



# 中国免疫规划和肺炎控制

Immunization and Pneumonia Control in China

中国疾病预防控制中心免疫规划中心

NIP, China CDC

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2011.3



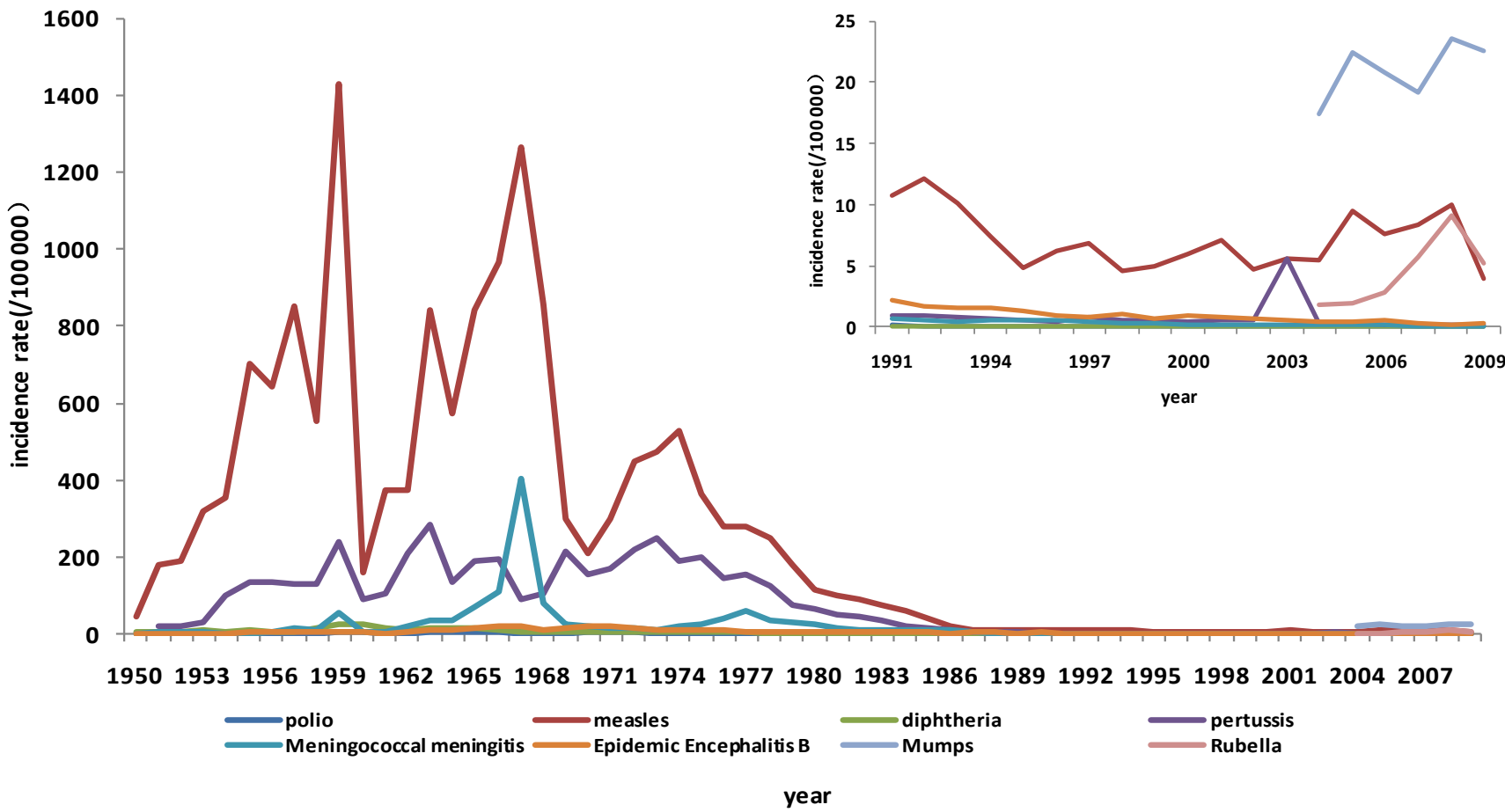
# 中国免疫规划历程

## Milestones of EPI in China

年代Time	重要活动或成就 Important activities or achievements
2010	麻苗强化、通过WHO对中国NRA职能评估 Measles campaign and NRA assessment
2009	甲流苗接种、乙肝疫苗15岁以下查漏补种 FluH1N1 campaign and Hep B vaccine catch-up for <15
2007	甲肝、流脑等15种疫苗可预防传染病纳入国家免疫规划 15 VPDs into NIP
2005	预防接种管理完善 Vaccines circulation and vaccination management regulation
2002	新生儿乙肝疫苗纳入免疫规划 Integrated HepB vaccine of newborn into NIP
2000	实现中国无脊灰目标 Achieved the goal of polio free
1995	以乡为单位EPI疫苗接种率85% Coverage rates of EPI vaccines > 85% by township
1990	以县为单位EPI疫苗接种率85% Coverage rates of EPI vaccines > 85% by county
1988	以省为单位EPI疫苗接种率85% Coverage rates of EPI vaccines > 85% by province
1978	计划免疫接种卡介苗等4苗防6病 4 vaccines preventing 6 infectious diseases
1960s	接种牛痘消灭天花 Eradicated smallpox

