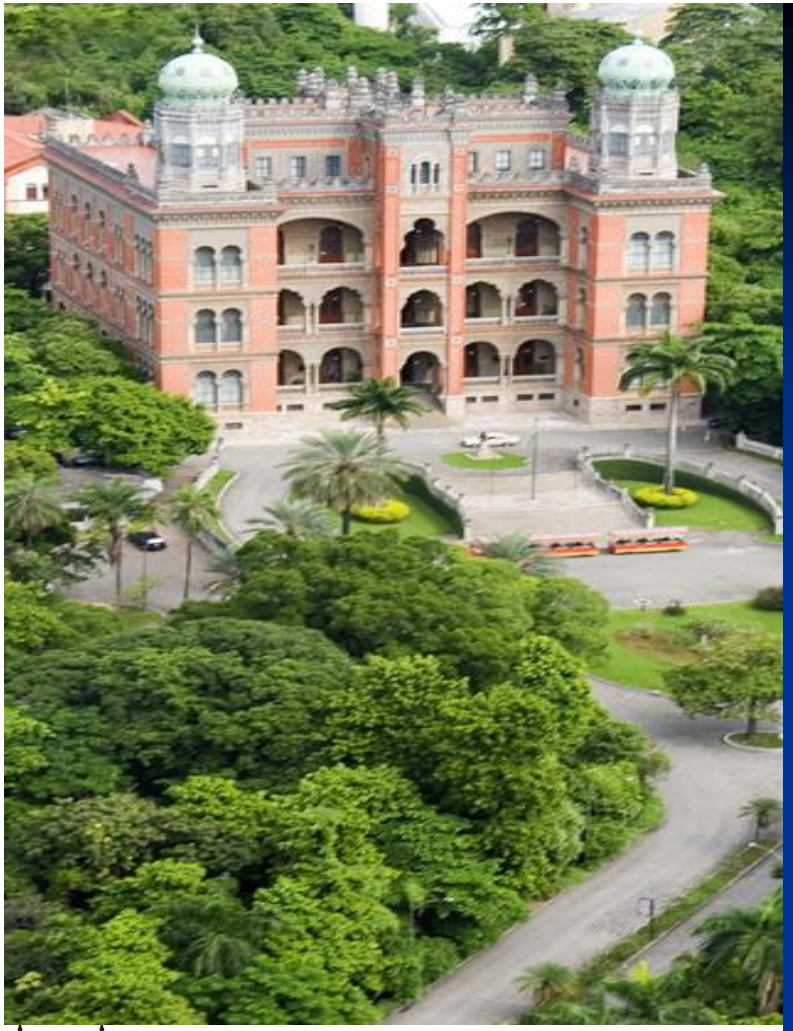

Ministério da Saúde

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em Imunobiológicos
Bio-Manguinhos

dcvmn DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK

3rd Regional Pneumococcal Symposium

13-14 February 2008

Istanbul, Turkey

Dr. Akira Homma

Bio-Manguinhos, Fiocruz

DCVMN

Developing Countries Vaccine Manufacturers Network
-DCVMN-

Formed in 2000, Bandung, Indonesia; formally organized July 2005

- To provide quality vaccines at affordable prices to the developing world
  - 19 members (Brazil, Cuba, China, Egypt, India, Indonesia, Iran, South Africa, Senegal, South Korea, Thailand);
  - 7 members WHO pre-qualified;

WHO Pre-qualified vaccines currently available from DCVMN

- BCG, DTwP, OPV, MMR, MR, Hep B, Yellow Fever, Rabies
- Made available through UNICEF, WHO and PAHO – also private export markets

