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Viral Hepatitis Prevention Board

VHPB technical meeting

Viral hepatitis in Europe's Beating Cancer Plan – Prevention and control of viral hepatitis as cancer prevention opportunities

Antwerp, Belgium

27-28 March 2025

The First 30 Years of the Universal Hepatitis-B Vaccination-Program in Italy: A Health Strategy with a Relevant and Favorable Economic Profile

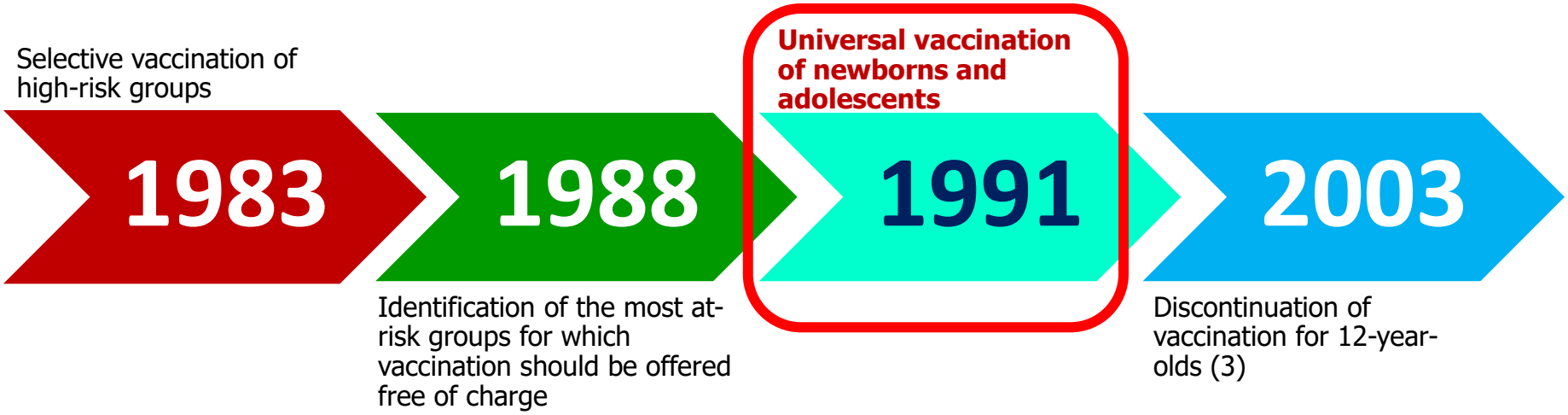
Paolo Bonanni

University of Florence, Italy

UNIVERSITÀ DEGLI STUDI FIRENZE
DSS DIPARTIMENTO DI SCIENZE DELLA SALUTE

HBV vaccination: the Italian strategy (Law 27/05/1991 n.165)

- **Mandatory vaccination of infants** at 3 months - 5 months -11°/12° month (together with other childhood vaccinations)
- **Mandatory vaccination of adolescents** at 12 years (3 doses per month 0, 1, 6)
- **HBsAg screening** in pregnant women
- **Vaccination of newborns** from HBsAg+ mother, at birth (4 doses) (1)
- Free **vaccination for risk groups** (2)



(1) Widely administered on a voluntary basis since 1984-85

(2) Since 1984 in some regions, since 1988 throughout the country

(3) By the end of 2003, the first infant cohort vaccinated in 1991 reached the age (12 years) when adolescent' vaccination takes place. Thus, vaccination of adolescents was stopped.

HBV vaccination coverage in Italy

HBV vaccination coverage in Italy (3 doses at 24 months of age): cohort 1991

The Italian Vaccine Coverage Survey Working Group. Childhood vaccination coverage in Italy: results of a seven-region survey, Bull WHO 1994;72:885–95

Table 3: **Percentage coverage of first and third doses of diphtheria–tetanus, poliovirus, and hepatitis B vaccines, by region, for children aged 12–23 months**[a]

		Campania			Lombardy				
Vaccine[b]	Abruzzi	Naples	Other	Liguria	Milan	Other	Marches	Molise	Tuscany
DT1	99.5 (98.6–100)[c]	98.6 (97.0–100)	99.1 (97.8–100)	99.5 (96.6–100)	100	100	100	100	100
DT3	95.2 (91.1–99.3)	77.1 (71.0–83.2)	87.2 (82.5–91.9)	96.7 (94.1–99.2)	91.0 (85.4–96.6)	94.8 (88.8–100)	98.6 (97.0–100)	95.2 (92.2–98.3)	95.2 (91.6–98.9)
OPV1	99.5 (98.6–100)	98.6 (97.0–100)	98.1 (96.3–99.9)	99.5 (98.6–100)	100	100	100	99.5 (98.6–100)	100
OPV3	97.6 (95.7–99.6)	77.6 (71.5–83.7)	88.2 (83.7–92.6)	96.7 (94.1–99.2)	91.0 (85.4–96.6)	97.6 (95.3–100)	98.6 (97.0–100)	94.3 (90.9–97.7)	95.2 (91.6–98.9)
HBV1	89.2 (80.9–97.4)	84.4 (76.4–92.4)	79.3 (67.5–91.1)	94.0 (88.7–99.3)	96.6 (91.8–100)	99.2 (97.7–100)	95.7 (89.8–100)	82.3 (71.6–93.9)	98.3 (90.7–100)
HBV3	62.5 (51.3–74.8)	62.3 (53.9–70.7)	63.1 (50.4–75.7)	85.9 (78.7–93.2)	79.3 (68.8–89.8)	92.2 (87.9–96.0)	87.1 (78.7–95.6)	68.3 (56.3–80.2)	81.0 (68.3–93.8)