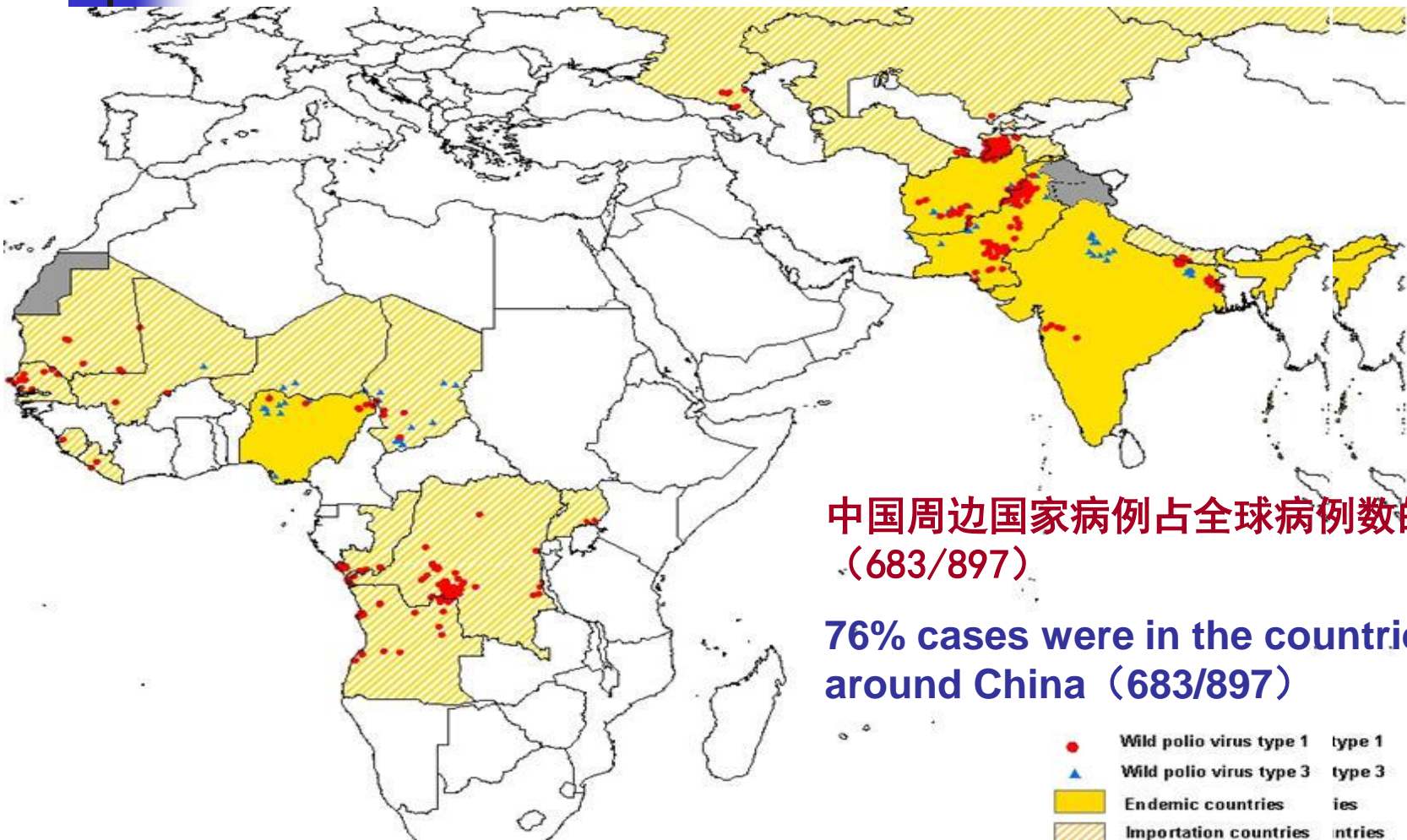
# Incidence rate of VPDs in China, 1950~2009

## 1950~2009年全国主要疫苗针对传染病报告发病率(/10万)



# 全球脊灰疫情 (截至2010年12月21日)

Total cases	Year-to-date 2010	Year-to-date 2009	Total in 2009
Globally	897 ↓	1517	1604
• in endemic countries:	216 ↓	1188	1256
• in non-endemic countries:	681 ↑	329	348



中国周边国家病例占全球病例数的76% (683/897)

76% cases were in the countries around China (683/897)

- Wild polio virus type 1 type 1
- ▲ Wild polio virus type 3 type 3
- Endemic countries ies
- ▨ Importation countries ntries

