PERTUSSIS VACCINATION

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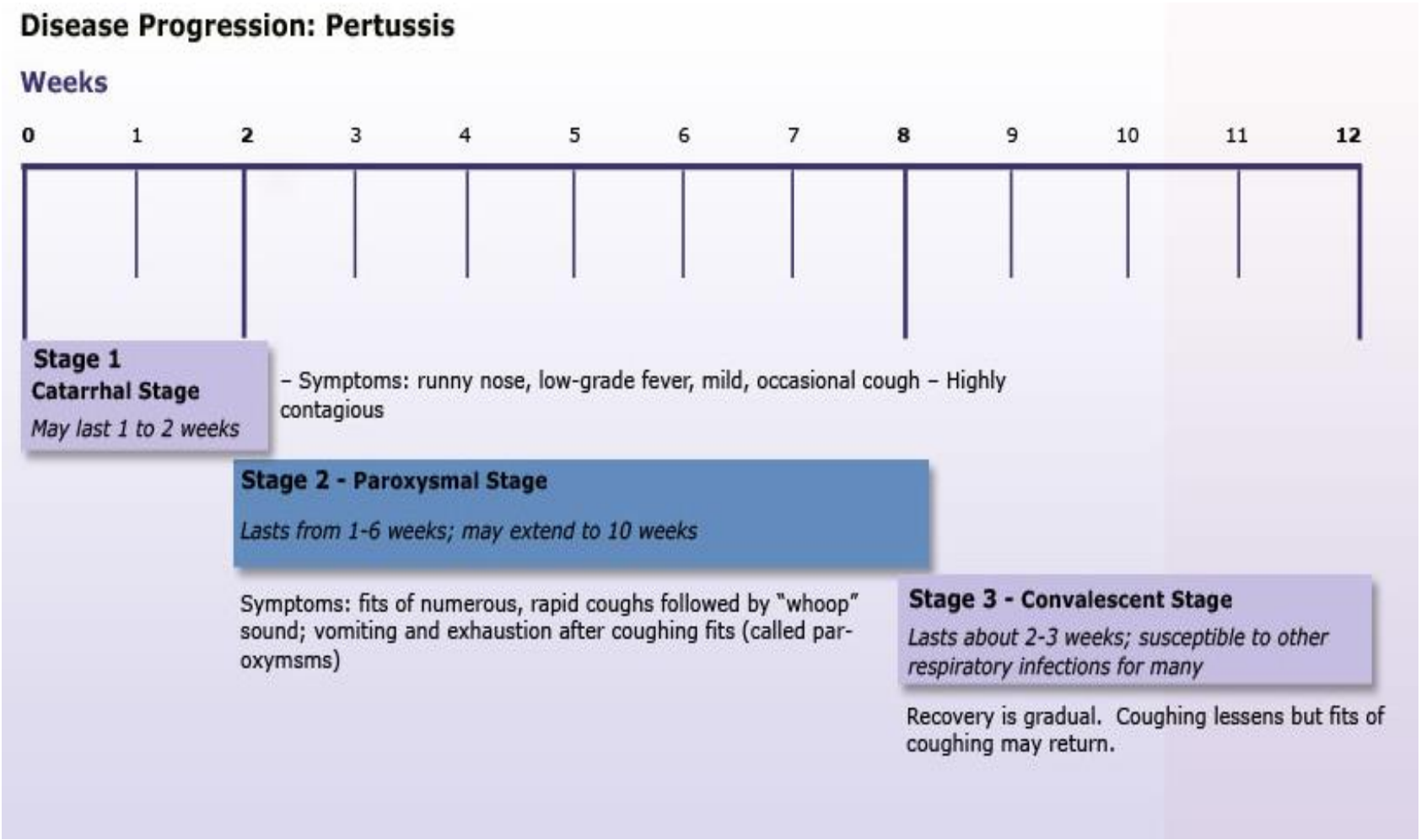
Pertussis Disease Progression



Centers for Disease Control and Prevention. Pertussis.

