01 General Information

This chapter provides information on the following:

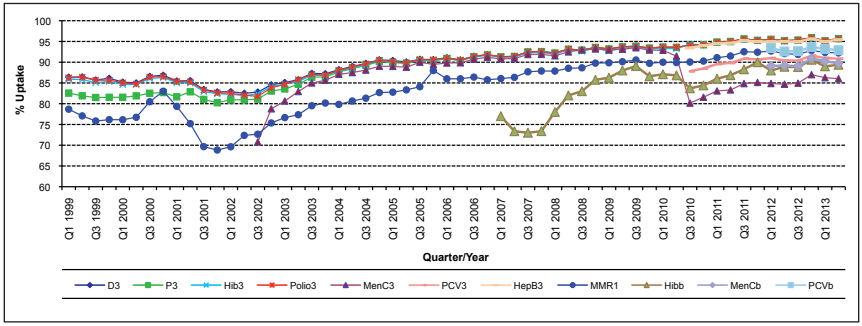
- Vaccine uptake and surveillance of vaccine-preventable disease
- Reporting of adverse reactions and quality defects
    - Terms used for frequency of adverse events
- Procurement and distribution of vaccines within the cold chain
- Definitions
- Abbreviations
- Useful websites
- Bibliography

Vaccine uptake and surveillance of vaccine-preventable disease

The Health Protection Surveillance Centre (HPSC), www.hpsc.ie is responsible for the surveillance of communicable diseases, for examining the incidences of vaccine-preventable illness and for examining trends in the uptake of vaccines (see Figure 1.1).

The HPSC receives immunisation uptake data from each Health Service Executive (HSE) region and reports on uptake rates nationally, by HSE region and by Local Health Office area. These reports are published each quarter on its website.

Figure 1.1 Quarterly immunisation uptake rates (%) in Ireland at 24 months 1999 - Q2 2013.
Source: HPSC



Irish legislation specifies the infectious diseases ("Notifiable diseases") that medical practitioners and clinical directors of a diagnostic laboratory are required to notify to a Medical Officer of Health as soon as they become aware of or suspect that a patient is suffering from or is the carrier of a notifiable infectious disease.

The HPSC collates and analyses these notifications weekly. Of particular relevance to vaccine preventable disease, the HPSC monitors the notifications of vaccine-preventable diseases and seeks to determine if vaccine failure has occurred or if there are areas with undervaccinated individuals at risk of disease so that catch-up programmes can be implemented.

The impact of vaccination programmes is closely monitored and any changes of epidemiology of vaccine preventable disease analysed e.g. an emergence of Hib disease was seen in fully vaccinated children in 2005. This coupled with evidence that Hib vaccine efficacy is of longer duration in those immunised after 12 months of age led NIAC to recommend a 4th dose be given at 12 months and a catch-up Hib dose be offered to children aged 1 to under 4 years of age to further protect this age group from Hib disease.

Reporting of adverse reactions and quality defects

All suspected adverse reactions should be reported to the IHealth Products Regulatory Authority (HPRA) using the Yellow Card System or electronically www.hpra.ie. Reports should be as detailed as possible and include the batch number of the vaccine.

Terms used for frequency of adverse events

Description	Detectable range
Very common	>1/10
Common	>1/100 and <1/10
Uncommon	>1/1,000 and <1/100
Rare	>1/10,000 and <1/1,000
Very rare	<1/10,000

Quality defects are also monitored by the Health Products Regulatory Authority (HPRA) , using a similar 'Freepost' Green Card System or electronic notification. Quality defects include missing labels/label texts, container defects, altered product appearance, particles in product etc. Full details of the defect and the batch number should be given on the Green Card. Cards are available from the IMB website.

Procurement and distribution of vaccines within the cold chain

The National Immunisation Office (NIO) oversees the implementation of the national immunisation programme of the Health Service Executive (HSE) and is responsible for the procurement and distribution of vaccines used in publicly funded programmes. All other vaccines are sourced from the vaccine manufacturer. The NIO also provides information leaflets for the general public and health-care professionals. It hosts a website www.immunisation.ie and is involved in developing a national IT register for immunisations.

All vaccines are sensitive to heat, cold and light and must be kept at temperatures between +2 to +8°C. Vaccines must be stored within this specific temperature range to ensure their potency and to comply with their licence. The 'Cold Chain' is the system of transporting, storing and maintenance of vaccines within appropriate temperatures and protection from light from the time of manufacture to administration.

The National Cold Chain Service delivers vaccines for publicly funded programmes to General Practitioner (GP) surgeries, hospitals, Local Health Offices and pharmacies with validated temperature records up to the point of delivery.

Other vaccines can be sourced from the vaccine manufacturer or local pharmacy.

