UK Guidance on Best Practice in Vaccine Administration
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- Jeannett Martin for her help drafting the section on ‘Consent’

Foreword: Reference has been made to the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) throughout this guidance. It is anticipated that the Nursing and Midwifery Council (NMC) will take over the role of the UKCC in April 2002 as well as taking on the work of the four national boards.
This guidance has been developed and endorsed by the following organisations:

- Association of Occupational Health Nurse Practitioners
- British Travel Health Association
- Community Practitioners and Health Visitors Association
- Royal College of General Practitioners
- Royal College of Nursing
Introduction

The principal aims of immunisation are threefold:¹

- To protect the individual from infectious diseases, with associated mortality, morbidity and long term sequelae
- To prevent outbreaks of disease
- Ultimately to eradicate infectious diseases world-wide, as in the case of smallpox

Nurses are now the major force in administering vaccinations not only within the childhood immunisation programme but also increasingly in administering travel vaccines and in the annual influenza vaccination campaign. In agreeing to undertake this work, nurses assume professional accountability and should ensure that they keep up to date with all aspects of immunisation as outlined in the United Kingdom Central Council’s (UKCC) ‘Guidelines for Professional Practice’.² A doctor who delegates the task of immunisation to a nurse also has a responsibility to see that they are adequately trained and have the opportunity for regular updates.³

**BOX 1²**

**UKCC Guidelines for Professional Practice 1996**

“As a Registered Nurse... you are personally accountable for your practice and, in the exercise of your professional accountability, must....

Maintain and improve your professional knowledge and competence

Acknowledge any limitations in your knowledge and competence and **decline** any duties or responsibilities unless able to perform them in a safe and skilled manner”
Introduction

Immunisation is a safe and highly effective method of preventing infectious disease. Successful immunisation depends upon:

- Production of a safe and effective vaccine
- Maintenance of the cold chain during vaccine transportation and storage
- Injection into the correct anatomical site of an appropriate recipient
- Correct injection technique

This guidance outlines the step by step process and techniques involved in vaccination, from taking a vaccine out of the refrigerator to disposal of the needle and syringe at the end of the procedure. The information provided should be used in conjunction with the ‘Green Book’ and will not therefore go into detail about individual vaccines. Nurses administering vaccines have a duty to be informed about each vaccine they administer and should use resources such as the ‘Green Book’ and the most recent Summary of Product Characteristics (SPC) or Patient Information Leaflet (PIL - found within the vaccine packaging) to update themselves on information relating to a particular disease area or product.

Practices should also keep on file any Chief Medical Officer (CMO) or Chief Nursing Officer (CNO) correspondence regarding vaccination. Such correspondence should always be shared at a Primary Care Organisation level (see section: ‘Further information sources’ for CMO and CNO contact details).

Note: The information contained in this document will be relevant to a range of healthcare professionals including practice nurses, occupational health staff practitioners, health visitors, midwives and general practitioners (GPs). Throughout this document the healthcare professional administering the vaccine is referred to as the 'nurse'. In addition, the person receiving the vaccine i.e. the vaccinee, client, child or adult, will be referred to as the 'patient'.

References:

2. United Kingdom Central Council for Nursing, Midwifery and Health Visiting. Guidelines for Professional Practice 1996
3. Salisbury D M, Begg N T. Department of Health, Immunisation Against Infectious Disease. UK: HMSO 1996; Ch. 6: 17
Patient Group Directions and guidelines

- Nurses must be aware of their legal position when administering a vaccine that has not been individually prescribed by a doctor.

- Since August 2000 Patient Group Directions (PGDs) have become a legal requirement throughout the UK for any prescription-only medicine (POM) administered to a patient for whom no individual prescription exists.

In the absence of legislation allowing nurses to prescribe a wide range of medicines – such as vaccines – alternative means have been developed to facilitate their supply and administration. During the 1990s nurses utilised the ad hoc system of ‘group protocols’ which was given more credence by the Crown Report of 1998. Legislation was introduced in 2000, which made legal the supply and administration of medicines by nurses to undifferentiated patients under a formal agreement with a prescribing doctor. From August 9th 2000 such agreements became known as ‘Patient Group Directions’.

PGDs are written agreements for the supply and administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They can be used for homogeneous patient groups where presenting characteristics and requirements are sufficiently consistent to be catered for by such a non-specific direction, although patients who can be identified before they need a specific medicine should receive that medicine on a patient-specific basis.

The law governing the use of PGDs applies UK-wide since August 2000. The law is equally applicable to all countries within the UK and national guidance is available from the Department of Health (DoH) for England, the Welsh Assembly for Wales and the Scottish Executive Health Department in Scotland. However, the Northern Ireland Assembly has yet to issue guidance on the use of PGDs. Throughout the UK, PGDs should now be drafted to conform with the prevailing legislation. The Royal College of Nursing produces additional guidance and explanation concerning the use of PGDs.
Note that the law restricts the use of PGDs to the NHS or organisations providing care for NHS patients as part of a contract with the NHS. It is expected that legislation will be brought forward to cover the independent sector, but in the meantime it is suggested that where PGDs might be considered to be in the best interests of patients, they should be drawn up and used in line with the national guidance. Nurses using PGDs in non-NHS settings should seek guidance from their professional organisation/insurer.

- Practices should ensure that PGDs applicable to their own surgery/workplace are in place – these should be drawn up by a multidisciplinary team at either Primary Care Organisation or Health Authority (HA) level (please refer to Appendix one for a list of the information that must be included in a PGD)

- The PGD replaces a Group Protocol for the administration of a medicine – it does not replace the need for a protocol (guidelines) which describes the standard of care given in a particular situation (note: all outdated protocols should be kept on file for future reference)

- Guidelines are templates for a consultation and are necessary to demonstrate the way in which a particular surgery or clinic undertakes immunisation

- The information must be available for new or deputising staff to familiarise themselves. In the event of a complaint or legal action the information will also demonstrate the standard of care that is given by a particular establishment

**Note:** This guidance can form part of a protocol for immunisation or travel clinics, as can any other written material which a practice or clinic chooses to use during a consultation – further information is available in Appendix one.
**Black Triangle Vaccines**

“The black triangle symbol indicates newly licensed medicines that are monitored intensively by the Medicines Control Agency (MCA)/Committee on the Safety of Medicines (CSM). Such medicines include those that have been licensed for administration by a new route or drug delivery system, or for significant new indications which may alter the established risks and benefits of that drug.”

“For medicines showing the black triangle symbol, the MCA/CSM asks that all suspected reactions (including those not considered serious) are reported through the

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**BOX 2**

**Black Triangle Vaccines**

- These can be given under a PGD, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation (JCVI)
- The PGD should state what action is to be taken if adverse events are reported

**Unlicensed Vaccines**

- Vaccines that do not have a product licence in the UK cannot be given under a PGD
- They should have a specific prescription signed by a doctor

**Off-Label Use of a Licensed Vaccine**

A licensed product can be administered outside its licensed indications under a PGD providing:

- Such use is justified by best practice
- The status of the product is clearly described
- There is acceptable clinical evidence for the use of the product for the intended indication

**Note:** Please refer to Appendix one for further information on PGDs and the information that should be included in them.

