Session 1

The aims of immunisation, national policy and schedules
Aim

• The aim of this session is to explain the aims of immunisation, and describe national policy and schedules
Learning Outcomes

At the end of session, you should be able to:

• Explain the different factors that inform policy decisions

• Describe how immunisation programmes are monitored through the use of surveillance
Learning Outcomes (cont.)

• Access current vaccine policy through the Green Book and Chief Medical Officer letters and updates

• Describe how vaccine trials are carried out before a vaccine is released, and how safety and efficacy are monitored after their release
Explain the Different Factors That Inform Policy Decisions

When considering the use of any vaccine the goal must first be defined in relation to that particular disease i.e. What do we hope to achieve / what is possible?

The options are:

• Control
• Elimination
• Eradication
Control, Elimination or Eradication (cont.)

**Control** is a reduction in the incidence, prevalence, morbidity or mortality of an infectious disease to a locally acceptable level.

**Elimination** is reduction to zero of the incidence of disease or infection in a defined geographical area.
Control, Elimination or Eradication Cont.

**Eradication** is permanent reduction to zero of the worldwide incidence of infection – as has been seen with smallpox. This is, so far, the only disease that had been eradicated by vaccination.
Control, Elimination or Eradication Cont.

The Global Polio Eradication Initiative aims to eradicate polio through worldwide vaccination against polio virus – despite best attempts to achieve this by the year 2000 – this goal has not yet been met.
Surveillance of Disease (cont.)

• In order to know if public health interventions such as vaccination are effective, we need to carry out **surveillance**.
• Surveillance is described as:

  *The ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health* (CDC, 2001)
Surveillance of Disease (cont.)

This tells us whether measures such as vaccination are making any difference / being effective

This helps us plan further actions!
Surveillance of Disease (cont.)

The following methods are among the ways used to collate data on vaccine preventable diseases as we now have various other ways of monitoring impact.

- Notifications
- Laboratory reports
- Enhanced surveillance schemes
Notifications

• The purpose of notifications is to quickly detect a possible outbreak of disease so that further investigation and action can be taken
• Clinical suspicion of a notifiable infection is all that is required (i.e. Laboratory confirmation is not needed)
• Notifications are useful for illustrating disease trends over time
• Notifications of infectious diseases comes under the Public Health etc. (Scotland) Act 2008.
Notification (cont.)
Pertussis Notifications, Scotland 1943 - 2012
Notification (cont.)
Diseases marked * require urgent notification i.e. within working day. Follow up written / electronic notification within 3 days is still required.

- Anthrax
- * Botulism
- Brucellosis
- * Cholera
- * Clinical syndrome due to E.coli 0157
- * Diphtheria
- * Haemolytic uraemic syndrome (HUS)
- * Haemophilus influenzae type b (Hib)
### Notifications (cont)

- * Measles
- * Meningococcal disease
- Mumps
- Necrotising fasciitis
- Paratyphoid
- Pertussis
- Plague
- * Poliomyelitis
- * Rabies
- Rubella
- * Severe Acute Respiratory Syndrome (SARS)
- * Smallpox
- Tetanus
- Tuberculosis (respiratory or non-respiratory)
- * Tularemia
- * Typhoid
- * Viral haemorrhagic fevers
- * West Nile fever
- Yellow Fever
Laboratory Reports

• Laboratory reports of notifiable organisms are collated centrally by Health Protection Scotland and reported to local Health Protection Teams (HPTs) so that the local HPTs are aware of any activity / events within their own areas.
Enhanced surveillance is necessary to monitor the effectiveness of current and new vaccination programmes to detect any changes in epidemiology.

Health Protection Scotland plays a central role in Scotland’s enhanced surveillance systems which are often undertaken in partnership with other key organisations.
Enhanced Surveillance Schemes (cont.)

Enhanced surveillance schemes are currently in operation for:

- Meningococcal disease
- Haemophilus influenzae type B (Hib)
- Tuberculosis
- Pneumococcal disease
- Influenza
- Measles
- Human papilloma virus
Enhanced Surveillance Schemes (cont.)

