



MINISTERIO  
DE SANIDAD  
Y CONSUMO

# Hepatitis vaccination policy in Spain

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*Viral Hepatitis Prevention Board Meeting  
Madrid, November 23, 2006*

# Background

- Public system with universal coverage
- Devolution of Health affairs to the Autonomous Communities (AC)
  - 1979-1985: Devolution of Public Health affairs
  - 80's – 2001: Health care competencies transferred

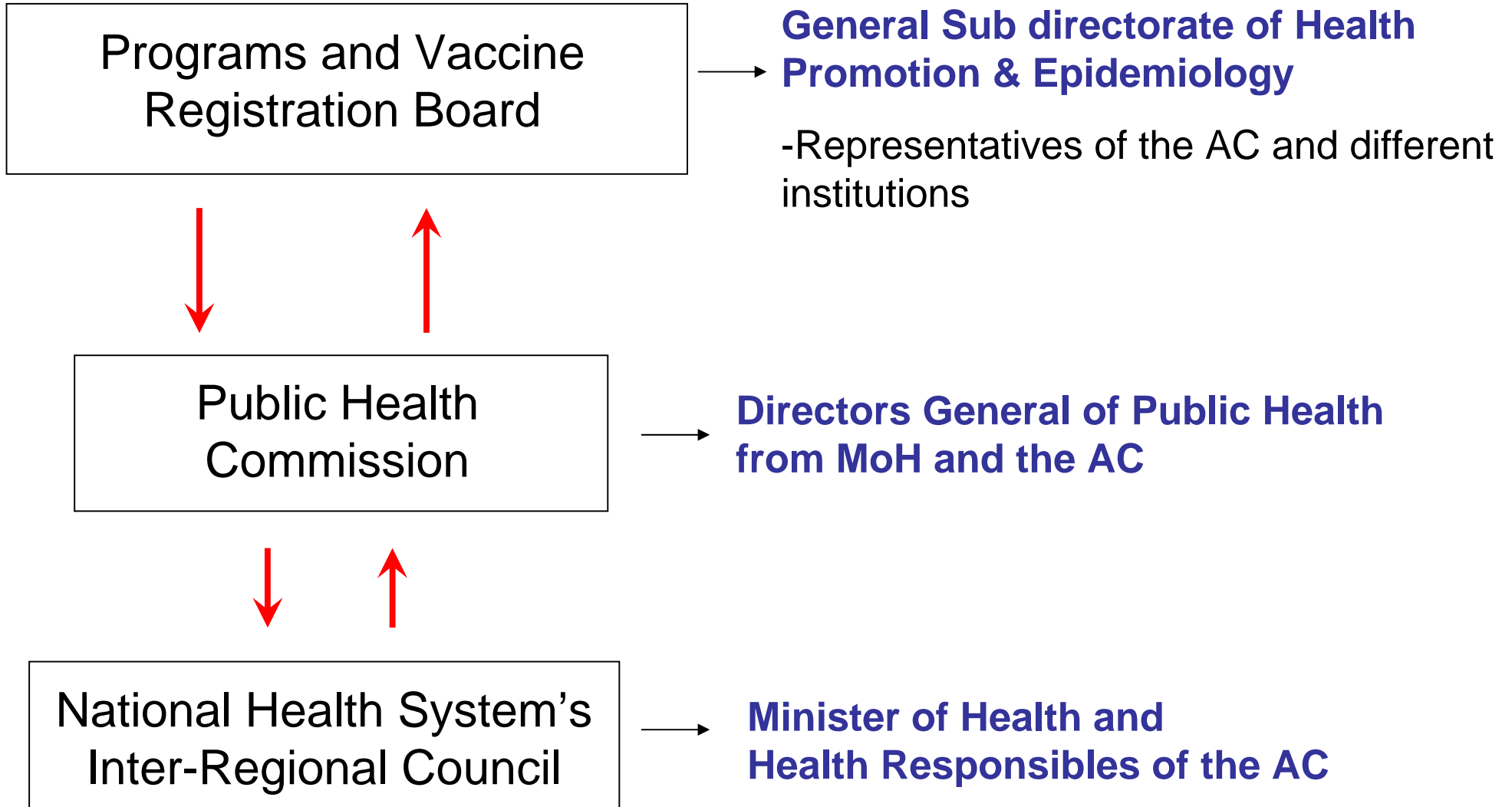
Need for coordination among the AC in relation to health programs and vaccination policies

- Inter-Regional Council of the NHS
  - Coordination and communication
  - Public Health Commission

# Background

- **1988: Permanent Commission for follow up of Health Programs**
- **1991: Programs and Vaccine Registration Board**
  - Coordinated by the General Sub directorate of Health Promotion & Epidemiology
  - Representatives from the Vaccination Programs of each AC
  - Different institutions
- **1992: Public Health Commission**
  - Directors General from the MoH and AC
  - Boards, Commissions and Working groups account to this Board