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“For medicines showing the black triangle symbol, the MCA/CSM asks that all suspected reactions (including those not considered serious) are reported through the
Yellow Card scheme. An adverse reaction should be reported even if it is not certain that the drug has caused it, or if the reaction is well recognised, or if other drugs are given at the same time."10

References:

1. United Kingdom Central Council for Nursing, Midwifery and Health Visiting website December 2000 (www.ukcc.org.uk/cms/content/Advice/Patient%20group%20directions%20(group%20protocols).asp)


BOX 3\textsuperscript{1,2,3,4}

- All vaccines have a predetermined shelf life, and expiry dates will be clearly marked on the outer packaging of each product.

- The expiry date is dependent upon the vaccine being stored in the correct manner and maintenance of the cold chain, throughout the shelf life of the product.

- Breaks in the cold chain may result in loss of potency of a vaccine and ultimately to vaccine failure.

- Most vaccines must be kept at temperatures between 2\textdegree and 8\textdegree C – nurses should consult the product packaging to ensure vaccines are being stored at the correct temperature.

- Vaccines are heat sensitive and may deteriorate if kept at temperatures higher than those recommended.

- Freezing deteriorates some vaccines, and may fracture glass containers.

**Vaccine Storage Protocol**

Practices should ensure that:

- There is a designated person (and deputy) responsible for ordering and storage of vaccines\textsuperscript{3}.

- Reception staff are aware of the importance of ensuring that vaccines are handed over to the person responsible for them as soon as possible and know what action to take if either the person or their deputy is unavailable.

- If the person receiving the vaccine delivery is unhappy about maintenance of the cold chain and the length of time spent in transit (i.e. more than 48 hours\textsuperscript{1}) then they should refuse to accept the order and return it to the supplier – if the vaccine has been posted the date and time of dispatch should be clearly marked by the sender so it is clear when the package left optimum storage conditions\textsuperscript{2}.
The Refrigerator

The refrigerator in which the vaccines are stored should:

- Be specifically designed for this purpose (i.e. a ‘pharmacy’ or ‘vaccine’ refrigerator)
- Be large enough to hold the stock carried by the particular surgery, taking into consideration year-round needs (influenza programmes etc)
- Have sufficient room around the vaccine packages for air to circulate, thus enabling the temperature to remain constant
- Have a lock which complies with Control of Substances Hazardous to Health (COSHH) regulations – a lock will also discourage people from opening the door unnecessarily

Domestic refrigerators are not suitable for storing vaccines as the temperature fluctuates considerably and the design is generally inappropriate (shelves in the doors for example should not be used for storing vaccines).

Best practice ensures that:

- Electricity supply to the refrigerator is safeguarded against inadvertent breaks, by use of a switchless electrical socket or a taped plug clearly marked: ‘Pharmacy fridge – do not switch off’
- Practice guidelines state what action should be taken in the event of a power failure, including a contact (name and number)
  - Centrally supplied vaccines – contact the district pharmacist (who should have a policy for dealing with this situation)
  - Vaccines purchased by the practice – contact the manufacturers or consult the BNF for further information about specific vaccines

Note: ‘Patient-held vaccines’ should be discouraged as the cold chain is interrupted. In cases where ‘patient-held vaccines’ are used, the individual should be encouraged to bring the vaccine(s) into the surgery straight away for administration or storage until required.
**Monitoring the Refrigerator Temperature**

Best practice ensures that:

- The temperature of the refrigerator storage compartment is monitored, preferably daily but at least at the beginning of each immunisation session – using an independent maximum and minimum thermometer located in the main body of the refrigerator, regardless of whether there is an alarm system or integral thermometer.

- A chart is kept to record this information – each day’s readings should be dated and timed and the thermometer reset after each reading.

- The vaccine protocol stipulates what action should be taken if the temperatures recorded fall outside the desired range and that such action taken is recorded.

- Vaccines are transferred to another fridge or cool box while the fridge is defrosted and the temperature is continued to be monitored to maintain the cold chain.

**Organisation of Stock Within Refrigerator**

Best practice ensures that:

- The refrigerator is not used to store anything other than vaccines or drugs.

- Certain shelves are designated for different vaccines – this should be listed on the outside of the fridge to minimise the length of time the door is kept open when searching for a vaccine.

- Stock is properly rotated (i.e. new stock is put at the back so the oldest stock is always used first).

- Vaccines are stored in the manufacturer’s packaging – many are sensitive to light and thus will deteriorate if taken out of boxes for any length of time.

- Correct stocks are ordered – over ordering can lead to problems with storage.

**Note:** Suppliers of influenza vaccines should stagger order deliveries as required.
Maintenance of Cold Chain During Clinic Sessions

Vaccines should never be left out. They should be removed from the refrigerator just before use, or if a busy session is anticipated, then vaccines can be transferred to a cool box to prevent frequent opening and closing of the fridge door to maintain the cold chain. Vaccines needed for sessions in schools, outlying clinics or home visits should be transported in an appropriate cool box and returned to the vaccine refrigerator as soon as possible after the session. It may be helpful for the nurse to record the amount of time that vaccines are kept out of the refrigerator.

Note: Vaccine ampoules/vials should not come into direct contact with ice packs used in cool boxes.

Stock Control

Vaccines are valuable and should not be wasted, regardless of whether they are centrally supplied or bought by the practice. Travel vaccinations potentially generate income for the practice so a system should be in place to ensure that all vaccines are accounted for and, where appropriate, vaccination claims are made. A stock control book/database makes this task much easier, and also helps maintain the cold chain as information is available without having to open the fridge door for long periods to examine stock.

The book (preferably loose-leaf folder)/database should:

- Keep track of orders, expiry dates and running totals of vaccines
- Include a designated section for each vaccine with columns for patient details, date of administration and running totals
- Incorporate the refrigerator temperature-monitoring chart so that all the information is kept in one place
- Be dedicated to one fridge – there should be a book for each fridge in practices or clinics where there is more than one
- Be completed by all staff who administer vaccines
References:


2. Shepherd D. Storage of vaccines: safe or hazardous? *Practice Nursing* 1995; 6: 4


4. Allcock A. Vaccine storage. *Practice Nursing* 1993 (7 Sept-20 Sept); 20

Situations in which vaccination should be postponed or omitted

There are few contra-indications for the use of vaccines. Chapter 7 of the ‘Green Book’ covers this issue in detail. Nurses should be familiar with services in their area for dealing with individuals who may have a medical history that requires a cautious approach to vaccination (e.g. pregnant women) and encourage referral to the prescribing doctor rather than discourage vaccination. Most areas have systems in place to treat such individuals e.g. a paediatrician with a special interest in immunisation, travel medicine specialists or a Consultant in a Communicable Disease Control (CCDC) who may run specialised immunisation clinics.

Nurses are often the first point of call for anxious parents and hence need to be well informed with all the facts about individual vaccines, particularly when the media have raised fears about the safety of vaccination. Nurses should present balanced information to parents and should not allow themselves to be influenced by ill-informed media coverage of an issue or their own personal opinion. If they feel unable to answer an individual’s query, they should discuss it with the prescribing doctor or with other sources of specialist information (see above paragraph).