# AFP病例监测和强化免疫

## AFP surveillance and OPV SIA

### ■ 全国AFP监测系统数据分析与报告

#### The results from AFP reporting system

- 2010年1~10月全国4249例，0~14岁儿童报告发病率：  
1.84/10万

4249 AFP cases reported from Jan to Oct, 2010, Reported incidence for children aged 1 – 14 years: 1.84/100,000

### ■ 2009/2010年度OPV强化免疫

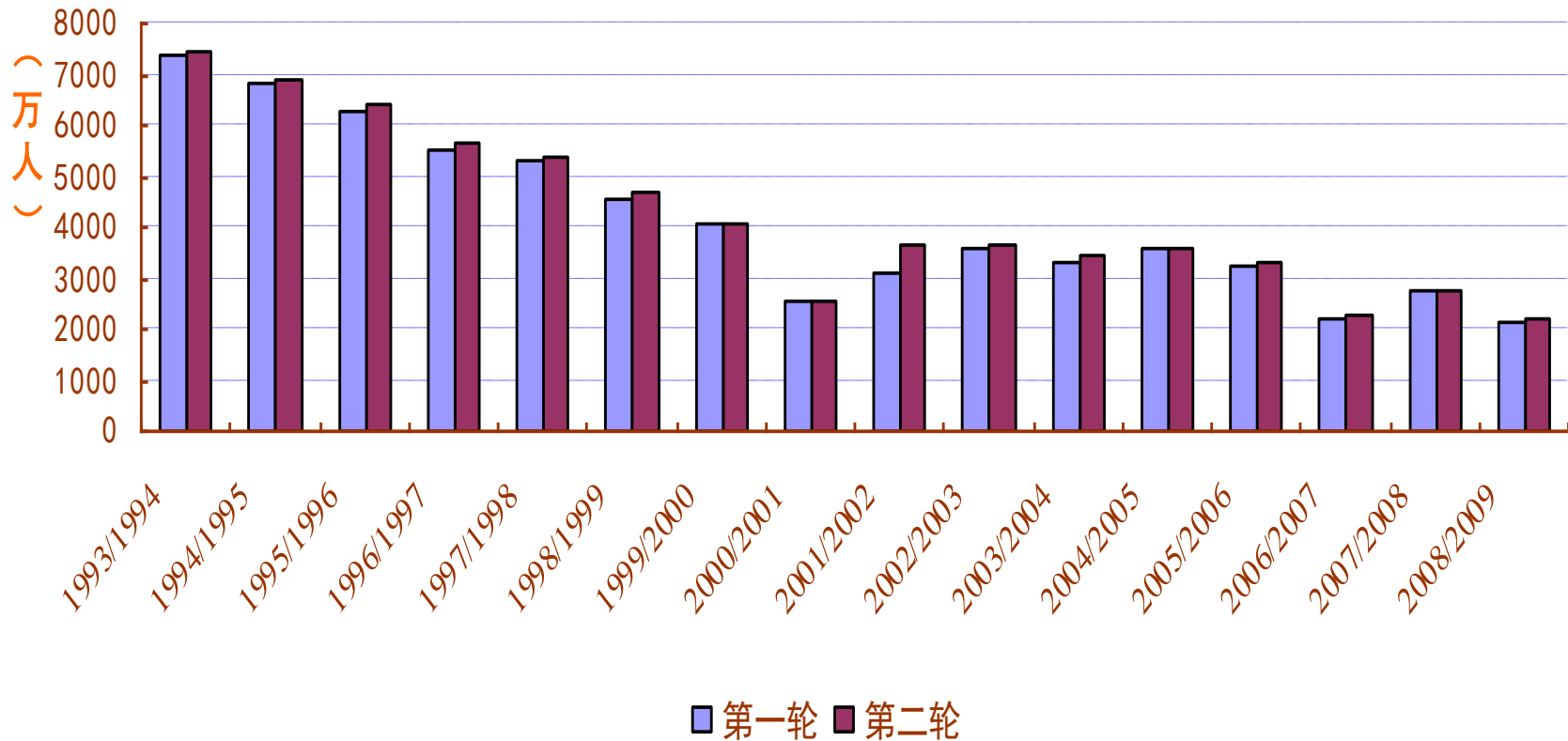
#### OPV SIAs in year 2009/2010

- 两轮分别接种20800580人、16428132人，接种率分别为  
94.57%、97.54%。

Two rounds SIAs covered 20800580, 16428132 children

# Polio vaccine supplementary immunization activity

## 1993年-2009年OPV强化免疫接种情况



# DG of WHO Supporting Measles SIA in China

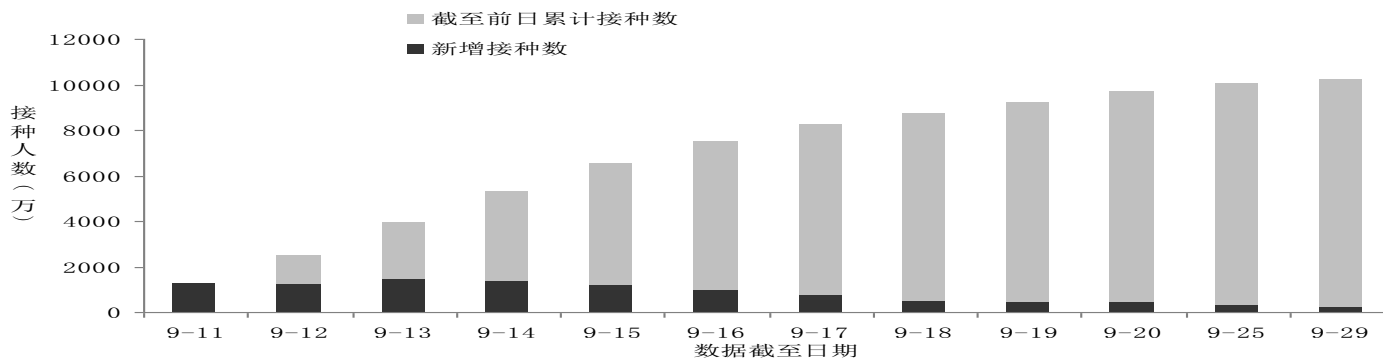
- 卫生部下发《2010年全国麻疹疫苗强化免疫活动方案》
- 卫生部召开消除麻疹工作会议



# 全国麻疹疫苗强化免疫活动 Measles Campaign 2010

## ■ 强化免疫主要结果

- 全国报告实种人数1亿3百万
- 103 million children vaccinated

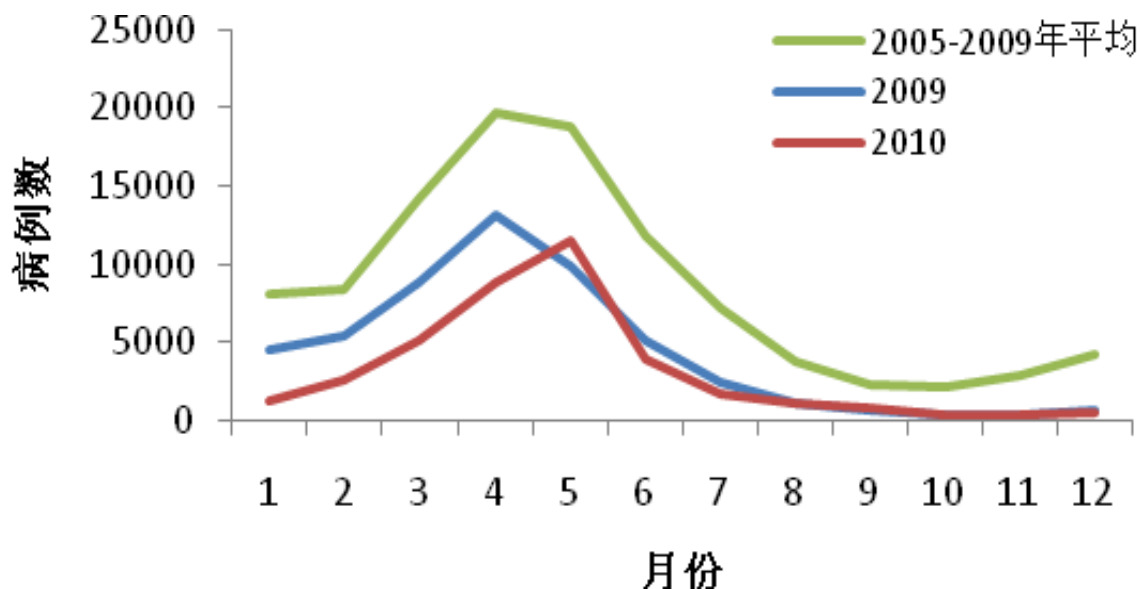


- AEFI 共14995例，发生率14.65/10万，异常反应发生率2.41/10万，严重异常反应发生率0.30/10万
  - 无群体性AEFI事件报告 **No cluster AEFI**
  - 无与强免有关的死亡病例报告 **No death**

# 全国消除麻疹进展 Measles elimination

2010年全国共报告麻疹病例38159例，报告发病率2.86/10万

- 与2009年相比，2010年报告病例数减少了27.63%.
- **Decreased 27% compared with the period in 2009**