Epidemiology

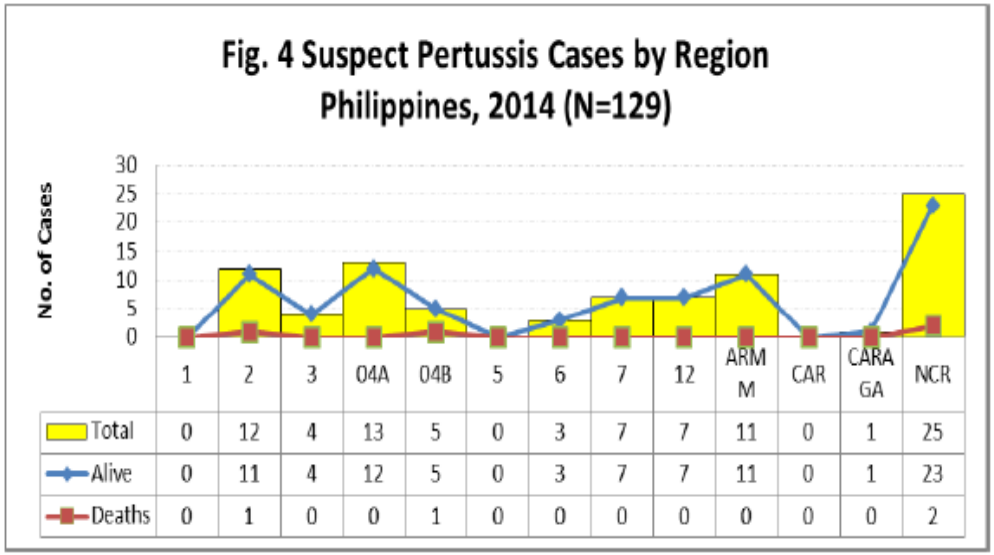
- Epidemic cycles have been occurring **every 2 to 5 years** (typically 3 to 4 years)
- **2014 global vaccination coverage** with 3 doses of a pertussis-containing vaccine was estimated at **86%**
- Shift age distribution of pertussis **towards older age groups** (adolescents and young adults) in **some high income countries**

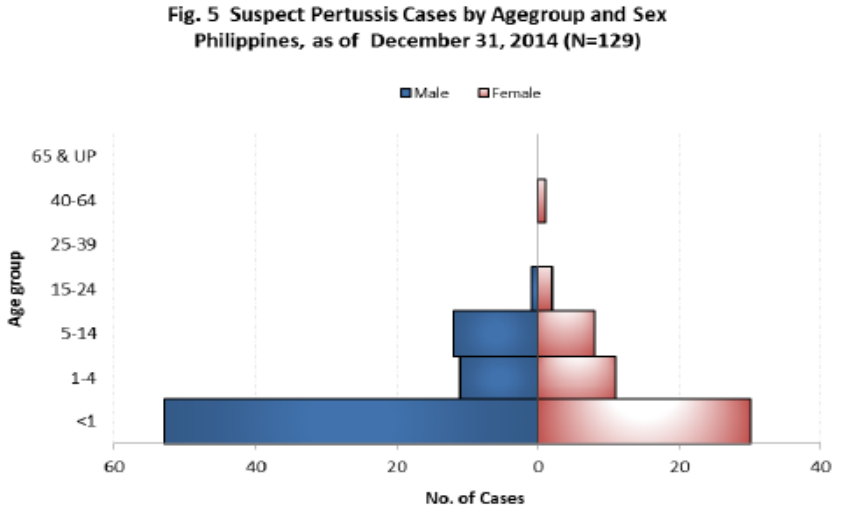
World Health Organization Position Paper on Pertussis Vaccines. August 2015

Pertussis Disease Burden

- **2014 Global figures:**
  - 139,786 cases
  - 89,000 estimated deaths
- **2015 Local figures:**