DCVMN provides 2/3 of vaccines used in the world

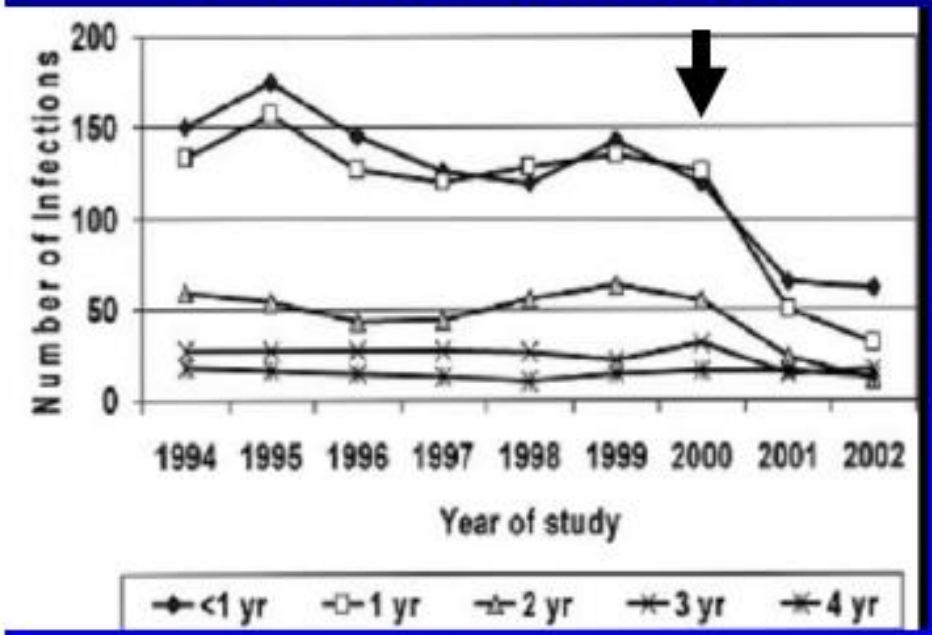
- Most are expanding capacity and adding new technologies and products
- R&D efforts towards Hib, Rotavirus, Pneumococcal, Meningococcal, JE and others

DCVMN Pneumococcal Vaccine Development Projects

- Biological Evans – 7-10 valent conjugate - 2012/15;
- BioMed CPS - 11 valent conjugate - 2009/12;
- Shantha Biotech- conjugate and protein technology
- BioVac Institute – Regional approach;
- Finlay Institute - 8-13 valent – synthetic vaccine; Conjugation tech 4 years for clinical study;
- China National Biotechnology Co. – 23 valent PS
- Serum Institute of India - 14 valent conjugate
- Bio-Manguinhos / Fiocruz – conjugate & proteins - 2017
- Butantan - PS (3-Valent) - PspA (2-3-Valent) conjugate; Whole cell non-encapsulated inactivated/Harvard

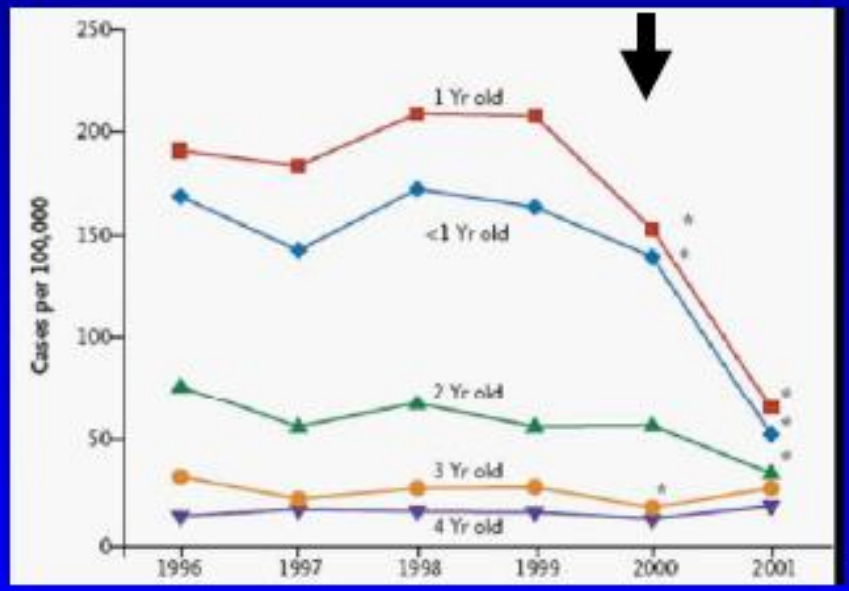
Declines in invasive pneumococcal disease following vaccination, USA