**BOX 4**

**Contraindications to Immunisation**

**General Vaccines**

- Acute febrile illness
- **Severe** local or systemic reaction to a preceding dose – refer to the prescribing doctor where history is unclear
- Pregnancy – preferable not to vaccinate except where the risk of disease may outweigh the risk of vaccination, in which case refer to the prescribing doctor

**Live Vaccines**

- Immunosuppression – either by chemotherapy, radiotherapy or steroids, or HIV infection
- Where possible, live vaccines should be administered either on the same day at different sites, or with a gap of three weeks between the vaccines (this also applies to Heaf/Mantoux tests)
Situations in which vaccination should be postponed or omitted

Exceptional Circumstances

If any course of immunisation is interrupted, it should be resumed as soon as possible.1 Where a course of vaccination has been interrupted it may be advisable to seek advice from the prescribing doctor or from the Medical Information Department of the relevant vaccine manufacturer (please refer to the contact details on the vaccine packaging). It is never necessary to re-start a course of vaccination.

Good clinical practice dictates that where possible the same brand of vaccine should be used to complete a course. If the same brand is unavailable then the SPC should be consulted and an alternative brand of the same vaccine (and the same schedule) should be considered.2

References:


Consent

Obtaining consent has two functions:

- Clinical function – to foster trust and co-operation with patients
- Legal function – to ensure that a person’s right to autonomy has been addressed in order to prevent a charge of battery

Cases heard in the civil courts have confirmed that individuals who have capacity to consent have the legal right to autonomy within decision making.\(^1,2,3\) A person would be held to have capacity (competence) to consent if they are able to meet the three-stage test of being able to:\(^2\)

- Comprehend and retain the information
- Believe it
- Consider the facts and make an informed decision

Adults

All adults are assumed to have capacity to consent unless it can be demonstrated that they do not meet the criteria outlined above. Therefore, unless a person is unconscious and in a life threatening situation, consent must be obtained before any healthcare treatment is provided.\(^2\) It must be voluntary and not obtained under pressure or duress.\(^3\)

If an adult lacks the capacity to consent (e.g. flu vaccination for elderly people with severe dementia in nursing homes), the law does not allow for consent or refusal by one adult (e.g. relative) on behalf of another. The decision to treat would be made by the health professional in charge of their care on the basis of the patient’s ‘best interests’. However, in more serious situations it is advisable to discuss the options with relatives as they may be able to give a view on what the patient would have wanted when they did have capacity to consent.
**Children**

The DoH states: “Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, someone with parental responsibility must give consent on the child’s behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.”

**Implications for Practice**

Guidance from the DoH and statutory bodies to healthcare professionals advises that in order to ensure consent is valid, patients must be given adequate information on which to base their decision to proceed with or refuse treatment. Consent can be given verbally, given in writing or implied.

The process of obtaining consent for vaccination should be the same whether the consent obtained is written, verbal or implied (e.g. holding out an arm to be vaccinated). Before the patient can make their decision they need to have a clear explanation and an opportunity to ask questions about:

- The need for vaccination
- The vaccine and number of doses required
- The risks associated with the disease the patient is being immunised against
- The risks/side effects associated with the vaccine
Written consent is not a legal requirement. However, one advantage of the consent form is that it can be constructed to demonstrate what information was provided before consent was obtained and also that the patient had been given the opportunity to ask questions.

People are entitled to change their minds and withdraw consent. Therefore, if an adult attends a course of vaccinations, consent should be checked at each visit. Any refusal of recommended vaccination should be recorded.

Parental consent for a young child’s vaccination also needs to be obtained at each visit. The person giving the immunisation should be satisfied that parental consent has been obtained. This may be written authorisation or verbal (i.e. a telephone instruction). If in doubt, vaccination should be postponed. Management of parental refusal of child vaccination should be in line with local policy and may involve offering a parent the opportunity of a referral to the GP or community paediatrician so that they can discuss their concerns.

References:
2. Re C (adult: refusal of medical treatment) 1994 1 All ER 819
3. Re T (consent to treatment) 1992 2 FLR 458 CA
5. General Medical Council. Seeking Patients Consent; the Ethical Considerations UK: GMC 1999
6. United Kingdom Central Council for Nursing, Midwifery and Health Visiting website www.ukcc.org.uk/cms/content/Advice/Consent.asp. 14 June 2001
Preparing the vaccine equipment

Before starting a vaccination session or travel consultation, best practice ensures that the nurse:

- Is conversant with local policy on needle stick injury (see section: ‘Needle stick injuries’)
- Makes sure that someone is aware that a vaccine session is about to begin
- Has all the equipment e.g. telephone, vaccines and stationery required (see Box 5)
- Has ensured the room is equipped with suitable seating, ventilation, lighting and a sink/hand cleansing facilities
- Has ensured there are sufficient chairs for all patients and carers

BOX 5

Material Required

Stationery:
- Pre-vaccination checklist/risk assessment questionnaire
- Consent has been obtained
- Patient information sheet – available from Health Promotion England (HPE), the Health Education Board for Scotland (HEBS), Public Health Protection Division (PHPD) of the National Assembly for Wales and the Health Promotion Agency for Northern Ireland (via local Health and Social Services Boards/Trusts) (see section: ‘Further information sources’ for contact details)
- Advice sheet on possible post-vaccination side effects and their management - also available from the organisations listed above
- ‘Patient-held record cards’/Personal Child Health Record (PCHR)
- Certificate of Vaccination (for yellow fever or meningitis for the Hajj)
- Any existing patient records
- Data collection forms – child health immunisation record sheets/unscheduled immunisation forms
Before Vaccination

Nurses should ensure that the appointment is long enough to:

- Assess patient’s suitability for immunisation following a risk assessment
- Advise on possible side effects
- Answer patient queries
- Obtain informed consent
- Consult the patient’s records if available
- Administer the vaccine
- Complete all documentation

Patients will be more distressed and anxious if they feel that the nurse is in a hurry. There is also a higher risk of procedural omissions if a session is rushed. These issues need to be discussed when protocols are being drawn up, and nurses must bear in mind their own professional responsibilities when time is allocated for clinic sessions. Primary care employers and managers should seriously consider these needs.

