

Vaccination programmes in residential care services

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Within this document we use the term “residential care service” as any 24-hour service which is regulated by the Care Inspectorate. This could be a care home (with or without nurses), school care accommodation and so on.

Background

We have found nurses administering vaccines to people living in registered care services without appropriate consent and a legal direction to authorise administration.

When **ANY** nurse administers vaccines to someone over 16 while they are living in a residential care service they need to ensure:

- They have consent, either from the resident or from a welfare guardian or welfare power of attorney (welfare proxy) with the relevant powers. If this is not possible then there should be a certificate of Incapacity Section 47 certificate where the medical professional has included wording similar to "treatment and prevention of infection" or "influenza/shingles vaccination" etc. on the certificate or associated treatment plan
- That if they are **not** an NHS employee there is a patient specific direction (PSD)/prescription to authorise administration
- They understand that an NHS patient group direction (PGD) cannot normally be used to authorise administration by someone who is **not** an NHS employee
- If a nurse who is NOT an NHS employee is being asked to administer a vaccine under the authority of a PGD, the nurse must ensure they are named on and have signed the PGD. Their employer (normally the provider of the care service) is aware that they are performing this function and the provider has relevant insurance cover in relation to the nurses practice. The nurse should seek confirmation of those arrangements before undertaking the role.
- If they are an NHS employee and being authorised to administer the vaccine using the NHS Boards patient group direction (PGD) that they are named on the PGD.

Some NHS Boards have issued additional information for GPs and NHS nurses around these issues.

Introduction

This guidance tells you how vaccines should be supplied and administered to children and adults in residential care services.

Information on the yearly vaccination programmes and recommendations on who should be offered vaccines can be found on the SHOW (Scotland's Health on the Web) website <http://www.scot.nhs.uk>

Vaccines are prescription only medicines (POM).

This guidance will help you make sure that:

1. the person (or their representative) has consented to have the vaccine
2. vaccines are supplied and administered legally
3. vaccines are stored correctly
4. appropriate records are kept

Normally the community pharmacy dispenses medicines based on instructions the GP has written on an NHS prescription. However most routine vaccines available through the NHS are not supplied this way and come from bulk stocks held by the GP Practice.

It may be that the vaccines are sent to the care service some time before they are going to be administered. The make-up of influenza vaccine changes from year to year so it is important that any vaccines from the previous season are discarded before the new season stock is delivered to the home.

Consent

People who are offered vaccines must either give informed consent or be treated in accordance with Scottish law. Practitioners should follow best practice in obtaining consent. For guidance on this, see:

<http://www.gmc-uk.org>

Children may be able to consent if the health professional responsible for treatment considers them capable. Otherwise, the parent or guardian can consent. See <http://www.nhsinform.co.uk> for more information on this.

Adults (normally persons over 16) are presumed to have capacity unless there is good evidence that they do not. If they are not capable of giving consent, treatment must be given in accordance with the Adults with Incapacity (Scotland) Act 2000 (the 2000 Act). The code of practice for practitioners working with Part V of the 2000 Act gives detailed guidance on what to do.

<http://www.gov.scot>

For adults who appear to lack capacity to consent to vaccination, here are the steps to take:

1. The practitioner primarily responsible for prescribing the treatment assesses the person's capacity. See the above link to the code of practice for the definition of incapacity and how to carry out this assessment.
2. If the person is incapable, there must be a certificate of incapacity under section 47 of the 2000 Act. The latest version of the three-year certificate and Adults With Incapacity (Scotland) Act 2000 Part 5 – Medical Treatment – Flowchart can be downloaded. <http://www.scotland.gov.uk>
3. Treatment can be given under the general authority of this certificate as long as it complies with the principles of the Act*. If the person resists, try again later, using people who know him/her well to help by gentle persuasion. "Force" cannot be used unless "immediately necessary" and it is unlikely that this would apply to vaccination.
4. The general authority does not apply if there is already a person with the authority to consent on the person's behalf. This would be a welfare attorney or welfare guardian with the specific power to consent to treatment. If there is such a person, they should give their consent unless it is not practicable (for example the attorney or guardian might not be contactable for a period of time).
5. If the attorney or guardian disagrees with vaccination, the practitioner should meet with them to discuss the need for vaccination. If there is still

disagreement, contact the Mental Welfare Commission for Scotland who will appoint an independent practitioner to give a decision on the treatment.

