regard to promptly and effectively managing any immediate adverse events. There must be sufficient space so that it is possible to easily get the patient into the recovery position and/or a suitable position for performing resuscitation, and the floorspace in the premises must be suitable if a patient faints or collapses. Ideally, there should also be access to an oxygen supply. In some settings this will require the provision of portable oxygen: any decision to not carry oxygen should be made on the basis of a local risk assessment.



## **2.2 Vaccinations should be actively offered to eligible individuals according to national recommendations**

Recommendations for the age at which vaccines should be administered are informed by the age-specific risk for a disease, the risk of disease complications, the ability to respond to the vaccine and the impact on spread in the population. The schedule should therefore be followed as closely as possible.

Effective systems should be in place to ensure all vaccines in the national immunisation programme are offered and recommended to eligible individuals according to the schedule, and on an annual basis for seasonal vaccines such as flu. This includes clear communication to parents about the need to register their newborn infant at a GP practice and a straightforward process that facilitates them to do so. It is important that local and cross-border multi-agency working is in place to support vulnerable individuals and families that have additional challenges – such as those who are homeless, and those who, for whatever reason are living in temporary accommodation and/or who move frequently – to obtain their vaccinations on time.

Waiting lists for routine vaccinations are not acceptable. The number of appointments that are made available for vaccination should be closely matched to the number of eligible individuals and kept under review so that population changes are accounted for (for example people moving into or out of a GP surgery's catchment area, including new births). Ensuring access to appointments for the primary vaccination of infants should not lead to the development of a waiting-list and delays for older children. Individual and herd immunity may wane in the absence of prompt access to the recommended reinforcing doses.

As well as providing enough appointments to ensure timely vaccination at all ages, sufficient flexibility is necessary to accommodate different needs and complexities. For instance, a longer appointment might be required, such as for new parents, or when several vaccines are recommended at the same age, or when there is a requirement to establish the vaccination history and subsequent transfer onto the UK schedule of a child newly arrived in the UK (see 2.5). New entrants to the UK should receive information about the UK schedule and support to access vaccination [NG218: 1.3.5].

During pregnancy, women are offered vaccines at specific gestational stages to benefit them and/or their unborn child. Providing timely counselling and information is essential to support informed consent (3.1) and an initial recommendation and offer of vaccination at the optimum time.

Individuals in risk groups should be identified and actively offered immunisations according to national recommendations, both formally (call/recall) and opportunistically, for example during routine check-ups (see 2.6). It is important that vaccination offers are made at the optimal time, for example, the flu vaccination is offered annually during a time-limited period prior to the expected onset of flu disease activity, and eligibility for a number of vaccines recommended for older adults is aligned to them reaching a specific birthday/age.

Contracts, coding, data systems and payment arrangements should support the provision of timely vaccination.



# 2.3 An effective system should be in place to invite those who are eligible for vaccines and remind/recall those who do not make an appointment or present for vaccination

Contracts, data systems and payment arrangements should support the provision of call/recall arrangements. Booking systems and processes should be straightforward and timely and not present a barrier to service users.

The named vaccination lead (see 9.3) for each provider of immunisation services should be responsible for ensuring that people who are eligible for vaccination are identified and that timely offers/invitations are made and reminders are sent to them in line with their contractual responsibilities. The content of invites should comply with NICE guidance [NG128: 1.3.2, 1.3.11 and 1.3.12; NG103:1.4.3 – 1.4.6] and include accessible information (see 3.3).

There should not be sole reliance on using an electronic means of contact as system issues may sometimes occur and not everyone has digital access or digital literacy (see 2.4 and 3.3).

There should be coordination at a local level [NG218: 1.3.1]. Ensuring data on local population immunisation registers (for example, the local Child Health Information System (CHIS)) and in GP records are accurate and up to date is essential to enable effective invitation of eligible individuals [NG218: 1.22 to 1.2.6]. There should be an agreed process for ensuring that newborn infants on the specialist hepatitis B vaccination pathway (for infants born to mothers who have a hepatitis B infection) are very quickly registered with a GP so that they can receive their 4-week dose of vaccine on time as delays increase their risk of becoming infected.

Where local population immunisation registers are not used as the basis for automatically calling/recalling patients, providers should ensure that a suitable alternative system is in place.

