

TEMPORARY PROGRAMME PERTUSSIS VACCINATION FOR PREGNANT WOMEN

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Pertussis/whooping cough

The disease



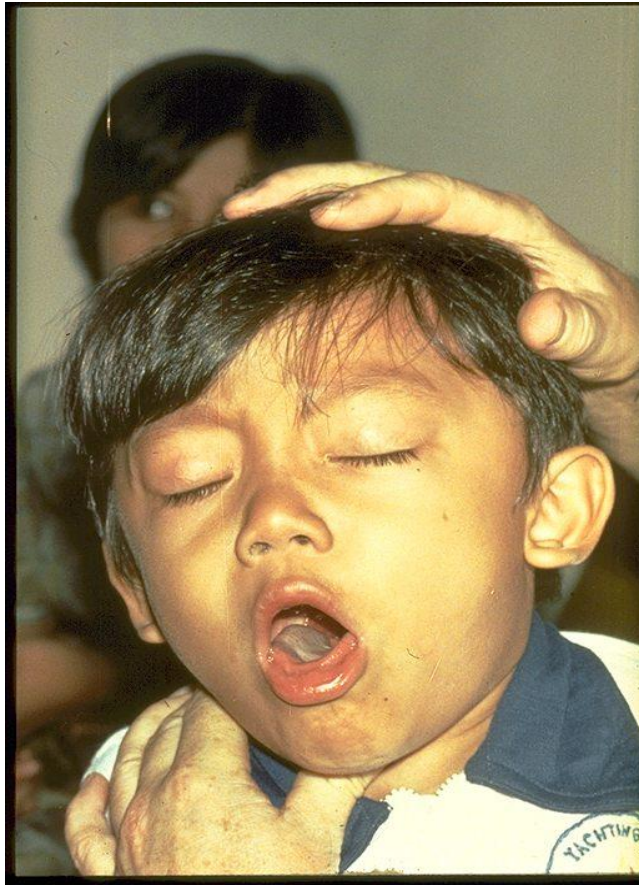
Whooping Cough

- **Disease of the respiratory tract caused by *Bordetella pertussis***
 - Starts with cold-like symptoms, develops into bouts of severe coughing followed by characteristic whoop or vomiting
 - Coughing can last for two to three months
- **Spreads easily from person-to-person in droplets produced by coughing or sneezing**
- **Incubation between 6 and 20 days (usually 7-10 days) and infectious from 6 days after exposure to 3 weeks after onset of typical paroxysms**
- **Most dangerous in children under 1 year of age who are also at risk of the serious complications**

Older children and adults may simply have prolonged cough – infection often goes unrecognised

Symptoms of Pertussis

Photo courtesy of WHO



- **Initially: cold-like symptoms - runny nose, watery eyes, sneezing, fever and a mild cough**
- **Followed by: gradually worsening cough, which develops to paroxysms of coughing followed by characteristic whoop**

Complications of Pertussis

- **Respiratory – the majority of cases involve some degree of collapsed lung and/or pneumonia**
- **Neurological – lack of oxygen leading to altered consciousness, convulsions, permanent brain damage, death**
- **Severe weight loss and dehydration due to vomiting**
- **Sudden death - babies may stop breathing, apnoeic attacks**
- **Despite low levels of disease, pertussis remains a significant cause of death in infants <6m**