- Not all enhanced surveillance schemes (ESS) are the same. An example of an ESS is meningococcal disease where surveillance data is recorded jointly by HPS and the Scottish Haemophilus, Legionella, Meningococcus and Pneumococcus Reference Laboratory (SHLMPRL), to which all hospitals in Scotland send samples.
Enhanced Surveillance Schemes (cont.)
For further information on ESS go to the HPS website
Surveillance of Vaccine Uptake

It is important to obtain accurate data on vaccine uptake.

- Information on primary immunisation is recorded in the Scottish Immunisation Recall System (SIRS) which covers all NHS Boards in Scotland
- Uptake rates at 12 and 24 months and at 5 and 6 years are calculated quarterly
- Uptake rates by NHS Board are published in the HPS Weekly Report along with additional information about vaccine preventable diseases or ISD http://www.isdscotland.org//Health-Topics/Child-Health/Immunisation/
Vaccine Policy

UK vaccination policy is based on recommendations made by the Joint Committee on Vaccination and Immunisation (JCVI).

JCVI is an independent Departmental Expert Committee and a statutory body. It was originally an advisory body for polio immunisation and became JCVI in 1963.
JCVI

- Has no statutory basis for providing advice in Scotland but the Scottish Government Health and Social Care Directorate usually chooses to accept the JCVI’s advice and recommendations.

- Recommendations are used by governments to make policy – JCVI is not a policy maker in its own right
JCVI (cont.)

- Formulates advice and recommendations based on appraisal of best scientific evidence and/or expert opinion.
- Processes involved are robust, transparent, and comprehensive
- Appraisal of available evidence is from a wide range of resources
JCVI (cont.)

- JCVI vaccine recommendations are published in the ‘Green Book’ (Immunisation Against Infectious Diseases) which all immunisers should be familiar with
- The hard copy of the Green Book is out of date and should not be used; The Green Book online is continually updated

Green Book: Public Health England: Immunisation Against Infectious Diseases

‘The Green Book’

- The Green Book is the joint clinical guidance of UK health departments for health professionals who administer immunisations or provide information or advice on them
‘The Green Book’ (cont.)

The importance of the Green Book cannot be over-estimated for immunisers.

In Session 3 of this programme, you will utilise the Green Book in order to obtain essential information about vaccines and vaccine administration etc.
CMO Letters

• Chief Medical Officer (CMO) letters are key communications between the Scottish Government Health and Social Care Directorates and the NHS

• Scottish vaccination recommendations and any variations to the Green Book are communicated via CMO letters
<table>
<thead>
<tr>
<th>Reference</th>
<th>Name of Publication</th>
<th>Date</th>
<th>View</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMO2015/10</td>
<td>Advice on contraindications for shingles vaccine - green book chapter update</td>
<td>22/09/2015</td>
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<td>CMO2015/10</td>
<td>Meningococcal ACWY (Men ACWY) vaccination programme: university freshers and adolescents aged 14-18</td>
<td>23/06/2015</td>
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<tr>
<td>CMO2015/11</td>
<td>Introduction of meningococcal group B (Men B) vaccination programme in 2015/16</td>
<td>10/07/2015</td>
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<tr>
<td>CMO2015/13</td>
<td>Scottish childhood flu vaccination programme 2015-16</td>
<td>10/07/2015</td>
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Dear Colleague

DETAILS OF THE 2015-16 SHINGLES (HERPES ZOSTER) VACCINATION PROGRAMME

Introduction
1. This year’s shingles programme will run from 1 September 2015* until 31 August 2016. The programme is aimed at:
   - People aged 70 years (routine)
   - People aged 78 years (catch-up).

Additional considerations in 2015-16
2. Opportunistic Vaccination: Those who were eligible for the programme since it began in September 2013 (and who did not previously take up the offer of vaccination) can still be vaccinated if they ask for it. Vaccine should not be offered to anyone who is aged 80 or over, even if they have previously been eligible, as efficacy of the vaccine declines with age.

