

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 vaccine within the cold chain
- Definitions
- Abbreviations
- Useful websites
- Bibliography

Vaccine uptake and surveillance of vaccine-preventable disease

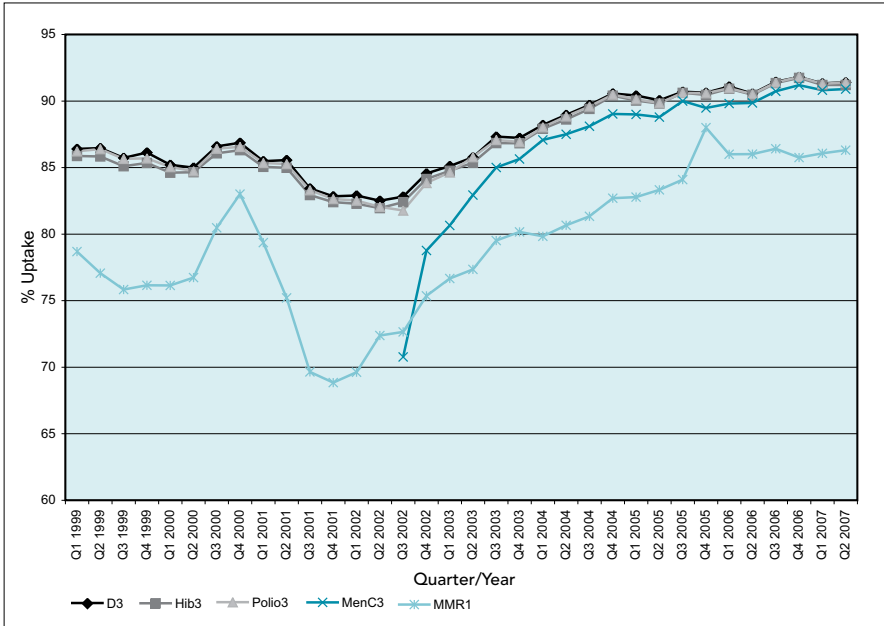
The Health Protection Surveillance Centre (HPSC), Middle Gardiner Street, Dublin 1 (www.hpsc.ie) is responsible for the surveillance of communicable diseases, examining the incidences of vaccine-preventable illness and examining trends in the uptake of vaccines (see figure 1.1).

The HPSC receives immunisation uptake data from each Health Service Executive (HSE) area and reports on uptake rates nationally, by HSE area and by Local Health Office area. These reports are published each quarter on its website www.ndsc.ie/hpsc/A-Z/VaccinePreventable/Vaccination/.

Irish legislation specifies the infectious diseases that medical practitioners 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. There is a similar requirement for a clinical director of a diagnostic laboratory to notify a Medical Officer of Health as soon as an infectious disease is identified in that laboratory.

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Figure 1.1 Quarterly immunisation uptake rates (%) in Ireland at 24 months. Source: HPSC (1999-2007/Q2)



Note: T3 and P3 uptake rates similar to D3; therefore only D3 plotted

The HPSC collates and analyses these notifications weekly and also produces quarterly and annual reports.

The HPSC particularly monitors the notifications of vaccine-preventable diseases and seeks to determine if vaccine failure has occurred. A good example of how this works was the detection of an increase in the number of Hib cases in fully vaccinated children in 2005. This led to concerns that a 3-dose infant schedule was no longer sufficient to maintain long-term protection. A similar situation had emerged in the UK a number of years previously.

In response to this emerging trend in Ireland, and coupled with the scientific evidence that Hib vaccine efficacy is higher in those immunised at older than 12 months of age than in children vaccinated routinely as infants, the National Immunisation Advisory Committee (NIAC) recommended that a catch-up Hib dose be offered to children under 4 years of age, in order 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 Irish Medicines

Board (IMB), Kevin O'Malley House, Earlsfort Terrace, Dublin 2, using the Yellow Card System. This is a 'Freepost' system and cards are available from the Irish Medicines Board at the above address, or may be downloaded from their website, www.imb.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 Irish Medicines Board (IMB), using a similar 'Freepost' Green Card System. 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 Irish Medicines Board at the above address.

