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Scientific Committee on Vaccine Preventable Diseases

Recommendations on Seasonal Influenza Vaccination for the 2011/12 Season and Recommendations on the use of 13-valent Pneumococcal Conjugate Vaccine in Childhood Immunisation Programme

Dr Chow Chun-bong
Chairman, Scientific Committee on Vaccine Preventable Diseases

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Outline

(A) Recommendations on Seasonal Influenza vaccination for the 2011/12 Season

- Global and local influenza activities in 2010/11 season
- SCVPD recommendations on priority target groups
- Seasonal influenza vaccine

(B) Recommendations on use of PCV13 in Childhood Immunisation Programme

- Local activities of invasive pnuemococcal diseases
- Overseas experience
- Updated SCVPD recommendations
- PCV13

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(A) Recommendations on Seasonal Influenza Vaccination for the 2011/12 Season

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Global and local influenza activities in 2010/11 season

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Global influenza activity in 2010/11 season

- Influenza A (H1N1) viruses
  - Influenza A(H1N1) 2009 viruses co-circulated in varying proportions with A(H3N2) and B viruses
  - Low level of seasonal H1N1 activity
- Influenza A (H3N2) viruses
  - Influenza A(H3N2) viruses were detected in many parts of the world with widespread activity reported in several countries
  - The majority of recent viruses were antigenically and genetically similar to the vaccine virus A/Perth/16/2009
- Influenza B viruses
  - B/Victoria/2/87 lineage viruses predominated in many parts of the world but B/Yamagata/16/88 lineage viruses predominated in China
- It is expected that Influenza A(H1N1) 2009, A(H3N2) and B viruses will co-circulate in the 2011-2012 northern hemisphere season

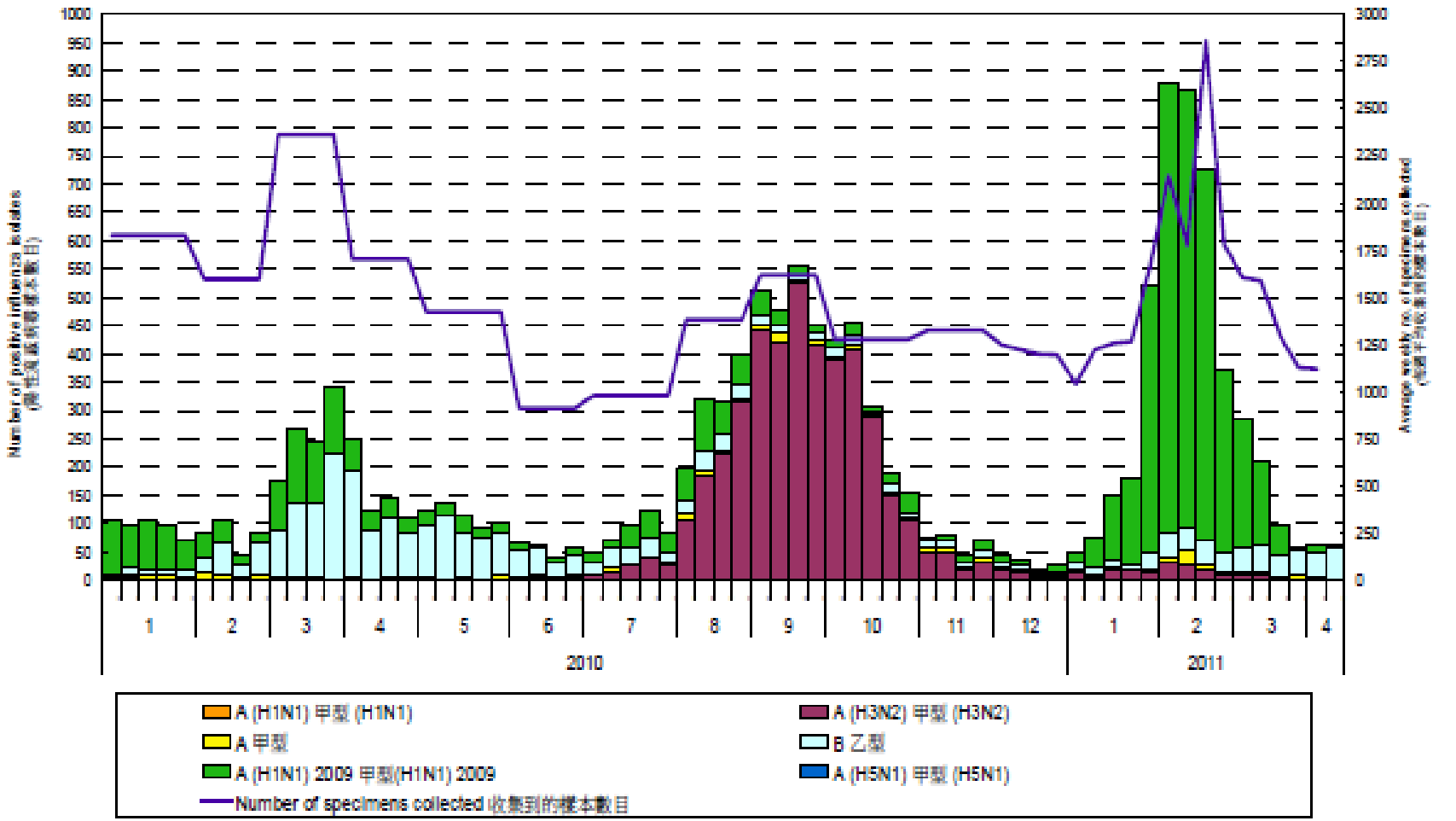
Local Situation of Influenza Activity

- In the 2010/11 winter influenza season, Influenza A(H1N1) 2009 constituted about 90% of the circulating influenza viruses; the remaining ones were influenza A(H3N2) and influenza B

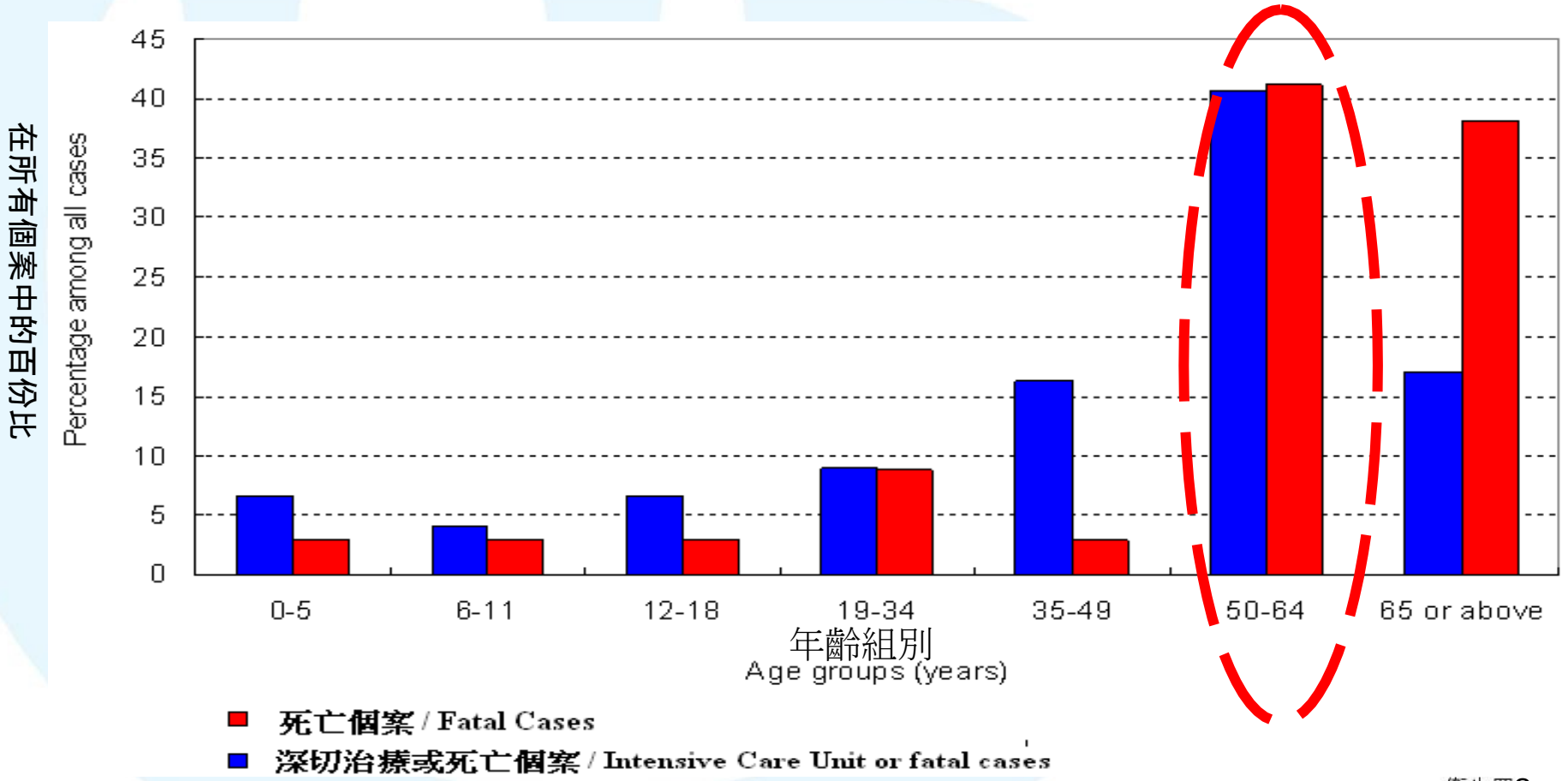
- From January 24 to March 31, 2011, CHP recorded a total of 123 severe cases (ICU cases or deaths), including 34 fatal cases