  (January-June 27)
  - 80 cases
  - 2 deaths



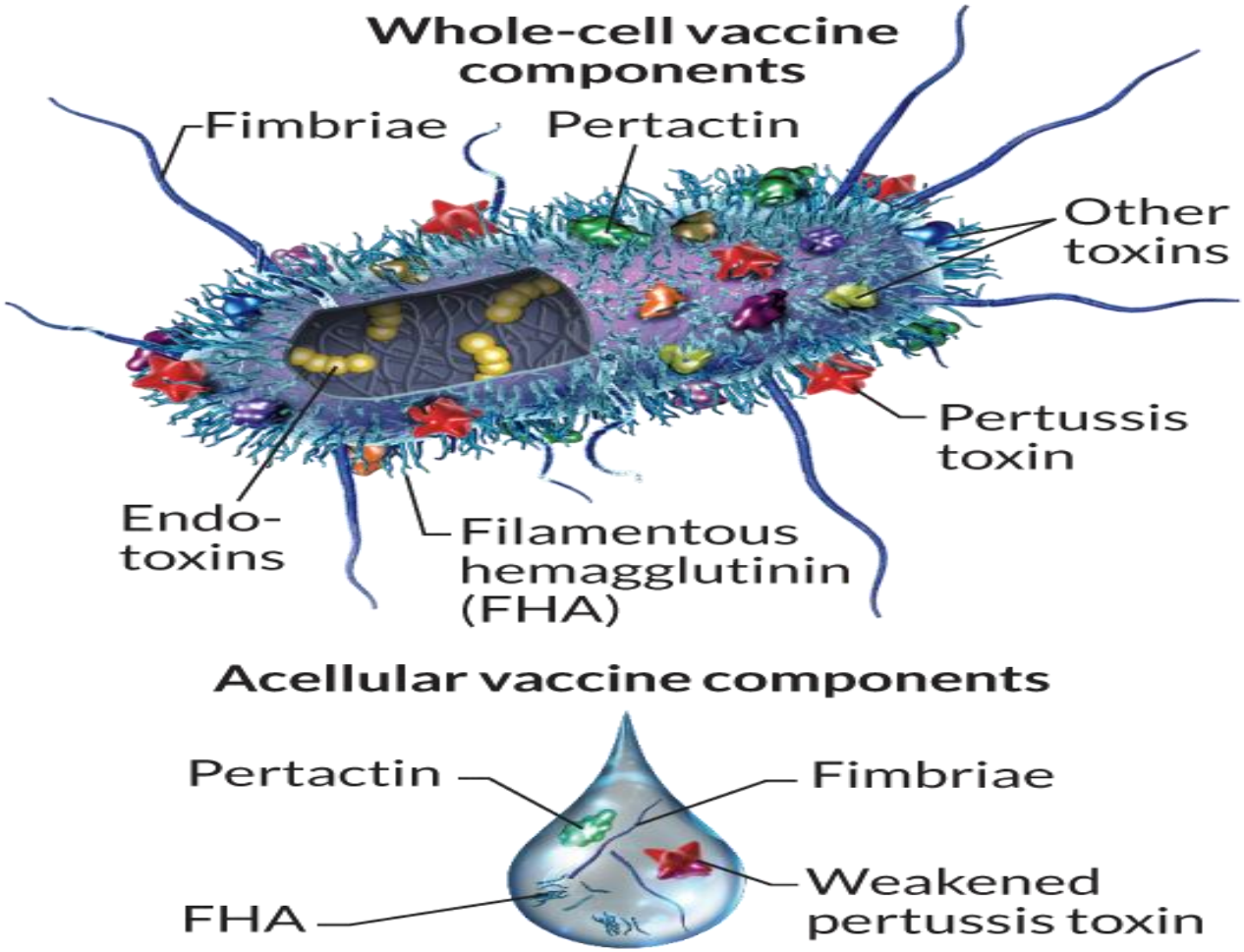


WHO Position Paper August 2015

- Main Revisions:
  - Replaces the position paper published in October 2010 and includes the revised guidance on the choice of pertussis vaccines published in July 2014
    - choice of pertussis vaccine – whole cell pertussis (wP) or acellular pertussis (aP) vaccine – reflecting the updated guidance published in 2014
    - incorporating recent evidence on the use of additional strategies, particularly vaccination during pregnancy, for prevention of early infant mortality.