3. Early Immunisation Opportunity: Any GP who wishes to start vaccinating from 1 August 2015* (ahead of the official date), to help use up pre-existing vaccine stock can do so.

4. Zostavax® is the only shingles vaccine with market authorisation available in the UK. It contains live, attenuated virus derived from the Oka/Meck strain of varicella zoster virus. This vaccine is contraindicated in some patients (eg immunosuppressed). An easy to use tool has been created to help with eligibility and screening for contraindications for use by healthcare practitioners. This tool can be accessed at: http://www.hps.scot.nhs.uk/immvax/shinglesvaccine.aspx.
National Immunisation Schedule

• This is the term used to encompass all universally recommended vaccines within the country and includes vaccines given to all infants, children and other age-based recommendations for older ages.

• There are also particular vaccines recommended for certain at risk clinical groups

• Vaccines used in the occupational health setting or for travellers abroad are additional to the national schedule.
National Immunisation Schedule (cont.)

The overall aim of this is to reduce the incidence of serious infectious diseases using vaccines that are safe and effective.

Factors to consider:

• What is the goal: control; elimination; eradication?

• What is target population: all = universal vaccination; only ‘at risk’ = targeted or selective?
National Immunisation Schedule (cont.)

- What is coverage target: the % population required to be vaccinated to achieve the aim (this will depend on the infectiousness of the disease and the effectiveness of the vaccine)

- What is the optimal number, timing and spacing of vaccine doses?

- What age is the best time to vaccinate taking into account factors that affect the immune response (e.g. maternal antibody or age-related warning immune responses in older age) and the age at which optimum protection is needed
<table>
<thead>
<tr>
<th>When to Immunise</th>
<th>Diseases protected against</th>
<th>Vaccine given</th>
<th>Site*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months old</td>
<td>Diphtheria, tetanus, pertussis (whooping cough), polio and Haemophilus influenzae type b (Hib)</td>
<td>DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)</td>
<td>Thigh</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal disease</td>
<td>PCV (Prevenar 13)</td>
<td>Thigh</td>
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<tr>
<td></td>
<td>Rotavirus</td>
<td>Rotarix</td>
<td>By mouth (orally)</td>
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<tr>
<td></td>
<td>Hib and meningococcal group B (MenB)</td>
<td>MenB (Bexsero)</td>
<td>Left thigh</td>
</tr>
<tr>
<td>3 months old</td>
<td>Diphtheria, tetanus, pertussis, polio and Hib</td>
<td>DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)</td>
<td>Thigh</td>
</tr>
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<td></td>
<td>Hib and meningococcal group B (MenB)</td>
<td>MenB (Bexsero)</td>
<td>Left thigh</td>
</tr>
<tr>
<td>4 months old</td>
<td>Diphtheria, tetanus, pertussis, polio and Hib</td>
<td>DTaP/IPV/Hib (Pediacel or Infanrix IPV Hib)</td>
<td>Thigh</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal disease</td>
<td>PCV (Prevenar 13)</td>
<td>Thigh</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps and rubella (German measles)</td>
<td>MMR (Priorix or MMR VaxPRO)</td>
<td>Upper arm/thigh</td>
</tr>
<tr>
<td></td>
<td>Hib and meningococcal group B (MenB)</td>
<td>MenB (Bexsero)</td>
<td>Upper arm/left thigh</td>
</tr>
<tr>
<td>Between 12 and 13 months old – within a month of the first birthday</td>
<td>Hib and meningococcal group C</td>
<td>Hib/MenC (Menitorix)</td>
<td>Upper arm/thigh</td>
</tr>
<tr>
<td></td>
<td>Pneumococcal disease</td>
<td>PCV (Prevenar 13)</td>
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<td></td>
<td>Hib and meningococcal group B (MenB)</td>
<td>MenB (Bexsero)</td>
<td>Upper arm/left thigh</td>
</tr>
<tr>
<td>2 to 11 years – annually</td>
<td>Influenza (flu)</td>
<td>FluTzan Tetra (flu nasal spray – if nasal spray unsuitable, use inactivated flu vaccine)</td>
<td>Nasal spray (both nostrils), injection if nasal spray contra-indicated</td>
</tr>
<tr>
<td>3 years 4 months old or soon after</td>
<td>Diphtheria, tetanus, pertussis and polio</td>
<td>DTaP/IPV (Repevax) or DTaP/IPV (Infanrix-IPV)</td>
<td>Upper arm</td>
</tr>
<tr>
<td></td>
<td>Measles, mumps and rubella</td>
<td>MMR (Priorix or MMR VaxPRO) (check first dose has been given)</td>
<td>Upper arm</td>
</tr>
<tr>
<td>Girls aged 11 to 13 years old</td>
<td>Cervical cancer caused by human papillomavirus (HPV) types 16 and 18</td>
<td>Gardasil</td>
<td>Upper arm</td>
</tr>
<tr>
<td>Around 14 years old</td>
<td>Tetanus, diphtheria and polio</td>
<td>Td/IPV (Revaxis), and check MMR status</td>
<td>Upper arm</td>
</tr>
<tr>
<td></td>
<td>Hib and meningococcal groups ACWY</td>
<td>MenACWY (Nimenrix or Menvax)</td>
<td>Upper arm</td>
</tr>
</tbody>
</table>