Sentinel surveillance



Kaplan, Pediatrics 2004

Population-based surveillance



Whitney, New England J 2003

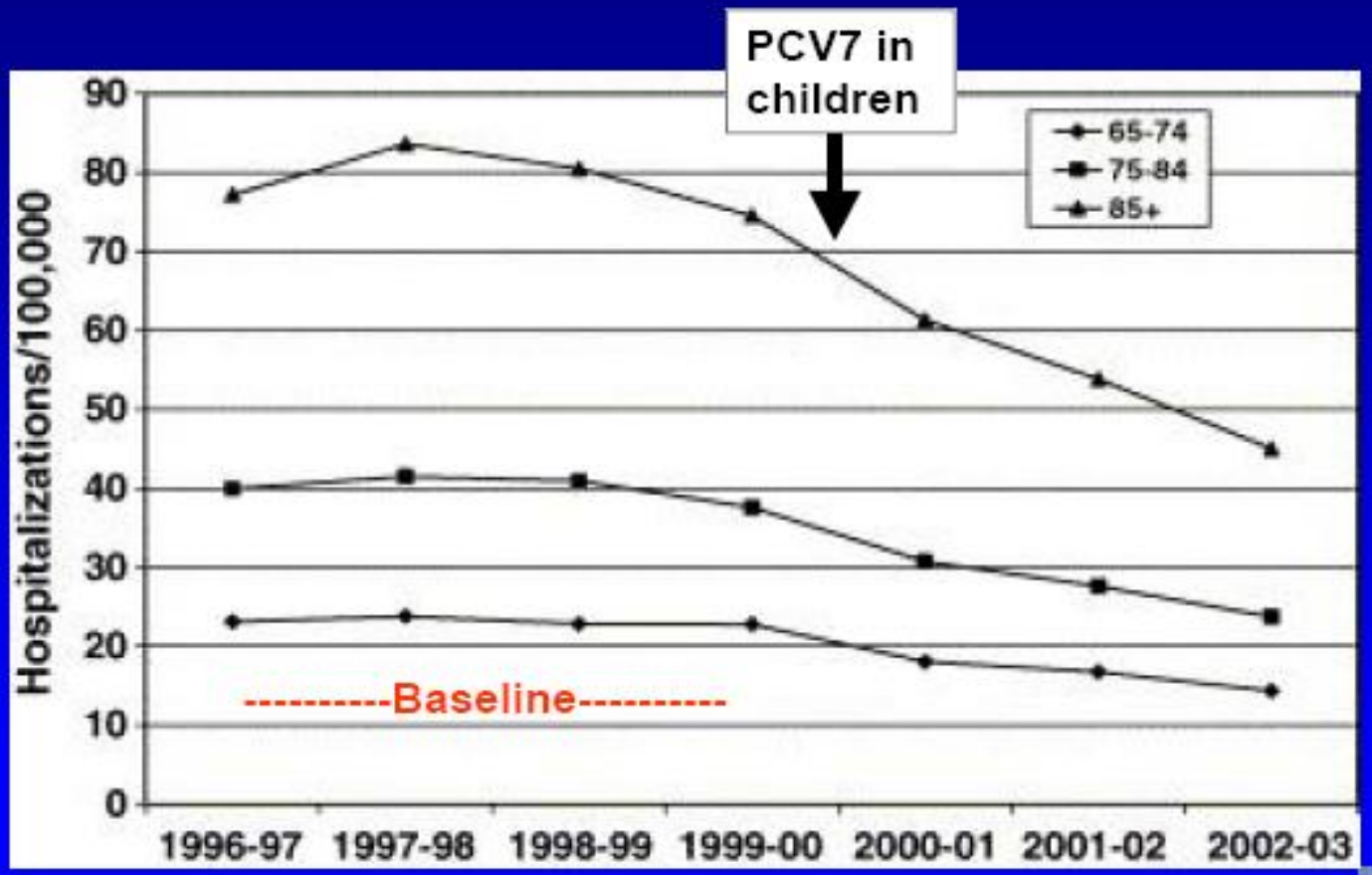
CDC

Vaccine-Type Invasive Disease in Children <5 Years