# Background



# State Health Administration & Vaccines

- Spanish Drug Agency:
  - responsible for evaluation
  - authorization and registration
- Directorate General of Pharmacy and Health Products:
  - authorisation for public financing and pricing
  - maintenance of a strategic, State-run deposit
- Directorate General of Public Health :
  - recommendations
  - coordination of immunization schedules
  - coverage analysis
  - evaluation of the routine immunization schedule

# State Powers (Vaccines)

- Regulation of conditions and minimum requirements aiming to maintain the confluence, harmonization, coordination and cohesion between all the autonomic initiatives and vaccination guidelines
- Focal point on vaccines for international institutions and organizations

# Primary immunization

- All immunizations for vaccines included in the National Immunization Schedule (NIS) are voluntary.
- Spain has got high NIS vaccine coverage levels in all AC
- Most vaccines are given by paediatricians
- Some vaccines may be given in schools
- The NIS is followed, practically in all of the Communities
- In a couple of them, additional vaccines are provided (e.g., hepatitis A)
- In other Communities, there might be slight differences on the recommended ages for a specific vaccine

# Vaccines financing

- Each AC is responsible for purchasing the vaccines for their region.
- All vaccines recommended are free of charge and paid by the AC
- Theoretically, a Community might not agree to support a new vaccine recommended by the Vaccines' Board or by the Public Health Commission if it could not afford the expenses.



# Hepatitis B Vaccination

# Evolution of Hepatitis B vaccination

1983- Ministry of Health: Royal Decree 3179/1983,  
Recommendations of vaccination of high risk groups

- a) Patients under periodical hemodialysis or blood transfusions
- b) Staff from Hemodialysis, Laboratories, Surgical and Dental Services
- c) Mentally disabled inpatients of institutions and staff working at these institutions
- d) Household members and sex partners of persons with chronic HBV infection
- e) Persons that have frequent skin punctures not controlled by a health professional (drug addicts, etc...)
- f) For specific cases where particular circumstances may recommend use of this vaccine

# Evolution of Hepatitis B vaccination

1990: Agreement of the Inter-Regional Council

- a) Newborns to chronically infected mothers
- b) Patients under periodical hemodialysis or blood transfusions
- c) Recipients of certain blood products (e.g., hemophiliacs)
- d) Healthcare workers or others with occupational exposure to blood or blood products
- e) Inmates and staff of long-term correctional facilities
- f) Mentally disabled inpatients of institutions and staff working at these institutions
- g) Household members and sex partners of persons with chronic HBV infection
- h) Persons with several sex partners
- i) Persons that have frequent skin punctures not controlled by a health professional (drug addicts, etc...)
- j) International travelers who will live or work for six or more months in areas with high levels of chronic HBV infection
- k) Travelers who travel frequently to high endemic areas and are at risk of having sexual contacts
- l) For specific cases where particular circumstances may recommend use of this vaccine

# Evolution of Hepatitis B vaccination

## **1992, Agreement of the Inter-Regional Council :**

- Intensify efforts to enlarge the current coverage of “Hepatitis B vaccination of newborns to chronically infected mothers”
- AC, within their resources, must develop in a reasonable time Hepatitis B vaccination of adolescents between 12- 13 years
- To continue and increase Hepatitis B vaccination in high risk groups

## **1996, Agreement of the Inter-Regional Council :**

- Includes Hepatitis B vaccination in adolescents in the immunization schedule of all AC
- In some AC, vaccination of newborns is also included

**CONSEJO INTERTERRITORIAL DEL SISTEMA NACIONAL DE SALUD  
CALENDARIO DE VACUNACIONES RECOMENDADO (1996)**

Aprobado por el Consejo Interterritorial el 24 de julio de 1995

VACUNAS	EDAD											
	2-3 meses	4-5 meses	6-7 meses	12 meses	15 meses	18 meses	6 años	7 años	10 años	11 años	13 años	14 años
<b>Poliomielitis</b>	<b>VP01</b>	<b>VP02</b>	<b>VP03</b>		<b>VP04</b>		<b>VP05</b>					
<b>Difteria-Tétanos-Pertussis</b>	<b>DTP1</b>	<b>DTP2</b>	<b>DTP3</b>		<b>DTP4</b>		<b>DT</b>					<b>Td <sup>(b)</sup></b>
<b>Sarampión Rubéola Parotiditis</b>				<b>TV 1 <sup>(a)</sup></b>						<b>TV 2</b>		
<b>Hepatitis B</b>									<b>HB3 dosis <sup>(b)</sup></b>			

<sup>(a)</sup> En situación de especial riesgo una dosis a los 9 meses o antes.

<sup>(b)</sup> También se vacunarán recién nacidos cuando las Autoridades Sanitarias lo estimen oportuno, así como a los recién nacidos hijos de madre portadora y a los grupos de riesgo.