Particular attention should be paid to actively identifying and inviting (and making arrangements to vaccinate) individuals in clinical risk groups and underrepresented cohorts (for example, vaccine uptake is lower for individuals who have a learning disability or neurological condition), and those who may not be able to easily access services such as individuals who are housebound, resident in a care home, receiving neonatal or other inpatient care, children and young people not accessing education, or not registered with a GP, as well as those unlikely to complete their immunisation schedule, which may include families or people who are homeless and those who are living in temporary accommodation [NG128: 1.3.7 to 1.3.10;1.3.13; 1.3.21 to 1.3.23].

It is important that the system is sufficiently flexible to re-appoint non-attendees. There should be arrangements to identify and follow up patients who have not presented for vaccination after repeat invitations, based on locally agreed protocols [NG218: 2.1.7; 1.3.14 to 1.3.20].

For vaccination services provided in settings other than primary care, access to data that enables identification of and contact with eligible individuals (and/or their parent or carer, as appropriate) is crucial. For example, school-based immunisation services require timely access to school registers/rolls, next of kin contact details and class lists in order to send invites, information and consent forms to parents and to organise and ensure the smooth-running of vaccination sessions on school premises; primary care vaccinators require similar collaboration from care home staff.

Processes and support for staff should be embedded in all health, social care and other statutory organisations with a role in the commissioning and provision of vaccination services (including local authorities), to enable the best-interest sharing of confidential information within and between these organisations, thereby facilitating an offer of vaccination, in line with Caldicott Principle 7: "The duty to share information for individual care is as important as the duty to protect patient confidentiality". Failure to appropriately share data or facilitate direct communication between providers of vaccination services and the intended recipients must not be barriers to immunisation.



#### 2.4 Barriers to immunisation should be identified and addressed

However, the precise combination of barriers and facilitators to vaccination uptake is often dependent on context and the population concerned. Service users should be consulted to determine what improvements could be made to facilitate access to immunisation services – drawing on approaches such as WHO TIP. This may include immunising outside of routine immunisation/baby clinics sessions, extending clinic times and ensuring enough immunisation appointments are available. [NG218: 1.1.9 to 1.1.13 and Boxes 1 and 2].

Service providers should collect data, such as ethnicity, that may be relevant for analyses of inequities in delivery and ensure that they have up to date contact and other relevant information such as specific communication needs [NG218: 1.2.8].

Primary care providers should have a robust process for identifying people who are housebound and arranging a domiciliary visit to discuss and offer/administer any vaccinations for which they are eligible.

Consideration should be given to the potential role of all health and social care providers and of providers of other non-healthcare services, including staff in supported living settings and care homes, and in secondary and tertiary NHS services, who may all have opportunities to identify people who are eligible for vaccination, and could either signpost them to the relevant vaccination service(s) or provide further information to support them to access vaccination services.

Staff providing social care and support to individuals in any setting should have an agreed process for responding to invitations for vaccination that the people in their care receive, which may include arranging a domiciliary visit or an appointment and assisting them, as necessary, to prepare for and attend, for example by signposting them to information and/or arranging transport.

Where vaccination is offered outside of a health or care setting, partnership working is necessary to promote optimal uptake, for example, school staff and school-aged immunisation teams need to ensure that sessions are not planned when children and young people may be on school trips or taking exams and to facilitate the smooth running of the sessions.

#### Barriers to immunisation include:

- complex and/or overly restrictive booking arrangements; a lack of transparency/clear explanation to service users about how and when to book; limited options for booking that exclude certain people – for example, as a result of digital poverty or a lack of technical skills/digital literacy; those with a low reading age or whose first language is not English; individuals who have a physical or sensory impairment or a learning difficulty or learning disability; absence of additional support for those who need it
- inflexibility of appointment arrangements specific days/time only; inconvenient clinic times (in relation to other responsibilities such as work and childcare); inconvenient locations; too few appointments available so that vaccinations become overdue; appointment times of insufficient length to allow for a discussion about vaccine concerns
- venues that are not family-friendly, culturally appropriate or otherwise suitable for the intended service users (for example, breastfeeding mothers, children, large families, older adults, those with physical disabilities or a learning disability)
- long waiting times once the individual has arrived at the venue; lack of space in which to comfortably wait; inflexible approach when unforeseen circumstances have resulted in the person/parent/carer arriving late
- no or only limited/unpredictable access to translation services or other forms of accessible communication that allow for a range of abilities
- health care professionals having insufficient knowledge of the immunisation schedule and/or legal mechanisms for vaccine administration (resulting in missed opportunities to advise/signpost/vaccinate
- service users lacking access to information about the immunisation schedule
- sub-optimal management of vaccines and vaccine supplies
- erroneous 'contra-indications' (see criteria 8)
- over-bureaucratic prescribing procedures.