ABCs 1998-2005

CDC unpublished data and MMWR Sep 16, 2005

CDC

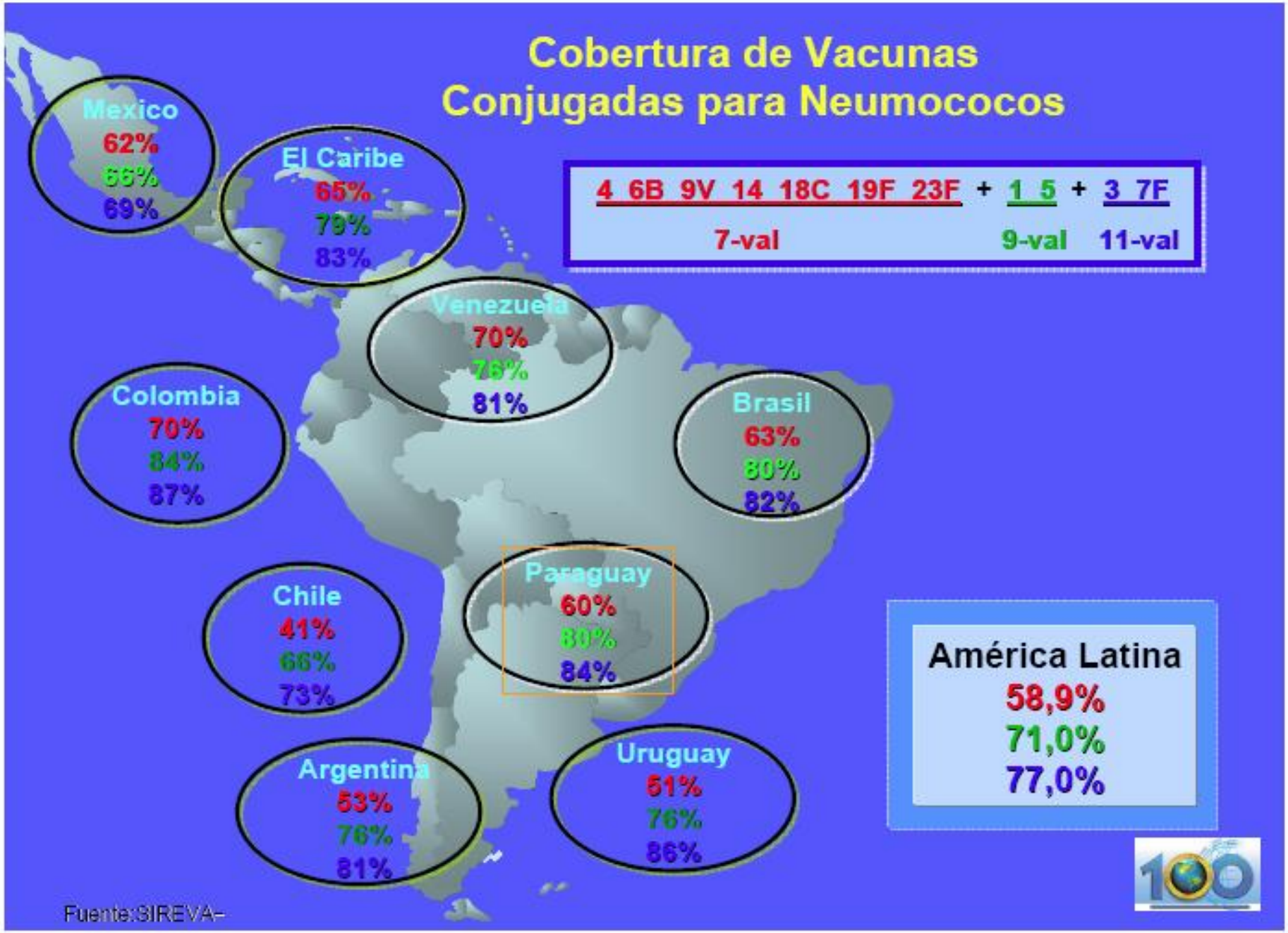
Hospitalization for invasive pneumococcal disease, ≥65 yr olds (Medicare data)



