Core Topic 7

Legal Aspects of Vaccination

Health Protection Agency

Learning outcomes

To understand the legal requirements of data protection

To understand the legal framework of consent

To understand the legal aspects of supply and administration of vaccines

Learning Objectives

- Describe the legal basis for requiring data protection

- Describe the reasons for requiring good documentation and communication of information on vaccination

- Define supply and administration issues

- Define the role of Patient Specific Directions (PSDs) and Patient Group Directions (PGDs) in immunisation

Legal Issues in Vaccination

- Confidentiality
- Consent
- Supply and administration

Confidentiality

Immunisation Data

Individuals/Parents should be informed:

- How data on immunisation is stored
- How it may be used
- Who will be able to access it

Important to stress that such information is predominantly used to monitor efficacy of current vaccination programmes

Confidentiality of Personal Information - Related Legislation

- Data Protection Act (www.dataprotection.gov.uk)
- The 1998 Data Protection Act set standards which must be satisfied when obtaining, holding, using or disposing of personal data
- The Data Protection Act covers anything with personal identifiable information (e.g. health, personnel, occupational, finance, suppliers, and contractors)
- You are required by law to comply with the Data Protection Act 1998

Caldicott Report

- March 1996 the Department of Health published guidance on the '*Protection and Use of Patient Information'*

- Caldicott Committee was established to review and improve the way the National Health Service handles and protects patient information

- Identified 6 principles, similar in many respects to the principles outlined in the *Data Protection Act*

Caldicott principles

1. Justify the purpose(s) for using patient data
2. Don't use patient-identifiable information unless it is absolutely necessary
3. Use the minimum necessary patient-identifiable information
4. Access to patient-identifiable information should be on a strict need to know basis
5. Everyone should be aware of their responsibilities to maintain confidentiality
6. Understand and comply with the law, in particular the Data Protection Act

- As an employee of the Trust you are required to follow the Caldicott principles as laid down by the NHS Executive

- All NHS organisations are now required to have a Caldicott Guardian

Documentation

- date of administration
- title of vaccine(s) administered
- batch number
- expiry date
- site(s) of administration
- information as appropriate to CHIS; GP record; patient-held record e.g. PHCR, travel card

Consent

Consent

- Consent must always be obtained before every immunisation
- Giving and obtaining of consent should be viewed as a process and not a one-off event
- Must be given voluntary and freely, after achieving an understanding of what is involved
- Person providing consent should be offered as much information as they reasonably need to make their decision

How should consent be sought?

- Consent should be sought on the occasion of each immunisation visit
- Health professional providing the immunisation should ensure consent has been obtained
- Prior *agreement* for the child to be included in the immunisation programme is not valid consent

Consent process should include

- what immunisation(s) are to be given
- which disease(s) will be prevented
- benefits and risks of immunisation versus risks of disease(s)
- possible side effects and how to treat
- any follow-up/action required
- any new information
- agreement to proceed

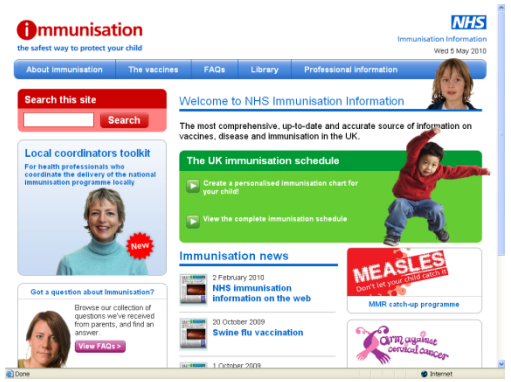
Wide range of Information available based on current scientific evidence and clinical advice

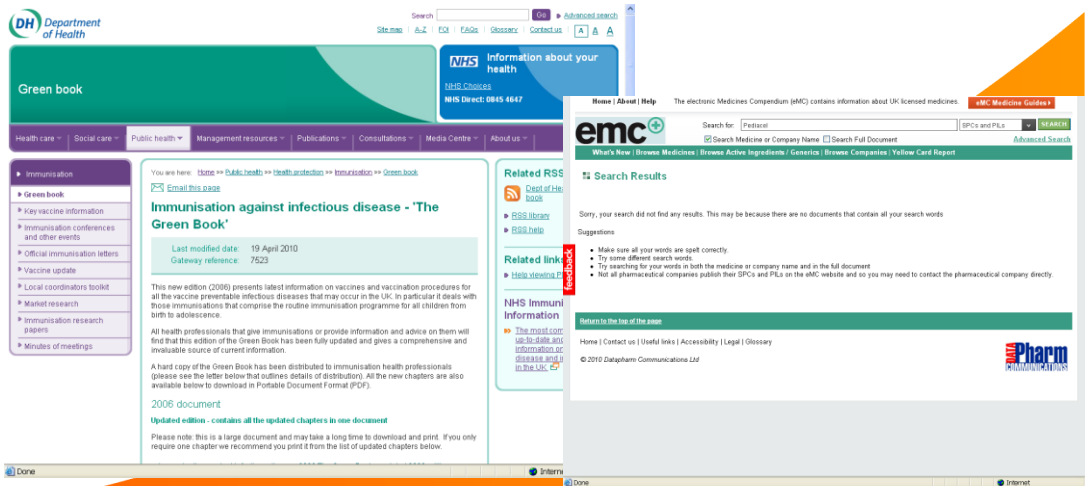
- NHS Immunisation information
  www.immunisation.nhs.uk
  - Leaflets
  - Posters
  - Fact sheets
  - Website

  (Translations available)

- Green book

- Manufacturers PIL & SPC





Capacity to consent

Key question:

"can this patient understand and weigh up the information needed to make this decision?"