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**BOX 5**

**Material Required (continued)**

Equipment for vaccination:

- Appropriately sized syringes – 1ml and 2ml
- Selection of needles – 21G, 38mm (1½ inches): 23G, 25mm (1 inch): 25G, 16mm (5/8 inch) (please refer to section: ‘Choice of needle’)
- Cotton wool
- Sharps container
- Gloves if required (need should be assessed for individual situations)
- Resuscitation equipment/drugs for anaphylaxis
- Oxygen and appropriate masks if available
Pre-vaccination Checklist

Before vaccination, best practice ensures that:

- The recipient is fit and well - children can be vaccinated if they have minor infections e.g. upper respiratory tract infection, diarrhoea or otitis media without fever\(^1\)
- There are no contraindications
- The patient or parent understands all aspects of vaccination including possible side effects – give written information where required
- Consent has been granted

References:

1. Salisbury D M, Begg N T. Department of Health, *Immunisation Against Infectious Disease*. UK: HMSO 1996; Ch. 5: 14, Ch. 7: 20-21
Preparing and dealing with anxious people

Many people of all ages are anxious about injections. Nervous mothers can pass on their anxiety to their young children. Teenagers and young adults can become particularly nervous, often due to peer pressure. Nurses should consider the following when giving injections to anxious patients:

- Adopt a calm, sympathetic approach
- Use distraction techniques with both adults and particularly children as these can be very effective (i.e. engage them in a conversation about a subject of interest, sport, TV or current topical story)¹
- Prepare the vaccine and administer the injection (where possible) out of sight of the patient
- Explain that an injection is a quick and simple procedure and not the same as taking blood – often individuals who have had bad experiences with blood tests think the procedures are similar

Fainting

Infants and babies rarely faint,² but can be quite shocked after the experience. It is often appropriate for a patient over this age who is particularly anxious or has a history of fainting to be given an injection lying down. Fainting is more common in individuals who have not recently eaten. Consideration should be given in such situations to the positioning of the individual receiving the vaccine in order to reduce any risk of injury should the patient faint.

Young Children

If a parent or carer is particularly anxious about observing their child receive injections it is advisable to have another member of staff to assist holding the child during the procedure. It is also important to recognise that children appear to suffer less trauma when parents value vaccinations and the child has been prepared for what is going to happen.¹
Preparing and dealing with anxious people

Where a child needs to be given more than one injection at a visit it can be helpful for two members of staff to inject simultaneously, as the child is usually not aware that two injections have been given and hence distress is minimised. This is usually appropriate for children who are old enough to receive injections in the upper arm (see section: ‘Administration of vaccine’ – Box 7).

The procedure could follow that outlined below:

- Sit the child on the parent’s lap with both arms accessible
- Face the child forward, looking at something of interest
- Engage the child in conversation
- Give both injections simultaneously, using a prearranged signal (e.g. count of three)

**Local Anaesthetic Cream**

The routine use of a local anaesthetic cream is not practical in the primary care setting but is an option for occasional use in situations where fear of pain is preventing immunisation from occurring. As the cream is a prescription-only medication and it takes up to an hour to be effective, its use needs to be planned in advance.

**References:**

Preparation of vaccine

Vaccination is an aseptic technique and thus thorough hand washing and cleanliness of all equipment used are imperative. The nurse should:

- Check storage conditions (temperature monitor chart)
- Wash hands thoroughly
- Check the name and expiry date on the vaccine package
- Check that the colour and appearance of the vaccine are correct
- Check the dose is appropriate for the patient’s age

Reconstitution

Where a vaccine has to be reconstituted prior to administration, use only the diluent supplied and note the time scale in which it must be used after dilution (usually one to four hours). Nurses should ensure that:

- Neither the vaccine nor the diluent has passed its expiry date
- Each dose is drawn up as required - if a multidose vial is to be used, do not draw up in advance for the whole session
- Only one type of vaccine is mixed in each syringe, unless specifically stated by the manufacturer
- Any vaccine which contains particles or whose colour differs from the SPC description is discarded

BOX 6

Reconstitution

- A green needle (21G x 38mm (1½ inch)) should be used to draw up the diluent and to inject it slowly into the ampoule containing the vaccine
- Injecting diluent rapidly into the vaccine may cause frothing, which can affect the dilution and consequent potency of the vaccine; shaking the ampoule may have a similar effect
BOX 6

Reconstitution (continued)

- If the freeze-dried powder does not instantly dissolve in the diluent, gently rotate the ampoule until it dissolves rather than shaking it.

- Draw the appropriate dose up into a clean syringe and change the needle to the appropriate size and gauge for administration to the specific patient.

- When removing liquid from a vacuum-sealed ampoule, first inject the equivalent measure of air to the volume of liquid to be removed.

- When drawing up from a glass ampoule, use a needle gauge no larger than 21G to eliminate the possibility of glass fragments being drawn up.

- Where possible change a needle after it has passed through a rubber bung before administration to a patient.

- For quantities less than 1ml use a graduated 1ml syringe.

- Discard unused reconstituted vaccines at the end of the session.

References:

Administration of vaccine

Skin cleansing is not necessary in socially clean patients. Soap and water are adequate where a nurse feels skin cleansing is required. If spirit swabs are used the skin should be allowed to dry before the vaccine is administered (this is essential for live vaccines which may be inactivated by alcohol).¹

Adopting the correct technique for immunisation is vital for:

- Minimising patient discomfort during and after the procedure
- Ensuring the optimum immune response in the patient

Following risk assessment of the patient, nurses should decide upon the appropriate anatomical site, needle size and product.

Injection Site and Route of Administration

Nurses should be familiar with the:

- Route of administration for each vaccine administered
- Local guidelines in place

Reference can be made to either the ‘Green Book’, local guidelines or the product SPC. Further guidance should be obtained from the prescribing doctor. Vaccines should be administered:

- Via either the intramuscular (IM) or deep sub-cutaneous (SC) route.¹ The exceptions to this are the oral polio and oral typhoid vaccines and the BCG, which is given by an intradermal (ID) technique¹
- In the deltoid muscle or anterolateral aspect of the thigh
- Using the appropriate size and length of needle

Consideration should be given to the correct method of administration in people with coagulopathies.
BOX 7

Route of Administration

- There is general agreement that infants under one year should receive all vaccines in the anterolateral aspect of the thigh (see Figures 1a, b and c) since the deltoid muscle is not sufficiently developed.

- Over the age of one there is an element of choice.

- For older children and adults, the deltoid muscle is the preferred site (see Figures 2a and b).

- Do not use the gluteal muscle for vaccination, as it is highly unlikely that the vaccine will reach the muscle, and this may result in poor immune response to the vaccine (this has been demonstrated with hepatitis B vaccine\(^1,3\)). In addition there is a risk of damage to underlying structures such as the sciatic nerve.

- The deltoid muscle is also easier to access in most patients and results in less embarrassment for older children and adults.
Figure 1a: The anterolateral aspect of the thigh
Source: The Australian Immunisation Handbook

Figure 1b: Cross section - anterolateral aspect of the thigh
Source: The Australian Immunisation Handbook
Figure 1c: Administration of an IM injection to an infant using the anterolateral aspect of the thigh
Source: Mike Wyndham, Medical Picture Collection
Figure 2a: Left lateral view of the deltoid muscle – the dots indicate the area parameters recommended for administration of the vaccine.

Figure 2b: Administration of an IM injection into the deltoid muscle of an adult.
References:


Choice of needle

The correct length and gauge of the needle are key in ensuring that the vaccine is delivered to the correct location as painlessly as possible and with maximum immunogenicity. The colour on the hub of the needle refers to the gauge rather than the length of the needle. Thus, while different gauges can be obtained in different lengths, Box 8 outlines the standard sizes in the UK. The higher the number referring to the gauge, the narrower the lumen of the needle.