## 2.5 Every effort should be made to minimise the number of immunisation appointments required for the individual in line with national recommendations

Vaccinators and other staff providing advice about vaccinations should, as part of their training, be fully informed that whilst the recommended eligibility criteria (such as an individual's age or weeks of pregnancy) and intervals between vaccines should be adhered to there is no limit to the number of scheduled vaccines that can be administered at any one time. They should endeavour to minimise immunisation visits by optimising the number of vaccines given at each appointment and have a confident approach during appointments where the administration of several vaccines is required, such as for individuals who are behind with the schedule, not appropriately immunised for their age or require multiple vaccines prior to travel. To facilitate this, these staff should understand why it is safe and effective to administer multiple vaccines (unless it is specifically stated not to give together) and be able to explain this to vaccine recipients and address any concerns that they may have.

All appointments should be of sufficient length to allow a discussion and identify and address any concerns (utilising appropriate resources (see 3.2 and 3.3)), obtain fully informed consent, administer the vaccine(s), give post vaccination advice and complete documentation [NG218: 1.1. 22].

#### 2.6 Immunisation status should be assessed at every opportunity in the appropriate setting and vaccines offered according to national recommendations

Policies and protocols that facilitate opportunistic immunisation should be in place. Every effort should be made to assess immunisation status whenever possible, for example, during postnatal check-ups, health visiting contacts with families, general practice appointments for newly registered patients, school health contacts, new entrant screening and chronic disease annual reviews, when providing in- and out-patient care and in drug clinics and children's centres, etcetera ([NG218: 2.1.9 to 2.1.17; NG103: 1.3.1; QS145: Quality statement 4] and MECC). Ideally, any vaccines needed should be offered at this time. Where this is not possible, a referral or signposting should be made to an appropriate provider for completion of the schedule (NG2.1.19). Where vaccines are administered opportunistically in other settings, it is important that the patient's primary care provider is informed so that their records can be updated.

# 2.7 There should be timely access to immunoglobulin and vaccine for the management of a case and their contacts, and for the control of a cluster of cases or an outbreak, of vaccine-preventable infectious disease

There should be established arrangements for the administration of vaccine or immunoglobulin to individual cases and contacts of a case requiring these, within and between each organisation that has a role in vaccination. To be effective such measures usually require rapid deployment. There is an expectation that general practice will provide this service to their registered patients.

Ensuring that systems are in place to manage a cluster of cases or an outbreak of a vaccine-preventable infectious disease requires addition preparatory work and multi-agency coordination (see 9.5).



#### 3.1 Healthcare professionals should recommend vaccination

The opportunity to discuss vaccination with a trusted health care professional has been shown to be a hugely important factor for those who are initially uncertain about taking up the offer of vaccination and is something that individuals/parents/carers want and value.

It is normal for individuals/parents/carers to have questions about vaccination and they may prefer to have a separate appointment/visit solely to discuss these without the pressure of having to make an immediate decision. This may be with a different healthcare professional to the person who will administer the vaccine (for example, parents may speak to their family's health visitor but receive the vaccine from the practice nurse at the local GP surgery). If this is the case, this appointment/visit should be offered in time to allow vaccination – if then accepted – to take place at the correct time.

#### 3.2 Recipients of vaccines and/or their parents or carers should be advised about the benefits and risks of immunisation to enable an informed decision to be made and valid consent to be obtained

Information should be provided to recipients of vaccines and/or their parents or carers about the diseases prevented by each vaccine, which vaccines are recommended and when they should be given. Information should also be provided about the risks of vaccination, but appropriately balanced by information about the risks of the diseases and the benefits of the vaccine in preventing infection. Information should be provided in a variety of different languages, in a culturally appropriate manner and in accessible formats. Sufficient time should be given to allow full discussion with vaccine recipients and/or their parents or carers to ensure they are fully informed on every occasion (NICE 1.1.22).

