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Consent

Introduction

It is a legal and ethical principle that valid consent must be obtained before starting personal care, treatment or investigations. This reflects the rights of individuals to decide what happens to their own bodies and consent is a fundamental principle of good healthcare and professional practice.

Healthcare professionals (or other non-registered healthcare workers) who do not respect these principles may be liable to legal action and/or action by their professional body.

Case law on consent develops and changes over time. Those involved in seeking consent for immunisation should keep up to date with latest developments, legal rulings and their employing organisations' policies and procedures on consent. The General Medical Council (GMC) publish and maintain a factsheet on "Key legislation and case law relating to decision making and consent", which is referenced at the end of this chapter.

Principles of consent for immunisation

For consent to immunisation to the valid, it must be given freely, voluntarily and without coercion by an appropriately informed person who has the mental capacity to consent to the administration of the vaccines in question. This will be the person themselves,

someone with parental responsibility for an individual under the age of 18 years (16 years in Scotland), someone authorised to do so under a Lasting Power of Attorney (LPA) for health and welfare, or someone who has the authority to make treatment decisions as a court appointed deputy.

People have the right to be involved in decisions relating to their treatment and care. The exchange of information between the healthcare provider and the individual is key to ensuring informed consent:

- consent is a process rather than a one-off event. Consent may be withdrawn at any time and consent obtained for 1 immunisation does not necessarily remain in place for all future doses of a course of immunisation. Where consent has been obtained for a full course, however, it is not necessary to seek consent again for each subsequent vaccine unless new information has come to light. It is good practice to check that the individual is content to proceed at each stage. Consent may need to be re-sought if evidence arises that suggests the initial course consented for may not provide as high a level of protection or may have a different safety profile than was initially communicated. This would include, for example, if the course was expected to lead to more significant or more common adverse events than outlined initially. Consent may also need to be

re-sought if the initial number of doses offered, or type of vaccine for that individual is changed mid-course. For example, if the course will offer a different level of protection by covering fewer diseases or strains

- people must be listened to, given the information they require to make decisions about immunisation and given sufficient time and support to understand that information. Information should be provided in a way the individual can understand, ideally before the immunisation appointment
- Information should include details of the process, the benefits of immunisation, and the risks, including rare and common side effects and what to do if they occur. Where feasible, healthcare professionals seeking consent should find out what matters to individuals so that they can share relevant information about the benefits and risks of immunisation, including the risks of not proceeding with immunisation.
- Healthcare professionals should start with the assumption that all adults have the capacity to provide consent to their treatment. If indicated, they should be assessed regarding their capacity to make a specific decision in line with legal requirements. The capacity of an individual to provide consent can change. Where an individual lacks the capacity to provide consent, it is good practice to consult with those close to them (for example family, carers), those who advocate for them, or those with legal authority for example with a Lasting Power of Attorney.
- There is no requirement for consent to immunisation to be in writing, but it is good clinical practice to record that a discussion has taken place and consent has been obtained. The completion of a consent form is not a substitute for the provision of meaningful information sufficient to meet the individual's needs.

Consent in adults

Adults are those aged 18 years (16 years in Scotland) or over. An adult must consent to their own treatment.

Adults without the capacity to provide consent

Under English law, no one is able to give consent on behalf of an adult who is unable to consent to examination or treatment for themselves. The Mental Capacity Act (2005) applies to those aged 16 years and over and is designed to protect and empower people who may lack the mental capacity to make their own decisions about their care and treatment.

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

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

Resources on consent and mental capacity

Mental Capacity Act 2005 (2005). Accessed at: https://www.legislation.gov.uk/ukpga/2005/9/contents

Mental Capacity Act Code of Practice (2007) Accessed at: https://www.gov.uk/government/publications/ mental-capacity-act-code-of-practice

NHS Website Mental Capacity Act (2021). Accessed at: https://www.nhs.uk/conditions/social-care-and- support-guide/making-decisions-for-someone-else/mental-capacity-act/

Local Government Association (2015) Mental Capacity Act 2005: A brief guide for providers of Shared lives and other community services https://www.local.gov.uk/publications/mental-capacity-act-2005-brief-guide- providers-shared-lives-and-other-community

NHS Website (2021). Mental Capacity Act. Accessed at https://www.nhs.uk/conditions/social-care-and- support-guide/making-decisions-for-someone-else/mental-capacity-act/

Assessing capacity https://www.nhs.uk/conditions/consent-to-treatment/capacity/

Consent in children and young people

At 16 years of age a young person is presumed in law to have the capacity to consent, so young people aged 16 or 17 years should consent to their own medical treatment.

For infants and young children not competent to give or withhold consent, consent can be given by a person with parental responsibility, provided that person is capable of consenting to the immunisation in question and is able to communicate their decision. Where this person brings the infant or child in response to an invitation for immunisation and, following an appropriate consultation, presents the infant or child for that immunisation, these actions may be considered evidence of consent.

The Children Act 1989 sets out who has parental responsibility for a child. Mothers automatically have parental responsibility for their children.