World Health Organization Position Paper on Pertussis Vaccines. August 2015

Whole cell pertussis vs acellular pertussis

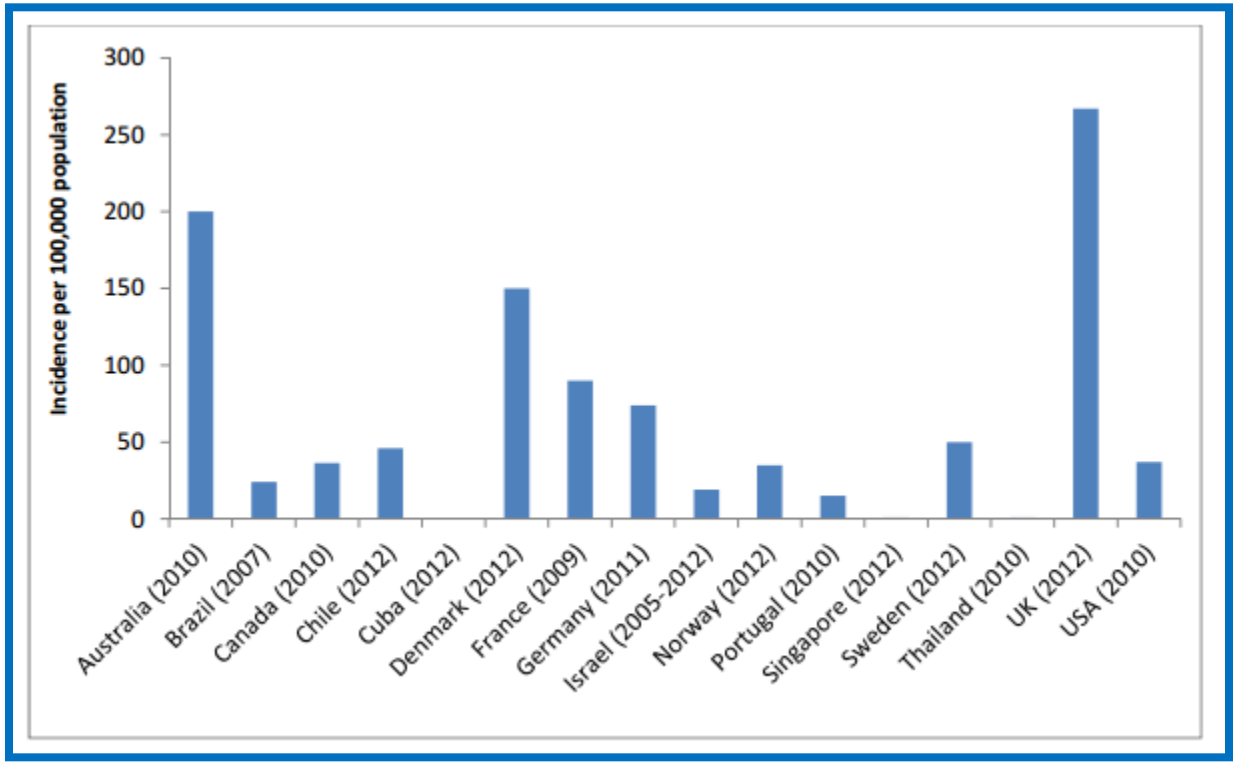


Vaccine Characteristics

	Whole Cell Pertussis	Acellular Pertussis
Content	Cultures of selected B. pertussis strains that are subsequently killed, usually by heating or treatment with formalin	First aP vaccine was developed in Japan in 1981 Contain one or more of the following purified antigens: PT, FHA, PRN, and FIM types 2 and 3.
Adjuvants, Preservatives	Contain aluminium salts as adjuvant, and some have thiomersal or phenoxyethanol added as preservatives in multidose vials	Vaccines differ in adjuvants, and the use of preservatives, such as thiomersal and phenoxyethanol
Dose	0.5 ml; anterolateral thigh of children aged <12 months and in the deltoid muscle in older age groups	0.5 ml; anterolateral thigh of children aged <12 months and in the deltoid muscle in older age groups
Schedule	Licensed for use starting at 6 weeks of age and manufacturers recommend 3 doses for the primary series and an interval of at least 4 weeks between the doses. Some manufacturers also recommend a booster dose.	Licensed for use starting at 6 weeks of age and manufacturers recommend 3 doses for the primary series with an interval of at least 4 weeks between the doses, as well as 1 or 2 booster doses

World Health Organization Position Paper on Pertussis Vaccines. August 2015

Issue #1 Pertussis Resurgence



No evidence of a broad resurgence of pertussis at the global level

- Increase in cases could be attributed to a **sustained decrease of vaccine coverage, variable coverage at the district level, changes in surveillance practices** as well as **problems with the specificity of diagnostic tests**