Consent is a regulated activity (Regulation 11) under the Health and Social Care Act 2008. The Care Quality Commission (CQC) states that it must be obtained lawfully and by a staff member with the necessary knowledge and understanding of the care/procedure for which they are obtaining consent. Staff obtaining consent for vaccination must have received appropriate training (see criteria 8). Non-registered vaccinators must not work beyond their role/ competence and should refer vaccine recipients and/or their parents or carers to a registered health care professional to respond to requests for additional information prior to vaccination. Guidance about consent as applied to immunisation is provided in chapter 2 of the Green Book.

Whilst written consent is not routinely required, the records should indicate that discussion has taken place and that the recipient and/or their parent or carer have agreed to the vaccination. Where consent forms are used, the completion of a consent form is not a substitute for the provision of meaningful information and/or clinical discussion sufficient to meet the individual's needs.



## 3.3 Leaflets in an accessible format must be consistently provided to support informed consent

The availability of accessible resources, containing accurate information, is integral to both promoting knowledge and confidence in vaccination and in obtaining valid consent. Written or verbal information should be available in a form that can be easily understood by the individual who will be giving the consent. This should be provided in a culturally appropriate manner and in an accessible format [NG218: 1.3.3 and 1.3.4]. Where English is not the first language, properly recognised interpreters should be used. Enhanced support or an assessment of an individual's mental capacity to consent may be required for some individuals [NG218: 1.3.6].

Paper resources should be readily available for intended vaccine recipients, and/or their parents or carers, within healthcare facilities including GP surgeries. They should be offered during appointments with healthcare staff, included with written invitations and be accessible in the public/waiting areas. The paper resources available from the UKHSA are sustainably sourced and fully biodegradable. Electronic resources should be used in conjunction with rather than instead of paper resources, recognising that access to the internet is not equitable and electronic resources cannot reach everyone.

The UKHSA has developed a comprehensive suite of leaflets, and other assets, to provide information to the public and support consent to vaccination. The information they contain is based on the current scientific evidence and clinical advice. These are available, free of charge to read, and order and/or download in a wide and increasing number of different languages and accessible formats, including easy-read, large-print and Braille, and as audio and video files, the latter including British Sign Language (BSL). There are additional resources for some programmes, for example template invitation letters that have been developed with behavioural insights teams to support flu vaccination in schools. Similarly, the four UK countries also provide a wide range of printed and online information to support all aspects of the immunisation programme.

These nationally produced resources should be used in preference to locally developed materials, especially when translation is required, to ensure consistency and avoid the risk of legal challenge due to misleading or incorrect information.



## **3.4 Vaccination should be widely promoted in healthcare and community settings**

Up-to-date vaccine-related information should be provided in a number of different locations commonly used by vaccine recipients/parents and carers, including but not confined to venues where vaccination is carried out, for example, GP surgeries, antenatal clinics, health visiting clinics, children's centres, hospital and community clinic waiting areas and pharmacies, as well as schools, universities, libraries and local community venues. Specialist clinics should consider promoting vaccination for individuals in at risk groups who they frequently encounter, for example, having information about flu vaccination in a podiatry clinic attended by people with diabetes, or in the X-ray or spirometry departments for persons with chronic respiratory illness when the annual flu vaccination programme is soon to commence or is in progress.

As well as leaflets, the UKHSA produces posters and videos for display. Local health and social care organisations should consider ways of using information displays to correctly signpost individuals to the appropriate local provider(s).

## 3.5 Accurate information about vaccination should be easily accessible to staff with a role in vaccination, whatever the setting in which they work

All staff involved in immunisation (including those who may be asked for advice and those who provide services) should be familiar with the most up-to-date and reliable vaccine information, such as that provided by the UKHSA, so that they are able to answer questions confidently and also provide individuals with written information and links to trustworthy websites. They should also have easy access to up-to-date national policies and guidelines, including the Green Book and official communications to the NHS from the UKHSA and other NHS and government organisations, in order to both increase/maintain their knowledge and provide a source of accurate information when they have questions or uncertainties [NG218: 2.1.18].



## 4.1 Every eligible person should be assessed for suitability prior to immunisation

An assessment should be undertaken at each appointment, prior to vaccination, by an appropriately trained and competent registered healthcare professional. This should include confirmation of eligibility, current state of health, contraindications and previous vaccine history.

