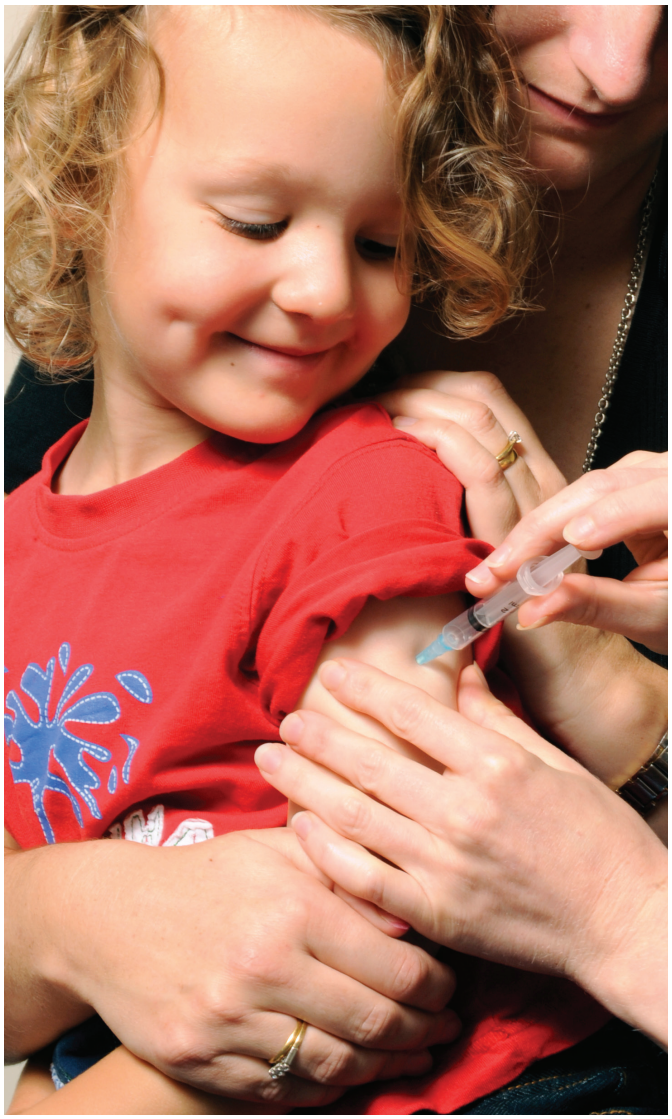
Health Protection Agency

Quality criteria for an effective immunisation programme



FACULTY OF PUBLIC HEALTH

NaTHNaC National Travel Health Network and Centre

Royal College of Nursing

CPHVA

Association of Directors of Public Health

RCPCH Royal College of Paediatrics and Child Health
Leading the way in Children's Health

SAPHNA School And Public Health Nurses Association

The Royal College of Midwives

RCGP Royal College of General Practitioners

Royal Pharmaceutical Society

BGTHA The British Global and Travel Health Association

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Quality criteria for an effective immunisation programme

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An expert advisory group consisting of individuals from different professional backgrounds, led by the Health Protection Agency (HPA), was formed to produce this document. The group drew on their wide range of experience in many different areas of immunisation policy and practice.

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Association of Directors of Public Health (ADPH)
British Global Travel Health Association (BGTHA)
Community Practitioners and Health Visitors Association (CPHVA)
Faculty of Public Health (FPH)
National Travel Health Network and Centre (NaTHNaC)
Royal College of General Practitioners (RCGP)
Royal College of Nursing (RCN)
School and Public Health Nurses Association (SAPHNA)[1]
Royal College of Midwives (RCM)[1]
Royal College of Paediatrics and Child Health (RCPCH)
Royal Pharmaceutical Society

[1]The Royal College of Midwives and the School and Public Health Nurses Association, whilst unable to formally endorse the document, have confirmed their support for it.

Background

The national immunisation programme in England has been highly successful in achieving a marked decline in the incidence of vaccine preventable diseases (VPDs). However, such success can reduce both the public and health professionals' perception of the severity of these diseases and the need for immunisation. Health professionals involved in immunisation face a growing number of complex challenges. These include a plethora of widely available vaccine related information, some of which may be inaccurate or misleading, and the increasing complexity of the immunisation schedule. Continued efforts are therefore required to maintain the success of the national programme, reduce geographical variation in vaccine uptake and to ensure World Health Organization (WHO) targets are met.

The NHS Constitution[1] states that it is the right of individuals to receive the vaccinations recommended by the Joint Committee on Vaccination and Immunisation (JCVI) and laid out in the Immunisation against Infectious Disease (Green Book) and Chief Medical Officer letters.[2,3] Vaccines recommended by JCVI as part of the national immunisation programme are based on evidence of cost-effectiveness.

The national immunisation programme is delivered in a variety of settings, by a large number of professionals from different disciplines, to individuals of all ages. The programme involves the co-ordination of multiple organisations at national, sub-national and local level. Therefore, it is important to set out the key criteria to be used when delivering and assessing an immunisation programme that aims to maximise vaccine uptake and thereby protect the population from VPDs.