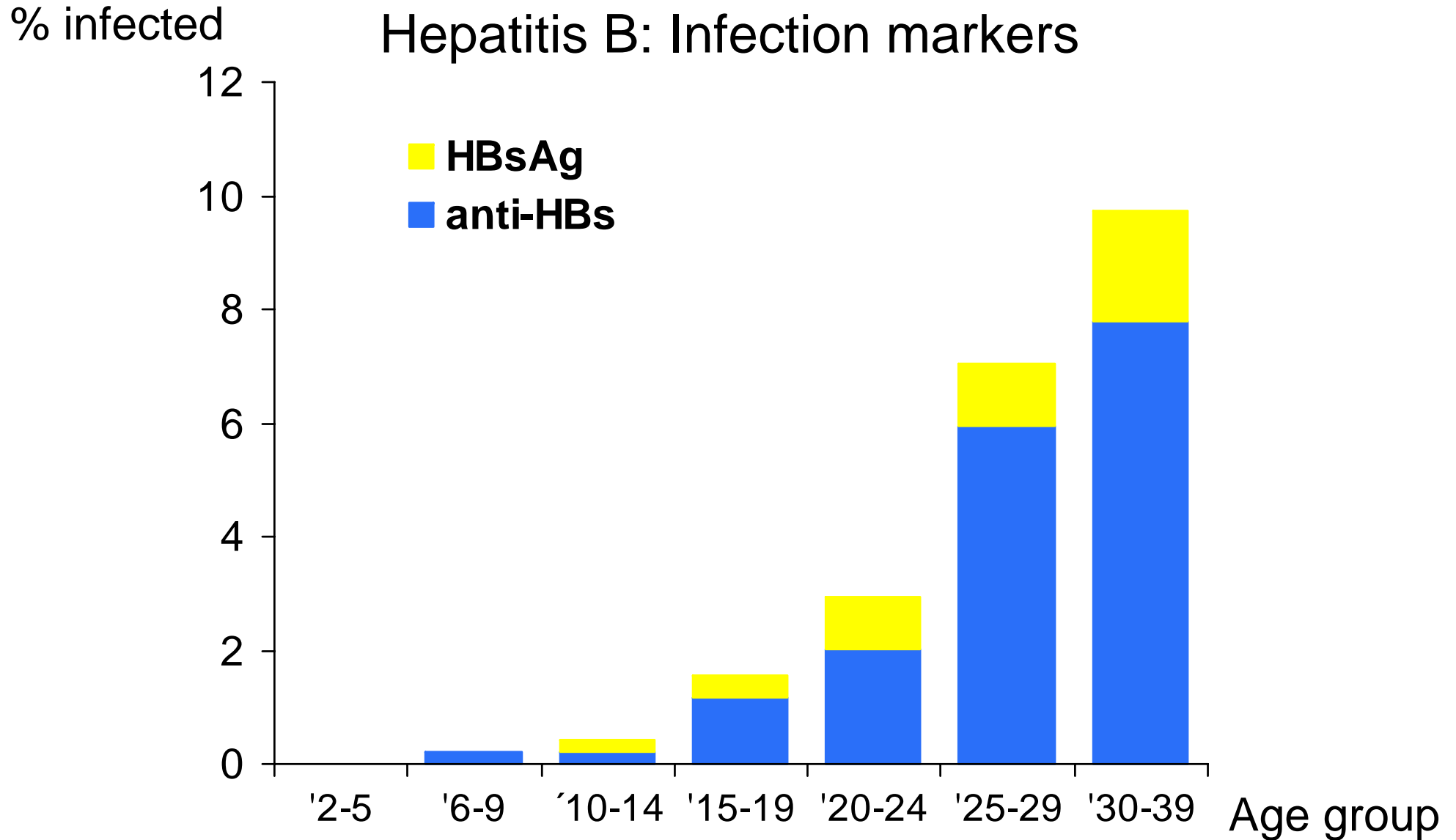
<sup>(d)</sup> Se aconseja proceder a la revacunación cada 10 años.

# National Seroprevalence survey, 1996

## Anti-HBc Prevalence

<b>Age group</b>	<b>Sample size</b>	<b>Prevalence</b>	<b>95%CI</b>
2-5	418	0	0
6-9	439	0,3	0 - 0,9
10-14	481	0,6	0 - 1,7
15-19	513	1,3	0,4 - 2,2
20-24	545	3,7	1,9 - 5,5
25-29	539	7,4	3,6 - 11,3
30-39	564	9,8	6,7 - 12,9

# National Seroprevalence survey, 1996



# Evolution of Hepatitis B vaccination

## **13-1-2003, Agreement of the Inter-Regional Council :**

- All AC include HBV vaccination for newborns, with the following schedule: 0,1,6 months or 2,4,6 months.
- For those children born to chronically infected mothers, schedule will be 0,1,6 months