A medical assessment of an individual's eligibility for immunisation may occasionally be required for those who may otherwise be excluded, for example, an individual who has recently had a bone marrow transplant or where there is an uncertain history regarding a possible contraindication.

When non-registered staff are undertaking a vaccinator role, providers should put in place individual patient-level and system checks that support that role, including the correct legal mechanisms for vaccine administration (see 4.2), protocols that clearly delineate their role and the thresholds for escalation to a registered healthcare professional (RHCP) and access to support from a RHCP should it be required. Each appointment must be of sufficient length to allow adherence to the protocols and safe vaccine administration.

## **4.2 Vaccines should be given within the regulatory framework for administering medicines**

Patient Group Directions (PGDs), Patient Specific Directions (PSDs) and – in occupational health settings – Written Instructions (WIs) enable a wide range of healthcare professionals to immunise individuals without the need for a personal prescription and full assessment, by a doctor, at the time of vaccination. However, it is still essential to assess the individual's suitability prior to administration of the vaccine. For vaccinations that cannot be administered at that time within the existing regulatory framework, provision should be made to defer or refer to another healthcare professional or provider able to offer the vaccination in a timely manner.

## 4.3 Immunisation should only be withheld or deferred where a valid contraindication exists

Almost all individuals can be safely vaccinated with all vaccines. Immunisation is contraindicated or should be deferred in only a very few individuals, for example, following an anaphylactic reaction to a component or a previous dose of the vaccine, live vaccines during pregnancy, and for individuals who are immunosuppressed as a result of disease or treatment. Where immunisation is temporarily contraindicated, these individuals should be regularly reviewed and immunised at the earliest opportunity should their clinical circumstances change. Vaccinators should receive training so that they understand how the immune system functions and how vaccines work, and, therefore, why some vaccines are not recommended or should be deferred for certain individuals. They should be familiar with and refer to national guidelines such as the Green Book and other sources for specific information about contraindications. Where there are discrepancies between national guidelines and a vaccine manufacturer's Summary of Product Characteristics (available from the electronic medicines compendium) then national guidelines should be followed.

If there are concerns about suitability for immunisation, healthcare providers should promptly seek appropriate expert advice from a consultant paediatrician or physician, immunisation specialist and/or commissioning team, health protection specialist or medicines information pharmacist. It is important not to withhold vaccines unnecessarily and to minimise any delay in offering protection. Where immunisation is temporarily contraindicated, for example, in pregnancy or during immunosuppressive therapy, these individuals should be regularly reviewed and immunised at the earliest opportunity.

## 5.1 National guidance and recommendations should be followed for the transporting, storing and handling of vaccines

It is important to ensure that all staff involved in the provision of an immunisation service (including non-clinical staff) are familiar with national and local guidelines and have timely access to relevant communications, including national safety alerts. It is good practice for organisations to have a designated individual responsible for ensuring safe custody of all pharmaceuticals, including vaccines.

Local storage and handling protocols should be written in accordance with national recommendations and vaccine manufacturers' Summary of Product Characteristics. Guidance should be sought from appropriate local/regional experts such as medicines management pharmacists or immunisation commissioning personnel. These should be reviewed regularly to ensure they remain in line with current best practice and national recommendations. Regular audit of storage and handling procedures should be carried out.

It is essential that the vaccine cold chain is maintained at all times to ensure that each vaccine remains within its product licence and to preserve vaccine effectiveness and avoid wastage.

The storage and handling protocol should include the maintenance of accurate records of vaccine stock, a record of vaccine fridge temperatures taken at the frequency recommended in the Green Book chapter 3 and what to do if temperatures fall outside of the correct range. Stock management procedures should be in place to ensure sufficient vaccine supply, prevent inadvertent use of expired vaccines and reduce the expense of wastage.

Each organisation's named vaccination lead (see 9.3) is responsible for ensuring that best practice is followed for ordering, storing, distributing and disposing of vaccines, in all settings (see the Green Book chapter 3 for the full guidance that should be followed).



# 6.1 Accurate and complete lifelong records of an individual's immunisation status should be maintained and should be accessible to the appropriate professionals

Accurate accessible records of offers of immunisations and of vaccines administered are important for individual clinical management, monitoring vaccine coverage and enabling the recall of recipients, if required [NG218: 1.2.20 to 1.2.26].