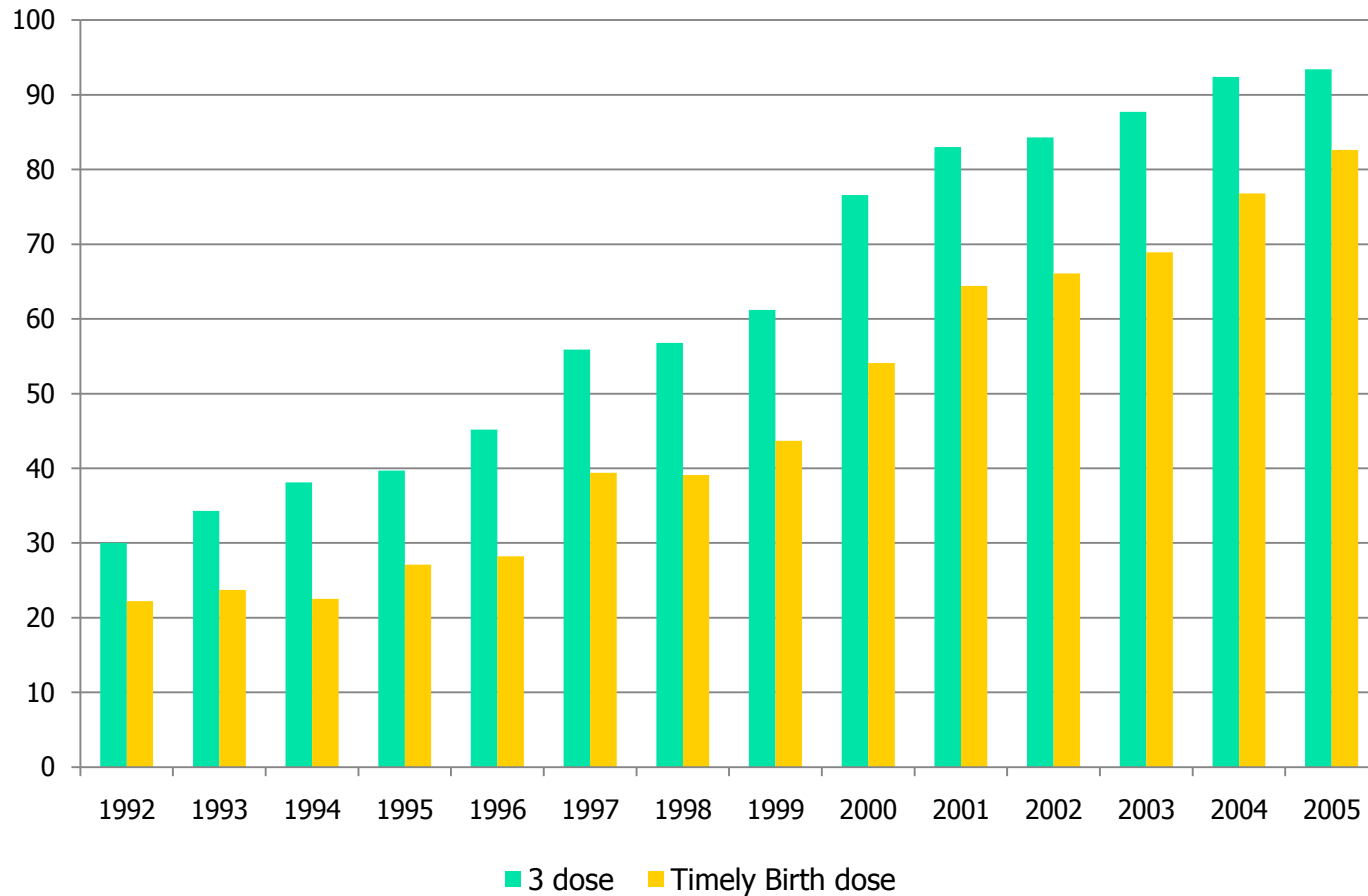
**2010年麻疹报告病例数降至历史最低水平！**

**Report cases in 2010 fell to the lowest in history**

2005~2010年全国麻疹病例发病月分布（按审核日期统计）

# 1992~2005年出生儿童乙肝疫苗接种率

## HepB vaccine coverage rates of children born from 1992 and 2005



# 与1992年比较，2006年儿童HBsAg阳性率大幅下降

## HBsAg positive rate dropped substantially

- 全人群HBsAg阳性率从9.75%降到7.18%

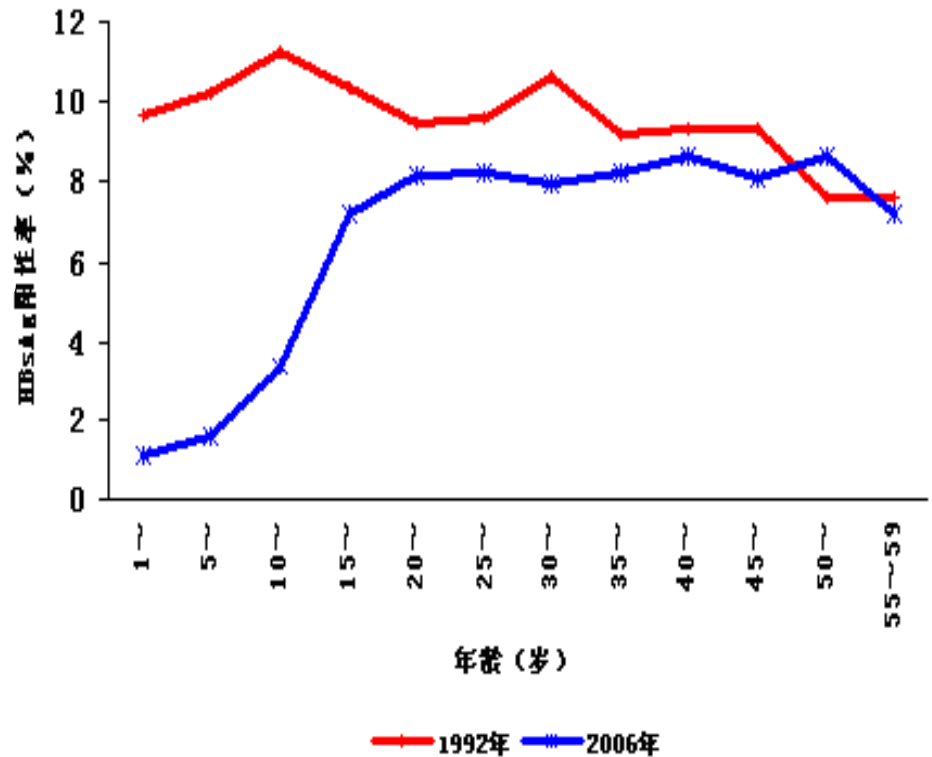
HBsAg positive rate decreased from 9.75% to 7.18% for whole population

- 5岁以下儿童HBsAg阳性率低于1%

HBsAg positive rate <1% for children <5 yrs

- 2005年出生儿童HBsAg阳性率为0.67%。

HBsAg positive rate was 0.67% for children born in 2005.