**CONSEJO INTERTERRITORIAL DEL SISTEMA NACIONAL DE SALUD**  
**CALENDARIO DE VACUNACIONES RECOMENDADO (2006)**  
 Aprobado por el Consejo Interterritorial el 29 de marzo de 2006

VACUNAS	EDAD													
	2 meses	4 meses	6 meses	12 meses	15 meses	18 meses	3 años	4 años	6 años	10 años	11 años	13 años	14 años	16 años
<b>Poliomielitis</b>	VPI1	VPI2	VPI3		VPI4									
<b>Difteria-Tétanos-Pertussis</b>	DTP <sub>1</sub>	DTP <sub>2</sub>	DTP <sub>3</sub>		DTP <sub>4</sub>			DTP <sub>5</sub> o DT					Td	
<b>Haemophilus-influenzae b</b>	Hib1	Hib2	Hib3		Hib4									
<b>Sarampión Rubéola Parotiditis</b>				TV1			TV2 <sup>(a)</sup>							
<b>Hepatitis B</b>	HB3 dosis 0; 1-2; 6 meses									HB3 dosis <sup>(b)</sup>				
<b>Meningitis Meningocócica C</b>	MenC1	MenC2 <sup>(c)</sup>			MenC3 <sup>(d)</sup>									
<b>Varicela</b>										V V Z <sup>(e)</sup>				

<sup>(a)</sup> Niños no vacunados en este rango de edad, recibirán la segunda dosis entre los 11-13 años.

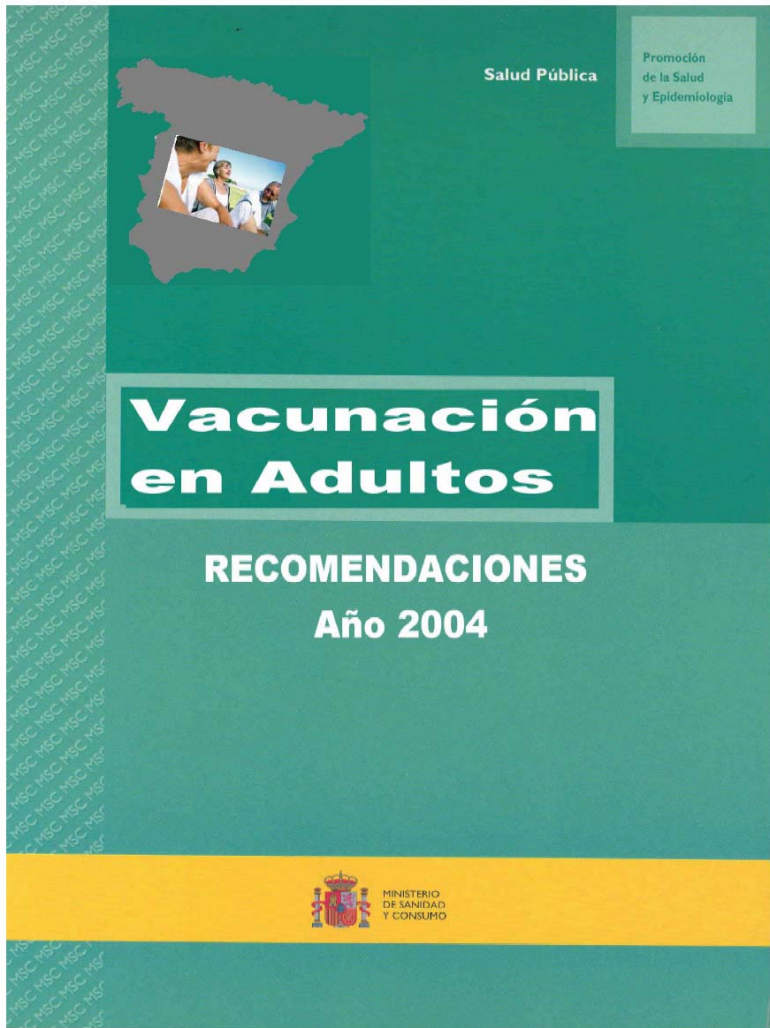
<sup>(b)</sup> Niños que no han recibido la primovacuna en la infancia.

<sup>(c)</sup> Se administrarán dos dosis de vacuna MenC entre los 2 y 6 meses de vida separadas entre sí al menos dos meses.

<sup>(d)</sup> Se recomienda administrar una dosis de recuerdo a partir de los doce meses de vida.