Purpose

This document defines the key elements for the implementation and delivery of a safe, equitable, high quality, efficient immunisation service which is responsive to the needs of vaccine recipients and/or their carers.

This document is intended for all those involved in immunisation programmes, including commissioners, providers and advisors. Every aspect of the immunisation programme is considered—from ensuring that vaccines are handled properly, staff are trained and vaccines readily accessible, to the administration of vaccines to all eligible individuals as recommended by JCVI. It is intended that these quality criteria are not context specific and can be applied to any setting in which vaccines are administered, for example, primary care, secondary care, schools, care homes, prisons, occupational health, travel clinics, independent immunisation clinics and domiciliary and traveller sites.

These quality criteria provide a useful framework for all staff involved in commissioning, designing, providing and auditing immunisation 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 document is set out in the following sections—vaccine accessibility, assessment prior to immunisation, effective communication about vaccines, transport, storage and handling, documentation, adverse event/incident reporting, training and co-ordination.

1 Vaccine Accessibility

1.1 Vaccines should be readily accessible in the appropriate setting(s) and actively offered to eligible individuals according to national recommendations

Effective systems should be in place to ensure all vaccines in the national immunisation schedule are offered to eligible individuals at the recommended age. Individuals in risk groups should be identified and actively offered immunisations according to national recommendations.

The setting(s) most likely to achieve highest uptake in the target group(s) should be selected whether it be primary care, hospital inpatient/outpatient, school, domiciliary settings, pharmacies, prisons or care homes, etc. For example, whilst routine infant and pre-school immunisations are predominantly delivered in primary care, for vaccines delivered to school-aged children, e.g. human papillomavirus vaccine (HPV), school-based programmes may achieve higher uptake. For some vaccinations, multiple providers (based on local geography and demographics) may be required to maximise access.

1.2 An effective system should be in place to invite those who are eligible for vaccines and remind/recall those who fail to attend

Where local population immunisation registers are not used as the basis for automatically recalling patients, providers should ensure that a suitable alternative system is in place. Particular attention should be paid to actively identifying individuals in clinical risk groups, as well as those unlikely to complete their immunisation schedule. 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 fail to attend after repeat invitations based on locally agreed protocols.

1.3 Barriers to immunisation should be identified and addressed

Barriers to immunisation include inflexibility of appointment arrangements, long waiting times, poor knowledge of the immunisation schedule, sub-optimal management of vaccine supplies, erroneous ‘contra-indications’ (see criteria 8) and over-bureaucratic prescribing procedures. Service users should be consulted to determine what improvements could be made to facilitate access to immunisation services. This may include immunising outside of routine immunisation/baby clinics sessions, extending clinic times and ensuring enough immunisation appointments are available.

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

Immunisers should be fully informed that there is no limit to the number of vaccines that can be administered at any one time. They should therefore endeavour to minimise immunisation visits by optimising the number of vaccines administered at each appointment. This may be required for individuals who are behind with the schedule, not appropriately immunised for their age or require multiple vaccines prior to travel.[4]

1.5 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, postnatal check-ups, newly registered patients, in- and out-patient care, drug clinics, school health check-ups, new entrant screening, chronic disease annual reviews, children's centres, etc. Ideally, any vaccines needed should be offered at this time. Where this is not possible, a referral should be made to an appropriate provider and arrangements should be made for completion of the schedule. 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 Assessment prior to immunisation

2.1 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 healthcare professional. This should include current state of health, contraindications and previous vaccine history.

A medical assessment of an individual's eligibility for immunisation may occasionally be required in those who may otherwise be excluded e.g. an individual who has recently had a bone marrow transplant.

2.2 Vaccines should be given within the regulatory framework for administering medicines

Patient Group Directions (PGDs) and Patient Specific Directions (PSDs)[5] enable a wide range of healthcare professionals to immunise individuals without the need for a personal prescription and full medical assessment by a doctor. It is still essential to assess the patient'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 provider able to offer the vaccination.

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

Almost all individuals can be safely vaccinated with all vaccines. In only a very few individuals, immunisation is contraindicated or should be deferred, e.g. anaphylactic reaction to a component or a previous dose of the vaccine. Immunisers should refer to national guidelines and other sources for specific information on contraindications. Where there are discrepancies between national

guidelines [2] and a vaccine manufacturer's Summary of Product Characteristics, 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 co-ordinator, pharmacist or health protection specialist. It is important not to withhold vaccines unnecessarily and to minimise any delay in offering protection. Where immunisation is temporarily contraindicated, e.g. in pregnancy or during immunosuppressive therapy, these individuals should be regularly reviewed and immunised at the earliest opportunity.