McBean, Vaccine 2005

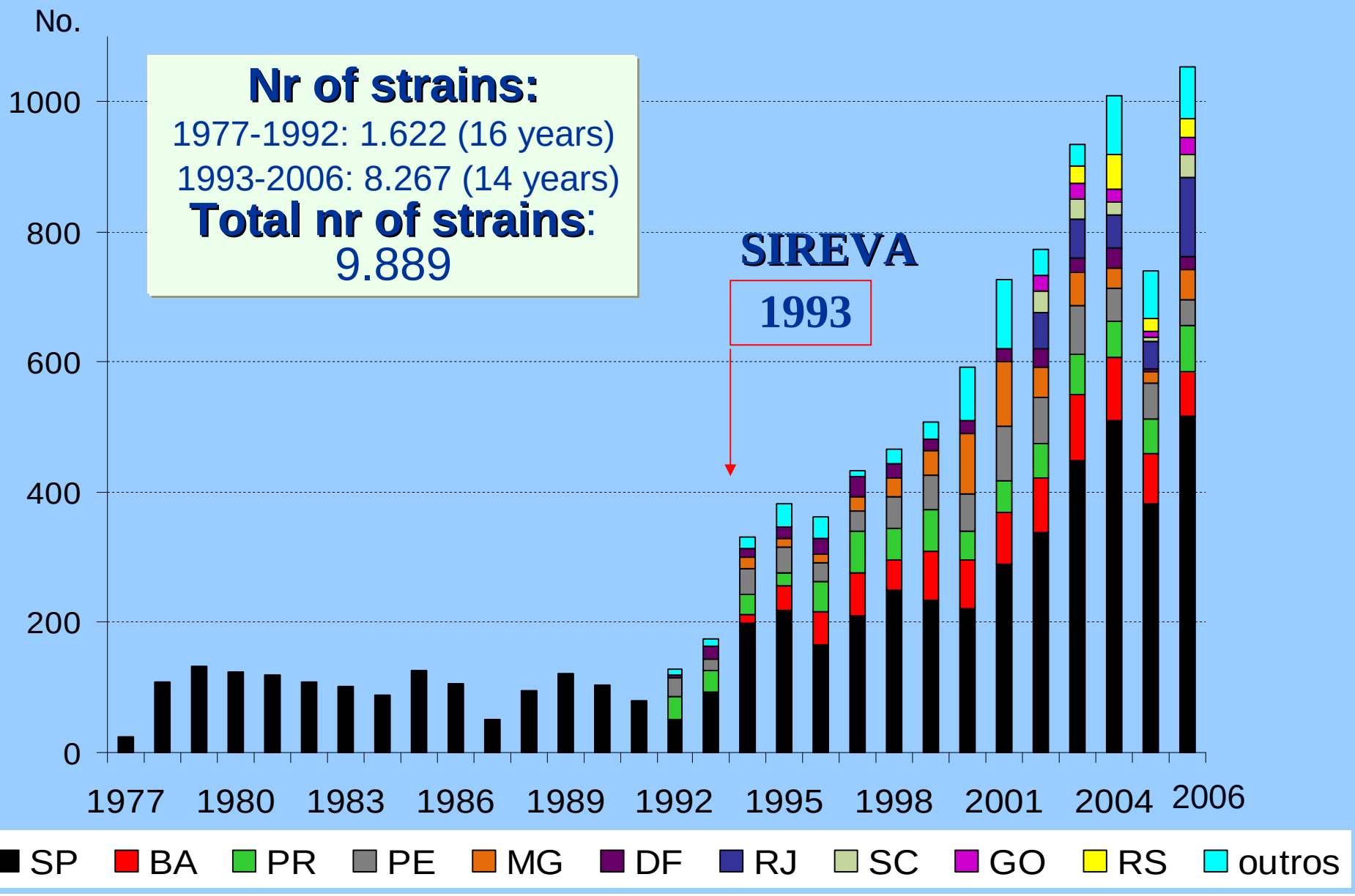
CDC

Cobertura de Vacunas Conjugadas para Neumococos

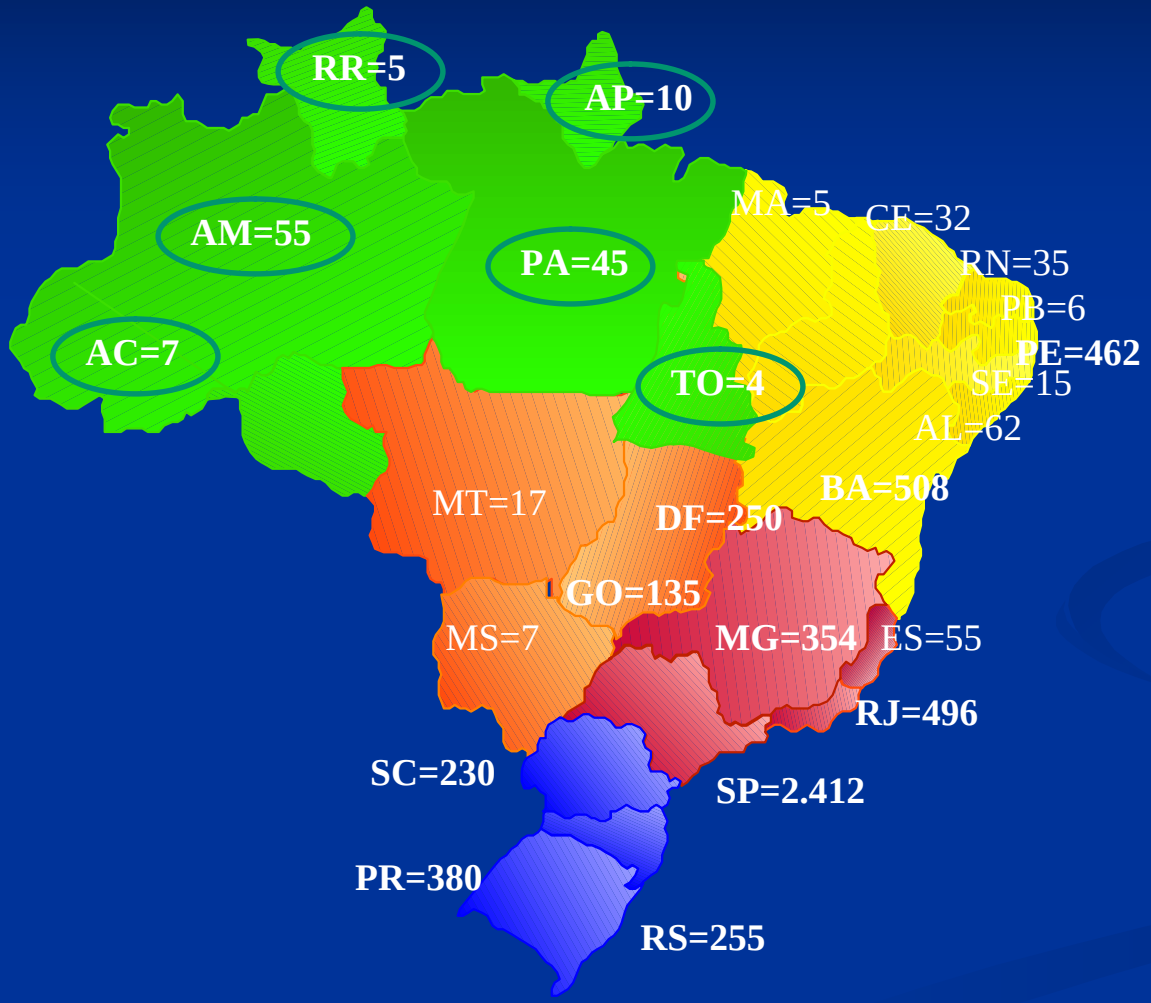


Fuente:SIREVA-

BRAZIL/SIREVA: Distribution of *S. pneumoniae* isolates during 30 years in Brazilian states - 1977-2006