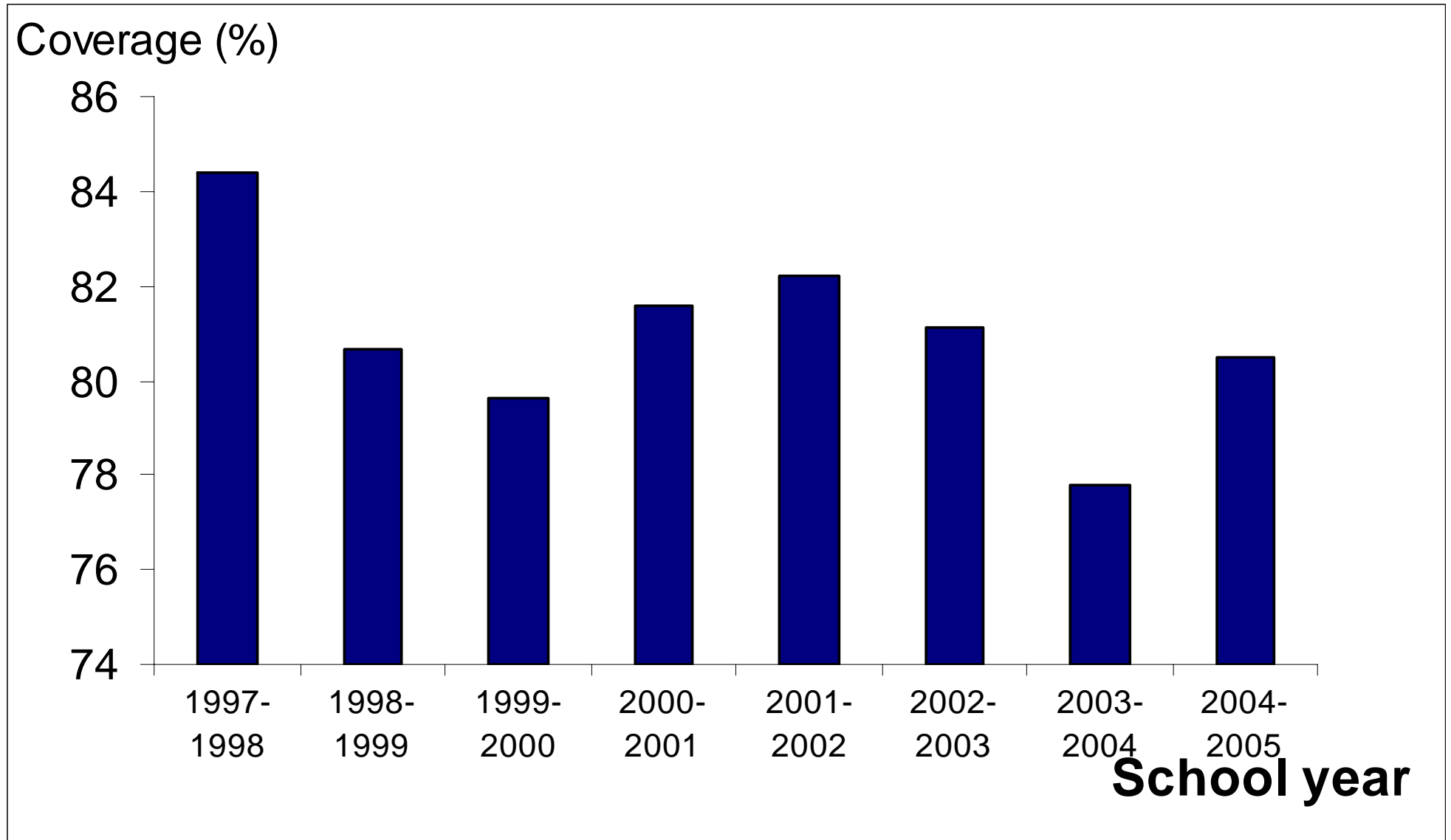
<sup>(e)</sup> Personas que refieran no haber pasado la enfermedad ni haber sido vacunadas con anterioridad, siguiendo indicaciones de la ficha técnica.

# Evolution of Hepatitis B vaccination



- Patients under a Transplantation program
- HIV infected persons
- Persons with a chronic hepatic disease