Pertussis

Notifiable disease – laboratory reports all cases to PHA duty room

Suspect and test – swab/pcr or serology if >14 days after symptom onset

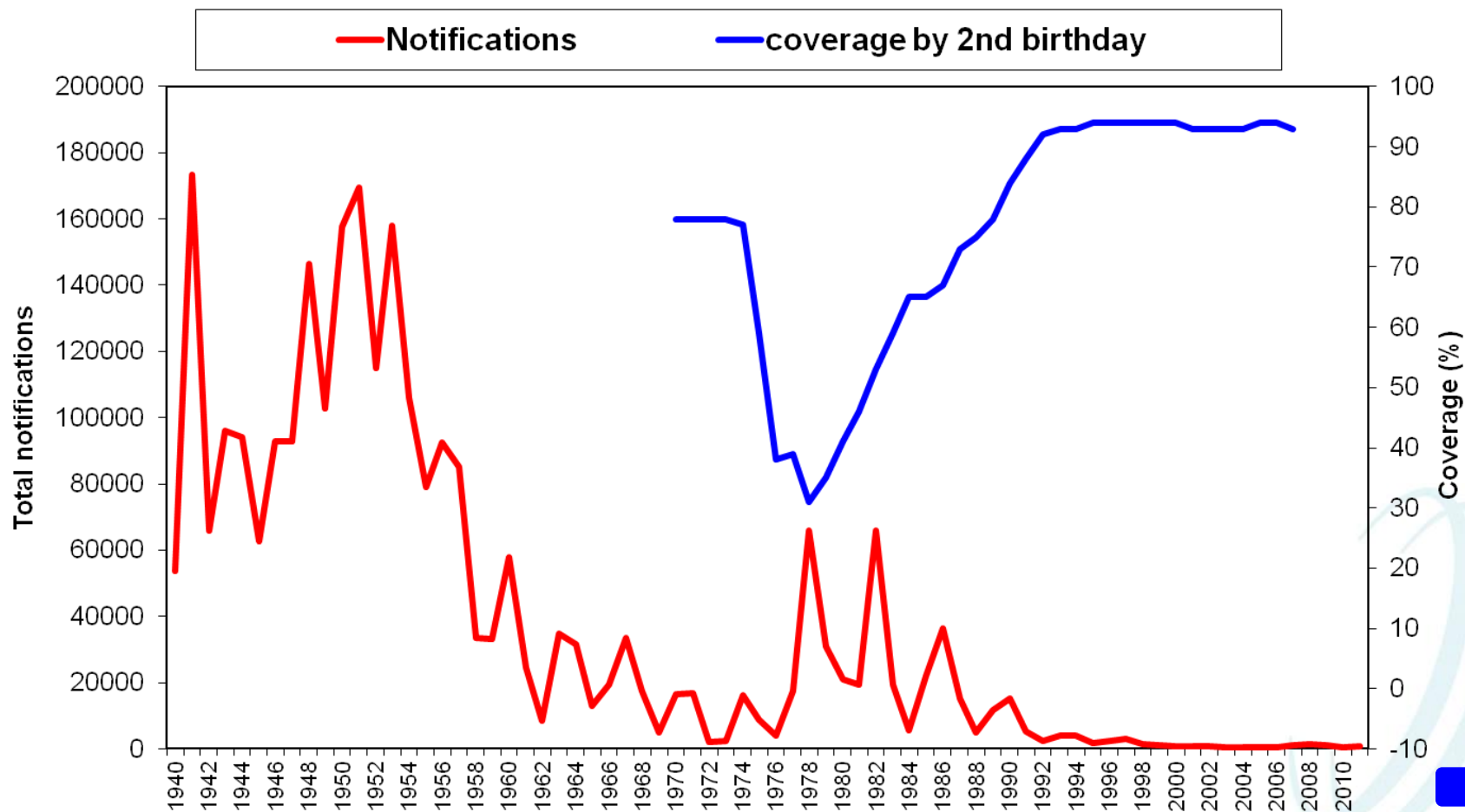
Guidance for prophylaxis (where there is vulnerable contact in household) and treatment