Brazil: *S. pneumoniae* - 2000-2006 (7 years), 5.842 strains



2000-2006

North: 1,2%

Northeast: 22%

Mid West: 6,2%

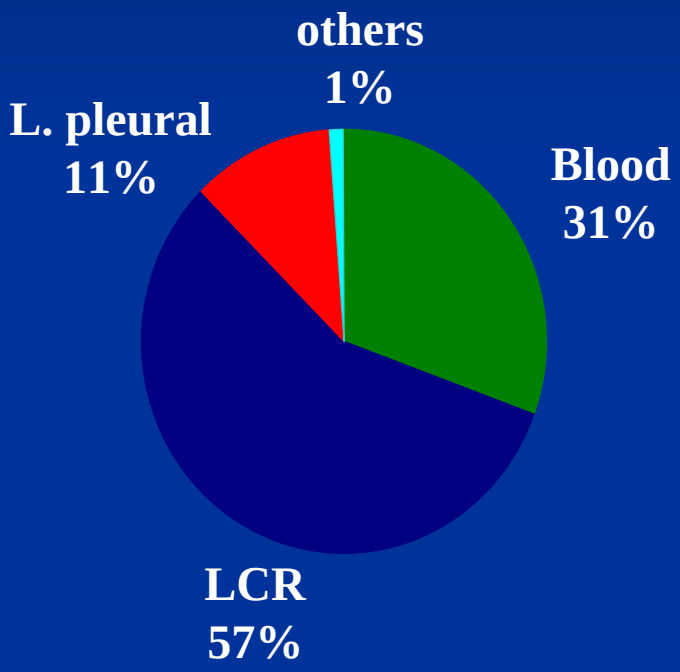
Southeast: 58,3%

South: 12,3%

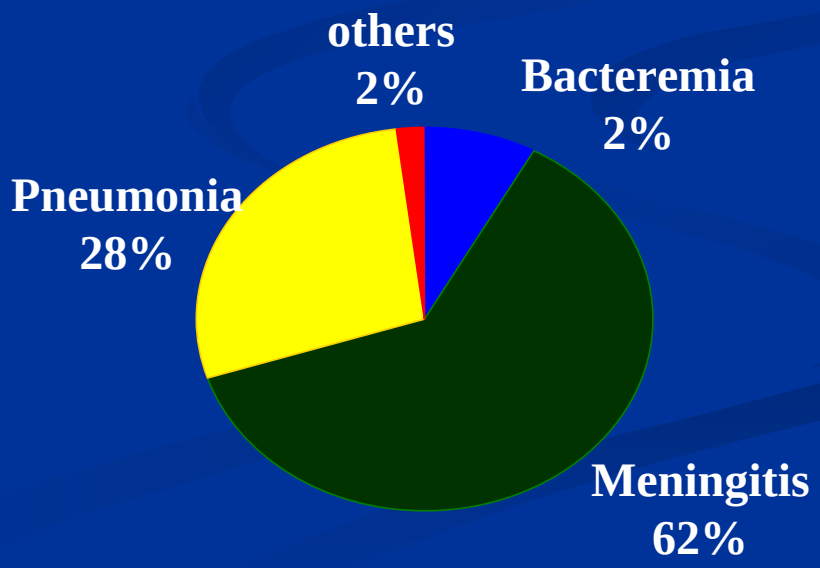
≤ 5 years: 2.380 strains

Brazil: *Streptococcus pneumoniae* – 2000-2006, 5.842 strains

Clinical Material



Clinical Diagnostic



Vaccination Policy

Vaccination against Pneumococcus

Background

• 1999: introduction of pneumococcal 23-valent vaccine for elderly people (annual campaign) and for special groups (institutionalized elderly and chronic diseases).