# Hepatitis B Vaccine Coverage in Adolescents



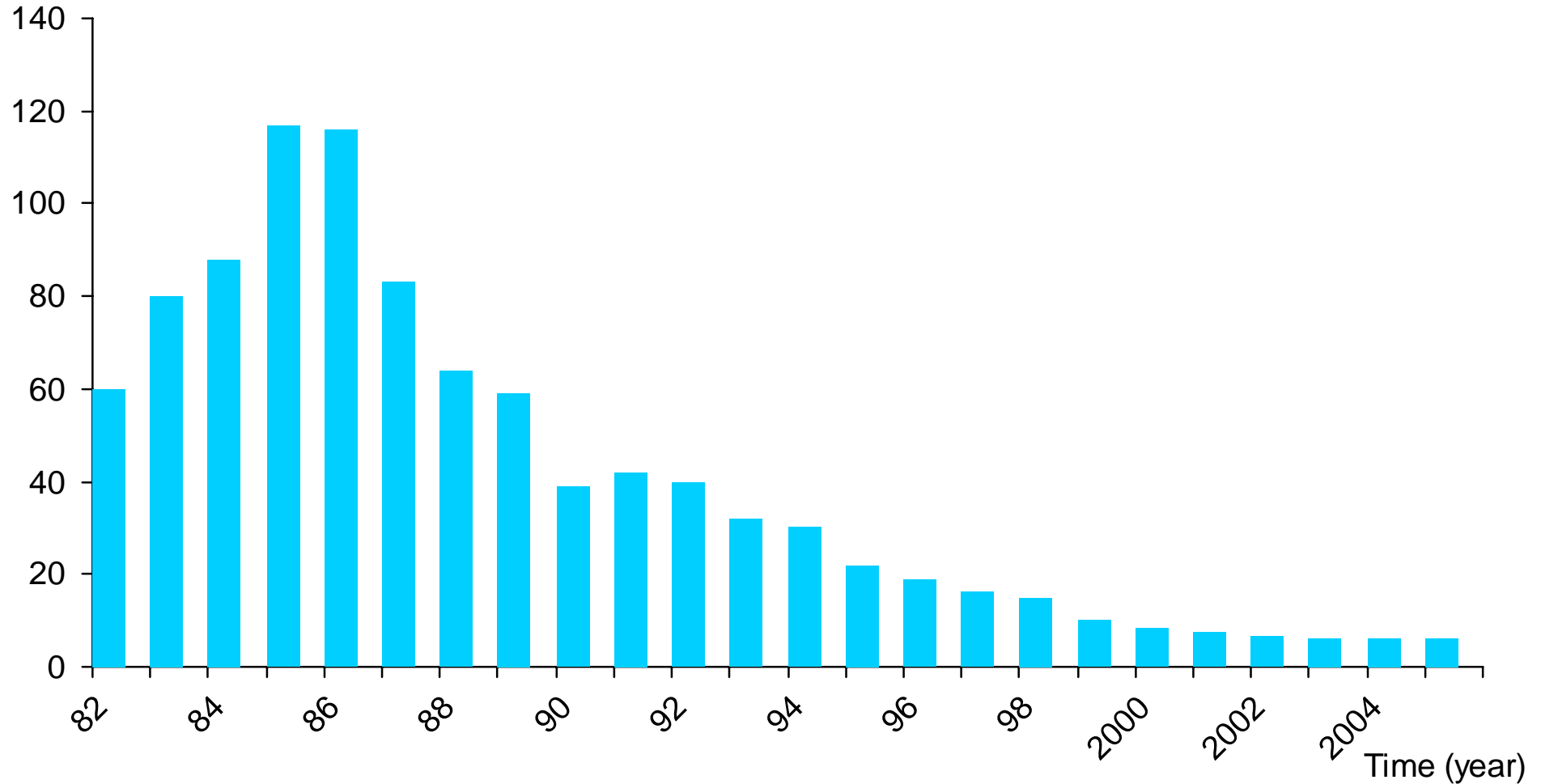
# Hepatitis B Vaccine Coverage, in Children by AC (2003-2005)

COMUNIDADES AUTÓNOMAS	2003	2004	2005
Andalucía	93,8	97,9	92,8
Aragón	97,7	100	100
Asturias	98,3	98,5	97,6
Baleares	96,7	96,4	91,8
Canarias	92,9	94,1	94,1
Cantabria	94,6	92,1	98,1
Castilla La Mancha	95,9	96,9	98,8
Castilla Y León	97,8	98,2	96,9
Cataluña	94,7	98,8	98,6
C. Valenciana	97,6	98,1	96,5
Extremadura	96,2	97,1	94,8
Galicia	96,5	98,7	98,7
Madrid	97,7	96,4	94,4
Murcia	98,4	98,0	99,3
Navarra	94,6	95,7	98,3
País Vasco	96,1	95,3	95,2
Rioja	97,9	96,8	97,4
Ceuta	100	**	**
Melilla	100	98,5	100
<b>TOTAL NACIONAL</b>	<b>97,6</b>	<b>96,9</b>	<b>96,1</b>

# Hepatitis, Spain 1982-2005

Annual incidence (by 100.000 inhab)