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1287142671506

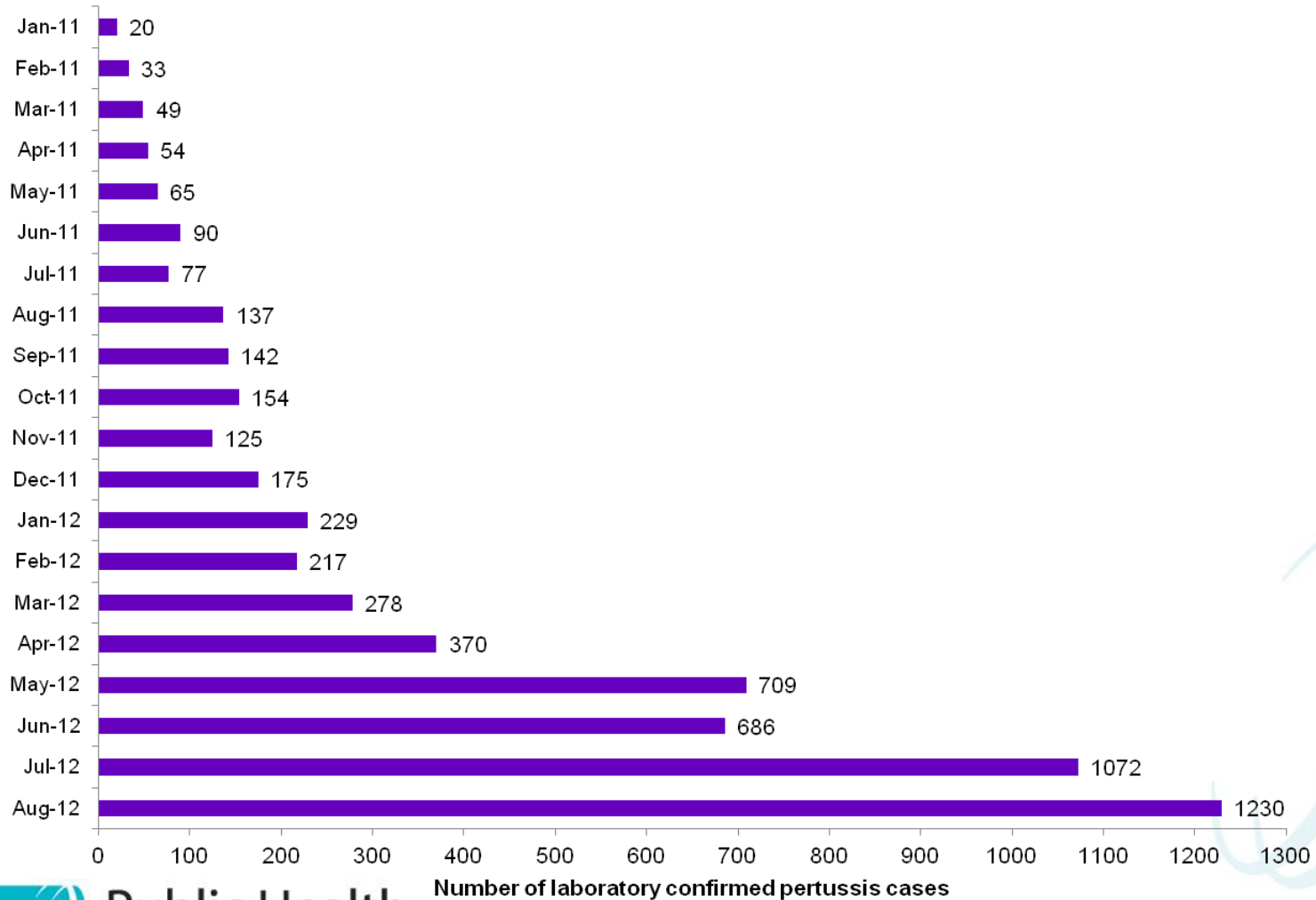
Increase in pertussis in UK