3 Effective communication about vaccines

3.1 Recipients of vaccines and/or their carers should be advised about the benefits and risks of immunisation to enable an informed decision to be made

Information should be provided to recipients of vaccines and/or their carers on the diseases prevented by each vaccine, which vaccines are recommended and when they should be given. Information should also be provided on the risks of vaccination, but appropriately balanced by the benefits of the vaccine in preventing infection. Information should be provided in a variety of different languages, in a culturally appropriate manner and an accessible format. Up-to-date vaccine-related information should be provided in a number of different locations commonly used by vaccine recipients/parents, e.g. pharmacies, schools, libraries and local community venues. Translation services should ideally be available where required.

Sufficient time should be given to allow full discussion with vaccine recipients and/or their carers to ensure they are fully informed on every occasion. Whilst written consent is not routinely required, the records should indicate that discussion has taken place and that the recipient and/or their carer have agreed to the vaccination.

3.2 Accurate information about vaccination should be easily accessible to immunisers in a variety of appropriate settings

Immunisers should be familiar with the most up-to-date and reliable vaccine information, such as that provided by the Department of Health, so that they are able to provide individuals with written information and links to trustworthy websites.[6]

All staff involved in immunisation (including those who may be asked for advice and those who provide services) should have easy access to up-to-date national policies and guidelines, including the Green Book[2] and letters from the CMO and the Department of Health.[3]

4 Transport, storage and handling

4.1 National guidance and recommendations should be followed in the transporting, storing and handling of vaccines

It is important to ensure that all relevant staff (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 (SPC). Guidance should be sought from appropriate local experts such as pharmacists. 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.

To ensure the vaccine remains within its product licence, it is essential that the vaccine cold chain is maintained at all times 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 least once a working day and what to do if temperatures fall outside of the 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.

5 Documentation

5.1 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 immunisations are important for individual clinical management, monitoring vaccine coverage and enabling the recall of recipients, if required. The following information should be recorded once the expiry date has been checked for each vaccine administered:

- Vaccine antigens e.g. Td/IPV and/or product name e.g. Revaxis
- Batch number
- Dose administered
- Site(s) & route(s) used
- Date immunisation given
- Name of immuniser
- Expiry date

Vaccines given in primary care should be recorded in the patient's general practice record. Vaccines administered outside the general practice setting, e.g. in school, should also be documented in the patient's general practice record. To facilitate appropriate clinical care, the transfer of such information should be an explicit requirement in contracts.

The immunisation records of every person should be transferable to the next registered healthcare professional or team responsible for the person's future care in line with Caldicott Principles. 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 their immunisation records to identify incompletely immunised individuals, monitor coverage and review the immunisation service as a whole.

Vaccines administered should be reported in a timely way so that information can be included in the local population immunisation register, e.g. 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.

5.2 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, e.g. Personal Child Health Record (PCHR) or a patient-held record, and advised of their responsibility to maintain and present this record in 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.

6 Adverse event/incident reporting

6.1 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 potentially serious adverse events following immunisation to their immuniser.

Immunisers should record any suspected vaccine reaction promptly, accurately and completely in the patient's medical notes and should also report it to the Medicines and Healthcare Products Regulatory Agency (MHRA) (via the Yellow Card Scheme[7]) 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 carers.

Adverse reactions should be recorded in the patient-held record, e.g. PCHR, immuniser's record, patient's general practice record and, ideally, any local population immunisation register.

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

When programmatic errors occur, e.g. failure of a call/recall system or cold chain failure, there should be a system in place to establish an incident team, if needed, depending on the scale of the error.

Since errors in vaccine administration, e.g. wrong vaccine, incorrect dose, expired vaccine given, can cause concern both to the recipient/parent and the immuniser, it is important the situation is dealt with as efficiently and transparently as possible. In the event of an error, immunisers should know whom to contact for expert advice, e.g. local immunisation co-ordinator, pharmacist, local Health Protection Unit (HPU), vaccine manufacturer. 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.

7 Training

7.1 Everyone who advises on or administers immunisations should be appropriately trained, competent and regularly updated according to national guidance

Those coordinating an immunisation service should consider the necessary competency of the staff involved and document this (e.g. within the PGD). All staff administering or advising on immunisations should be trained to an appropriate level of competence, e.g. as defined in the National Minimum Standards for Immunisation Training.[8] Training should be comprehensive and cover all topics in the Core Curriculum[9] as appropriate to the specific role of the immuniser. Those new to immunising should undergo a period of supervised practice and should have their knowledge and clinical competency assessed.

7.2 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

Immunisers should be able to seek further immunisation advice from experts where necessary for both adults and children, e.g. local immunisation co-ordinator, HPU, pharmacist. Arrangements should be in place to obtain specialist clinical advice for complex immunisation queries.

8 Coordination

8.1 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. Areas of responsibility include:

- Provision of training and dissemination of vaccine related information to all staff.
- Provision of expert advice.
- Maintenance of an up-to date population immunisation register.
- Feedback of coverage data and addressing areas with low uptake.
- Implementation of new programmes/campaigns.

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.

8.2 All healthcare staff, particularly those advising on or providing immunisation, should understand the relevant commissioning pathways and/or have access to advice on 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 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.

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