Procurement and distribution of vaccine within the cold chain

The National Immunisation Office (NIO) oversees the day-to-day implementation of the national immunisation programme by the Health Service Executive. The NIO is responsible for the procurement and distribution of vaccine within the cold chain. It also provides up-to-date information leaflets for parents and health-care professionals. It hosts a website www.immunisation.ie and is developing a national IT register for immunisations.

Cold chain management of vaccines

All vaccines are sensitive to heat, cold and light and must be kept at temperatures between 2-8°C. Leaving vaccines outside this temperature range can result in the loss of vaccine potency.

The 'Cold Chain' is the system of correct storage, transport and maintenance of vaccines to ensure that they are protected from inappropriate temperatures and light from the time of manufacture to administration.

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All routine vaccines are stored and delivered under temperature-controlled conditions by the HSE National Cold Chain Delivery Service to General Practitioner (GP) surgeries, hospitals and Local Health Offices.

Vaccine ordering and usage

- There should be a designated person in charge of the ordering, receipt and storage of vaccines.
- The designated person should order sufficient vaccines from the National Cold Chain Delivery Service on a monthly basis. In an emergency additional supplies can be delivered.
- 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.
- Vaccines stored outside temperature-controlled conditions should not be used.

Vaccine storage

- Vaccine refrigerators are recommended for the storage of vaccines. Manufacturers' recommendations on storage should be observed.
- Vaccines should be stored in the pharmaceutical refrigerator which should not be overfilled, to allow air circulate around the packages. **They should not be stored on the shelves or storage compartments of the door of non-pharmaceutical refrigerators.**
- Vaccines must be stored in their original packaging, which should not touch the sides or back of the refrigerator.
- Door-opening should be kept to a minimum.
- **Vaccines with the shortest expiry date should be used first. Vaccine stocks should be rotated so that vaccines with shorter expiry dates are at the front of the refrigerator.**
- A maximum/minimum thermometer should be used in refrigerators where vaccines are stored, irrespective of whether the refrigerator incorporates a temperature indicator dial. The maximum and minimum temperatures reached should be monitored and recorded daily. Temperature record logs are best kept close to the refrigerator for ease of reference.
- If temperatures outside the permitted range are recorded, or if there is a breakdown in supply or equipment, the Chief Pharmacist of the National Immunisation Office or the Senior Medical Officer should be contacted for further advice.
- The vaccine refrigerator should be defrosted regularly as ice builds up, and cleaned with a 1:10 solution of sodium

hypochlorite. Vaccines should be stored in another refrigerator or cool box while doing this.

- Records should be kept of refrigerator maintenance and servicing.
- 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.
- Food and drink must not be stored in refrigerators used for vaccines.

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 containers are preferable; once opened, multidose vials must not be kept after the end of the session.
- Unused vaccine, spent or partly spent vials should be disposed of safely by incineration.
- Contaminated waste and spillage should be dealt with by heat sterilisation, incineration or chemical disinfection as appropriate.
- **Expired vaccines must not be used and should be returned to the National Cold Chain Delivery Service company at the next delivery.**

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 not be left unattended in schools.
- Sharps bins should be collected regularly and be disposed of safely.

Definitions

Adverse reaction is an event that is harmful and unintended and that occurs following administration of medicinal products (substances normally used in humans for the prophylaxis, diagnosis or treatment of disease or for the modification of physiological function).

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.

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Basic 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.

Immunisation denotes the process of artificially inducing or providing immunity. This may be either active or passive.

Active immunisation is the administration of a vaccine or toxoid in order to stimulate production of an immune response.

Passive immunisation is the administration of preformed antibodies (such as HNIG, specific antibody preparation and antitoxins) in order to provide temporary immunity.

Immunoglobulin

Human immunoglobulin is that fraction of 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.