Vaccines given in primary care should be recorded in the patient's general practice record. Vaccines administered outside the general practice setting, for example in school or maternity settings, should also be documented in the patient's general practice record. Vaccines administered to children should, when it is available, also be recorded the Personal Child Health Record (PCHR) – commonly known as "the Red Book" (see 6.2). To facilitate appropriate clinical care, the timely transfer of such information should be an explicit requirement in contracts and, to support this, the use of available software and centralised electronic systems to facilitate real-time recording and sharing of immunisation records is recommended [NG218: 1.2.1]. The following information should be recorded for each vaccine administered:

- vaccine antigens for example Td/IPV and, ideally, also the specific product name such as Revaxis (products containing the same antigens may have different formulations; it is helpful to know which product was received in the event of an adverse event which may contraindicate the specific product in future)
- batch number
- dose administered
- site(s) and route(s) used
- date immunisation given
- name of vaccinator
- expiry date

The immunisation records of every person should be readily transferable, in a timely manner between all healthcare teams responsible for the different aspects of each person's care. [NG218: 1.2.1]. Organisations and their staff should be clear about what the responsibilities, limits and permissions are so that unnecessary barriers to data sharing are removed, so that all eligible individuals receive an accessible offer of vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination errors are prevented. Caldicott principle 7 applies: "The duty to share information for individual care is as important as the duty to protect patient confidentiality" so that all eligible individuals receive an accessible offer of vaccination deferrals and delays are avoided, and vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination at the scheduled time, vaccination deferrals and delays are avoided, and vaccination errors are prevented.

Vaccination records should also be easily accessible to appropriate professionals who are involved in the care of the patient or in preventing infection in the population. Providers should regularly review and validate their immunisation records to identify incompletely immunised individuals, monitor coverage and review the immunisation service as a whole [NG218: 1.2.5; 2.1.4 to 2.1.5; NG103: 1.5.1 – 1.5.4].

The named vaccination lead (see 9.3) is responsible for ensuring that all vaccinations administered are recorded and that records are validated and updated [NG128: 1.1.1].

Vaccines administered should be reported in a timely way so that information can be included in the local population immunisation register, for example, to the local Child Health department, to enable effective management of the local immunisation programme, including recall of non-attendees and monitoring local vaccine coverage. Data from local population immunisation registers or GP systems should be available to provide population coverage estimates that inform national vaccine policy.

It is important that commissioners, providers and organisers of GP practice vaccination services and child health information services (CHIS) understand each other's reporting systems and processes; the named immunisation lead in those organisations should take responsibility for this [NG218: 1.1.1].

## 6.2 All vaccine recipients and/or parents/carers should be provided with a record of their immunisations and encouraged to retain it

Every individual should be provided with a personal record of the immunisations they have received, for example, "the Red Book" or a patient-held record and asked to keep it safe and present it when required in the future. This record should include any additional vaccines that may be given for occupational and travel health indications.

Using the PCHR to record all vaccines administered will provide children with a lifelong record and encourage parents to engage in their children's immunisations, thereby improving the chances of completing the schedule.



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## 7.1 Healthcare professionals should report suspected vaccine reactions in accordance with the appropriate regulatory guidance

Individuals should be informed of expected vaccine reactions and encouraged to report any unexpected adverse reactions following immunisation to their vaccinator/vaccination provider.

Vaccinators should record any suspected vaccine reaction promptly, accurately and completely in the patient's medical notes. They should also report it to the Medicines and Healthcare Products Regulatory Agency (MHRA) (via the Yellow Card Scheme), even if they are uncertain as to whether the vaccine caused the adverse reaction. Reporting to the MHRA can also be done by vaccine recipients and/or their parent(s)/carer(s).

When managing possible vaccine reactions, healthcare professionals should avoid using language that irrevocably links the individual's signs and symptoms with vaccination, unless there is no doubt (for example, a local reaction at the site of immunisation occurring within the first few days after administration). It is important to avoid an individual being wrongly labelled as contraindicated for life.

Adverse reactions should be recorded in the patient-held record, for example, the PCHR, patient's general practice record, other clinical record (as appropriate) and, ideally, any local population immunisation register.

## 7.2 Programmatic and vaccine administration errors should be reported promptly in accordance with the relevant clinical governance system

When programmatic errors occur, for example, failure of a call/recall system or cold chain failure, there should be a system in place to establish a multi-disciplinary/multi-agency incident team, if needed, depending on the scale of the error.