WHO SAGE pertussis working group Background paper SAGE April 2014

Issue #2 Immunogenicity, Efficacy and Effectiveness

Whole Cell Pertussis	Acellular Pertussis
• **Significant differences** in the immune responses to various antigens have been observed with different wP vaccines • **Published data are limited**, and much of the available information refers to vaccine formulations no longer in use • **Systematic review** of the efficacy and effectiveness of pertussis vaccines included 49 randomized controlled trials and 3 cohort studies -**pooled efficacy** of wP vaccine against pertussis disease in children was 78% Efficacy of DTwp vaccines that were evaluated ranged from 46% to 92% • Direct effectiveness data for vaccines that are currently in use are not available	A **randomized controlled trial** comparing 3-component and 5-component aP-containing vaccines with a wP vaccine concluded that the efficacies of the wP vaccine and the aP vaccines were **similar against culture confirmed pertussis** with at least 21 days of paroxysmal cough

World Health Organization Position Paper on Pertussis Vaccines. August 2015

Issue #3 Vaccine Safety

Whole Cell Pertussis

- Frequently associated with minor local and systemic adverse reactions (1 in 2–10 vaccinations), such as local redness and swelling, induration, fever and agitation. Prolonged crying and febrile convulsions are not uncommon (<1 in 100 vaccinations); hypotonic–hyporesponsive episodes are uncommon (<1 in 1000–2000 vaccinations)
- There may be quite large differences in reactogenicity between different wP products

- **Serious adverse events**
  - None of the combination vaccines has produced any adverse events that had not been observed with the individual components.
  - A 2012 Cochrane review found that for both DTaP-HepB-Hib and DTwP-HepB-Hib the use of the combined versus separate vaccines did not result in an increase in the incidence of serious adverse events

World Health Organization Position Paper on Pertussis Vaccines. August 2015

Issue #4 Interchangeability of Vaccines

- The limited available data do not suggest that changing from a wP-containing to another wP-containing product, from an aP-containing to another aP-containing product, or between an aP-containing and a wP-containing vaccine has any effect on safety or immunogenicity.
- Therefore, if the previous type of vaccine is unknown or unavailable, any wP or aP vaccine may be used for subsequent doses, according to vaccine availability.

World Health Organization Position Paper on Pertussis Vaccines. August 2015

WHO Position Summary

- Every country should seek to achieve early and timely vaccination initiated at 6 weeks and no later than 8 weeks of age
- Maintain high coverage (≥90%) with at least 3 doses of assured quality pertussis vaccine at all levels
- Protection against severe pertussis in infancy and early childhood can be obtained after a primary series of vaccination with either wP or aP vaccine

World Health Organization Position Paper on Pertussis Vaccines. August 2015

WHO Position Summary

- Although local and systemic reactogenicity are more commonly associated with wP-containing vaccines, both aP-containing and wP-containing vaccines have excellent safety records

World Health Organization Position Paper on Pertussis Vaccines. August 2015

PPS/PIDSP/PFV Position Paper on Combination Vaccine Shortage 2015

Age group prioritization

- **Priority 1**
  - Primary series (0 to 12)
- **Priority 2**
  - First toddler booster (12 to 18 month)
- **Priority 3**
  - Pre school booster (4 to 6 years)

Dose prioritization within primary series

- **Priority 1**
  - 1st and 2nd dose
- **Priority 2**
  - 3rd dose

- If supply is lacking, a 2-dose regimen for the infant primary series can be used instead of 3 doses, with a 2-month interval between the 1st and 2nd dose
- It is important that infants receiving a 2-dose infant primary series receive the booster at 11-12 months of age (i.e. 2+1 schedule)

Vaccine Substitutions

Unavailable Vaccine	Vaccine Substitute
Dtap-IPV-HepB-Hib Primary infant series	Option 1:Dtap-IPV/Hib pentavalent + HepB standalone
	Option 2:Dtap-IPV tetravalent + Hib standalone + HepB standalone
Dtap-IPV/Hib First Toddler booster	Option 1:Dtap-IPV tetravalent + Hib standalone
	Option 2: Dtap-IPV-HepB-Hib
Dtap-IPV Pre-school booster	Option 1: Dtap + IPV standalone
	Option 2: Tdap + IPV standalone
	Option 3: Td + IPV standalone

PPS/PIDSP/PFV Position Paper on Combination Vaccine Shortage 2015

Thank You