# Success Story: Saving More Lives From HBV in China

May 2007

June 2007



## Progress in Hepatitis B Prevention Through Universal Infant Vaccination --- China, 1997--2006

Hepatitis B virus (HBV) infection is a leading cause of illness and death in China. Approximately 60% of the population has a history of HBV infecting 9.8% of persons in China are chronically infected with HBV and at risk for premature death from liver disease (1). Each year, an estimated 263,000 people in China die from HBV-related liver cancer or cirrhosis, accounting for 37%--50% of HBV-related deaths worldwide (2). Because most HBV infections occur during infancy or early childhood, when HBV infection is most likely to become chronic, vaccination of infants beginning at birth is the key strategy for preventing chronic HBV infection. This report describes China's progress in increasing coverage among infants with hepatitis B vaccine (HepB) at timely administration of the HepB birth dose (i.e., within 24 hours of birth). Infant vaccination coverage with both the timely birth dose and the complete vaccine series was substantially higher among children born during 2003 than among those born during 1997; timely birth-dose coverage increased from 29.1% to 75.8%, and HepB series completion increased from 70.7% to 89.8%. Furthermore, in economically disadvantaged populations in western and middle provinces\* targeted by the China-Global Alliance for Vaccines and Immunization (China-GAVI) project, reported coverage with timely HepB dose increased from 64% in 2004 to 81% in 2006, and coverage with the complete HepB series increased from 52% in 2001 to 92% in 2006. China has established a goal to redouble its commitment to increasing

### Hepatitis B Immunization

HepB was first recommended as subsequent doses at ages 1, 6, and 12 months. The 5-year China-GAVI government-designated program established a goal to redouble its commitment to increasing



The Journal of the American Medical Association

Vol. 298 No. 5, August 1, 2007

From the Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report

## Progress in Hepatitis B Prevention Through Universal Infant Vaccination—China, 1997–2006

JAMA. 2007;298:506–509.

MMWR. 2007;56:441–445

3 figures omitted

Hepatitis B virus (HBV) infection is a leading cause of illness and death in China. Approximately 60% of the population has a history of HBV infecting 9.8% of persons in China are chronically infected with HBV and at risk for premature death from liver disease (1). Each year, an estimated 263,000 people in China die from HBV-related liver cancer or cirrhosis, accounting for 37%--50% of HBV-related deaths worldwide (2). Because most HBV infections occur during infancy or early childhood, when HBV infection is most likely to become chronic, vaccination of infants beginning at birth is the key strategy for preventing chronic HBV infection. This report describes China's progress in increasing coverage among infants with hepatitis B vaccine (HepB) at timely administration of the HepB birth dose (i.e., within 24 hours of birth). Infant vaccination coverage with both the timely birth dose and the complete vaccine series was substantially higher among children born during 2003 than among those born during 1997; timely birth-dose coverage increased from 29.1% to 75.8%, and HepB series completion increased from 70.7% to 89.8%. Furthermore, in economically disadvantaged populations in western and middle provinces\* targeted by the China-Global Alliance for Vaccines and Immunization (China-GAVI) project, reported coverage with timely HepB dose increased from 64% in 2004 to 81% in 2006, and coverage with the complete HepB series increased from 52% in 2001 to 92% in 2006. China has established a goal to redouble its commitment to increasing

2007, 82, 209–224

No. 24

## Weekly epidemiological record Relevé épidémiologique hebdomadaire

15 JUNE 2007, 82ND YEAR / 15 JUIN 2007, 82<sup>e</sup> ANNÉE  
No. 24, 2007, 82, 209–224  
<http://www.who.int/wer>



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### Progress in preventing hepatitis B through universal infant vaccination: China, 1997–2006

Infection with hepatitis B virus (HBV) is a leading cause of illness and death in China. Approximately 60% of the population has a history of infection with HBV, and 9.8% of people in China are chronically infected with it and at risk for premature death from liver disease.<sup>1</sup> Each year, an estimated 263 000 people in China die from hepatitis B-related liver cancer or cirrhosis, accounting for 37–50% of hepatitis B-related deaths worldwide.<sup>2</sup> Because most hepatitis B infections occur during infancy or early childhood, when infection is most likely to become chronic, vaccinating infants at birth is the key strategy for preventing chronic infection.

This report describes China's progress

### Prévention de l'hépatite B par la vaccination universelle des nourrissons: progrès en Chine entre 1997 et 2006

L'infection par le virus de l'hépatite B (VHB) est une cause importante de morbidité et de mortalité en Chine. Environ 60% de la population a un antécédent d'hépatite B et 9,8% des Chinois sont des porteurs chroniques du virus et risquent de mourir prématurément d'une maladie du foie.<sup>1</sup> On estime que chaque année, en Chine, 263 000 personnes meurent d'un cancer du foie ou d'une cirrhose liés à l'hépatite B, ce qui représente 37% à 50% des décès liés à l'hépatite B dans l'ensemble du monde.<sup>2</sup> L'infection se produisant le plus souvent pendant la petite enfance, à l'âge où il y a le plus de risques qu'elle devienne chronique, la stratégie de base pour prévenir l'infection chronique est de vacciner les enfants à la naissance.

Il est ici question des progrès faits par la

• **19 million children prevented by infant immunization through 2005**  
 • **1992年以来儿童乙肝表面抗原携带者减少了1900万人。**