Since errors in vaccine administration, such as wrong vaccine, incorrect dose or expired vaccine given, can cause concern both to the recipient(s)/parent(s)/carer(s) and the vaccinator, it is important the situation is dealt with as efficiently and transparently as possible. In the event of an error, vaccinators should know whom to contact for expert advice, for example, a local immunisation co-ordinator, local Health Protection Team (HPT), vaccine manufacturer or medicines management pharmacist. A robust system should be in place to facilitate reporting so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised. National guidance on responding to vaccine incidents is available and should be consulted.

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# 8.1 Everyone who advises about and/or administers vaccines should be appropriately trained, competent and regularly updated according to national guidance [NG218: 1.1.19 to 1.1.21]

Training is integral to a successful, high quality immunisation programme.

The purpose of training is to facilitate safe and effective vaccination whilst acknowledging that providing a successful immunisation programme is more complex than simply administering a vaccine. The importance of ensuring appropriate trained staff cannot be underestimated (see, for example, 2.5, 3.2 and 4.3).

Those coordinating an immunisation service should consider the necessary competency of the staff involved and document this (for example, within the PGD).

All staff administering or advising about immunisations should be trained to an appropriate level of competence and confidence as defined in the National Minimum Standards and Core Curriculum for Immunisation Training, which is written for all healthcare staff whatever their role in delivering vaccination programmes.

Training should be comprehensive and cover all topics in the Core Curriculum as appropriate to the specific role of the member of staff (vaccinator and/or provider of advice about vaccination) and should also include reflection and sharing of lessons learned from practice and from vaccine related incidents or errors. The UKHSA publishes immunisation resources to support training and clinical practice for all aspects of delivery of the national programme. In addition, the four UK countries each have their own training arrangements and/or resources.

Those new to immunising should undergo a period of supervised practice and should have their knowledge and clinical competency assessed prior to commencing vaccinating independently.

It is also important that staff undertake regular updates in order to keep abreast of any new programmes, or amendments to existing policies and programmes. Updates should be provided at least annually; more frequent updates may be required if substantial changes to programmes or policies are made or when new vaccines are introduced. However, updating should be seen as a continuous ongoing process rather than purely as a one-off annual event.

The requirement to be trained and assessed as competent, and for staff to be given protected learning time to undertake this training and to develop the necessary knowledge, skills and confidence, should be included in contracts.

Lack of staff training in how to discuss vaccinations effectively is a barrier to vaccination [NG218: Box1], as is incomplete or inaccurate knowledge of the programme, immunisation schedules, and their underpinning principles. Delegating immunisation to a staff member who lacks knowledge, confidence or appropriate clinical support mechanisms and competence can lead to people accessing unreliable vaccine information elsewhere, unnecessary delays in vaccine administration, or vaccine refusal.

#### 8.2 Everyone who advises on or administers immunisations should know how to obtain expert advice and support for clinical issues and have easy access to this

Scenarios may arise within which, despite comprehensive training and the availability of published resources (8.1), vaccinators require additional support. When necessary, for both adults and children, vaccinators should be able to seek further vaccination advice from experts, such as a local immunisation co-ordinator with specialist immunisation and clinical public health expertise, commissioning team or health protection team (HPT). Local arrangements and contact details should be communicated to all vaccinators and staff providing advice about vaccination.

Additionally, arrangements should be in place to obtain specialist clinical advice for complex immunisation queries.

Access to vaccination advice is critical for timely and effective delivery of the national programme and must be maintained should changes be made to local, regional or national commissioning and/or public health arrangements.

#### 9. Coordination

## 9.1 The immunisation programme should be coordinated at the population level with defined roles and responsibilities

Due to the complexity of delivering immunisations in a variety of settings to people of all age groups, it is essential that the immunisation programme is co-ordinated at a population level, that includes, national, regional, local system and organisational coordination.

Areas of responsibility include:

- provision of training and dissemination of vaccine related information to all staff
- provision of expert advice, including responding to clinical and programmatic queries
- maintenance of an up-to date population immunisation register
- feedback of coverage data and addressing areas with low uptake
- implementation of new programmes/campaigns
- audit and feedback

Audit and feedback are key to providing an effective, high quality service and ensuring improvements are made where needed [NG218: 1.1.16 to 1.1.8; NG103: 1.5.1 – 1.5.4].