• 2002: introduction of conjugated pneumococcal 7-valent vaccine in the Special Reference Center for Immunobiologicals (CRIE).

Pneumococcal Vaccine – PNI Demand

7-Valent, conjugated

Year	Laboratory	Quantity	Price/Dose (USD)	Total (USD)
2003	Wyeth	**20,000**	46.68	933,660.00
2004		**3,500**	53.30	193,559.61
2005		**26,500**	54.84	1,453,135.00
2006		**26,250**	53.00	1,391,250.00
2007		**40,000**	NA	NA

23-Valent

Year	Laboratory	Quantity	Price/Dose (USD)	Total (USD)
2003	Sanofi Pasteur	**700,000**	7.33	5,131,430.00
2004	Sanofi Pasteur	**300,000**	8.18	2,455,056.53
2005	Sanofi Pasteur	**170,000**	8.67	1,474,574.32
2006	Merk	**370,000**	7.98	2,952,600.00
2007	NA	**370,000**	NA	NA

Potential Global Vaccine Market

	High Income Markets	Middle Income Markets	Low Income Markets	Total
Dosing Regimen	4	3 (?)	3 (?)	--
Vaccine Market (Mi doses)	40	130 (?)	135 (?)	305 (>)
Price/Dose (average est.)	$60	$20 (?)	$2 (?)	--
Vaccine Market ($B)	$2.4	$2.6 (?)	$0.3 (?)	$5.3 (?)

Production capacity: 100 Mi doses – Deficit of 200 Mi doses
DCVMN producers can come into market: 5-10 years

AMC, 2006

(?) questionable

A Role for DCVMN in the production of Pneumococcal conjugated vaccines for middle income countries

Vaccine	High Income	Middle Income	Low Income	Market
Price/Dose (average est.)	$60	$20	$2	--
Vaccine Market (Mi doses)	40	130	135	305
Population (Mi)	10	43	45	98

SOLVED

Push Mechanisms
DCVMN
PATH
GATES

In process for solution
GAVI
AMC
IFFim

CHALLENGE FOR MIDDLE INCOME COUNTRIES:

ACCELERATE THE INCORPORATION OF PNEUMOCOCCAL VACCINE

- Most of governments are convinced of the importance
  - data of impact of disease
  - epidemiological surveillance – serotype prevalence studies
  - cost-benefit studies
  - SAGE/WHO recommended
  - Sabin Institute
  - pneumoADIP

- Push mechanisms – New approach for vaccine development by big pharma; DCVMN laboratories; support from PATH, Bill & Melinda GATES, governments R&D investments – ??? years;

- Today´s situation - High demand and few offer of the conjugated vaccine = high price = big obstacle for introduction in middle income countries

CHALLENGES for new production plant in DCVMN countries

- Requires several serotypes for production;
- Complex PS/protein conjugation technology
  - CRM197; TT; DT; Hib D protein;
- Combination of > 10 different vaccines
- Requires very high investment (AMC)
  - New plant of production - US$ 180 million
  - Start-up - US$ 50 million
  - Period for production – 5 years with Tech Transfer

- More complex Regulatory requirements
- High cost and time consuming clinical studies
- WHO pre-qualification

ACCELERATE THE INCORPORATION OF PNEUMOCOCCAL VACCINE PRODUCTION TECHNOLOGY IN DCVMN COUNTRIES

- More producers must be involved *faster* in the production - increase availability and make its price affordable for middle income countries
  - Joint development work between/among DCVMN´s members – there are members with high technology capabilities – must get together;
  - Strengthen the Public-Private partnership for new technological development;
  - Transfer of Technology – create a win-win situation – requires a deep commitment from parties involved.

Thank you!

Ministério da Saúde

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dcvmn DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK

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