- Similar to previous influenza seasons, persons with pre-existing chronic medical problems had also higher rates of ICU or fatal outcome across all ages

Laboratory isolation of influenza viruses (2010-2011)

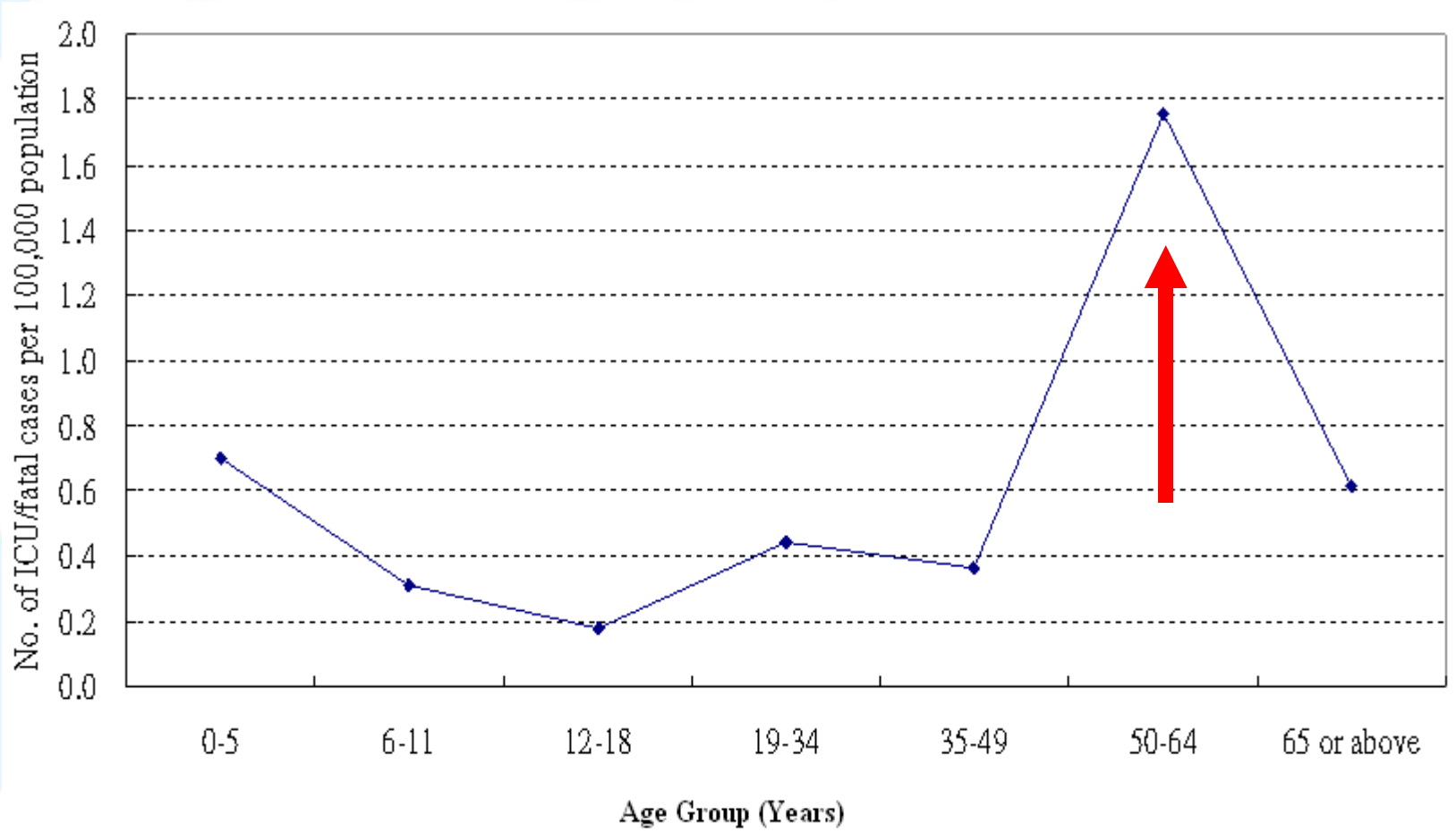


Age distribution of ICU or fatal influenza cases (January 24, 2011 – March 22, 2011)



ICU: Intensive Care Unit

Age-specific cumulative incidences of ICU or fatal cases (per 100,000 population in the age group) among persons without chronic disease



(January 24, 2011 – March 22, 2011)

Surveillance of influenza and other respiratory viruses in the UK 2010-2011 report

- In conclusion, influenza A/H1N1 (2009) was the main seasonal influenza virus in 2010/11, continuing to circulate and cause more disease in younger people than previously seen with seasonal influenza.
- Severe disease was reported more often in young and middle aged adults in the 2010/11 season, rather than children, compared with the previous pandemic period in 2009/10.
- Influenza B also circulated at higher levels in 2010/11 than in 2009/10.

Age specific percentages of local Influenza A(H1N1) 2009 cases having BMI≧30

Age group (yrs)	% of previously healthy Influenza A (H1N1) 2009 cases* with BMI≧30		% of population with BMI≧30		
	Non-severe cases (N=27,397)	Severe cases (N=102)		Population Health Survey 2003/04	Behavioral Risk Factor Survey 2010
0-14	0.8%	5.3%	No data	No data	No age-specific data
15-24	1.5%	9.1%	0.7%	0.8%	
25-34	2.1%	25.0%	4%	2.3%	
35-44	2.4%	5.6%		3.5%	
45-54	2.1%	7.7%	4.6%	4.3%	
55-64	1.8%	6.7%		2.3%	
65-74	0%	0%	3.6%	4.5%	
75-84	0%	0%		2.5%	
≧85	0%	(no case)	No data		
Overall	1.3%	**7.8%**	3.6% (15-84 yrs)	2.9% (≧15 yrs)	3.3% (18-64 yrs)

* For 2009-10 influenza season

Case–Control Study of Risk Factors for Hospitalization Caused by Pandemic (H1N1) 2009

Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 17, No. 8, August 2011

- **Abstract**

  We conducted a case–control study to identify risk factors for hospitalization from pandemic (H1N1) 2009 virus infection among persons >16 years of age in Sydney, Australia. The study comprised 302 case-patients and 603 controls. In a logistic regression model, after adjusting for age and sex, risk factors for hospitalization were pregnancy (odds ratio [OR] 22.4, 95% confidence interval [CI] 9.2–54.5), immune suppression (OR 5.5, 95% CI 2.8–10.9), pre-existing lung disease (OR 6.6, 95% CI 3.8–11.6), asthma requiring regular preventive medication (OR 4.3, 95% CI 2.7–6.8), heart disease (OR 2.3, 95% CI 1.2–4.1), diabetes (OR 3.8, 95% CI 2.2–6.5), and current smoker (OR 2.0, 95% CI 1.3–3.2) or previously smoked (OR 2.0, 95% CI 1.3–3.0).