**BOX 8**

*Standard UK Needle Gauge and Length*

<table>
<thead>
<tr>
<th>Colour</th>
<th>Length/Size</th>
<th>Gauge</th>
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<tbody>
<tr>
<td>Orange</td>
<td>10mm (⅜ inch) long or 16mm (⅜ inch) long or 25mm (1 inch) long</td>
<td>25 gauge</td>
</tr>
<tr>
<td>Blue</td>
<td>25mm (1 inch) long</td>
<td>23 gauge</td>
</tr>
<tr>
<td>Green</td>
<td>38mm (1½ inches) long</td>
<td>21 gauge</td>
</tr>
</tbody>
</table>

Whenever the SPC suggests that the vaccine can be given by either IM or deep SC route, the IM route is to be preferred. When giving an IM injection, the needle must be long enough to reach the muscle mass. The needle should be 25mm long to ensure it reaches muscle (in all but the smallest of babies¹). A study of the deltoid fat pad thickness in adults suggests that bodyweight and gender can help to determine the needle length appropriate for IM injection in the deltoid muscle of adults (see Box 9).²
It is a common misconception that the longer the needle, the more painful the injection will be. This is not the case as muscle fibres have fewer pain receptors than subcutaneous tissue. In addition to this, there is a growing body of evidence to suggest that post-vaccination discomfort is reduced by correct delivery of the vaccine into muscle.

If the vaccine is required to be given via the SC route a shorter needle may be adequate, but the gauge of the lumen should also be considered. There is evidence that a wider lumen allows the vaccine to disseminate over a wider area of tissue, thus reducing irritation to the site. A blue needle (23G x 25mm (1 inch)) should be used both for its wider lumen and because it will ensure an IM or a deep SC injection if the correct technique is adopted.

Another common misconception is that smaller doses (e.g. 0.5ml) of vaccine are better tolerated than larger doses (e.g. 1ml) and produce fewer local reactions. However, evidence suggests that both local and systemic reactions at the vaccination site are similar for both 0.5ml and 1ml doses.

**BOX 9**

**Recommended Choice of Needle Lengths**

<table>
<thead>
<tr>
<th>Category</th>
<th>Needle Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>25mm (1 inch) needle³</td>
</tr>
<tr>
<td>Women &lt;90kg</td>
<td>25mm (1 inch) needle</td>
</tr>
<tr>
<td>Women &gt;90kg</td>
<td>38mm (1½ inch) needle²</td>
</tr>
<tr>
<td>Men 60-118kg</td>
<td>25mm (1 inch) needle²</td>
</tr>
</tbody>
</table>
References:


Technique

Technique is important in determining where the vaccine will be deposited and its resulting efficacy.

**Patient Positioning**

Best practice ensures that:

- The appropriate limb is fully exposed – avoid having tight clothing above the injection site
- Patients are encouraged to sit while they are vaccinated (or to lie down if they are prone to fainting or particularly anxious)
- The upper arm is fully exposed, which may mean removing a shirt rather than rolling the sleeve up. This is important, because:
  - Otherwise the vaccine may be given too low and end up as an SC rather than IM injection with subsequent local reactions and suboptimal immune response
  - A tight shirt sleeve can act as a tourniquet and encourage bleeding at the injection site
- The muscle is relaxed – encourage the patient to either:
  - Let their arm hang by their side
  - Rest their hand on their hip/lap

When giving injections to babies and children, best practice ensures that:

- Babies and infants are held on their parent/carer’s knee (see Figure 1c)
- The parent understands the importance of not allowing the limb to move during the procedure and holds the child gently but firmly
- The child’s free arm is tucked behind the parent and the child cuddled into their body when the injection is to be given in the deltoid
- The arm to be injected is held close to the child’s body – the parent can hold the forearm to prevent movement
- While older children may choose to sit on their own, the parent may still be required to help hold the limb still
**Intramuscular (IM) Injection**

Nurses should ensure that:

- The skin is held firmly (not bunched) with the free hand\(^1\)
- The needle is introduced at a 90° angle\(^2\) (see Figure 3) – aspiration may be performed to ensure a blood vessel has not been penetrated. In the event of blood being aspirated the procedure should be started again with a new needle
- Following administration of the vaccine, the needle is removed smoothly
- Gentle pressure may be applied with a cotton wool or gauze swab for a few seconds if bleeding occurs

---

*Figure 3: Correct angle for administration of IM injection*
Subcutaneous (SC) Injection (Where Appropriate)

Best practice ensures that:

- The skin is bunched between the thumb and forefinger, in order to lift adipose tissue from underlying muscle, especially in thin patients³
- The needle is inserted at a 45° angle (see Figure 4) – it is generally agreed that aspiration is unnecessary for SC injections⁴
- The vaccine is injected slowly
- Gentle pressure is applied to the site with a cotton wool or gauze swab for a few seconds afterwards

Note: The site should not be rubbed or massaged as this can cause trauma to the injection site.

Figure 4: Correct angle for administration of SC injection
Intradermal (ID) Injections

BCG is always given by the ID route. The technique for ID injection takes some practice and should only be performed by someone who has been taught and assessed in this method of administration.

The preferred site for BCG is at the point of the insertion of the left deltoid muscle. Keloid scarring is more likely to occur if a site higher up the arm is used. When giving an ID injection for BCG, nurses should ensure that:

- A 25 gauge, 10mm (⅛ inch) needle is used.
- The patient’s left hand is on their hip so that the upper arm is at a 45° angle to the body.
- The skin is stretched taut with the thumb and forefinger of the free hand.
- The needle is:
  - Held with the bevel uppermost
  - Injected into the skin virtually parallel to the arm for about 2mm
  - Visible beneath the surface of the epidermis (as if under a layer of clingfilm)
- There is resistance following injection of the vaccine – a visible bleb should form where the vaccine has been deposited.

Note: If a bleb is not visible immediately withdraw the needle. The whole procedure should be re-started using the correct dose and technique.

- Patients or parents are advised about the likely formation of a scab and subsequent wound – as BCG is often performed at school an advice leaflet should be sent home for parents.

Note: A plaster or dressing should never be used to cover a BCG vaccination.

Consideration should be given to rabies vaccine, which may be administered via the ID route where appropriate.

Note: The use of the ID route for vaccines other than BCG is at the doctor’s own responsibility as this is not covered by the Manufacturer’s Produce License. If unsure contact the prescribing doctor.
Prefilled Syringes and Ampoules

When using vaccines that come with a fixed needle thought must be given to route of delivery. Following risk assessment, needle length and gauge should be considered. If it is felt that the needle length will not be sufficient to deliver the vaccine to the appropriate site (i.e. due to a thick layer of fat for IM injection) then an alternative should be sought.

Some vaccines are supplied with non-fixed needles or in ampoules, allowing individual choice on needle length.

Note: Where it is not possible to change the needle size (i.e. with fixed needles), the vaccine should never be transferred to another syringe.