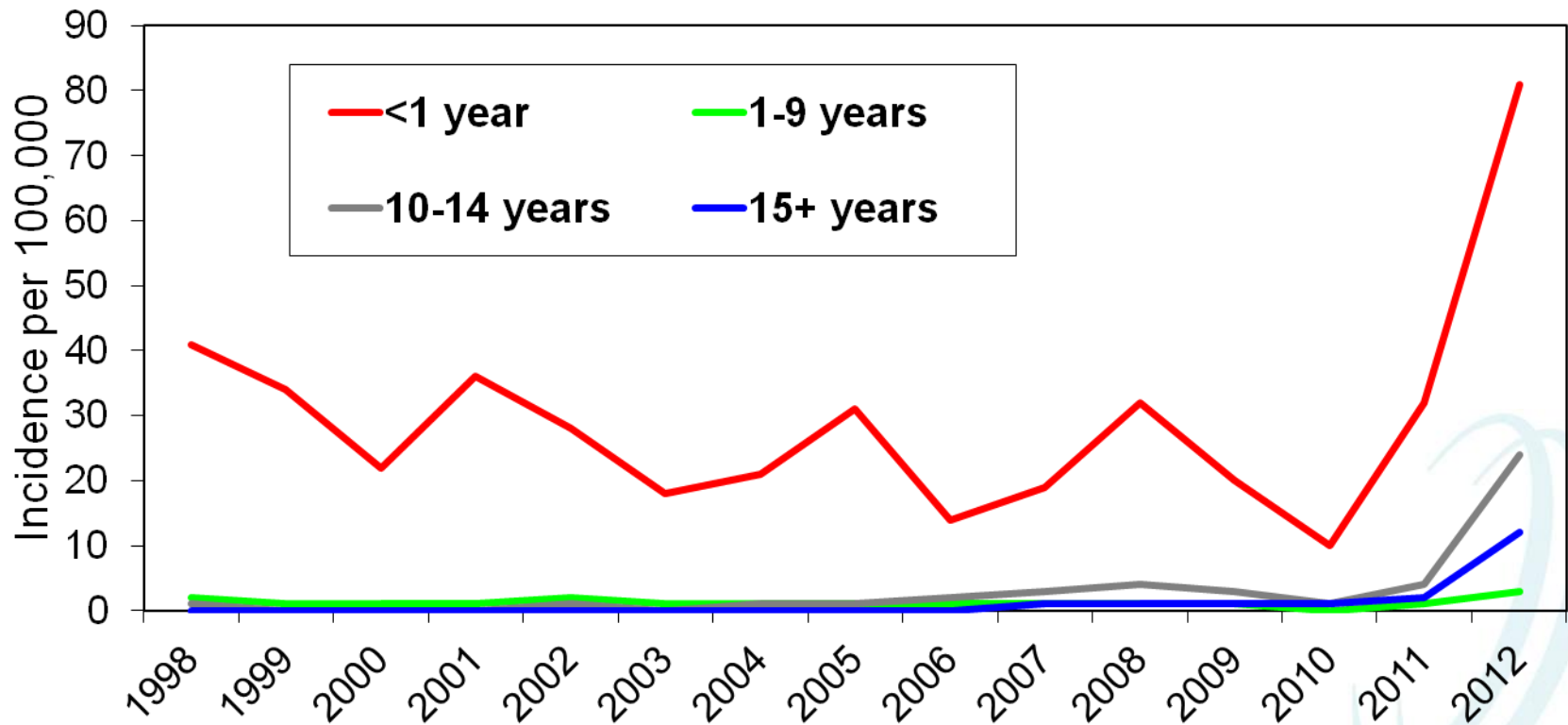
Whooping cough notifications and vaccine coverage 1940-2011 (England and Wales)