- Although **obesity** was not independently associated with hospitalization, it was associated with an increased risk of requiring mechanical ventilation. Public health messages should give greater emphasis on the risk for severe disease among **pregnant women** and **smokers**.

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SCVPD Recommendations on Priority Target Groups for 2011/12 season

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SCVPD Recommendations on Priority Target Groups for 2011/12 season

- **All members of the public can consult their family doctors to receive seasonal influenza vaccination for personal protection**
  - Serious influenza infection can occur even in healthy individuals.
  - Influenza vaccines are safe and effective

SCVPD Recommendations on Priority Target Groups for 2011/12 season

1. Elderly persons living in residential care homes
2. Long-stay residents of institutions for the disabled
3. Persons aged 50 years or above
4. Persons with chronic medical problems including obesity individual with BMI of 30 or above
5. Health care workers
6. Children aged 6 months to 5 years
7. Pregnant women
8. Poultry workers
9. Pig farmers and pig-slaughtering industry personnel

Chronic medical problems

- People with chronic illnesses mainly refer to those who have
  - Chronic cardiovascular (except hypertension without complication),
  - Lung diseases
  - Metabolic diseases
  - Kidney diseases
  - Immunocompromised
  - Children and adolescents (aged 6 months to 18 years) on long-term aspirin therapy
  - Chronic neurological condition that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration or those who lack the ability to care for themselves
  - Obesity (BMI >= 30)

Rationale for recommendations

- People aged 50-64
  - local influenza epidemiology of in 2010/11 season, which showed that people aged 50–64 years, irrespective of chronic medical problems, were having a higher risk of Influenza A(H1N1) 2009 related ICU admission and death, and
  - the prediction that Influenza A(H1N1) 2009 strain will continue to circulate in 2011/12 season
- Obesity (BMI=>30)
  - Current evidence suggests that obesity is an independent risk factor for severe Influenza A(H1N1) 2009 strain infection in the 2009/10 season
  - Influenza A(H1N1) 2009 strain was expected to continue to circulate in 2011/12 season

WHO's recommendation on seasonal influenza vaccine composition in 2011/12 (Northern Hemisphere)

- **an A/California/7/2009 (H1N1)-like virus**
  - Also known as Influenza A(H1N1) 2009 or Human Swine Influenza (HSI)
- **an A/Perth/16/2009 (H3N2)-like virus**
- **a B/Brisbane/60/2008-like virus**
- The composition is the same as that in:
  - 2010/11 Northern Hemisphere seasonal influenza vaccine
  - 2010 and 2011 Southern Hemisphere seasonal influenza vaccine

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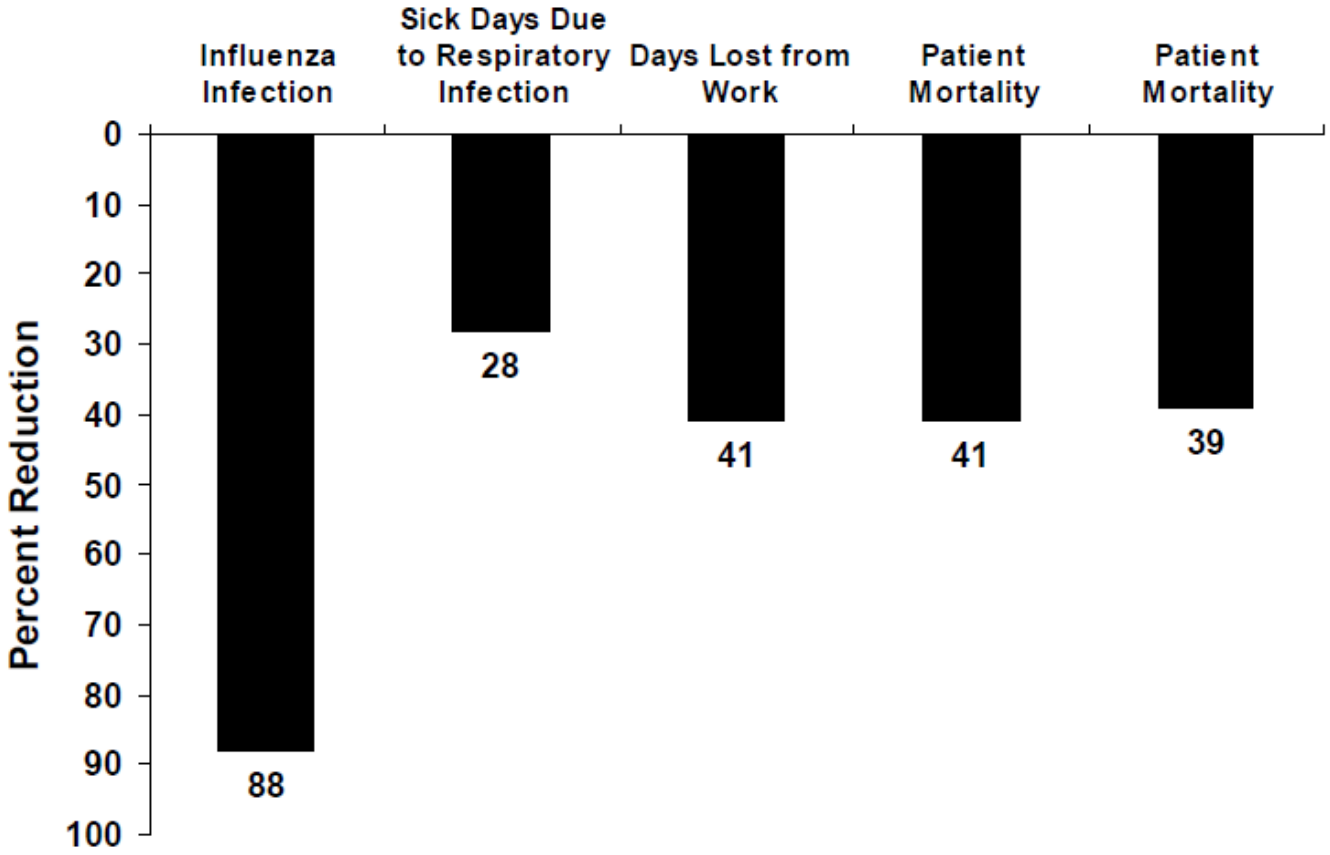
SHEA Position Paper:

Influenza Vaccination of Healthcare Workers

and Vaccine Allocation for Healthcare Workers During Vaccine Shortages

- Influenza vaccination has been shown to reduce morbidity, antibiotic use, and absenteeism in healthy adults, and to decrease serologically-confirmed and clinical influenza, hospitalization for pneumonia and influenza, and mortality in the elderly.
- Influenza vaccination has also been effective in large studies specifically targeting HCWs (Figure 1). Influenza vaccination reduces influenza infection in HCWs by 88%39 and decreases work absence due to respiratory illness by 28%.38 In two separate studies in geriatric long-term care facilities, total patient mortality was significantly lower in those sites where HCWs were routinely vaccinated when compared to sites where routine vaccination was not offered to HCWs (10% vs. 17% and 14% vs. 22%).
- Increased rates of HCW vaccination also correspond with a significant decrease in the incidence of healthcare-associated influenza.
- Finally, administration of influenza vaccine to healthy children of various ages has been shown to decrease morbidity and mortality in their close contacts and in their communities, supporting further the concept of immunizing HCWs to protect their high risk contacts.

Figure 1: Percent reduction in noted outcomes in healthcare workers (HCWs) receiving influenza vaccination.[35-39] All values were statistically significant when compared to unvaccinated controls ($p<0.05$).