References:

5. Salisbury D M, Begg N T. Department of Health, Immunisation Against Infectious Disease. UK: HMSO 1996; Ch. 5: 15-16 and Ch. 27: 185
Needle stick injuries

There is a risk of transmission of blood-borne viruses, including hepatitis B and C and HIV, via bodily fluids. Providing sterile equipment is used and aseptic techniques adopted, there is minimal risk of cross infection during the immunisation process. Any individual administering vaccines should, however, have had a full course of hepatitis B immunisation prior to vaccinating.

One area where there is a real risk of cross infection is with needle stick injuries. A wound caused by a needle:

- Before injection – does not carry a serious risk (although it may result in the loss of the vaccine)
- After injection – carries the risk of cross infection

**Note:** **Swabs used to arrest bleeding at an injection site are also a potential risk to both staff and other patients (e.g. the hepatitis B virus (HBV) can remain active in dried blood for up to one week**). **If a swab is used, the patient or carer should hold it in position.**

The precautions outlined in ‘Disposal of needles, syringes and waste products’ should reduce the risk of any cross infection, but if a needle stick injury does occur, nurses should:

- Encourage bleeding at the time of injury to reduce the risk of a virus entering the circulation

**Note:** **Further action will be determined by the local protocol in place, the status of the source patient and the HBV/HIV status of the injured party.**

- Report the incident immediately
  - In general practice – to his/her employer (advice should also be sought from the Public Health Laboratory Service or consultant in communicable disease control)
  - In clinic/hospital/school – to his/her manager and Occupational Health Department

It is important that nurses know who is their local point of contact if such an incident occurs.
BOX 10

Blood-borne Viruses: Risk of Transmission Following Percutaneous Injury

<table>
<thead>
<tr>
<th>Virus</th>
<th>Vaccine Available</th>
<th>Risk of Transmission</th>
<th>Post-Exposure Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Immunodeficiency Virus (HIV)</td>
<td>None</td>
<td>1:300</td>
<td>Post-exposure prophylaxis (PEP) using combination retroviral therapy</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>Yes: protects up to 90% of recipients</td>
<td>1:3 (if source is e antigen positive, i.e. very infectious)</td>
<td>Vaccine and/or immunoglobulin</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>None</td>
<td>1:30</td>
<td>No effective treatment at present</td>
</tr>
</tbody>
</table>

Note: The ‘Green Book’ provides advice on hepatitis B vaccine prophylaxis for reported exposure incidents.

References:


5. Salisbury D M, Begg N T. Department of Health, Immunisation Against Infectious Disease. UK: HMSO 1996; Ch.18: 95-107
Disposal of needles, syringes and other waste products

Best practice ensures that:

- All detachable labels required for record keeping are removed from the syringe prior to administering the vaccine.

- All needles and syringes are disposed of immediately following administration in a proper puncture-resistant sharps container – the container should be clearly identified and in accordance with BS7320.2

- Needles are never resheathed.2

- The groove provided on the sharps container is used for removing the needle from the syringe (this is not essential but the capacity of the container is improved if needle and syringe are separated).

- The sharps container is changed once it is two thirds full (i.e. once the filling line is reached), closing the full one securely.2

- No attempt is ever made to push contents down inside the sharps container.

- The sharps container is situated within easy reach and is not obstructed from view.

- The sharps container is not accessible to children who may come into the room.

- Portable sharps containers are used when immunising on home visits.

- Unused reconstituted vaccine is disposed of in the sharps container at the end of the session, as is any oral polio vaccine left over in multidose vials.

- All used cotton wool or swabs which may be contaminated with blood are disposed of in a clinical waste bin (never the ordinary waste bin) – if a clinical waste bin is not available any blood-stained material should be placed in the sharps bin as this will ultimately be incinerated.

- Local policy for disposal of medicines and clinical waste should be followed.
Disposal of needles, syringes and other waste products

References:


Anaphylaxis and observation of patient after immunisation

Anaphylaxis

Anaphylaxis following immunisation is extremely rare. As stated in the ‘Green Book’, during a three-year period (June 1992 - June 1995) in which 55 million doses of vaccine were supplied throughout the UK there were 87 reported episodes and no deaths. Although this is reassuring, it does not mean that staff involved in immunisation programmes should ignore the need for training in the management of anaphylaxis or having appropriate equipment ready. As outlined in the ‘Green Book’, nurses involved in administering vaccines should undergo adequate training in the recognition and treatment of anaphylaxis. Local PGDs should reflect this need.

Nurses working in remote rural areas will be involved in vaccination programmes. Where access to prompt emergency care is not so readily available this may produce some anxiety for nurses. Local policies should ensure adequate training in vaccination and anaphylaxis procedures and in addition should recommend that where possible nurses be accompanied by another responsible adult.

Note: This adult does not have to a member of the medical profession.

While anaphylaxis is rare, fainting and panic attacks associated with immunisation are not. Infants and babies rarely faint but can be quite shocked after the experience. Nurses must be able to deal with these and recognise the difference between anaphylaxis and fainting.

Section 10 of the ‘Green Book’ deals with this subject, and nurses should familiarise themselves with this subject and request training if this has not occurred within the last two years or in line with local policy (please see Appendix two provided by the Resuscitation Council).

Observation of the Patient

There is no clearly defined time limit during which most reactions occur following immunisation. If true anaphylaxis or fainting does occur, it is most likely to occur
Anaphylaxis and observation of patient after immunisation

within 10 minutes following vaccination, and the majority of adverse reactions to a vaccination will occur within two minutes.\(^2\) By the time nurses have checked the site for bleeding, the patient has replaced his/her clothing and the ‘patient records’ have been completed, any immediate problems should become apparent.

In the absence of any scientific evidence, best practice would dictate that the documentation is completed and the patient is assessed to be feeling well before leaving the practice.

References:


Documentation

Best practice ensures that the following information is documented:

- Vaccine name
- Dose given
- Site
- Batch number
- Expiry date

This information should be recorded in the following places:

- Patient’s GP records (or other ‘patient record’ depending on location)
- ‘Patient-held record card’/Personal Child Health Record (PCHR)
- Practice computer system
- Scheduled/unscheduled immunisation form (if appropriate)

Nurses should also complete the vaccine stock book and claim forms for reimbursement and item of service payment if appropriate, or ensure the details are passed on to the relevant member of staff.

The sticky labels which can be removed from the barrel of some prefilled syringes (containing the batch number and expiry date) are useful to:

- Speed up documentation
- Highlight all vaccinations within a patient’s records – this feature is useful to help ascertain an individual’s vaccine status at a later stage (the use of a vaccination record card within the GP records does, however, streamline this procedure and the sticky labels can be used on such a card)

There are often many different forms to complete after a vaccination and new members of staff may find it helpful to have a checklist.
Paperless practices need to ensure that a detailed summary of vaccinations is included with a patient’s records when they move away or change surgeries, so that this vital information is readily available for their new practice.

Patients should be encouraged to look after their own record of vaccination and to present it each time they or their child attends any establishment for immunisation.