Since these functions may be delivered by a number of individuals, there should be a named person who has overall responsibility for the immunisation programme at the population level, in addition to system leadership and coordination at national and regional/sub-national levels.

#### 9.2 National coordination and collaboration with public health commissioners and health protection leadership across regional and local commissioning boundaries are necessary to effectively deliver a consistent, high-quality, evidence-based and safe vaccination offer across the country

Links should be established between all those with an immunisation role, including the service providers. To ensure this, a forum should be in place to facilitate liaison and collaboration between those with commissioning and coordinating roles (including providers of specialist clinical advice) at a local and regional level both to enable communication and exchange of information with each other, and with the national immunisation team within UKHSA.

Integral to this, there should be regular online meetings, a dedicated email address, webinars and conferences that allow the exchange of up to date knowledge and information about clinical queries, incidents, practical and operational issues so that commissioning and health protection teams have access to expert clinical and policy advice that enables them to support providers.

These are vital components of the national programme and must be preserved if changes to commissioning or public health arrangements – locally, regionally or nationally – are made.



## 9.3 There should be a named vaccination lead for each organisation that commissions, provides or organises vaccination services

This individual should take responsibility for the oversight of these services, ensuring that standards are being met and that opportunities for vaccination are maximised. They should also work closely with others within and outside of their organisation, to understand current performance and where this can be improved [NG218:1.1.1 to 1.1.6].

Named vaccination leads are responsible for ensuring that there is coordination between providers and other services involved in organising and reporting vaccinations.

This is a core contractual requirement for GP practices. Leadership and coordination are important at all levels of larger organisations.

#### 9.4 All healthcare staff, including but not confined to those advising about or providing immunisation, should understand the relevant commissioning pathways and/or have access to advice about the local arrangements

Immunisation services may be commissioned at national and local level and different arrangements are in place for universal and selective programmes, and for outbreak response. Providers need to understand the arrangements for the provision and reimbursement [NG218: 1.1.7 and 1.1.8] of immunisation services so that they can ensure that eligible individuals are signposted to the correct service to access vaccination and to avoid delays in being offered protection.

A coordinated strategy, within and across organisations, to communicating information about vaccination eligibility and accessibility to staff will facilitate 'correct first time' signposting to an appropriate service and aligns with the Making Every Contact Count (MECC) approach to "helping individuals and communities significantly reduce their risk of disease".

## 9.5 Prior multi-agency planning and agreement are essential components of any outbreak response that requires the offer of vaccination or immunoglobulins

All commissioners and providers of NHS services have public health functions. As well as individual roles and responsibilities, the UKHSA, NHS organisations, local authorities and other bodies have a statutory collective responsibility to respond to an incident involving a vaccine preventable disease. This may be a case, cluster of cases or outbreak and requires them to implement measures, including the administration of vaccine or immunoglobulin when appropriate, to protect vulnerable individuals, reduce onward transmission and prevent further cases. To be effective, such measures usually require rapid deployment and multi-agency collaboration at a national and local level is crucial. There is an expectation that general practice should provide this service but also an understanding that a number of factors, including the scale of the required response, may necessitate a different delivery model. It is vitally important that plans, pathways and access to supporting resources and infrastructure are considered and agreed in advance so that a coordinated response can be promptly deployed when needed and access to vaccination is therefore timely and appropriate. In England, Integrated Care Boards (ICBs) have a pivotal role.



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#### Summary

Immunisation remains the cornerstone of public health. It has a key role in reducing health inequities and in protecting the population from global infectious disease threats. The national immunisation programme has been highly successful, but the sustained decline in uptake is of concern. Whilst much has been written about social media driven 'vaccine hesitancy', attitudinal studies indicate that very few individuals refuse vaccination for themselves or those for whom they care, but that there are many factors that discourage vaccine uptake. Therefore, although it may be challenging, these factors can and, crucially, must be addressed so that services meet users' needs and utilise every opportunity to offer vaccination.

By using these criteria and other resources published by the UKHSA and NICE as a blueprint, action must be taken by all involved to remove barriers, improve access and to further improve the quality of the delivery of the national vaccination programme. Doing so will have a lasting benefit for the vaccinated individuals, the wider population, and the health and social care systems throughout the UK.



#### About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation health secure.

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