Time to mandate influenza vaccination in health-care workers

The Lancet, Volume 378, Issue 9788, Pages 310 - 311, 23 July 2011

- The evidence that vaccinating doctors and nurses protects patients from infection, morbidity, and death is well established.
- The fact that influenza vaccination is safe and efficacious does not seem to be sufficient as a motivator to achieve high rates of compliance. It is time to make clear what the ethical reasons are for requiring vaccination and then to get a mandate in place in all health-care institutions and clinics.
- Vaccination is a duty that one assumes in becoming a health-care provider.
- Mandating vaccination is consistent with professional ethics, benefits many, including some of whom must rely on health-care workers to protect them, maintains a stable workforce, and sets an example that permits honest engagement with others working in hospital settings and with the general public in educating them to do the right thing about vaccination.
- Recommendations from APIC, AHA, ACP, AAFP, AAP….

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Seasonal Influenza Vaccine

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WHO's recommendation on seasonal influenza vaccine composition in 2011/12 (Northern Hemisphere)

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Seasonal Influenza Vaccine in Hong Kong

Vaccine	Trivalent Inactivated Influenza Vaccine			Live Attenuated Influenza Vaccine
Route	Intramuscular		Intradermal with deltoid as the recommended site	Intranasal
Brand	Non-adjuvanted	Novartis (Agrippal S1), Sinovac Biotech (Anflu), Glaxosmithkline (Fluarix), CSL (Fluvax), Sanofi-aventis (Fluzone, Vaxigrip), Shanghai INST (Influenza Vaccine), Solvay (Influvac), Adimmune Corporation (KKB/KI-FLU), Tianda Pharmaceuticals (TTB influenza vaccine)	Sanofi-aventis (Intanza Vaccine 15mcg/dose, Intanza Vaccine 9 mcg/dose)	MedImmune (Flumist)
	Adjuvanted	*Novartis (Fluad)-MF59 Adjuvant Berna (Inflexal V)-Virosome Adjuvant		
Indication	Age 6 months or above without contraindications*		Adults 18 years or above without contraindications	Healthy non-pregnant persons aged 2-49 years without contraindications

* Fluad is licensed for use in 65 years of age and over

Dosing Scheule

- One dose is adequate for
  - People 9 years or above
  - Children below 9 years, who have properly received one or more doses of seasonal influenza vaccine in or before 2010/11 season
- 2-dose regimen separated by at least 28 days for vaccine naïve children below 9 years would be recommended
- Healthy, non-pregnant persons aged 2-49 years can choose to receive TIV or LAIV if he/ she has not contraindications

Overseas reports on fever reactions in young children after seasonal influenza vaccination

- Noted increased risk of fever or febrile convulsions in young children following receiving seasonal flu vaccine, but the cause was not identified even after extensive investigation
  - Fluvax®, (Australia, NZ) --- Fever and convulsions after receiving 2010 southern hemisphere seasonal influenza vaccination
  - Afluria® (US) ---- Fever was 2 to 3 times more likely to occur in children aged 6 months to less than 9 years
  - Fluzone® (US) ---- Increase in the number of reports of febrile seizures following vaccination in younger than 2 years of age

- Actions taken by overseas health authorities
  - The Australian Technical Advisory Group on Immunisation (ATAGI) has advised children aged between 6 months to less than 5 years should not receive the 2011 Fluvax® vaccine
  - The US ACIP has recommended that Afluria® only be administered to persons in US aged ≥ 9 year
  - Recommendations for the use of Fluzone ® vaccine in children have not been changed in US

- All three vaccines were not imported to HK in 2010/11 season

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(B) Recommendations on the use of PCV13 in Childhood Immunsiation Programme

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Local activities of invasive pnuemococcal disease (IPD)