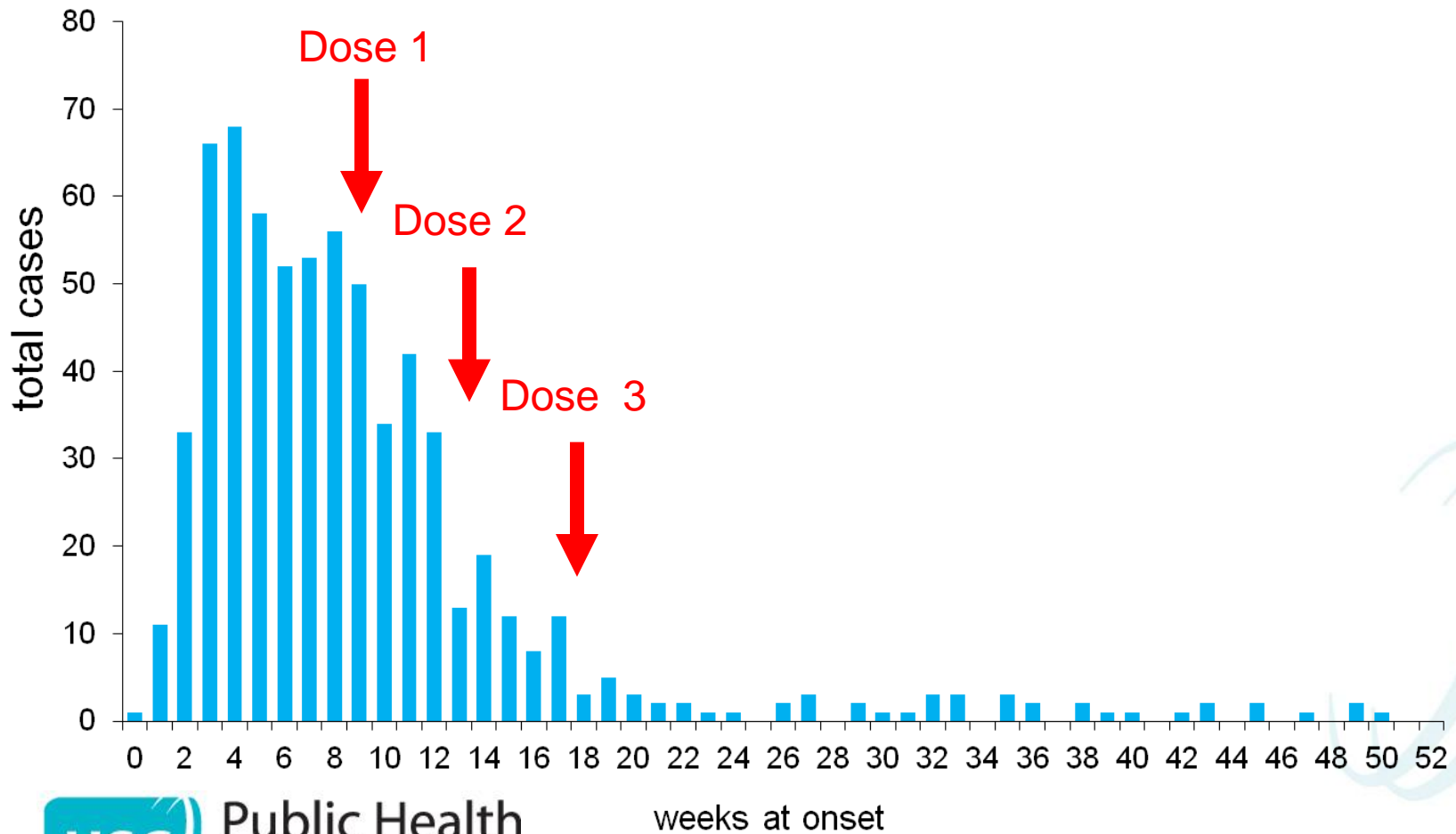
Laboratory confirmed cases by month, E&W 2011-Aug 2012