Annual incidence

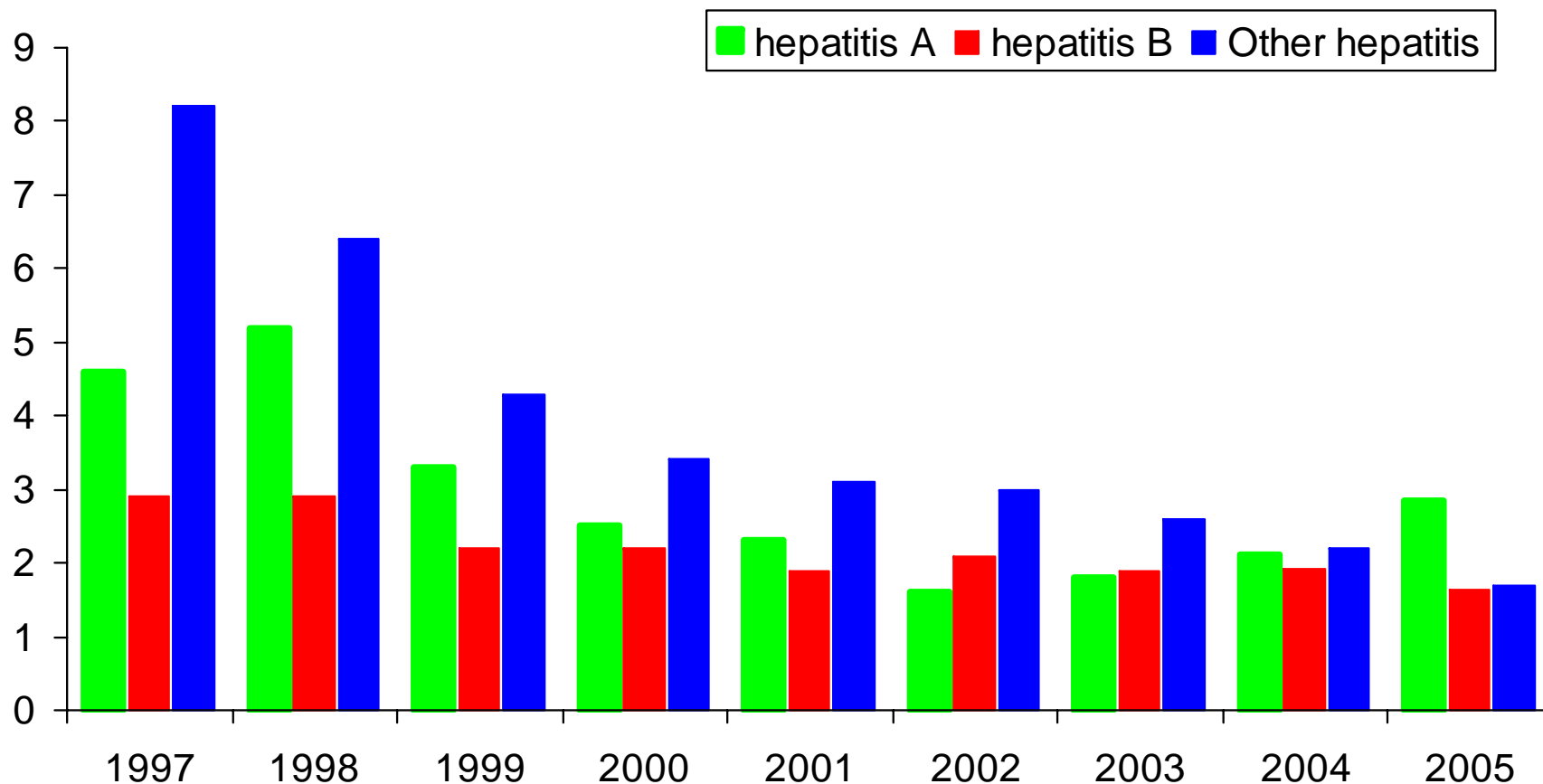


Source: National Centre for Epidemiology

# Hepatitis, Spain 1997-2005

Annual incidence (by 100.000 inhab)

Annual incidence

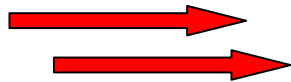


Source: National Centre for Epidemiology

# Hepatitis 2005, by Autonomous Community

Annual incidence (by 100.000 inhab)

	Hepatitis A	Hepatitis B	Otras hepatitis víricas
ANDALUCIA	2,65	1,11	1,49
ARAGON	1,56	3,37	3,63
ASTURIAS	0,49	1,66	2,74
BALEARES	0,79	4,19	3,14
CANARIAS	0,54	1,19	1,37
CANTABRIA	0,57	1,14	0,95
CASTILLA-LA MANCHA	4,85	2,23	1,60
CASTILLA-LEON	3,19	0,94	1,96
CATALUÑA	1,92	1,09	0,98
C.VALENCIANA	4,83	1,90	0,03
EXTREMADURA	5,01	1,91	1,73
GALICIA	0,45	1,52	3,94
MADRID	3,34	2,71	2,45
MURCIA	3,24	1,58	1,49
NAVARRA	3,54	0,75	0,00
PAIS VASCO	4,96	1,40	0,55
LA RIOJA	4,29	0,78	3,12
CEUTA	27,60	1,31	9,20
MELILLA	5,74	0,00	15,78
TOTAL ESTATAL	2,86	1,64	1,69



# Hepatitis A Vaccination



# National Seroprevalence survey, 1996

## Hepatitis A: Immune population by age

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<b>Age group</b>	<b>Sample size</b>	<b>HAV Ab Prevalence</b>	<b>95% CI</b>
2-5	420	1,1	0 - 2,3
6-9	441	4	1,1 - 6,9
10-14	482	4,6	2,7 - 6,6
15-19	515	14,8	9,8 - 19,8
20-24	546	29,1	23 - 33,1
25-29	540	42	36,6 - 47,3
30-39	565	77,3	72,9 - 81,8