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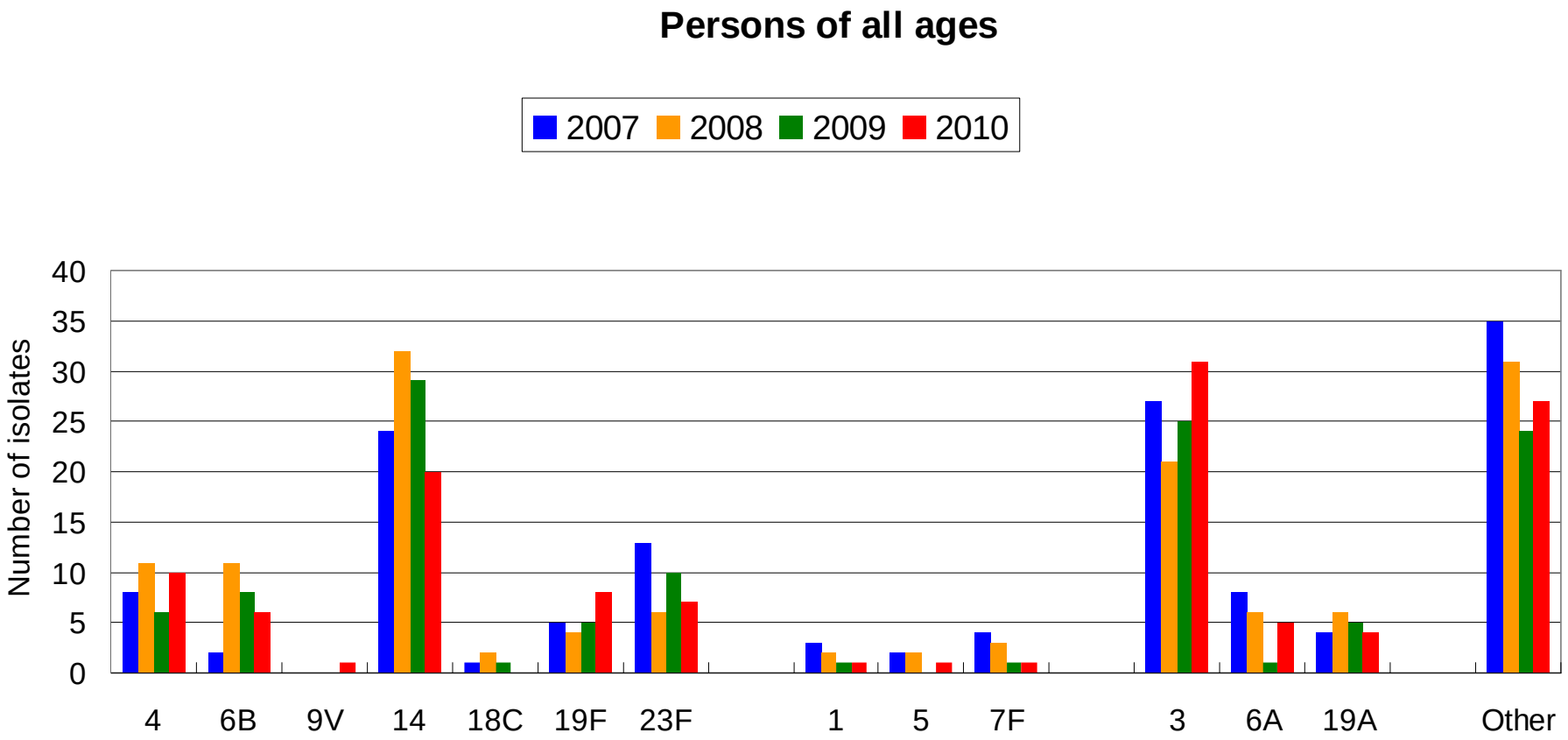
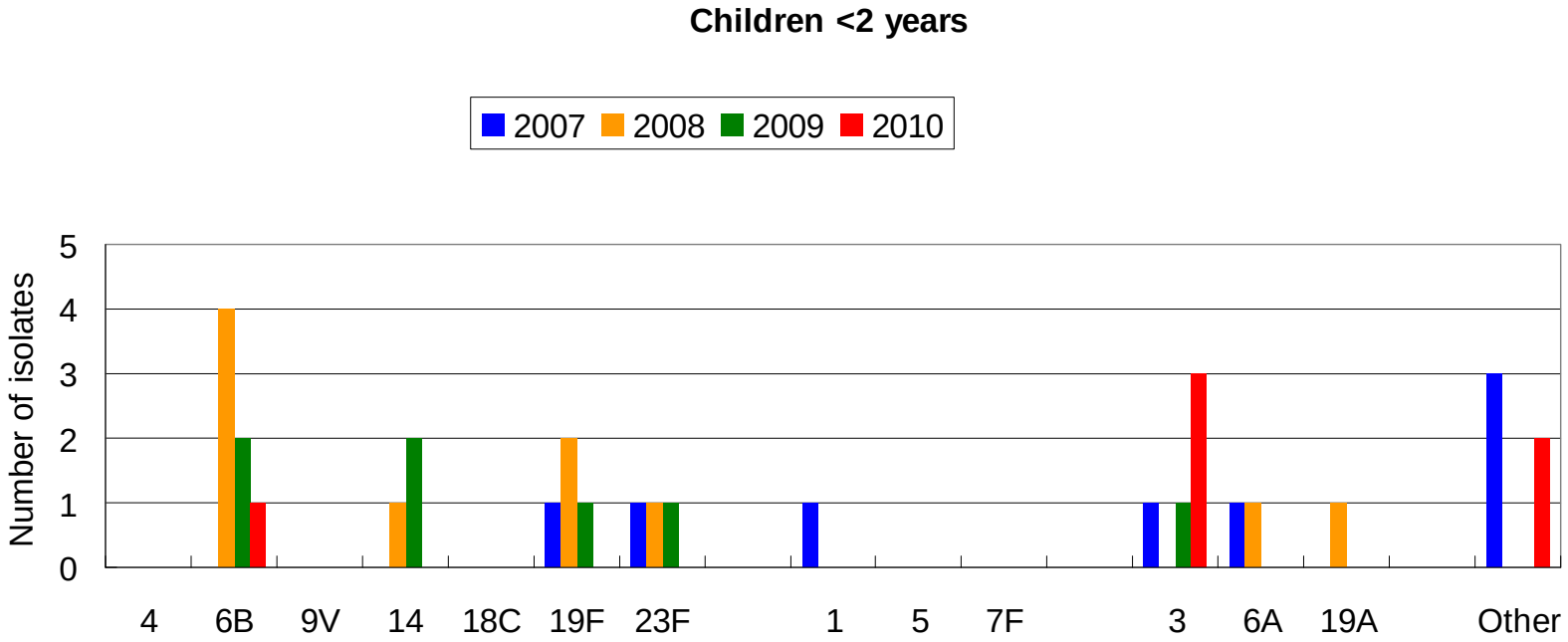
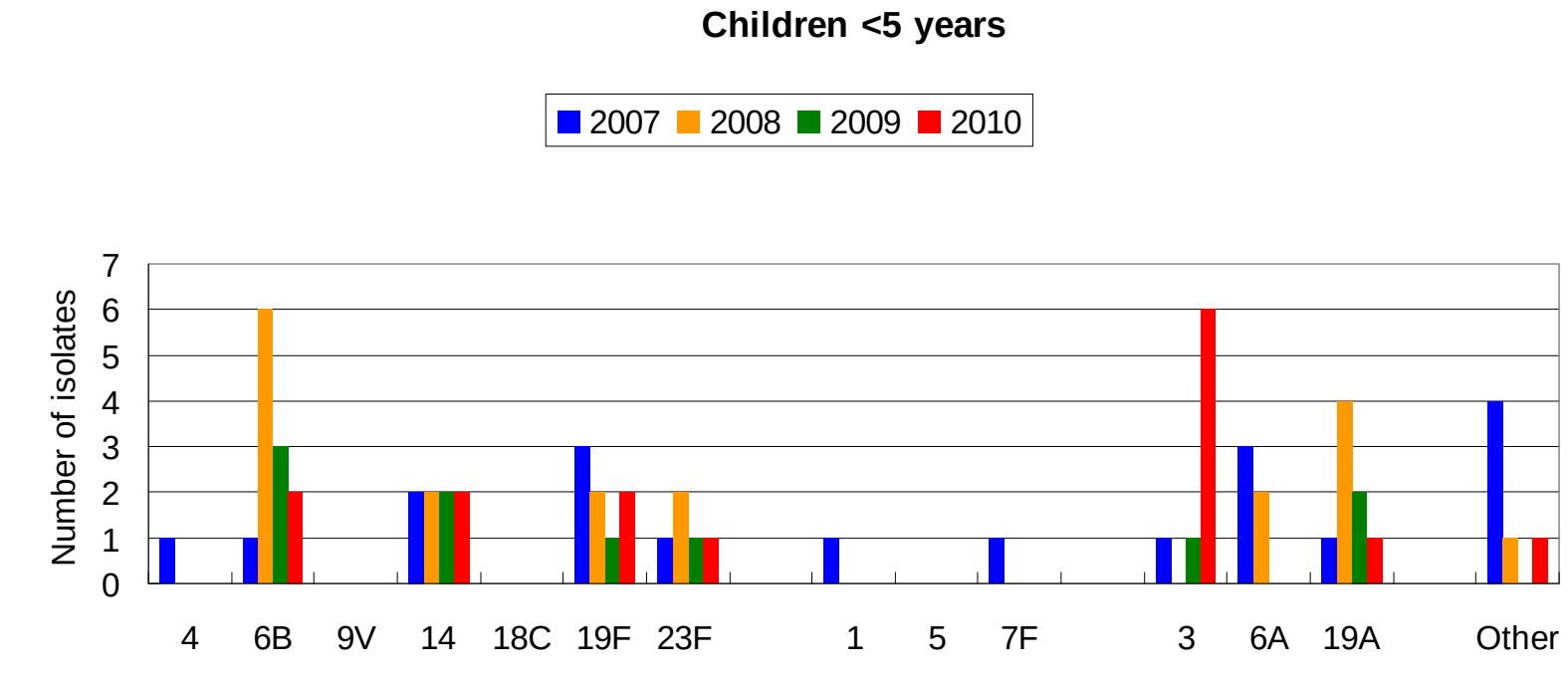
Serotype Distribution 2007-2010