Annual incidence of laboratory confirmed pertussis by age E&W 1998-2012



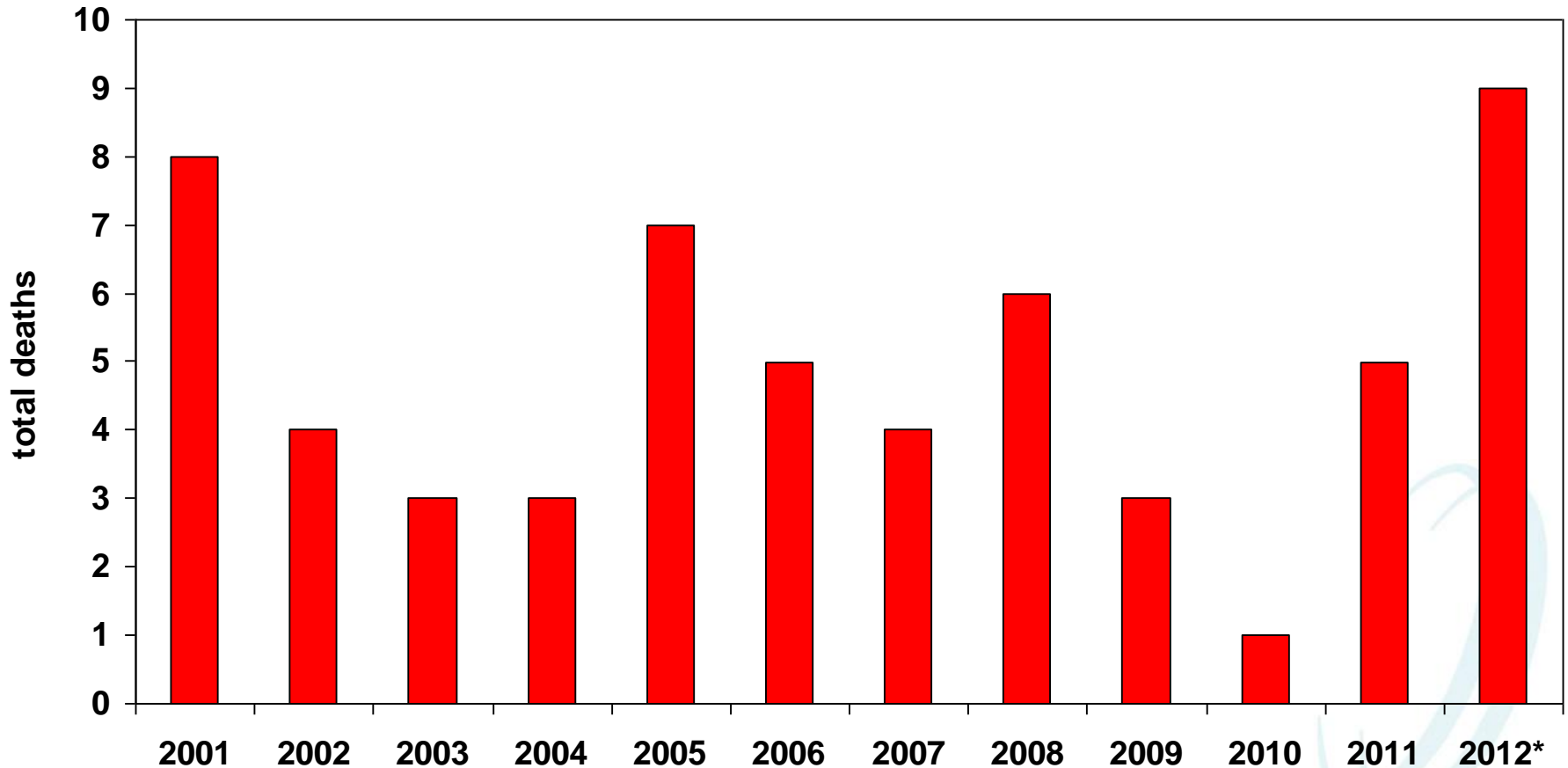
Confirmed cases in infants under 1 year, by week of age at onset (E&W 2011-2012)