Note: The need to take Vaccination Certificates for yellow fever and/or meningitis with them when travelling should be reinforced to appropriate patients.
## Local information form

**Prescribing Doctor:**

**Name:**

………………………………………………………………………………………………………………

**Contact details:**

………………………………………………………………………………………………………………

**District Pharmacist:**

**Name:**

………………………………………………………………………………………………………………

**Contact details:**

………………………………………………………………………………………………………………

**Community Paediatrician:**

**Name:**

………………………………………………………………………………………………………………

**Contact details:**

………………………………………………………………………………………………………………

**Consultant in Communicable Disease Control:**

**Name:**

………………………………………………………………………………………………………………

**Contact details:**

………………………………………………………………………………………………………………

**Occupational Health Department (Reporting Needle Stick Injuries):**

**Name:**

………………………………………………………………………………………………………………

**Contact details:**

………………………………………………………………………………………………………………
Local information form

Travel Medicine Physician

Name:
.........................................................................................................................

Contact details:
.........................................................................................................................

Vaccine Manufacturers of Choice:

One: Account number:
.........................................................................................................................

Name:
.........................................................................................................................

Contact details:
.........................................................................................................................

Two: Account Number:
.........................................................................................................................

Name:
.........................................................................................................................

Contact details:
.........................................................................................................................

Local Child Health Department

Contact details:
.........................................................................................................................
Further reading


Groswasser J, *et al.* Needle length and injection technique for efficient intramuscular vaccine delivery in infants and children evaluated through and ultrasonographic determination of subcutaneous and muscle layer thickness. *Paediatrics* 1997; 100: 400-403


United Kingdom Central Council for Nursing, Midwifery and Health Visiting. *Guidelines for the Administration of Medicines.* 2000

Watson J, *et al.* General *Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP).* CDC January 28, 1994/43(RR01); 1-38
Further information sources

**Government and NHS Resources**

1. NHS Direct (tel: 0845 4647) - [www.nhsdirect.nhs.uk](http://www.nhsdirect.nhs.uk)
2. Public Health Laboratory Service (tel: 020 8200 1295) - [www.phls.co.uk](http://www.phls.co.uk)

**England**

1. Department of Health (tel: 020 7210 4850) - [www.doh.gov.uk](http://www.doh.gov.uk)
2. Health Promotion England (tel: 020 7725 9030) - [www.hpe.org.uk](http://www.hpe.org.uk); [www.immunisation.org.uk](http://www.immunisation.org.uk)
3. Chief Medical Officer (tel: 020 7210 4850 - via DoH Public Enquiry Office) - [www.doh.gov.uk/cmoh.htm](http://www.doh.gov.uk/cmoh.htm)

**Northern Ireland**

1. Department of Health, Social Services and Public Safety (tel: 02890 520 500) - [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)
2. Health Promotion Agency for Northern Ireland (tel: 02890 311 611) - [www.healthpromotionagency.org.uk](http://www.healthpromotionagency.org.uk)
3. Chief Medical Officer (tel: 02890 520 500 - via the DHSSPS)
4. Chief Nursing Officer (tel: 02890 520 500 - via the DHSSPS)

**Scotland**

1. Scottish Centre for Infection and Environmental Health (tel: 0141 300 1100) - [www.show.scot.nhs.uk/scieh; www.travax.scot.nhs.uk](http://www.show.scot.nhs.uk/scieh; www.travax.scot.nhs.uk)
2. Scottish Executive Health Department (tel: 0131 556 8400 - via Scottish Executive) - [www.show.scot.nhs.uk](http://www.show.scot.nhs.uk)
3. Health Education Board for Scotland (tel: 0131 536 5500) - [www.hebs.com](http://www.hebs.com)
4. Chief Medical Officer (tel: 0131 244 2317) - [www.scotland.gov.uk/health/cmo](http://www.scotland.gov.uk/health/cmo)
5. Chief Nursing Officer (tel: 0131 244 2314)

**Wales**

1. Department of Health (tel: 02920 825 111) - [www.wales.gov.uk/subihealth/index.htm](http://www.wales.gov.uk/subihealth/index.htm)
2. Public Health Protection Division of the National Assembly for Wales (tel: 02920 826 312)
3. Chief Medical Officer (tel: 02920 825 111 - via DoH)
4. Chief Nursing Officer (tel: 02920 825 111 - via DoH)

**International Sites**

2. World Health Organisation (tel: 00 41 2791 2111) - [www.who.int](http://www.who.int)
3. Centres for Disease Control and Prevention (tel: 00 1 40 4639 3311) - [www.cdc.gov](http://www.cdc.gov)
4. International Society of Travel Medicine (tel: 00 1 77 0736 7060) - [www.istm.org](http://www.istm.org)
**Patient Groups/Information**

1. SENSE (tel: 020 7272 7774) - [www.sense.org.uk](http://www.sense.org.uk)
2. Patients’ Association (tel: 020 8423 9111) - [www.patients-association.com](http://www.patients-association.com)
4. Meningitis Research Foundation (tel: 080 8800 3344) - [www.meningitis.org](http://www.meningitis.org)
5. Doctor Patient Partnership (tel: 020 7383 6828) - [www.dpp.org.uk](http://www.dpp.org.uk)
6. Inmed Ltd (tel: 01453 769 033) - [www.inmed.co.uk](http://www.inmed.co.uk)
7. Scottish Centre for Infection and Environmental Health - [www.fitfortravel.scot.nhs.uk](http://www.fitfortravel.scot.nhs.uk)

**Other Organisations**

1. Royal College of Nursing (tel: 020 7409 3333) - [www.rcn.org.uk](http://www.rcn.org.uk)
2. RCN Travel Health Forum website: [www.rcn.org.uk/rcnforums/travelhealth](http://www.rcn.org.uk/rcnforums/travelhealth)
3. Royal College of General Practitioners (tel: 020 7581 3232) - [www.rcgp.org.uk](http://www.rcgp.org.uk)
4. The Vaccines Page - [www.vaccines.org](http://www.vaccines.org)
5. The Children’s Vaccination Programme (tel: 00 1206 2853 500) - [www.childrensvaccine.org.uk](http://www.childrensvaccine.org.uk)
7. British Travel Health Association (tel: 0141 300 1174) - [www.btha.org](http://www.btha.org)
9. Association of Occupational Health Nurse Practitioners (tel: 0116 281 3720) - [www.aohnp.co.uk](http://www.aohnp.co.uk)
11. Farillon (tel: 01708 330223) - [www.farillon.co.uk](http://www.farillon.co.uk)
12. Community Practitioners and Health Visitors Association (tel: 020 7939 7000) - [www.msfcpshva.org](http://www.msfcpshva.org)
PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

For action by: Health Authorities (England) - Chief Executive
NHS Trusts (England) - Chief Executives

Cc: Regional Office Prescribing Leads
Health Authorities (England) – Medical and Pharmaceutical Advisers
Health Authorities (England) – Directors of Public Health
NHS Trusts (England) – Medical Directors
NHS Trusts (England) – Chief Pharmacists
NHS Trusts (England) – Nursing Directors
Primary Care Groups/Trusts – Chief Executives

Further details from: Colin Pearson
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Quarry Hill
0113 2545975
colin.pearson@doh.gsi.gov.uk

Additional copies of this document can be obtained from:
Department of Health
PO Box 777
London
SE1 6XH
Fax 01623 724524
It is also available on the Department of Health web site at
http://www.doh.gov.uk/coinh.htm

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PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

Action

1. Chief executives should ensure that any current or new patient group directions comply with new legal requirements and the guidance set out in this circular. Failure to comply with the law could result in a criminal prosecution under the Medicines Act.