A father usually has parental responsibility if he is:

- married to the child's mother
- listed on the birth certificate (after a certain date, depending on which part of the UK the child was born in)
- has a court order confirming parental responsibility

Where immunisations are routinely offered in the school setting, consent differs depending on the age and competence of the individual child or young person. In secondary school age children, information leaflets should be available for the young person's own use and to share with their parents prior to the date that the immunisation is scheduled.

Where someone aged 16 or 17 years consents to vaccination, a parent cannot override that consent. Young people who understand fully what is involved in the proposed procedure

* Where a mass immunisation campaign is to be carried out in schools such as the MenC campaign 1999/2000, different guidance regarding information and consent would apply

(referred to as 'Gillick competent') can also give consent, although ideally their parents will be involved. If a Gillick-competent child consents to treatment, a parent cannot override that consent. If the health professional giving the immunisation felt a child was not Gillick competent then the consent of someone with parental responsibility would be sought.

If a person aged 16 or 17 years or a Gillick-competent child refuses treatment that refusal should be accepted.

Consent at the time of immunisation

The person with parental responsibility does not necessarily need to be present at the time the immunisation is given. Whilst a person may not abdicate or transfer parental responsibility, they may arrange for some or all of it to be met by 1 or more persons acting on their behalf (Section 2(9) of the Children Act 1989). There is no requirement for such arrangements to be made in writing.

Infants and children may be brought for immunisation by a person without parental responsibility, for example, a grandparent or childminder. Where they are brought for immunisation by someone who does not have parental responsibility the health professional would need to be satisfied that:

- the person with parental responsibility has consented in advance to the immunisation (i.e. they received all the relevant information in advance and arranged for the other person to bring the child to the appointment) or
- the person with parental responsibility has arranged for this other person to provide the necessary consent (i.e. they asked the other person to take the child to the appointment, to consider any further information given by the health professional, and then to agree to immunisation if appropriate)

Written consent

In the routine school-based immunisation programmes, an information leaflet and consent form are usually sent to the parent to complete and return as they are not present at the time of vaccination. Email or electronic forms of consent are increasingly being used.

Consideration should be given for appropriate routes to reach parents/families who may not easily access information digitally. Providers should make sure parents have sight of the NHS information leaflets.

Consent forms should not act as a barrier to immunisation and they should be as simple to complete as possible. Any clinical information being collected about the young person, such as their health and immunisation status, or medications being taken, should only be relevant to the immunisation(s) being offered, recognising the importance of using any opportunity to catch-up on other vaccines.

Disagreement between parents

Although the consent of 1 person with parental responsibility is usually sufficient (see Section 2(7) of the Children Act 1989), if 1 parent agrees to immunisation but the other disagrees, the immunisation should not be carried out unless both parents can agree to immunisation or there is a specific court approval that the immunisation is in the best interests of the child.

If there is any evidence that the person with parental responsibility may not have agreed to the immunisation (for example the notes indicate that the parent(s) have negative views on immunisation), or may not have agreed that the person bringing the child could give the necessary consent (for example suggestion of disagreements between the parents on medical matters) then the person with parental responsibility should be contacted for their consent. If there is disagreement between the people with parental responsibility for the child, then immunisation should not be carried out until their dispute is resolved.

A person giving consent on behalf of an infant or child may change their mind and withdraw consent at any time. Where consent is either refused or withdrawn, it is the duty of each healthcare professional to communicate effectively and share such knowledge and information with other members of the primary healthcare team.

Resources on consent in children and young people:

Department of Health and Social Care (2021). Parental rights and responsibilities. Accessed at: https://www.gov.uk/parental-rights-responsibilities/apply-for-parental-responsibility

Gillick competency and Fraser guidelines. Accessed at: https://learning.nspcc.org.uk/child-protection-system/ gillick-competence-fraser-guidelines

Care Quality Commission (2018). Gillick competency and Fraser guidelines. Accessed at https://www.cqc.org. uk/guidance-providers/gps/nigels-surgery-8-gillick-competency-fraser-guidelines

General Medical Council (2007) 0 - 18 years: Guidance for all doctors. Accessed at https://www.gmc-uk.org/ ethical-guidance/ethical-guidance-for-doctors/0-18-years

"Making decisions" paragraphs 22 to 33, 0–18 years: guidance for all doctors (2007): in https://www.gmc-uk. org/outcomes-legislation

Data Protection and recording

In line with data protection and Caldicott guidance, individuals should also be informed about how data on immunisation will be stored, who will be able to access that information and how that data may be used. It is important to emphasise that such information is used to monitor the safety and effectiveness of the current immunisation programmes. The healthcare record for each person, or for children, the Personal Child Health Record (PCHR) should be an accurate account of care planning and delivery. It is good practice for proper records of any discussions to be recorded in the individual's notes. In addition, for infants and children, the PCHR should also be completed with the involvement of the parent or guardian.