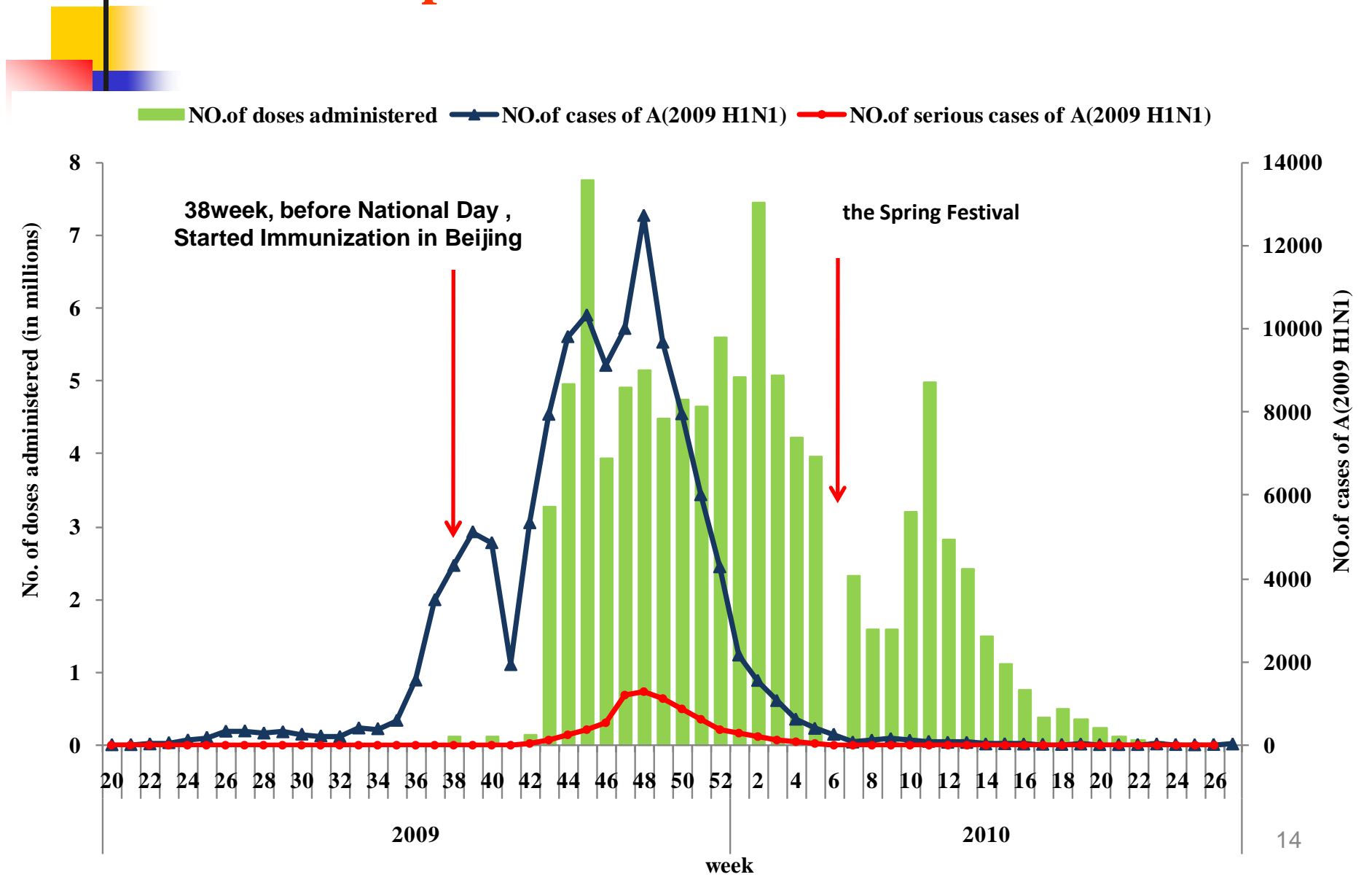
# 全球首家生产出甲流疫苗, 2009年

## First Country of H1N1 Influenza Vaccination

- 2009年6月3日收到NYMCX-179A株
- 卫生部和药监局授权, 中国CDC负责临床研究
- 10个厂家参加, 7省开展试验13000名志愿者
- 7月22日第一针接种
- 提出 $15\mu\text{g}/0.5\text{ml}$ , 1剂的免疫程序
  
- 2009年9月开始接种
- 总接种人数过亿

# 甲型H1N1流感疫苗接种及其异常反应监测

## H1N1 Influenza Epidemic Trend and Immunization Status



# 10个现场试验结果发表在Lancet

## Safety and immunogenicity of 2009 pandemic influenza A H1N1 vaccines in China: a multicentre, double-blind, randomised, placebo-controlled trial



Xiao-Feng Liang, Hua-Qing Wang, Jun-Zhi Wang, Han-Hua Fang, Jiang Wu, Feng-Cai Zhu, Rong-Cheng Li, Sheng-Li Xia, Yu-Liang Zhao, Fang-Jun Li, Shao-Hong Yan, Wei-Dong Yin, Kang An, Duo-Jia Feng, Xuan-Lin Cui, Feng-Chun Qi, Chang-Jun Ju, Yu-Hui Zhang, Zhi-Jun Guo, Ping-Yu Chen, Ze Chen, Kun-Ming Yan, Yu Wang

### Summary

**Background** The current influenza pandemic calls for a safe and effective vaccine. We assessed the safety and immunogenicity of eight formulations of 2009 pandemic influenza A H1N1 vaccine produced by ten Chinese manufacturers.

**Methods** In this multicentre, double-blind, randomised trial, 12 691 people aged 3 years or older were recruited in ten centres in China. In each centre, participants were stratified by age and randomly assigned by a random number table to receive one of several vaccine formulations or placebo. The study assessed eight formulations: split-virion formulation containing 7.5 µg, 15 µg, or 30 µg haemagglutinin per dose, with or without aluminium hydroxide adjuvant, and whole-virion formulation containing 5 µg or 10 µg haemagglutinin per dose, with adjuvant. All formulations were produced from the reassortant strain X-179A (A/California/07/2009-A/PR/8/34). We analysed the safety (adverse events), immunogenicity (geometric mean titre [GMT] of haemagglutination inhibition antibody), and seroprotection (GMT  $\geq$ 1:40) of the formulations. Analysis was by per protocol. Two sites registered their trial with ClinicalTrials.gov, numbers NCT00956111 and NCT00975572. The other eight studies were registered with the State

Published Online  
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DOI:10.1016/S0140-6736(09)62003-1

See Online/Comment  
DOI:10.1016/S0140-6736(09)62132-2  
DOI:10.1016/S0140-6736(09)62133-4

Chinese Center for Disease Control and Prevention, Beijing, China (X-F Liang MD, H-Q Wang PhD, Y Wang PhD); National Institute for the Control of Pharmaceuticals and Biological Products, Beijing.