Increasing vaccination rates or lowering age of vaccination

Most infant cases of pertussis are below six weeks of age. Thus, greater adherence to the routine childhood immunisation schedule that offers the first immunisation against pertussis at two months of age or shifting the age at which the first immunisation is offered to six weeks of age (the earliest age at which the vaccine is authorised for use) would have little impact on the incidence of pertussis in young babies

Number of deaths in infants under a year of age, England 2001-2012 (2012 to end-August)



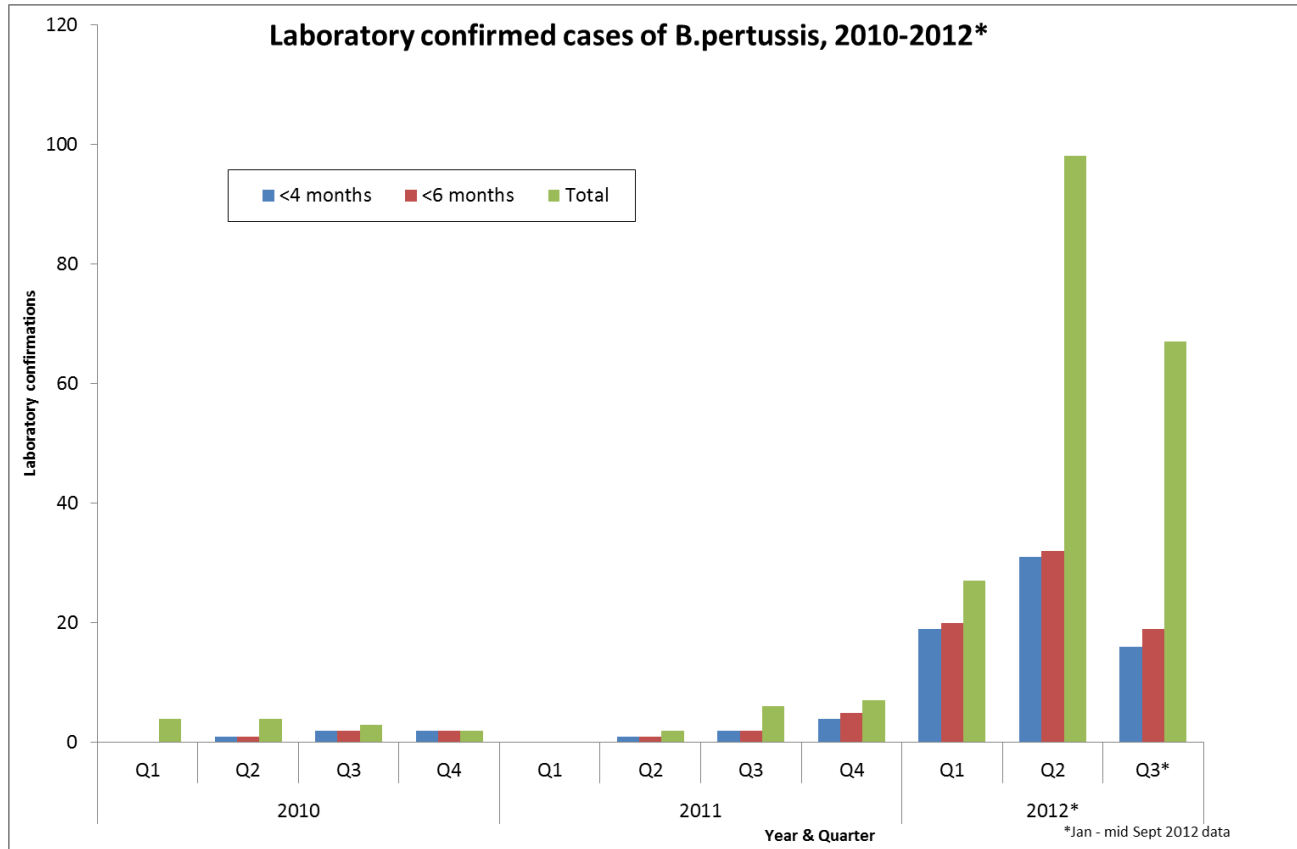
E&W Summary in 2012

- **Increase in all indicators of disease; 4,971 cases so far in 2012**
 - *Less than 10% of the levels reported before vaccination*
- **Highest incidence of disease in infants, followed by older children and adults**
 - *Very low incidence in the age groups covered by the current childhood vaccination programme*
- **Most cases in infants occur below the age that can be prevented by the current vaccination programme**
 - *at 2, 3 and 4 months of age, with booster at 3½ years*
- **All deaths in 2012 were in unvaccinated children below the age of three months**

Summary of long term whooping cough trends

- **Prior to the routine use of vaccination, over 100,000 cases of whooping cough reported each year in England and Wales**
- **Numbers of cases fell dramatically following the roll out of vaccination (by 1957)**
- **Epidemics (of up to 60,000 cases) occurred when vaccine coverage fell in the mid-1970s**
- **Vaccine coverage recovered and has exceeded 90% since the late 1980s**
- **Numbers of cases of whooping cough have been at historic low levels for over 20 years**

Rise in whooping cough in NI



NI cases to September 2012

192 confirmed cases of whooping cough in 2012, of all ages, in 2012

66 confirmed cases in infants under 6 months, with most of these under 3 months

Resulting hospitalisation, including ICU admission, for some of these infants

Reasons for the increase

- **Complete explanation is not clear, but many other developed countries have experienced recent increases in incidence**
USA, Canada, Australia, the Netherlands, Norway, France
- **Protection against whooping cough is not lifelong, even after natural disease**
- **Vaccinated people can get a mild infection, particularly as immunity wanes in adolescence and adulthood**
- **When pertussis is circulating, this boosts people's immunity and helps to stop transmission.**
- **After some time, the immunity wanes again and infection can spread more easily – leading to these regular epidemics (every four years).**

Response to rise in cases



New temporary programme from 1 October 2012.

Pertussis-containing vaccine for all pregnant
women from 28 weeks

Optimal period from 28-32 weeks gestation

Can be given up to onset of labour

Protecting infants at-risk

Joint Committee on Vaccination on Immunisation advice to 4 UK governments:

Vaccinating pregnant women is likely to be the most effective strategy to provide protection to newborn infants there is no evidence of risk to the mother or her baby. The Health Protection Agency will continue to monitor the levels of whooping cough and JCVI will keep this temporary programme under review.

The temporary programme would not control the outbreak, only lower its impact on the most vulnerable age group of the population

Protection for the infant

Vaccination boosts maternal antibody production in
10 days-2 weeks

Antibodies pass via placenta to foetus from 34 weeks
gestation

**Passive protection lasts weeks-months only so
baby requires normal vaccinations at normal
times**

Breast-feeding will not provide sufficient antibodies

Timing of vaccination

As soon as possible, organise routine vaccination for 28-32 weeks gestation

Catch-up of all women up to onset of labour, highest priority women 35-38 weeks gestation.

<2 weeks before delivery vaccination will help protect woman from whooping cough and therefore help protect infant from potential infection from mother but little or no passive transfer of antibodies

The vaccine - Repevax

Repevax (dTaP/IPV) is the **only** available pertussis-containing vaccine suitable for adults

One of pre-school boosters

No live components

Also protects against tetanus, diphtheria and IPV

Do **NOT** use Infanrix-IPV or Pediacel – not licensed for use in adults.