Source: PHLSB data





Source: PHLSB data

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Overseas experience

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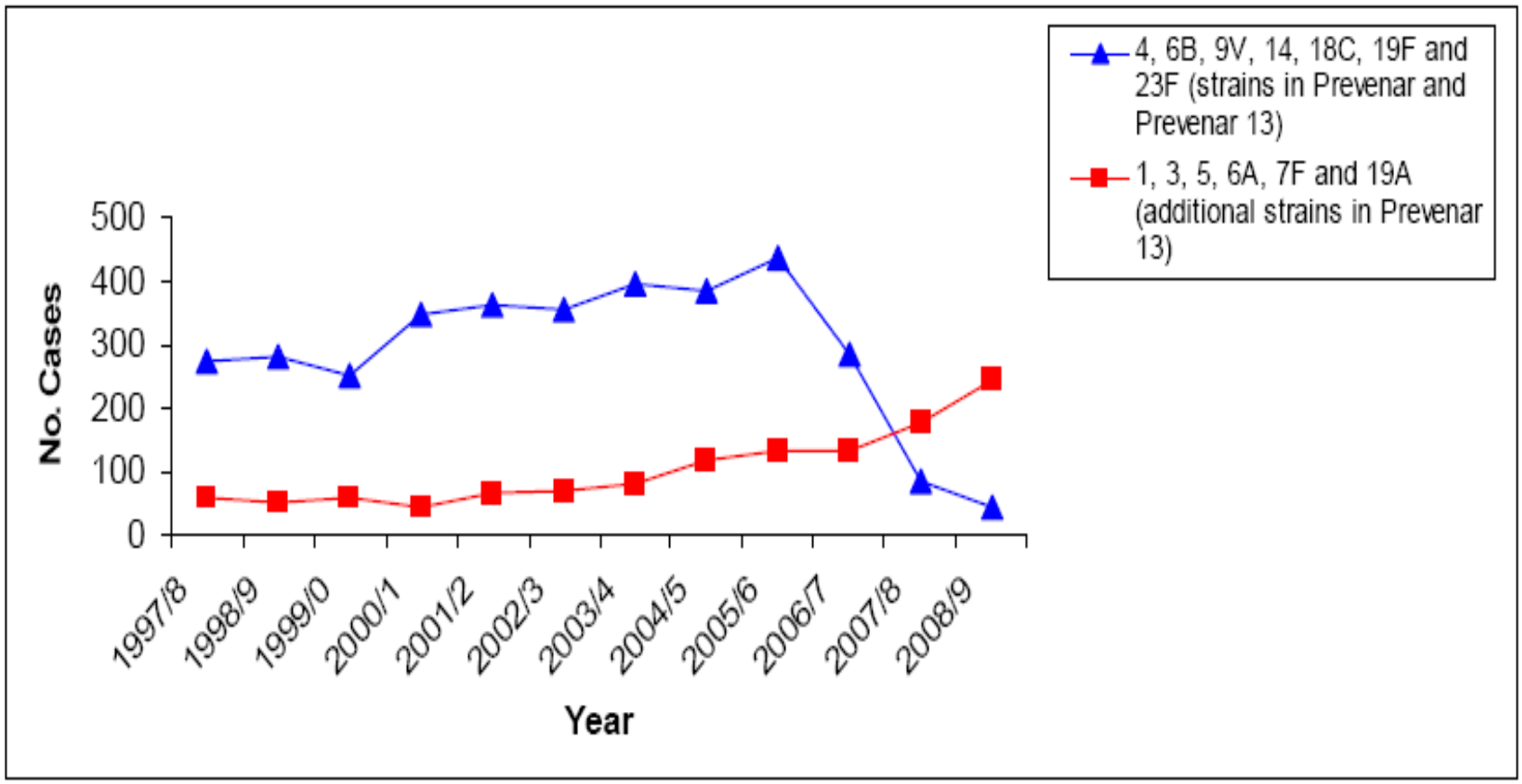
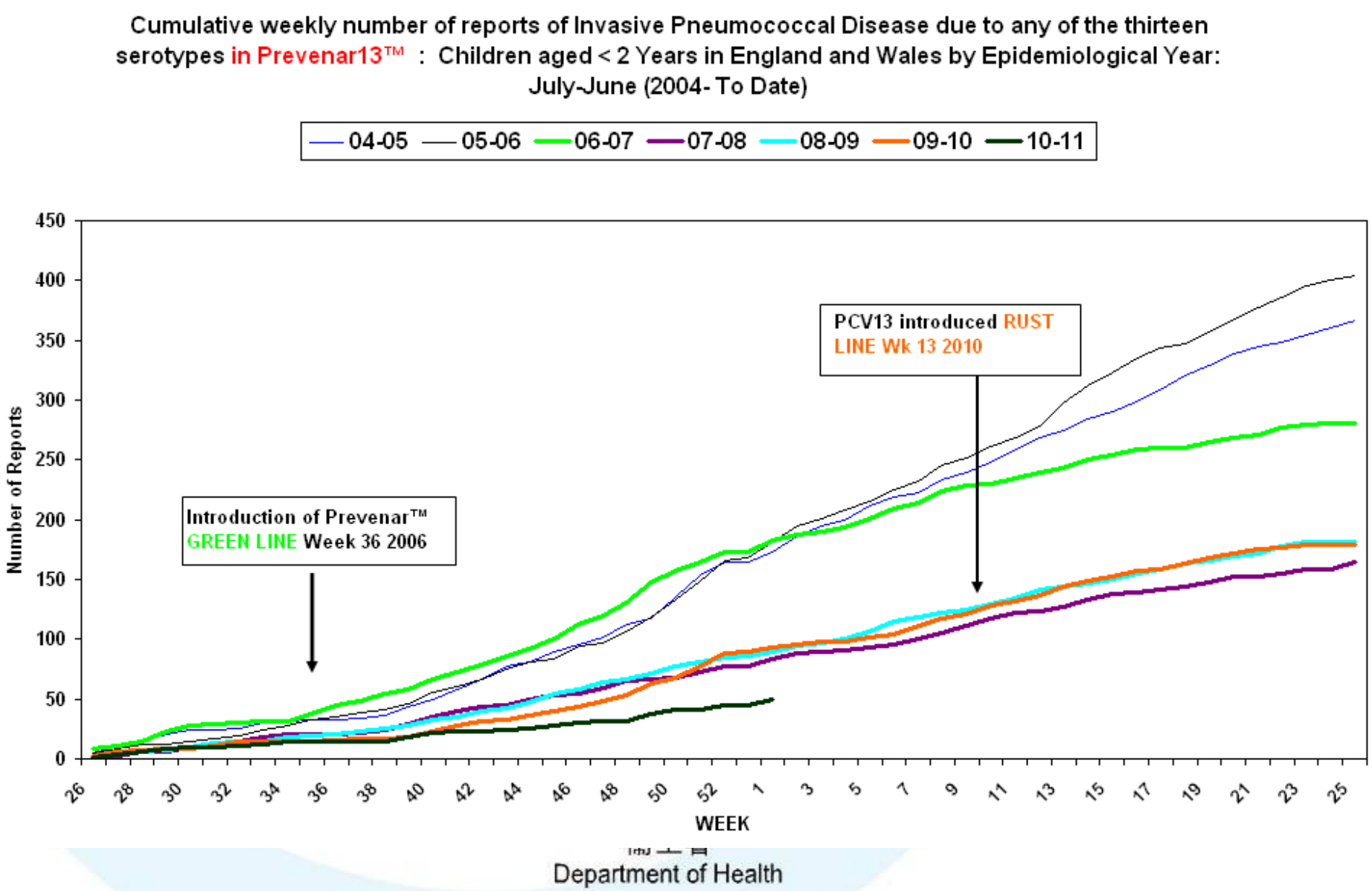
UK

Trend of IPD in the UK among children under five years



Adapted from "Dear Colleague" letter issued by the Department of Health, UK on 8 February 2010