# 国产甲流疫苗的安全性得到国际肯定

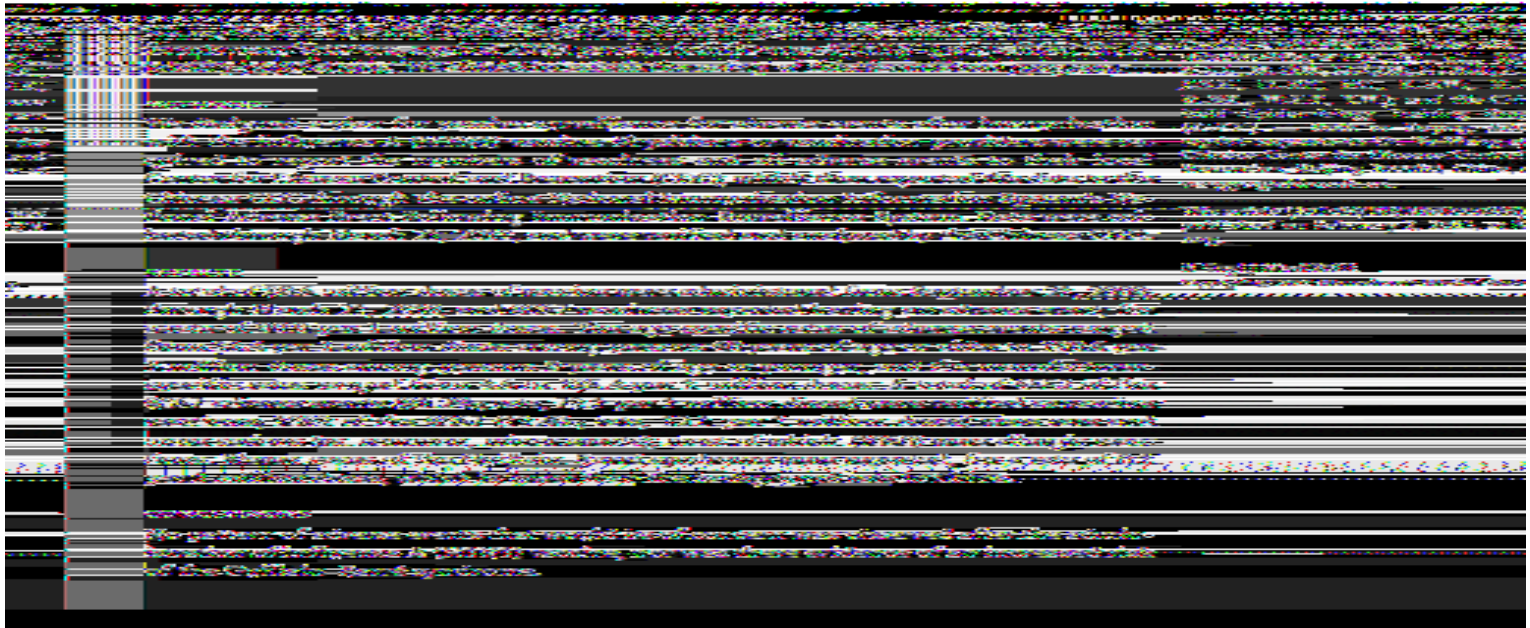
THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

## Safety of Influenza A (H1N1) Vaccine in Postmarketing Surveillance in China

Xiao-Feng Liang, M.D., Li Li, M.D., Ph.D., Da-Wei Liu, M.D., Ke-Li Li, M.D.,  
Wen-Di Wu, M.D., Bao-Ping Zhu, M.D., Hua-Qing Wang, M.D., Ph.D.,  
Hui-Ming Luo, M.D., Ling-Sheng Cao, M.D., Jing-Shan Zheng, M.D.,  
Da-Peng Yin, M.D., Lei Cao, M.P.H., Bing-Bing Wu, M.D., Hong-Hong Bao, M.D.,  
Di-Sha Xu, M.D., Wei-Zhong Yang, M.D., and Yu Wang, M.D., Ph.D.

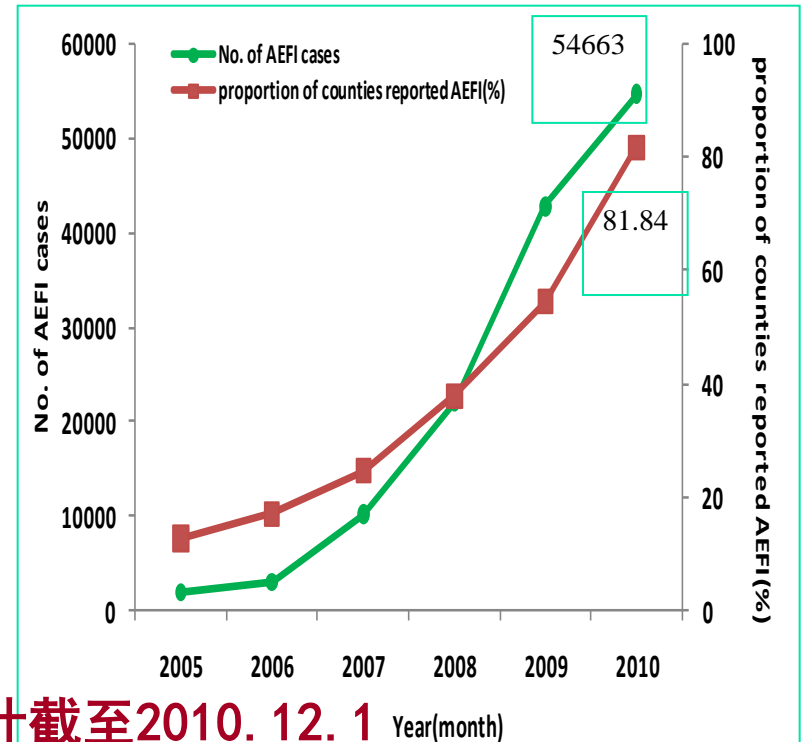
ABSTRACT



# 全国AEFI监测结果报告数和报告县创历史新高

## Number of the reported AEFI cases and counties reached highest in history

- 2010.1-11月，AEFI审核个案50046例，比去年同期增长45.29%
- Reported 50046 AEFI cases, increased 45.29%.



# NRA职能正式评估

## WHO NRA assessment

- 2010年12月WHO对我国的正式评估；

Dec, WHO NRA assessment to China

- 河北、上海和中国CDC接受考核。  
Evaluate in Hebei, Shanghai and China CDC

- 以96高分通过NRA上市后板块

Part of Postmarketing got 96.

- WHO3月1日宣布：中国SFDA疫苗监管系统符合国际标准。

WHO announced NRA in China was consistent with international standards



### Function Z: Post-marketing activities including surveillance of Ad

Indicator	Critical	Achieved	Sub-ind	Achieved Score
PM1: Institutional regulations and guide	✓	Yes	4 / 4	100% 1
PM2: Quality Management System for p	✓	Yes	1 / 1	100% 1
PM3: Roles and responsibilities of the k	✓	Yes	2 / 2	100% 1
PM4: Human resource management	✓	Yes	3 / 3	100% 1
PM5: Routine and functional system for	✓	Yes	6 / 6	100% 1
PM6: Capacity to detect and investiga	✓	Yes	4 / 4	100% 1
PM7: Regulatory outcome regarding va	✓	Yes	2 / 2	100% 1