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006131

Who can consent?

ADULTS: aged 18 or over

- must consent to their own treatment
- no-one can give consent for an adult who is unable to consent for him/herself unless there is a Lasting Power of Attorney (LPA) in place

Lasting Power of Attorney (LPA)

- LPA is a formal, legal document of two types:
1. personal welfare, including healthcare
2. property and affairs (financial matters)

- LPA must be set out on the right form and registered with the Office of the Public Guardian to be valid and before it can be used

- A personal welfare LPA will only take effect when a person has lost capacity to make a particular decision

Principles include:

•A person must be assumed to have capacity unless it is established that he lacks capacity

•A person is not to be treated as unable to make a decision unless all practicable steps to help him have been taken without success

•A person is not to be treated as unable to make a decision merely because he makes an unwise decision

•An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests

•Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action

Lasting Power of Attorney

If a personal welfare LPA does not include the authority to make the decisions which now need to be made, health and social care staff will make the necessary best interests decisions, but they should consult with the attorney and those close to the patient

Written consent

- No ***legal requirement*** for consent to be in writing
- Signature on a consent form not conclusive proof that consent has been given
- Should record the decisions and discussions that have taken place and type of information supplied to support the decision
- Where individuals/parent(s) disagree with immunisation, this should be shared/ recorded with all members of the Primary Health Care Team
- Consent law: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006131

Supply and administration of vaccines

Nurse Prescribing

All first level nurses and registered midwives are eligible to train to prescribe from the Nurse Prescribers' Extended Formulary

Medicines can only be prescribed to treat a specific range of conditions including routine childhood and specific vaccinations

Supply and administration of vaccines

- against a prescription written by an authorised prescriber (e.g. travel vaccines)
- against a PSD (e.g. routine childhood, flu)
- against a PGD (e.g. school led programme)

Patient Specific Directions

"...is a written instruction from an independent prescriber (*doctor, dentist or independent nurse prescriber*) to another healthcare professional, to supply and/or administer a medicine directly to a named patient, or to several named patients."

Chapter 5 Immunisation by nurses and other healthcare professionals.

Immunisation Against Infectious Disease (The Green Book)

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

When should a PSD be used?

- Usual method for vaccine supply and administration for routine childhood schedule
- Authorised by GP/independent nurse prescriber at 6-8 week check and written instruction recorded in PCHR or
- scheduled/unscheduled clinic list signed by prescriber
- Technically a patient assessment by the healthcare professionals instructed to supply/administer the vaccine should not be required BUT

Please note: Good practice dictates the immuniser check the recipient is fit and well and there are no contraindications, prior to vaccination.

Patient Group Directions

"a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment."

NHS National Prescribing Centre Patient Group Directions(2004):A practical guide and framework of competencies for all professionals using patient group directions www.npc.co.uk/publications/pgd/pgd.pdf

PGDs

- are *nothing* to do with nurse prescribing
- are *legal* documents for the supply and administration of Prescription Only Medicines (POMs)
- only qualified, fully competent and properly trained healthcare professionals can sign up and work to PGDs
- healthcare professional is responsible for assessing that the patient fits the criteria in the PGD
- there can be no deviation from the PGD

Changes in legislation

- HSC 2000/026 - modifications of Medicines Act 1968
- Prescription Only Medicines Human Use Amendment Order 2000
- Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment No 2 Regulations 2000

PGDs

- Must contain specific information
- Be drawn up by multidisciplinary group
- Signed by doctor, pharmacist and organisational lead
- Signed by named healthcare professionals
- Every patient must fit *exactly* criteria in PGD
- Must have start/expiry date
- Must be reviewed at least every two years
- Evidence changes nullify existing PGDs

Scope and Limitations of PGDs

- PGDs are not a form of prescribing but provide a legal framework for the supply and/or administration of vaccines
- Healthcare professionals signing up to PGDs must be fully competent qualified and trained in all aspects of immunisation
- Patient's may present directly to a healthcare professional working to PGDs in their service, without seeing a doctor
- Healthcare professionals working to a PGD is responsible for assessing that the patient fits the criteria in the PGD

What is Clinical Governance?

- Framework through which NHS organisations are accountable for continuously improving standards of patient care and the quality of their services
- Safeguarding high standards of health care delivery
- Creating an environment of consistent high quality and clinical care excellence

How does this relate to Immunisation?

Clinical governance is relevant across all area of immunisation practice

For example:

- Ensuring all immunisers are trained and regularly updated
- Vaccines are correctly stored and handled

Adherence to Clinical governance framework should be monitored through regular audit of the vaccine service offered by the Trust

Legal ratification

Health professionals are reminded that the information contained in these slides has been sourced from original legislation and chapters 3 (Consent) and 5 (Immunisation by nurses and other healthcare professionals) in the Green Book.

Both these chapters have been ratified by the Department of Health's legal advisers prior to publication.

Useful references

- **DH Reference guide**
  www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005762
- **Consent: what you have a right to expect: a guide for children and young people**
- **http://www.dh.gov.uk/assetRoot/04/01/90/21/04019021.pdf**
- **Consent: what you have a right to expect: a guide for parents**
- **http://www.dh.gov.uk/assetRoot/04/01/91/68/04019168.pdf**
- **Children Act, 1989, section 2(7)**

Minimum slide set created by:

Immunisation, Hepatitis and Blood Safety Department,

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to assist teaching of the *Core Curriculum for Immunisation Training*

(see http://www.hpa.org.uk/infections/topics_az/vaccination/training_menu.htm)

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