6. If an adult is incapable and has no welfare attorney or guardian, **nobody else can consent on his/her behalf**. Treatment is covered by a section 47 certificate. If any person objects to the vaccination, they need to get an injunction from the Sheriff, otherwise it can go ahead.
7. The Code of Practice advises that it saves a lot of time and effort to have an annual review of health care and a treatment plan that accompanies a certificate of incapacity. "Prevention and treatment of infection" specified on the treatment plan, will cover vaccination and any antibiotic treatment during the period of the certificate. If this has been done, there is no need to issue a separate certificate each time vaccination or antibiotic treatment is needed.

*The principles of the Act that apply are:

- any intervention must benefit the person
- it must be the least restrictive option in relation to the person's freedom
- the past and present wishes of the person must be taken into account (this would include an advance statement)
- the views of others should be sought where reasonable and practicable. It is good practice to make relatives aware of the intention to give the vaccine.

Sometimes care service staff are asked to get consent forms completed/signed on behalf of the GP before the vaccine is supplied or administered. Care service staff need to know if there is anyone who has the legal power to give consent on behalf of an incapable resident.

The resident's friends or relatives, or care home staff who do not have the appropriate legal powers to consent to medical treatment cannot sign these consent forms.

The Mental Welfare Commission has published Working with the Adults with Incapacity (Scotland) Act - Information and guidance for people working in adult care settings <http://www.mwscot.org.uk>

In Appendix 2 of the Mental Welfare Commission document there is a checklist to record information about anyone who is a welfare guardian or power of attorney and the powers they have.

Vaccine Supply and Administration

The authority for a person to supply and/or administer the vaccine is given by:

- a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber, or
- a Patient Specific Direction (PSD), or
- a Patient Group Direction (PGD).

For legal reasons (relating to PGDs in general), it must be emphasised that nurses employed by care service organisations are not normally covered by PGDs.

This means the need for a vaccine must normally be individually assessed by the prescriber, and written authorisation (prescription or PSD) provided for each named resident, before care staff can administer the vaccine.

Written prescription

In most cases the GP will issue the stock and no pharmacist will be involved. Because of this the written prescription might not be on an NHS GP10 form. The prescription could be written on notepaper in a similar format to a private prescription.

Prescriptions need to be written/printed legibly in ink, dated, state the full name and address of the person receiving the treatment, and be signed in ink by the prescriber.

Patient Specific Direction (PSD)

A PSD is a written instruction from a doctor or dentist or other independent prescriber for a medicine to be supplied or administered to a named person. These can be instructions written in the person's notes, or a note sent to a treatment room for the administration of a medicine or a course of medicine. PSDs can be the directions for administration written by the prescriber in the Medicines Administration Chart, sometimes called the 'Drug Kardex'.

In a flu vaccine clinic or care service, a list of named people to be supplied or administered the vaccine can be signed by the doctor or independent prescriber. This needs to be more than just a list of names: people have to be identifiable, for example with the use of the community health index (CHI) number, their date of birth or similar.

In most cases where either NHS Staff or the care service's staff (who are not employed by the NHS) are going to administer the vaccines in care services, this will be authorised by a prescription or a patient specific direction.

Patient group direction (PGD)

PGDs are written instructions for the supply and/or administration of medicines to groups of patients who may not be individually identified before they arrive for treatment.

All healthcare professionals using PGDs must be individually named by the person authorising the PGD. They must act in accordance with their appropriate code of professional conduct.

A PGD drawn up by the NHS cannot normally authorise administration of vaccines by non-NHS staff employed in residential care services.

Currently in Scotland residential care services cannot set up an Independent PGD to authorise their staff to administer medicines.

Skills, experience and training

The person administering a vaccine needs to have the necessary experience, skills and training to administer the vaccine; and know how to recognise and initially treat anaphylaxis. If the person prescribing the vaccine delegates the administration to care service staff, they must ensure the care service staff have the necessary skills and experience to do this.

Anyone administering the vaccine should be prepared to discuss the benefits and risks and know:

- the type of vaccine
- how it works
- expected side effects and how to manage them
- the risks of not being immunised.

The Green Book has the latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK.

<https://www.gov.uk>

If two vaccinations are being given in one limb, at least 2.5cm should be left between them.

Anaphylaxis (severe allergic reaction)

A protocol for the management of anaphylaxis and Adrenaline (Epinephrine) 1:1000 injection should be available at the time of administration.

Most residential care services do not routinely hold stock of Adrenaline (Epinephrine) 1:1000 injection. If administration of the vaccine is delegated to either NHS staff or care service employees the prescriber must ensure that there is a supply of Adrenaline.

Vaccine storage

Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold. Storage outside the recommended temperature range may speed up loss of potency which cannot be reversed. All vaccines must be stored in accordance with the manufacturers recommended temperature range, which is usually 2 to 8 degrees centigrade.