# 中国肺炎监测及疫苗使用

**Pneumonia surveillance and vaccines**

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# 近年各相关机构开展的工作

## Research and works in recent years

- 肺炎球菌血清型调查 Investigation of pneumococcal serotypes
  - 1982~1985年, 18个省、自治区、直辖市
  - 2000~2002年, 北京、上海和广州
- 病原体的流行病学调查 Epidemiological investigation of pathogens
  - 2003.12~2004.11, 中国7城市12中心CAP病原体的流行病学调查  
Investigation of CAP pathogens in 12 centers, 7 cities.
  - 2005, 我国CAP致病原的构成情况, 上海、北京 Spectrum of CAP Pathogens
- 肺炎疾病负担 The burden of pneumococcal disease
- 抗生素耐药性监测 Antibiotic resistance
- 肺炎球菌性疾病防治研讨会 Seminar for Pneumococcal disease prevention

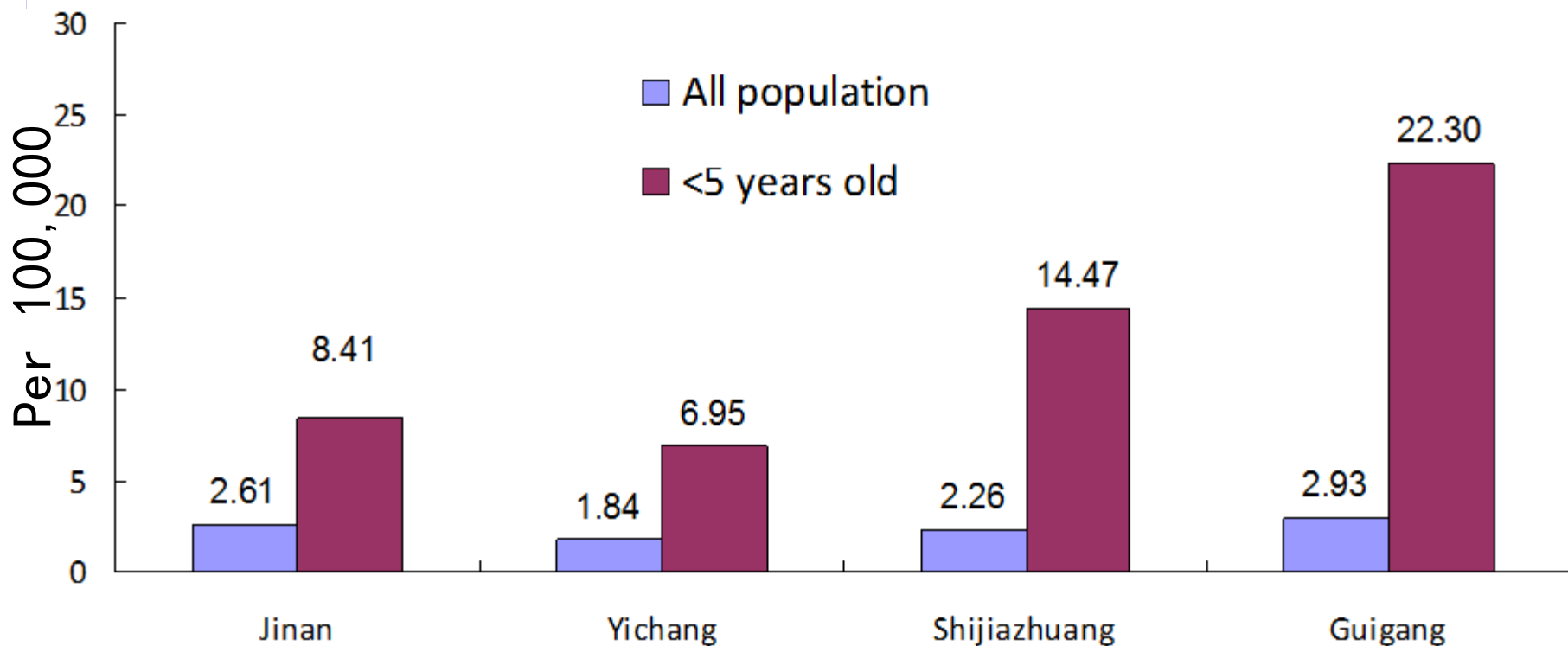
# 我国肺炎监测现状

## Pneumonia surveillance in China

- 不明原因肺炎监测系统 Unexplained pneumonia surveillance system
  - 2007年报告不明原因肺炎病例28例，其中3例确诊为人禽流感病例。  
28 unexplained pneumonia cases were reported in 2007, including 3 confirmed human bird flu cases.
- 流感/禽流感监测系统 China flu/bird flu surveillance system
  - 截至2008年3月，已报告29例。 29 cases were reported.
- 中美新发传染病合作项目“肺炎监测项目” China–US cooperation project on Emerging Infectious Diseases – “pneumonia surveillance project”
  - 试点阶段：广东珠海、湖北荆州、辽宁盘锦 Sentinel sites: Zhuhai, Jingzhou, Panjin

# 细菌性脑膜炎发病率

## Estimated probable bacterial meningitis (PBM) incidence (/100,000/yr)



■ 急性脑膜炎脑炎监测系统 Acute Meningitis and Encephalitis Surveillance

■ 2006-2009年，卫生部、WHO合作项目

■ 2010年~ 中国疾控中心

# 实验室确诊的细菌性脑膜炎病例构成

## Spectrum of the Lab Confirmed Bacterial Cases

- 74例实验室确诊的细菌性脑膜炎病例

74 were lab confirmed bacterial meningitis

- 18 (24.3%) 为CSF培养结果

18 (24.3%) cases were CSF culture confirmed

- 62 (83.8%) 为PCR检测结果

62 (83.8%) cases were real-time PCR confirmed

- 39 (52.7%) *S. pneumoniae*
- 26 *N. meningitidis* (predominantly group C)
- 9 Hib

# 肺炎球菌疫苗

## Pneumococcal vaccines

### ■ 目前我国使用疫苗种类：

#### ■ 23价肺炎球菌多糖疫苗

23 valent Pneumococcal Polysaccharide Vaccine

#### ■ 7价肺炎球菌结合疫苗

7 valent Pneumococcal Conjugate Vaccine

### ■ 2010年1-10月疫苗接种报告情况：

#### ■ 23价肺炎球菌多糖疫苗 1,762,692剂次

PPSV23 1,762,692 doses

#### ■ 7价肺炎球菌结合疫苗 235,037剂次

PCV7 235,037 doses



# 下一步

## Next Step

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- 明确肺炎发病率等疾病负担

Surveillance for the incidence of Pneumonia

- 肺炎球菌血清型流行病学调查

Investigation of the serotypes of the Pneumonia

- 目前肺炎球菌应用评价

Evaluation of the Pneumococcal vaccines used in China

- 关注新疫苗研究

Pay attention to the researches of new vaccines

*thanks!*