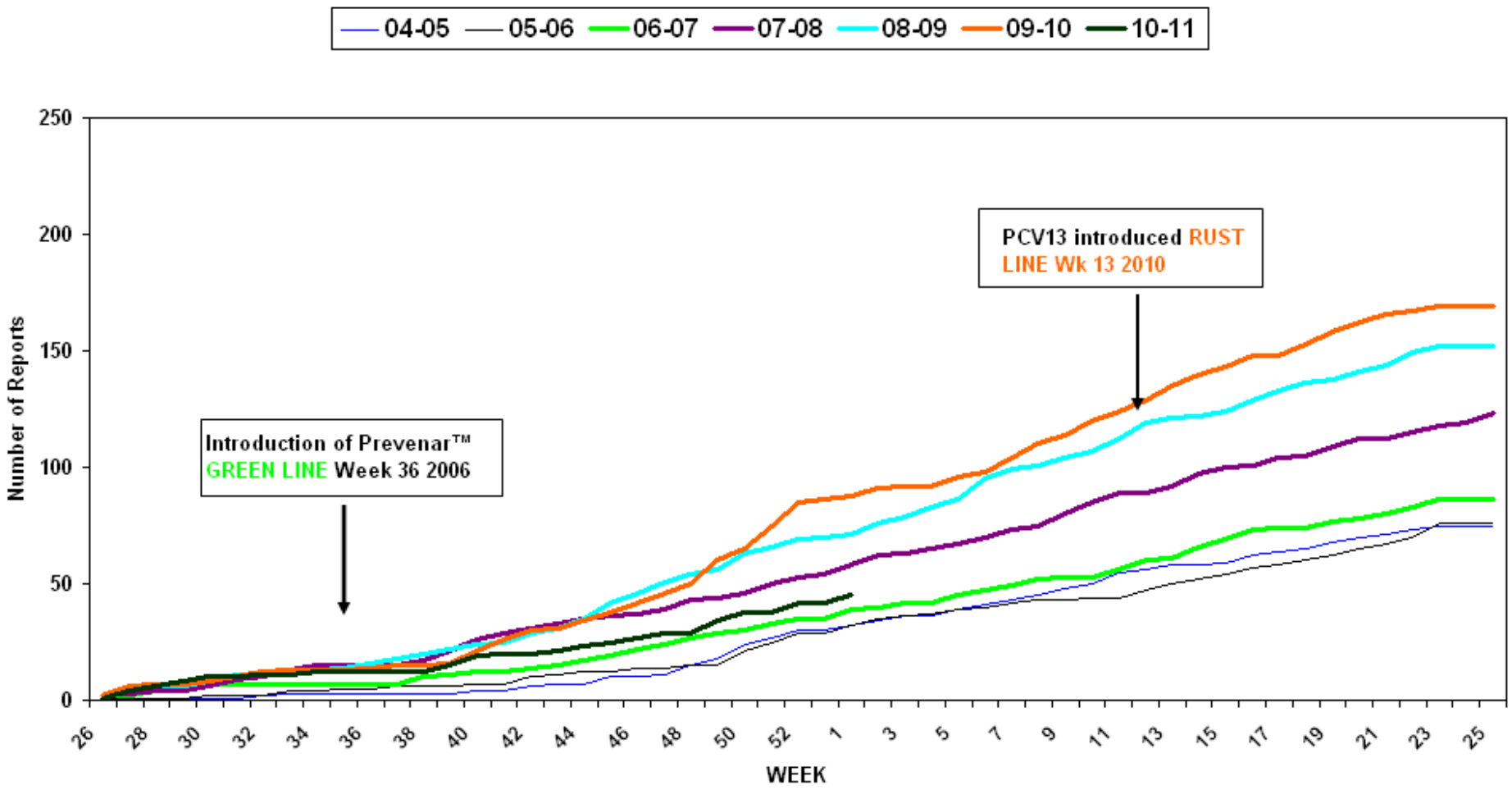
PCV13 serotypes



Source: HPA

6 additional serotypes in PCV13

Cumulative weekly number of reports of Invasive Pneumococcal Disease due to any of the six serotypes in Prevenar13™ but not in PCV7 : Children aged < 2 Years in England and Wales by Epidemiological Year: July-June (2004- To Date)

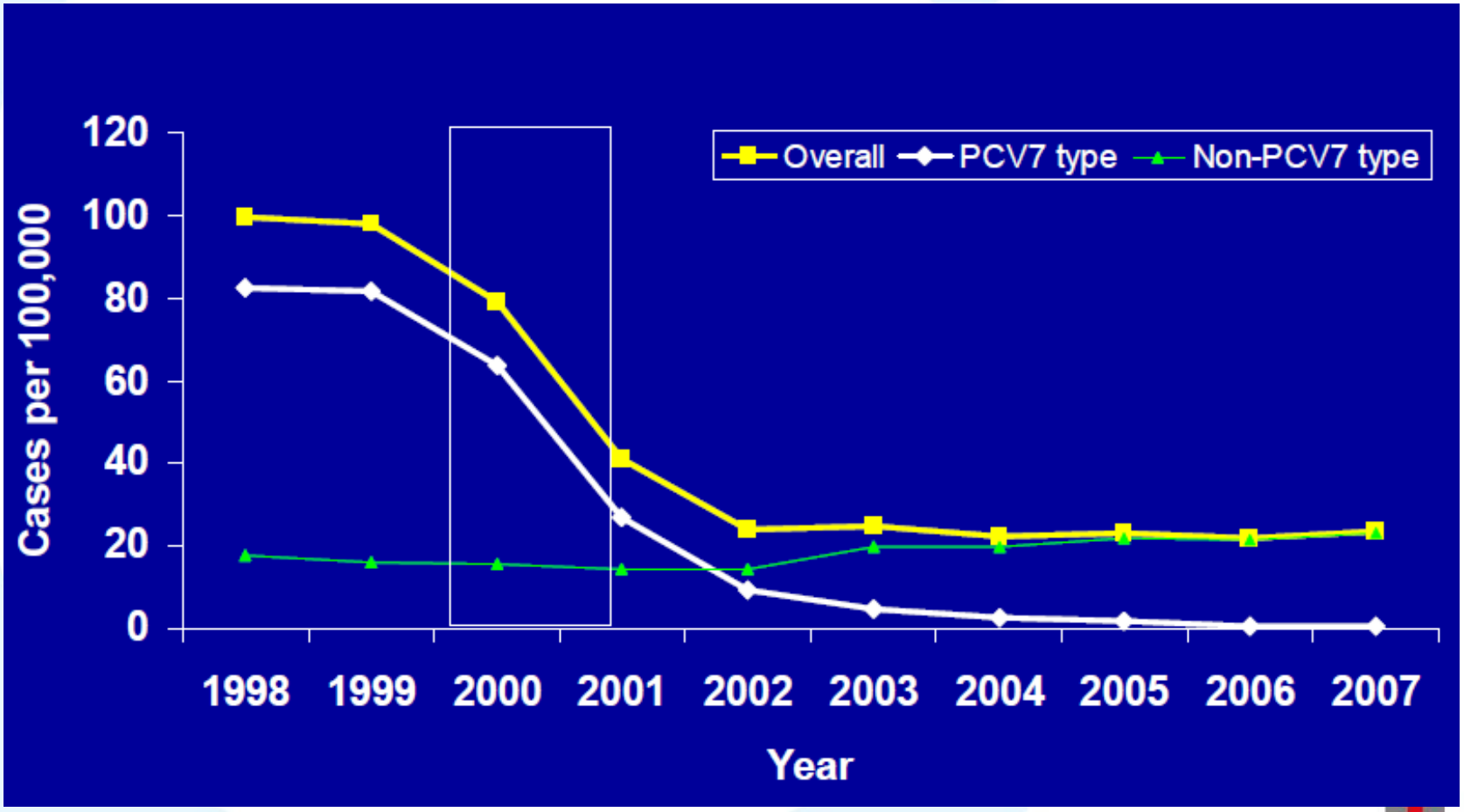


Department of Health

Source: HPA

US

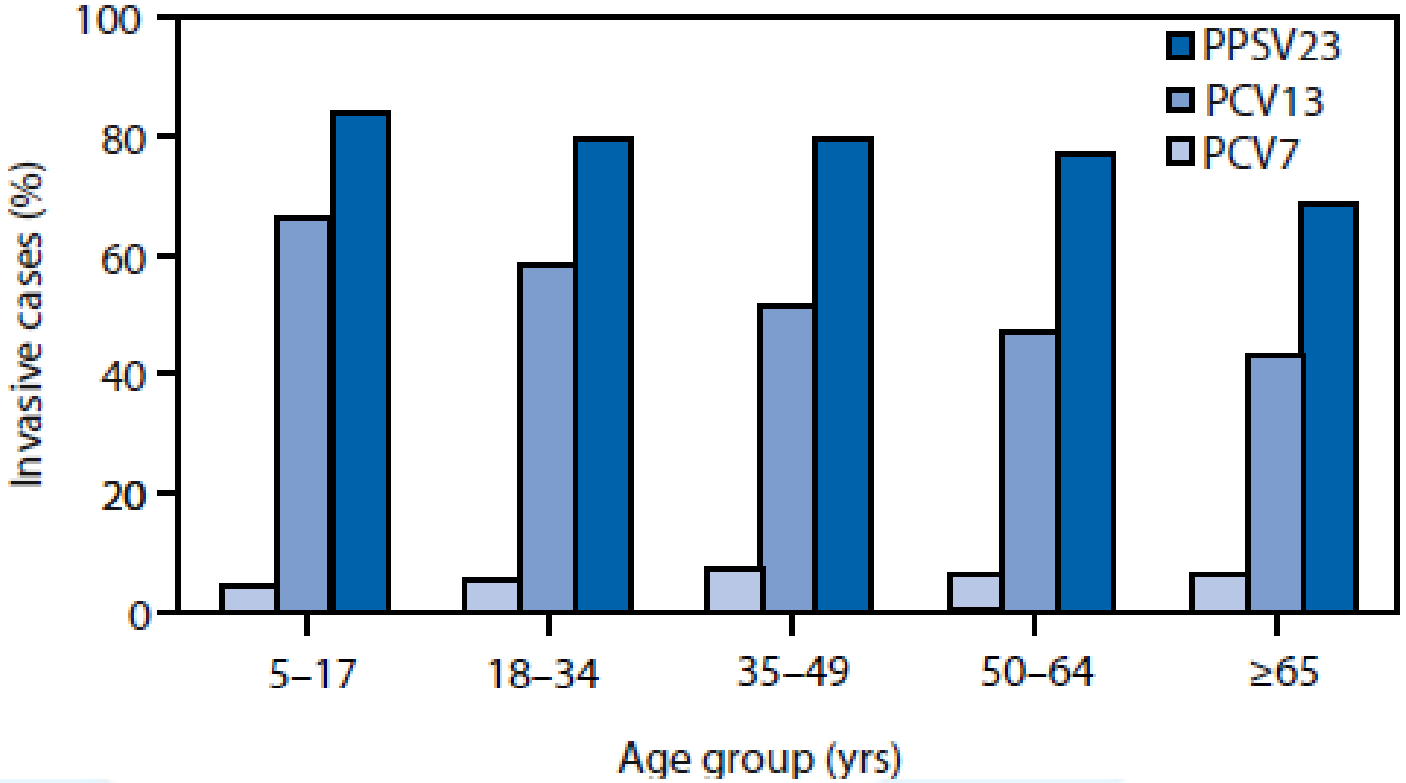
Trend of IPD in the US among children <5 years