*Where two or more injections are required at once, these should ideally be given in different limbs. Where this is not possible, injections in the same limb should be given 2.5 cm apart. For more details see Chapters 4 and 11 in the Green book.

**Non-routine immunisations for at-risk babies**

- At birth, 1 month old, 2 months old and 12 months old | Hepatitis B | Hep B | Thigh
- At birth | Tuberculosis | BCG | Upper arm (intradermal)
- 6 months old to 2 years – annually | Influenza (flu) | Inactivated flu vaccine | Upper arm
Immunisation Co-ordinator

The immunisation co-ordinator is a very useful resource – if you do not know who this is or how to contact within your own local board, you should find out.

The role is normally carried out by a Consultant in Public Health or Health Protection.

The remit varies among boards.
Immunisation Co-ordinator (cont.)

Examples:

- Overseeing co-ordination of immunisation schedules and campaigns
- Monitoring surveillance methods
- Giving advice to other healthcare professionals and the public
- Ensuring access to education for healthcare professionals
- Overseeing development of local Board policies and protocols
Vaccine Trials

The Medicines Act, 1968 requires that medicines are licensed before being allowed onto the UK market.

Most medicines are licensed by the European Medicines Agency (EMEA). Prior to licensing, a vaccine must be shown to be:

- Effective
- Safe
- Stable
Vaccine Trials (cont.)

Vaccine clinical trials aim to:

- Measure antibody response and efficacy
- Establish the nature of systemic and local side effects

There are 4 phases in vaccine trials:
1. Initial trials
2. Larger studies
3. Larger studies again, potential assessing vaccine efficacy
4. Post-licensing surveillance
Vaccine Trials (cont.)

Phase 1: vaccine is given to a small number of healthy volunteers to look for serious adverse events; limited value in assessing immunogenicity

Phase 2: given to a sample of the population who will be targeted to have the vaccine once licensed; ideally a double blind trial
Vaccine Trials (cont.)

Phase 3: under controlled conditions in the target population, larger studies are conducted, including measurement of immune response, and potentially vaccine efficacy.

Vaccine Efficacy is calculated using a formula which uses the incidence rate (new cases in a population), in those unvaccinated and incidence rate in those vaccinated.
Vaccine Trials (cont.)

Once the first 3 vaccine trial phases have been passed, the vaccine may be given a license for use in the UK.

Phase 4 of the trial period involves post-licensing surveillance where there is a further period where the vaccine is closely monitored. Vaccines in this category are marked as black triangle.