Background

2. HSC 1998/051 enclosed copies of a Report on the Supply and Administration of Medicines under Group Protocols (the legal term for which is now Patient Group Directions). These are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The Report recommended that the legal position should be clarified.

3. The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under patient group directions should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

The law

4. The relevant modifications to the provisions in and under the Medicines Act 1968 are contained in the Prescription Only Medicines (Human Use) Amendment Order 2000, the Medicine (Pharmacy and General Sale – Exemption) Amendment Order 2000 and the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000. The changes come into force on 9 August 2000. The legislation applies to the NHS, including private and voluntary sector activity funded by the NHS. Therefore it covers treatment provided by NHS Trusts, Primary Care Trusts, Health Authorities (including SHAs), GP or dentist practices, Walk-in Centres and NHS funded family planning clinics. It does not otherwise apply to the private and voluntary sectors (further legislation is proposed in due course).

5. The patient group direction must be signed by a senior doctor (or, if appropriate, a dentist) and a senior pharmacist, both of whom should have been involved in developing the direction. Additionally the patient group direction must be authorised by the HA, SHA, NHS Trust, Primary Care Trust or Primary Care Group (in its capacity as a sub-committee of the HA). Clinical Governance Leads are probably best placed to do this.

6. The qualified health professionals who may supply or administer medicines under a patient group direction are nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthoptists; physiotherapists and ambulance paramedics. They can only do so as named individuals.

7. The legislation specifies that each patient group direction must contain the following information:

   • the name of the business to which the direction applies;
   • the date the direction comes into force and the date it expires;
   • a description of the medicine(s) to which the direction applies;
   • class of health professional who may supply or administer the medicine;
   • signature of a doctor or dentist, as appropriate, and a pharmacist;
   • signature by an appropriate health organisation;
   • the clinical condition or situation to which the direction applies;
   • a description of those patients excluded from treatment under the direction;
• a description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral;
• details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered;
• relevant warnings, including potential adverse reactions;
• details of any necessary follow-up action and the circumstances;
• a statement of the records to be kept for audit purposes.

Additional guidance

8. NHS bodies should already be following the recommendations in the Review Team’s Report. In particular

• Patient group directions should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies.

• A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.

• All professions must act within their appropriate Code of Professional Conduct.

• Appropriate document(s) should be signed by each member of the multi-disciplinary group, the Clinical Governance lead on behalf of the authorising NHS organisation and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years.

9. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs made up by a pharmacist. In particular there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded. The NHS Executive document Controls Assurance Standard – Medicines Management (Safe and Secure Handling) provides guidance on related legislative requirements and best practice.

10. The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under patient group directions.

11. It is important that the use of any medicine is consistent with the Summary of Product Characteristics for the relevant product (save in special circumstances – see paragraph 13) and any relevant guidance from NICE.

Antimicrobials

12. Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee should ensure that any such directions are consistent with local policies and subject to regular external audit.

Black Triangle Drugs and medicines used outside the terms of the Summary of Product Characteristics

13. Black triangle drugs (i.e., those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product Characteristics
Characteristics (eg, as used in some areas of specialist paediatric care) may be included in PGDs provided such use is exceptional, justified by current best clinical practice (eg, NICE guidance) and that a direction clearly describes the status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation. Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

Controlled Drugs

14. The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971. However, the Medicines Control Agency is initiating discussion with the Home Office about a possible amendment to the Misuse of Drugs Regulations to allow the use of substances on schedules 4 & 5 under PGDs.

Other exemptions and restrictions

15. Ambulance paramedics, midwives and chiropodists are already exempt from certain requirements of the Medicines Act. These exemptions, which allow them to administer or supply certain specified medicines without the directions of a doctor, will continue and are not affected by the new provisions for PGDs. The administration of radiopharmaceuticals continues to be regulated by the Medicines (Administration of Radioactive Substances) Regulations 1978 and should not be included in patient group directions.

Regional Office monitoring

16. Regional Offices have been asked to develop arrangements to monitor and share good practice. A website will be developed to provide examples of model directions. The Joint Colleges Ambulance Liaison Committee is devising a set of model directions for use by ambulance paramedics.

This Circular has been issued by:

Dr Sheila Adam
Deputy Chief Medical Officer/Health Services Director
Fig. 1  Anaphylactic reactions: treatment for adults by first medical responders

1. An inhaled beta2-agonist such as salbutamol may be used as an adjunctive measure if bronchospasm is severe and does not respond rapidly to other treatment.
2. If profound shock judged immediately life threatening give CPR/ALS if necessary. Consider slow IV adrenaline (epinephrine) 1:10,000 solution 0.5ml (500 micrograms) IM. Note the different strength of adrenaline (epinephrine) that may be required for IV use.
3. If adults are treated with an Epipen, the 300 micrograms will usually be sufficient. A second dose may be required. Half doses of adrenaline (epinephrine) may be safer for patients on amitriptyline, imipramine, or beta blocker.
4. A crystalloid may be safer than a colloid.
Appendix two

Consider when compatible history of severe allergic-type reaction with respiratory difficulty and/or hypotension especially if skin changes present

Oxygen treatment when available

Stridor, wheeze, respiratory distress or clinical signs of shock

Adrenaline (epinephrine) 1:1000 solution

>12 years: 500 micrograms IM (0.5ml)
6-12 years: 250 micrograms IM (0.25ml)
>6 months - 6 years: 120 micrograms IM (0.12ml)
<6 months: 50 micrograms IM (0.05ml)

Repeat in 5 minutes if no clinical improvement

Antihistamine (chlorpheniramine)

>12 years: 10-20mg IM
6-12 years: 5-10mg IM
1-6 years: 2.5-5mg IM

IN ADDITION

For all severe or recurrent reactions and patients with asthma give Hydrocortisone

>12 years: 100-500mg IM or slow IV
6-12 years: 100mg IM or slow IV
1-6 years: 50mg IM or slow IV

If clinical manifestations of shock do not respond to drug treatment give 20ml/kg body weight IV fluid. Rapid infusion or one repeat dose may be necessary

1. An inhaled beta2-agonist such as salbutamol may be used as an adjunctive measure if bronchospasm is severe and does not respond rapidly to other treatment.
2. If profound shock judged immediately life threatening give CPR/ALS if necessary. Consider slow intravenous (IV) adrenaline (epinephrine) 1:10,000 solution. This is hazardous and is recommended only for an experienced practitioner who can also obtain IV access without delay. Note the different strength of adrenaline (epinephrine) that may be required for IV use.
3. For children who have been prescribed Epipen, 150 micrograms can be given instead of 120 micrograms, and 300 micrograms can be given instead of 250 micrograms or 500 micrograms.
4. Absolute accuracy of the small dose is not essential.
5. A crystalloid may be safer than a colloid.

Fig. 2   Anaphylactic reactions: treatment for children by first medical responders
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