Adapted from a PowerPoint "PCV13 disease burden estimates & options for catch-up immunization" presented by CDC in ACIP meeting (26 June 2009)

US

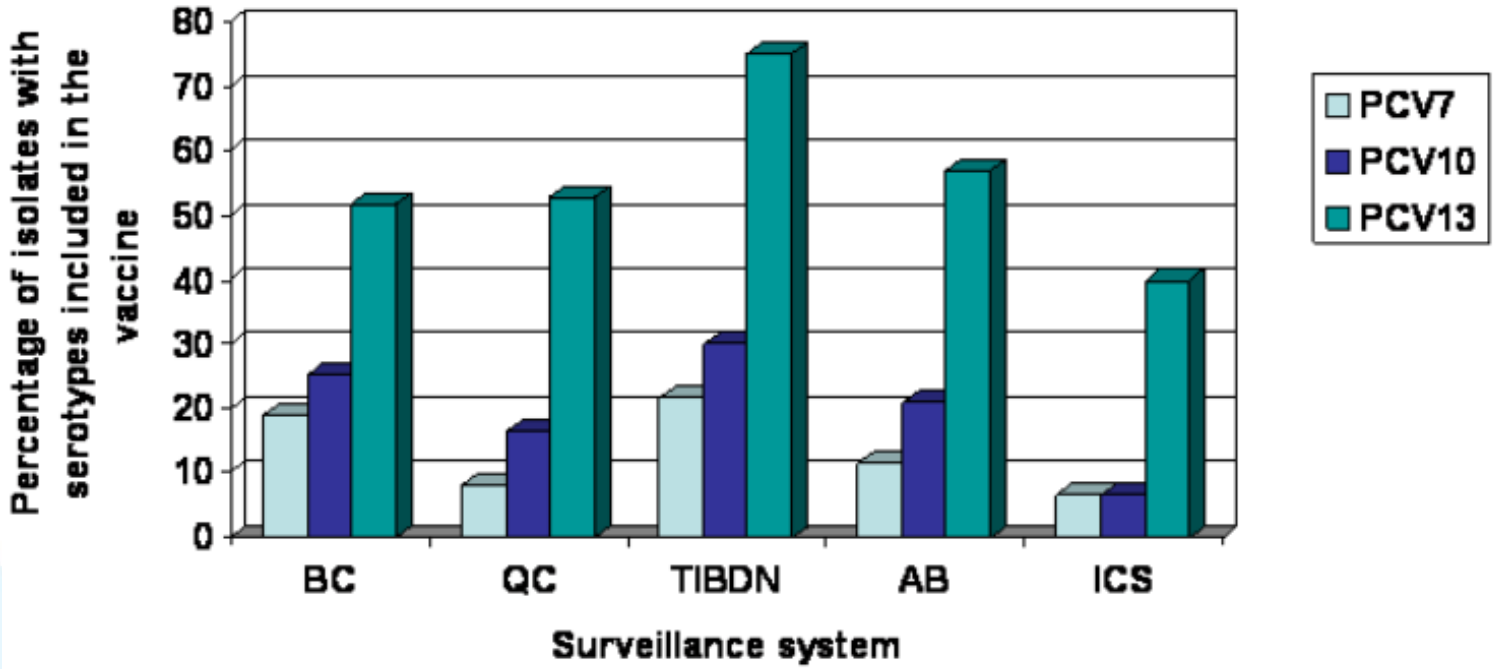
Proportion of cases of IPD in the United States caused by serotypes contained in different pneumococcal vaccines, by age group (2008)



(Adapted from MMWR 2010;59(RR-11)10)

Canada

Percentage of isolates causing IPD in children aged 6 months to 5 years with serotypes included in different PCV (2007-2008)



BC: British Columbia; QC: Quebec; TIBDN: Toronto Invasive Bacterial Diseases Network; AB: Alberta, ICS: International Circumpolar Surveillance Network (Northern Canada)

Adapted from Canada Communicable Disease Report 2010;36(ACS-12)

Canada

Province	Type of PCV	Schedule
British Columbia	PCV13	2, 4, (6 months for high risk) and 12 months
Alberta	PCV13	2, 4, (6 months for high risk) and 12 months
Saskatchewan	PCV13	2, 4, 6 and 18 months
Manitoba	PCV13	2, 4, 6 and 18 months
Ontario	PCV13	2, 4, 12 months (low risk) 2, 4, 6 and 15 months (high risk)
Quebec	PCV13	2, 4 and 12 months
New Brunswick	PCV13	2, 4, 6 and 12 months
Nova Scotia	PCV13	2, 4, 6 and 18 months
Prince Edward Island	PCV7	2, 4, 6 and 18 months
Newfoundland and Labrador	PCV10	2, 4, 6 and 18 months
Northwest Territories	PCV13	2, 4, 6 and 18 months
Yukon	PCV7	2, 4, 6 and 18 months
Nunavut	PCV13	2, 4, 6 and 15 months

Overseas experience - summary

- A number of overseas countries have shifted to PCV13 for their national immunisation programmes

- The emergence of non-PCV7 serotype (e.g. 19A in the US) is one of the considerations.

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Updated SCVPD Recommendations on the use of PCV13 in Hong Kong Childhood Immunisation Programme

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Recommendations

- Taking into account the immunogenicity and safety profile of PCV13, overseas experience and recent trends in local surveillance data, it is considered that PCV13 is preferable over PCV7 and PCV10 for use in the Childhood Immunisation Programme of Hong Kong.

Recommendations

- SCVPD recommends that PCV13 be used as a direct replacement for PCV10 at any point during the course of immunisation.

- Such a schedule is expected to offer a non-inferior protection against IPD caused by the ten common pneumococcal serotypes contained in PCV10 and PCV13.

- The immunisation schedule for the remaining dose(s) should remain unchanged.

Recommendations

- The standard regimen of pneumococcal vaccination in the Childhood Immunisation Programme of Hong Kong should remain unchanged at the moment (i.e. 3-dose primary series at 2nd, 4th and 6th months of age with a booster dose at 12-15 months).

- SCVPD will continue to review scientific data and overseas experience on the effectiveness of possible alternative primary schedules.

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PCV13

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PCV13

- Registered in Hong Kong in May 2010
- Indication:
  - Prevention of *invasive disease, pneumonia and acute otitis media* caused by pneumococci in infants and children from *6 weeks to 5 years of age*
- Component
  - Pneumococcal polysaccharides
    - Serotypes 4, 6B, 9V, 14, 18C, 19F, 23F
      1, 5, 7F
      3, 6A and 19A
  - Conjugate protein: diphtheria toxoid CRM197
  - New excipients: Succinate buffer and Polysorbate 80 (P80)

Commonest Adverse Reactions

- Injection site reactions
  - Tenderness (41.0%-52.1%)
  - Induration (23.0%-32.6%)
  - Erythema (26.3%-43.6%)
- Fever (25.0%-43.0%)
- Irritability (61.9%-69.2%)
- Decreased appetites (36.6%-42.2%)
- Increased and/or decreased sleep (30.1%-59.0%)

EMEA Assessment Report for Prevenar 13 (EMA/798877/2009)

Serious Adverse Events

- 7 serious adverse events were considered to be related to PCV13 during clinical studies
  - febrile seizure/convulsion (2 reports)
  - fever (2 reports)
  - inconsolable crying (1 report)
  - vaccine allergic reaction (1 report)
  - bronchiolitis (1 report)
- Three deaths (sudden infant death syndrome) were reported and were considered not related o PCV13

EMEA Assessment Report for Prevenar 13 (EMA/798877/2009)

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Thank you

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