The person or organisation supplying of the vaccine must ensure there is adequate refrigerated storage in the care service if they plan to leave stock there. They must also ensure the cold chain is maintained during any transfer of the vaccine. This means a system must be in place to ensure that the vaccine is kept between 2 and 8 degrees centigrade at all times.

The temperature of this fridge needs to be measured at least once every day using a maximum/minimum thermometer and records of the maximum and minimum temperature in every 24-hour period should be recorded. Some NHS Boards may have policies which require more frequent temperature measurement and recording.

The care service needs to know what action to take if they find the temperatures have been out with this range for a period of time. Any concerns about inappropriate storage should be referred back to the organisation who supplied the vaccine to the care service.

Record keeping

Care services are expected as good practice to keep complete, accurate, up-to-date records of all medicines ordered, taken or not taken and disposed off.

Additionally, all residential services regulated under the Public Services Reform (Scotland) Act 2010 should also keep records as specified by the Care Inspectorate.

<http://hub.careinspectorate.com>

These records currently include the following.

- Details of the next of kin or of any person authorised to act or consent for the person using the service, including their name, address, telephone number and email address. Where necessary the information should also include

details of their relationship with the person using the service and where the person has power of attorney that has been activated, what type, for example, welfare or financial guardians.

- Care Homes for adults should keep copies in the care plan of any Adults with Incapacity (Scotland) Act 2000 section 47 certificate (medical certificate of incapacity).
- Detail of any incident that is detrimental to the health and welfare of a person using a service. This should include a person given wrong medication and/or wrong dose.
- An accurate and up to date record of the medicines people who use the service take, which the service are responsible for storing on the premises. This should include:
 - Medicines like flu vaccines or injections that will be stored in the service for NHS staff or Macmillan nurses to administer
 - All medicines that have been ordered, taken, not taken or disposed of.
- Records detailing any incidences where medication is given to a person using the service without their consent or that of a person duly authorised to consent on the person using the service's behalf.

This means services must record details of any vaccines supplied to them to store in advance of administration by either NHS or their own staff.

Care service staff administering vaccines

When administration of vaccines is carried out by healthcare professionals who are NOT employees of the NHS, then the care service needs to retain a copy of the document authorising the administration.

They must also record specific details of each vaccine. This should include:

- the type of vaccine, for example seasonal flu and the manufacturer's brand name for it
- the dose given
- the manufacturer's batch number – this is necessary in case problems associated with a particular batch are identified at a later date
- the expiry date – recording this provides evidence that it was checked prior to administration
- date given
- the place on the body where the injection is administered, for example left arm
- name, designation and signature of the person giving the injection
- name and designation of the person who prescribed the vaccine, for example by keeping a copy of the prescription or patient specific direction in the person's records.

NHS staff administering vaccines

Even though NHS staff will keep their own records, it is still good practice for the care service to keep records of the:

- type and brand name of the vaccines
- dates they were given
- part(s) of the body injected (for example, left arm)
- name and designation of the person administering the vaccines
- person who gave consent for the vaccine to be given.

Summary

Consent

- Children may consent if the health professional responsible for treatment considers them capable. Otherwise, the parent or guardian can consent.
- Adults (persons over 16) are presumed to have capacity unless there is good evidence that they do not.
- When an adult is incapable of giving consent, consent would be from a welfare guardian(s) or power of attorney(s) with the power to give consent or by a properly completed Section 47 Certificate of the Adults with Incapacity (Scotland) Act 2000.

Supply and administration

- Any person administering the vaccine must have the necessary experience, skills and training.
- A protocol for the management of anaphylaxis and Adrenaline (Epinephrine) 1:1000 injection should be available.

The person administering the vaccine is given the authority to do this by:

1. a separate prescription/written direction for each person in the care service, or
2. a patient specific direction (PSD) allowing supply/administration of vaccine to a list of named people in the care service, or
3. a patient group direction (PGD) naming the person who is authorised to administer vaccine to people in the care service who are not individually identified.

Note: A PGD developed by the NHS to authorise its employees to administer vaccines is unlikely to include authorisation for employees of care services.

Storage

- Vaccines are kept in a temperature range between 2 and 8 degrees Centigrade.
- Refrigerator temperatures must be checked at minimum daily using a maximum/minimum thermometer.
- The maximum and minimum temperatures should be recorded.
- Care service staff need to know what to do if the vaccines have been kept outwith this temperature range.

Records

Even when NHS staff administer vaccines, the care service needs to keep its own records.

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