Vaccination

Single dose of Repevax (regardless of number of foetuses)

IM injection in upper arm (deep sc if bleeding disorder present)

Few contraindications

- confirmed anaphylaxis to previous dose of pertussis, diphtheria, tetanus or polio

- confirmed anaphylaxis to any component of vaccine or any substances used in manufacture (formaldehyde, gluteraldehyde, neomycin, streptomycin, polymyxin B or bovine serum albumin)

- Acutely unwell with fever – postpone vaccination

Side effects

Common side effects in adults

headache

nausea, vomiting and diarrhoea

mild fever

joint and muscle pain

weakness

injection site reactions

Very rare – anaphylaxis, as with all vaccines

Report all adverse reactions –

<http://yellowcard.mhra.gov.uk/>



Vaccine safety

No evidence of risk to pregnancy or the infant

Repevax used for 10 years in childhood programme

Use of similar vaccine in US (without the polio component) in pregnant women for past 18 months does not give any cause for concern

Use of Repevax not contraindicated although SPC states use is not recommended – because pregnant women are excluded from trials

JCVI and Department of Health advice should be followed and over-ride SPC guidance.

Vaccine safety in pregnancy

JCVI note:

Long established use of diphtheria and tetanus vaccines in pregnant women with no safety concerns

Similarly, data on the use of polio vaccines during pregnancy raised no safety concerns. However, data on the use of acellular pertussis vaccines in pregnancy are more limited, although the available data do not give rise to safety concerns. It was also noted that Adacel® - one of the vaccines offered to pregnant women in the US – was similar in content to Repevax® with the exception of the additional inactivated polio components in Repevax®.

Adverse event reporting in Europe, while limited, indicated no serious adverse events associated with use of acellular pertussis containing vaccines during pregnancy.

Previous research

No evidence of risk from vaccinating pregnant women with inactivated viral or bacterial vaccines or toxoids

Co-administration

Can give with influenza vaccine or anti-D

If woman less than 28 weeks gestation do not delay flu vaccine so that can be co-administered – flu is dangerous at all stages of pregnancy.

Preferably separate limb

Record site



Repeat vaccinations

Woman becomes pregnant again while programme still in place – vaccinate again

Previous recent immunisation with pertussis, tetanus diphtheria and/or polio recently – vaccinate again

Repeat doses may increase likelihood of local reactions or fever but expected benefit outweighs this

Alternative Strategies

JCVI considered a number of alternative strategies but were convinced that vaccinating pregnant women was likely to be most effective and that there is no evidence of harm to the mother or her baby.



Organisation

PGD will be distributed as soon as possible
(should be week beginning 15th October)

LES and data collection form have been
distributed from Integrated Care, HSCB

Temporary programme but end date will
depend on course of outbreak – LES will be
reviewed end-March 2012

Resources

Leaflet and poster – supplies have been delivered or will be in next few days

CMO letter with Annex 1 and 2

No Green book update planned – Annex 1 supplements existing Green book guidance

Annex 2 is Factsheet with FAQ – some women may find this useful

Monitoring 1

Vaccine uptake will be monitored using monthly data returns (data collection fee payable for making these returns)

Uptake expected to be at least the same (60%) achieved for seasonal flu vaccination in pregnant women

Impact on infection –

Confirmed cases in infants

Vaccination status of mother of new confirmed cases of pertussis in infants will be sought

Monitoring 2

MHRA – yellow card scheme and Clinical Practice Research Datalink (CPRD) to follow pregnancy outcomes following vaccination

Assessing any impact on effectiveness of primary vaccinations

Stocks of Repevax

Additional Repevax for pregnant women in stock in Northern Ireland

Order in normal way

Ensure sufficient stock but do not over-order

Childhood programme

Very important to continue high uptake, at scheduled times, of childhood immunisations to continue protection against pertussis and other diseases

Pre-school booster important for longer-term boosting of pertussis immunity

Summary

The pertussis vaccine programme is working well – very low numbers in vaccinated children

However immunity from vaccine or from disease wanes over time – allows pertussis to spread in teenagers and adults

Babies too young to be fully vaccinated can then be exposed

Summary

Largest outbreak for many years

High attack rate in those < 3months – too young to be protected by vaccine

Very serious condition in this age group – most admitted to hospital including ITU admissions and deaths have occurred

Only strategy likely to reduce this morbidity and mortality is vaccination of pregnant women

This is safe for mother and baby.

Additional resources

CMO letter with Annex 1 and 2

http://www.dhsspsni.gov.uk/index/phealth/professional/cmo_communications/letters-and-urgent-communications-2012.htm

Leaflet, poster and factsheet

www.publichealth.hscni.net/whooping-cough

Green book – pertussis chapter <http://immunisation.dh.gov.uk/green-book-chapters/chapter-24/>

JCVI advice <http://transparency.dh.gov.uk/category/minutes-2/jcvi-minutes/>

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