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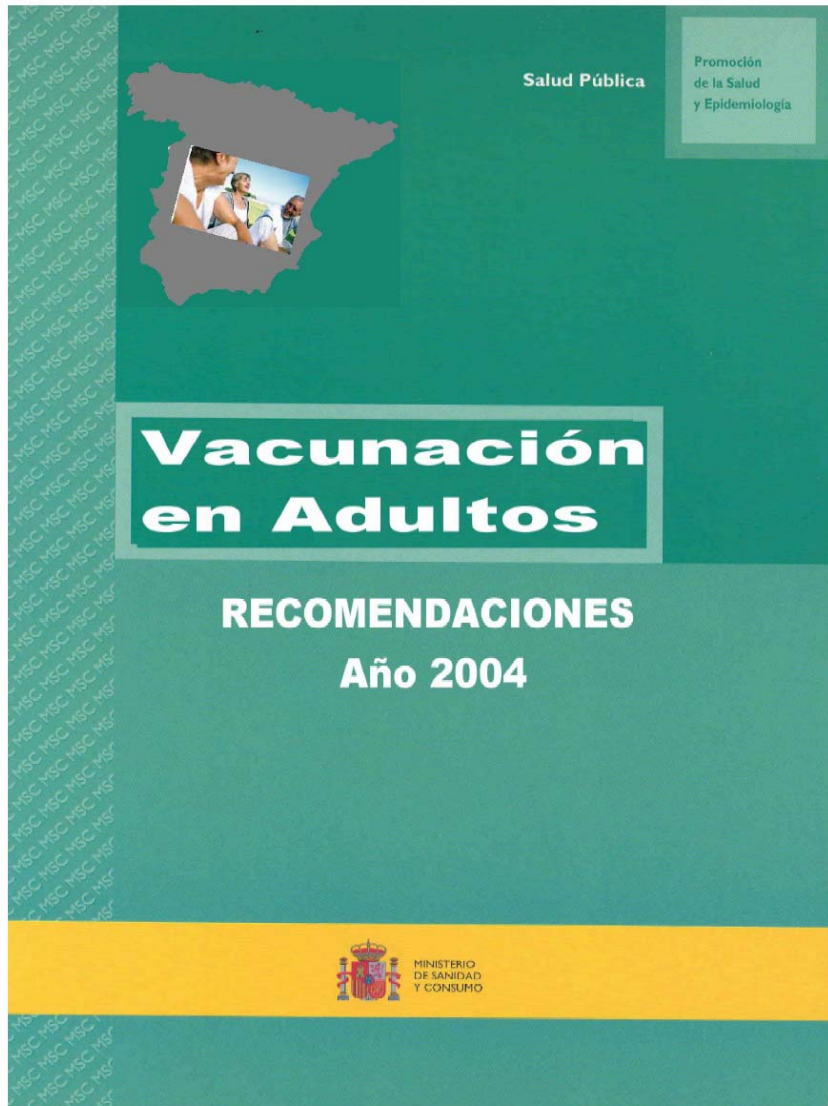
# Evolution of Hepatitis A vaccination

1993: **travelers to endemic areas + hemophiliacs**

1997: Recommendation to vaccinate the **following high risk groups**

- Travelers to areas where Hepatitis A is endemic
- Men who have sex with men and several sexual partners
- Injection drug users
- Household contacts or care givers of persons with Hepatitis A
- Staff with contact with non treated waste water
- Health staff of hospitals and health institutions
- Nurseries Staff
- Hemophiliacs
- Staff who are involved frequently in situations of disasters

# Evolution of Hepatitis A vaccination



2004:

- Staff who prepares food
- Patients under a Transplantation program
- HIV infected persons
- Persons with a chronic hepatic disease

# Evolution of Hepatitis A vaccination

- Routine immunization of children <2y: Ceuta & Melilla
- Pilot experience: Cataluña
  - Vaccination of adolescents (A+B)

# Conclusions

Devolution of Health matters to the AC

National immunization schedule is  
a result of consensus

# Conclusions

- Gradual implementation of hepatitis B vaccination due to:
  - re-structure process (devolution)
  - costs involved in vaccinating two target groups at the same time
  - Changing evidence in relation to the best age group to vaccinate
  - Adolescents' vaccination coverage: may be under estimated
    - method used (schools)
    - already vaccinated as newborns
  - Child vaccination coverage is similar to the coverage for other vaccines included in the primary immunization series

# Conclusions

- Hepatitis A :
  - Recommended to high risk groups
  - Communities with routine immunization: Ceuta and Melilla (epidemiological reasons)
  - Communities with a pilot experience: Cataluña