Resources to support consent

Written or verbal information should be available in a form that can be easily understood by the individual who will be giving the consent. Where English is not the first language, translations and properly recognised interpreters should be used. The 4 UK countries provide a wide range of public facing information, including leaflets, posters, videos, information packs, factsheets, and websites to support all aspects of the immunisation programme. This information is based on the current scientific evidence and clinical advice.

Unlicensed vaccines

Occasionally vaccines are recommended for use which do not have a UK marketing authorisation (i.e. a license). This is usually because there is a serious risk to public health from a vaccine preventable disease, but no suitable licensed vaccine is available. In response, MHRA may temporarily authorise the use of a vaccine that does not have a UK license, although the vaccine may be licensed in other countries and thus its efficacy and safety profile are known.

Use of vaccines outside of their marketing authorisation (license)

Vaccines which have a license may also be used in UK programmes, but such use is outside the terms of the marketing authorisation. For example, the interval between doses or the number of doses used in a UK programme may be different from that stated in the Summary of Product Characteristics (SmPC). In addition, whilst vaccines should be stored according to the conditions detailed in the SmPC, in the event of an inadvertent or unavoidable deviation of these conditions, where the vaccines have been assessed (in accordance with national vaccine incident guidelines) as still appropriate for use, this would constitute off-label administration.

Where authoritative advice or current practice supports the use of a medicine outside the terms of its license, it may not be necessary to draw attention to the license when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant. As with any vaccine, healthcare professionals should give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision.

Further information for healthcare professionals and the public is available here: https://www.gov.uk/government/publications/off-label-vaccine-leaflets

Professional guidance on consent

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

The Nursing and Midwifery Council (2018). The Code: Professional Standards of Practice and behaviour for nurses, midwives and nursing associates. https://www.nmc.org.uk/standards/code/

The General Medical Council provides guidance for doctors on decision making and consent (2020). Accessed at https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent

Health and Care Professions Council (2016). Standards of conduct, performance and ethics. Accessed at: https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/

The General Pharmaceutical Council (2018). In practice: Guidance on consent. Accessed at: https://www. pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_consent_june_2018.pdf

Arrangements in devolved nations

Advice on consent specific to Wales, Scotland and Northern Ireland is available or in preparation.

Scotland

Health professionals providing immunisation and vaccination services in Scotland should refer to the Scottish legislation and guidance. The Adults with Incapacity (Scotland)

Act 2000 and The Mental Health (Care and Treatment) (Scotland) Act 2003 provide for delivering healthcare to people who lack the ability to make treatment decisions for themselves. The Age of Legal Capacity (Scotland) Act 1991 outlines that someone has the capacity to make decisions around consent from the age of 16 years. However, even under the age of 16, a young person can have the legal capacity to make a consent decision on a healthcare intervention, provided that they are capable of understanding its nature and possible consequences; this is a matter of clinical judgement.

Further information can be found at:

Scottish Government (2019). Adults with Incapacity (Scotland) Act 2000: principles. Accessed at: https://www.gov.scot/publications/adults-with-incapacity-act-principles/

Scottish Government (2020). Mental health Legislation and Guidance. Accessed at: https://www.gov.scot/policies/mental-health/legislation-and-guidance/

Scottish Parliament (2020). Informed consent in Healthcare Settings. https://digitalpublications.parliament. scot/ResearchBriefings/Report/2019/1/10/Informed-Consent-in-Healthcare-Settings

Wales

Health professionals providing immunisation and vaccination services in Wales should refer to the Welsh legislation and guidance.

Further information can be found at:

NHS Wales (2017). All Wales model policy for consent to examination or treatment. Accessed at: https://nwssp.nhs.wales/ourservices/welsh-risk-pool/welsh-risk-pool-programmes/all-wales-consent-to- treatment-or-examination-improvement-programme/all-wales-model-policy-for-consent-to-examination-or- treatment/

Northern Ireland

Health professionals providing immunisation and vaccination services in Northern Ireland should refer to the Northern Irish legislation and guidance.

Further information can be found at:

Department of Health Northern Ireland (2003). Consent for examination, treatment and care. Accessed at https://www.health-ni.gov.uk/articles/consent-examination-treatment-or-care

Other key references

NHS Website (2019). Overview Consent to treatment. Accessed at: https://www.nhs.uk/conditions/consent-to- treatment/

General Medical Council (2020). Factsheet: Key legislation and case law relating to Decision making and consent. Accessed at: https://www.gmc-uk.org/-/media/documents/factsheet---key-legislation-and-case-law- relating-to-decision-making-and-consent-84176182.pdf

British Medical Association (2019). Consent and refusal by adults with decision-making capacity – A toolkit for doctors. Accessed at: https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/seeking-patient- consent-toolkit

British Medical Association (2019). Best interests decision-making for adults who lack capacity – A toolkit for doctors. Accessed at: https://www.bma.org.uk/advice-and-support/ethics/adults-who-lack-capacity/best- interests-decision-making-for-adults-who-lack-capacity-toolkit

Royal College of Nursing (2017). Principles of Consent: Guidance for nursing staff. Accessed at: https://qa.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2017/june/pub-006047.pdf?la=en