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Vaccine ordering

- There should be a designated person in charge of the ordering, receipt and storage of vaccines.
- When vaccines are delivered they should be checked against the order for any damage or discrepancy.
- Vaccines must be placed in the refrigerator immediately and not left at room temperature.

Vaccine storage and usage

- Vaccine refrigerators are recommended for the storage of vaccines.
- Vaccine manufacturers' recommendations on storage should be observed.
- Care should be taken to ensure that the electricity supply to the vaccine storage refrigerator cannot accidentally be interrupted. This can be achieved by using a switchless socket or by placing cautionary notices on plugs and sockets.
- Vaccines must be stored in their original packaging, which should not touch the sides or back of the refrigerator.
- The refrigerator should not be overfilled, to allow air circulate around the packages.
- Vaccines should not be stored on the shelves or storage compartments of the door of non-pharmaceutical refrigerators.
- Vaccines with the shortest expiry date should be used first.
- Vaccine stocks should be rotated so that vaccines with the shortest expiry dates are at the front of the refrigerator.
- Door-opening should be kept to a minimum.
- A temperature data logger should be placed in the refrigerator as a second monitor independent of the refrigerator thermometer. This provides a continuous temperature record.

  If such a device is unavailable a maximum/minimum thermometer should be placed in the refrigerator.
- Vaccine refrigerators should have a self defrost function so they do not require manual defrosting.
- Vaccine refrigerators should be cleaned with a 1:10 solution of sodium hypochlorite (Milton). Vaccines should be stored in another refrigerator while doing this.
- Records should be kept of refrigerator maintenance and servicing.
- Food and drink must not be stored in refrigerators used for vaccines.

Storage outside the cold chain

- If the temperature recorded is less than +2°C or greater than +8°C, contact the NIO (phone 01 867 6108 or 087 991 5452) for vaccines supplied by the National Cold Chain Service or the vaccine manufacturer for further advice. A risk assessment will be carried out and a recommendation made. The use of a vaccine stored at an incorrect temperature is based on a thorough understanding of the likely impact of the temperature variation on the vaccine and must be made on a case-by-case basis.

Disposal of vaccines

- Reconstituted vaccine must be used within the recommended period, varying from 1 to 4 hours, according to the manufacturer's instructions.
- Single-dose vials are preferable. Once opened, multidose vials must not be kept after the end of the session.
- Unused vaccine and empty or partly used vials should be disposed of safely into a sharps bin and then by incineration.
- Contaminated waste and spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate.
- Expired and damaged unopened vaccines must not be used and should be returned via the HSE National Cold Chain Service for HSE stock or by contacting the vaccine manufacturer for private stock.

Needles and syringes

- Needles and syringes must be securely stored and delivery and distribution recorded.
- Needles and syringes should be disposed of in sharps bins.
- Sharps bins must be stored safely at all times.
- Sharps bins should be collected regularly and be disposed of safely.
- Sharps bins should be securely closed when two thirds full and placed in a secure locked room for collection.

Definitions

Adverse drug reaction (ADR): a response to a drug which is harmful and unintended and which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

Adverse event following immunisation (AEFI): any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Antitoxin is a solution of antibodies derived from the serum of animals immunised with specific antigens (e.g. diphtheria antitoxin) used to achieve passive immunity or for treatment.

Immunisation: the process whereby a person is made immune or resistant to an infectious disease. This may be either active or passive.

> *Active immunisation* is the administration of a vaccine in order to stimulate production of an immune response.
>
> *Passive immunisation* is the administration of antibodies (such as HNIG, specific antibody preparation and antitoxins) in order to provide temporary immunity.

Immunoglobulin: Human immunoglobulin is that fraction of human blood plasma that contains antibodies, notably those against infectious agents. Preparations of immunoglobulin belong to two main categories:

- Human Normal Immunoglobulin (HNIG).
- Human Specific Immunoglobulin/Hyperimmune Globulin.

Passive immunity: the transfer of antibodies from one individual to another. Passive immunity can occur naturally, when maternal antibodies are transferred to the foetus through the placenta, and artificially, when high levels of antibodies specific for a pathogen or toxin are administered to non-immune individuals.

Reproductive number (R_0) is the average number of secondary infections resulting from each index case in a fully susceptible population. It is a measure of the transmissibility of an infection.

Toxoid is a modified bacterial toxin that has been rendered non-toxic but has the ability to stimulate the formation of antitoxin.

Vaccination: injection of a vaccine.

Vaccine: any preparation intended to produce immunity to a disease by stimulating the production of antibodies. Vaccines include, for example, suspensions of killed or attenuated microorganisms, or products or derivatives of microorganisms.

Conjugate vaccine is one where a protein or polysaccharide antigen is linked to a carrier protein e.g. meningococcal C conjugate vaccine.

Inactivated vaccine is a vaccine that contains killed bacteria or viruses, or a portion thereof e.g. inactivated polio vaccine.