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

Vaccine is a suspension of live attenuated or inactivated micro-organisms or fractions thereof, administered to induce immunity and thereby prevent infectious disease.

Inactivated vaccine is a vaccine that contains killed bacteria or viruses. The response may be weaker than for a live vaccine and so repeated doses are often needed.

Live attenuated vaccine is a vaccine that contains a weakened strain of live bacteria or viruses that replicate in the body and induce a longer-lasting immunity than inactivated vaccines.

Vaccination is the term used to refer to the administration of any vaccine or toxoid.

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
BCG:	Bacille Calmette Guerin vaccine
CNS:	Central Nervous System
CPR:	Cardiopulmonary Resuscitation
DTaP:	Adsorbed Diphtheria, Tetanus and acellular Pertussis vaccine
HAV:	Hepatitis A Virus
HBV:	Hepatitis B Virus
HBIG:	Specific Hepatitis B Immunoglobulin/Hyper-immunoglobulin
HBeAg:	Hepatitis B e Antigen
HBsAg:	Hepatitis B Surface Antigen
HCW:	Health-Care Worker
HDCV:	Human Diploid Cell Rabies Vaccine
Hib:	<i>Haemophilus influenzae</i> type b
HIV:	Human Immunodeficiency Virus
HNIG:	Human Normal Immunoglobulin
HRIG:	Human Rabies Immunoglobulin
HPSC:	Health Protection Surveillance Centre
HPV:	Human Papilloma Virus
HSE:	Health Service Executive
IBTS:	Irish Blood Transfusion Service
IM:	Intramuscular
IPD:	Invasive Pneumococcal Disease
IPV:	Inactivated Polio Virus vaccine
IU:	International Units
MDR-TB:	Multi-Drug Resistant Tuberculosis
MenC	Meningococcal C
MMR:	Measles, Mumps and Rubella
NIAC:	National Immunisation Advisory Committee
NIO:	National Immunisation Office
NVRL:	National Virus Reference Laboratory
OPV:	Oral Polio Vaccine
PCV:	Pneumococcal Conjugate Vaccine
PPD:	Purified Protein Derivative
PPV:	Pneumococcal Polysaccharide Vaccine
RCPI:	Royal College of Physicians of Ireland
ROI:	Republic of Ireland
SC:	Subcutaneous

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SSPE:	Subacute Sclerosing Panencephalitis
Td:	Tetanus toxoid, low-dose diphtheria toxoid
Tdap:	Tetanus, low-dose diphtheria and low-dose acellular pertussis vaccine
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

This document is available on the RCPI, NIO, HPSC and Department of Health and Children websites in pdf format. The electronic version of the document will be regularly updated as changes are introduced to our immunisation schedule.

Useful websites

For further information and debate on immunisation, the following websites may be useful.

American Academy of Pediatrics
www.aap.org/new/immpublic.htm

American Medical Association
www.ama-assn.org/medsci/immunize/vacautism.htm

Australian Skeptics Dr Steve Basser: Anti-immunisation scare: The inconvenient facts
skeptics.com.au/journal/anti-immune.htm

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

Department of Health and Children
www.dohc.ie/

Health Protection Surveillance Centre
www.hpsc.ie

Immunisation Action Coalition
immunize.org

National Alliance for Autism Research
www.naar.org/naar.asp

National Immunisation Office
www.immunisation.ie

National Institutes of Health
www.nih.gov

National Network for Immunization Information
www.immunizationinfo.org

Royal College of Physicians of Ireland
www.rcpi.ie

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

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Bibliography

HPSC (2006). Annual Report 2005. HPSC.

McVernon J, Trotter C, Slack M, Ramsay M (2004). Trends in *Haemophilus influenzae* type b infections in adults in England and Wales: surveillance study. *BMJ*, 329: 655-8.

Ramsay M, McVernon J, Andrews N, Heath P, Slack M (2003). Estimating *Haemophilus influenzae* type b vaccine effectiveness in England and Wales by use of the screening method. *J Infect Dis*; 188: 481-5.