Recombinant vaccine a vaccine produced through recombinant DNA technology e.g. hepatitis B and human papillomavirus vaccine.

Sub unit vaccine contains only specific antigenic proteins of an infectious agent e.g. acellular pertussis and some influenza vaccines.

Live attenuated vaccine is a vaccine that contains a weakened strain of live bacteria or viruses that replicate in the body e.g. BCG and MMR vaccines.

For convenience the term non live vaccine is used in these Guidelines to include conjugate, inactivated, recombinant and subunit vaccines.

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ALS	Advanced Life Support
Anti-HBc	Antibody to Hepatitis B Core Antigen
Anti-HBs	Antibody to Hepatitis B Surface Antigen
Anti-HCV	Hepatitis C antibody
BLS	Basic Life Support
CDC	Centers for Disease Control and Prevention
CNS	Central Nervous System
CPR	Cardiopulmonary Resuscitation
DOH	Department of Health
GVHD	Graft versus Host Disease
HAV	Hepatitis A Virus
HBV	Hepatitis B Virus
HBIG	Hepatitis B Immunoglobulin
HBeAg	Hepatitis B e Antigen
HBsAg	Hepatitis B Surface Antigen
HCW	Health-Care Worker
Hib	Haemophilus influenzae type b
HIV	Human Immunodeficiency Virus
HNIG	Human Normal Immunoglobulin
HPSC	Health Protection Surveillance Centre
HPRA	Health Products Regulatory Authority
HPV	Human Papillomavirus
HRIG	Human Rabies Immunoglobulin
HSE	Health Service Executive

HSCT	Haematopoeitic Stem Cell Transplant
IBTS	Irish Blood Transfusion Service
IM	Intramuscular
IPD	Invasive Pneumococcal Disease
IV	Intravenous
IVIG	Intravenous immunoglobulin
IU	International Units
MDR-TB	Multi-Drug Resistant Tuberculosis
NIAC	National Immunisation Advisory Committee
NIO	National Immunisation Office
NVRL	National Virus Reference Laboratory
PPD	Purified Protein Derivative
RCPI	Royal College of Physicians of Ireland
ROI	Republic of Ireland
SC	Subcutaneous
SmPC	Summary of Product Characteristics
SOT	Solid Organ Transplant
SSPE	Subacute Sclerosing Panencephalitis
TB	Tuberculosis
TIG	Tetanus Immunoglobulin
TST	Tuberculin Skin Test
TU	Tuberculin
VZ	Varicella-Zoster
VZIG	Varicella-Zoster Immunoglobulin
VZV	Varicella Zoster Virus
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis

Vaccine abbreviations:

4 in 1	Diphtheria, Tetanus, Pertussis, Polio vaccine
5 in 1	Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae B vaccine
6 in 1	Diphtheria, Tetanus, Pertussis, Polio, Haemophilus influenzae B, Hepatitis B vaccine
BCG	Bacille Calmette-Guerin vaccine
HDCV	Human Diploid Cell Vaccine
Hep A	Hepatitis A vaccine
Hep B	Hepatitis B vaccine
Hib	Haemophilus influenzae B vaccine

HPV	Human papillomavirus vaccine
IPV	Inactivated Polio Virus vaccine
MenACWY	Meningococcal A, C, W135, Y conjugate vaccine
MenC	Meningococcal C vaccine
MMR	Measles, Mumps, Rubella vaccine
OPV	Oral polio vaccine
PCV	Pneumococcal conjugate vaccine
PPV	Pneumococcal polysaccharide vaccine
Td	Tetanus and low dose diphtheria vaccine
Td/IPV	Tetanus, low dose diphtheria, inactivated polio vaccine
Tdap	Tetanus, low dose diphtheria and pertussis vaccine
Tdap/IPV	Tetanus, low dose diphtheria and pertussis vaccine, inactivated polio vaccine

These Guidelines are available on the RCPI, NIO, HPSC and Department of Health websites in pdf format. The electronic version of the document will be regularly updated.

Useful websites

For further information on immunisation see the following websites

American Academy of Pediatrics
www.aap.org

American Medical Association
www.ama-assn.org

Centers for Disease Control and Prevention (USA)
www.cdc.gov

Department of Health (Ireland)
www.doh.ie

Department of Health (UK)
www.dh.gov/uk/greenbook

Health Protection Surveillance Centre
www.hpsc.ie

Immunization Action Coalition
www.immunize.org

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Immunise Australia Program
http://www.immunise.health.gov.au/

National Immunisation Office
www.immunisation.ie

National Institutes of Health
www.nih.gov

National Network for Immunization Information
www.immunizationinfo.org

Public Health England
www.hpa.org.uk

Royal College of Physicians of Ireland
www.rcpi.ie

United Kingdom, Medical Research Council
www.mrc.ac.uk/index.htm

Bibliography

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