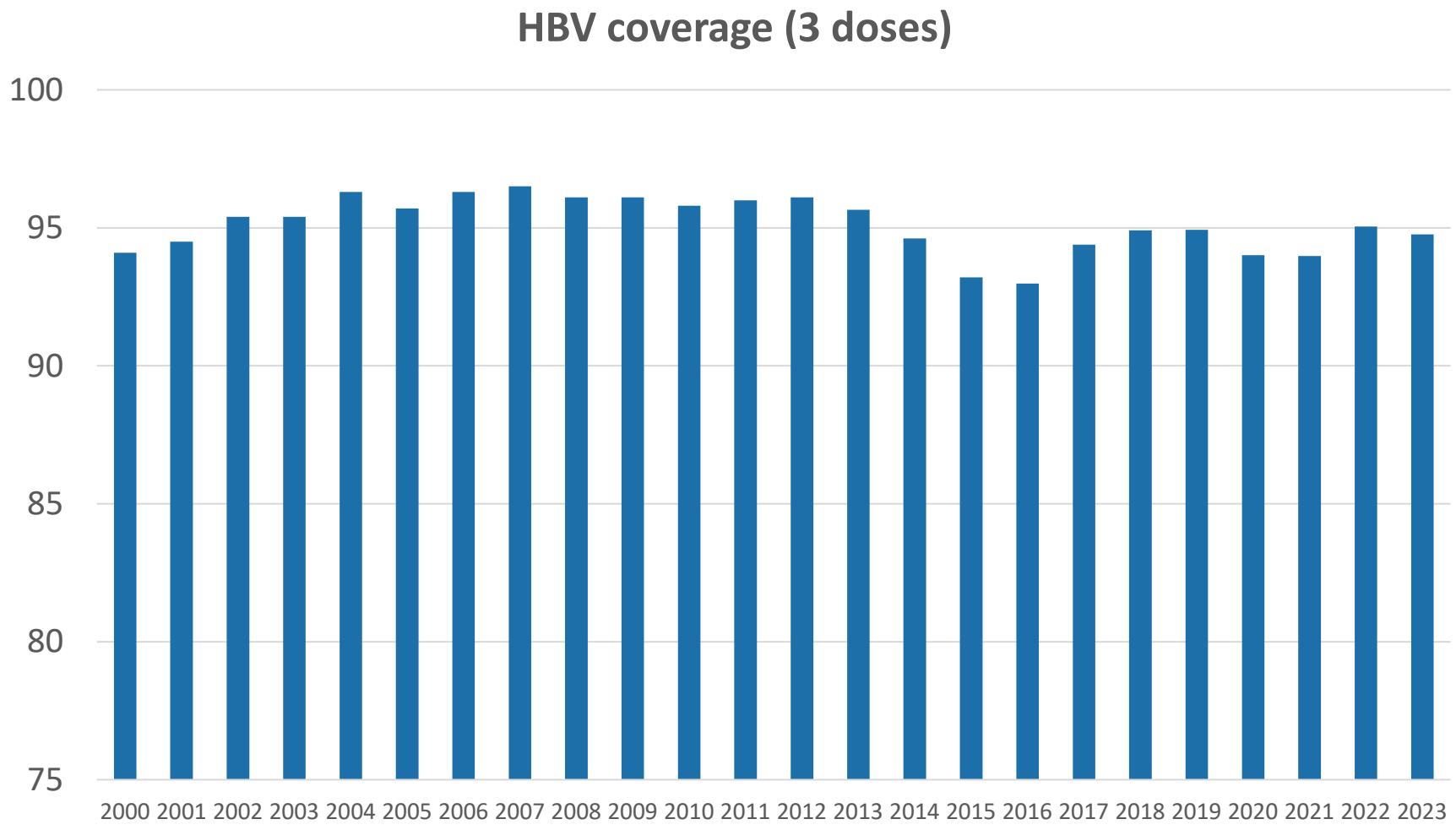
HBV vaccination coverage in Italy (3 doses at 24 months of age): cohort 1996

Salmaso S, Rota MC, Ciofi degli Atti ML, Tozzi AE, Kreidl P. and the ICONA Study Group: infant immunisation coverage in Italy: estimates by simultaneous EPI cluster surveys of regions. Bull WHO 1999;77:843–51

Coverage with three doses of hepatitis B vaccine (95%confidence intervals) at 24 months of age in 20 Italian Regions, 1998 (source: 5)

	Mean (95% CI)
Abruzzo	94.8% (91.4–98.2)
Basilicata	99.1% (97.8–100)
Bolzano	85.6% (80.6–90.7)
Calabria	94.8% (91.7–97.9)
Campania	97.6% (81.3–93.9)
Emilia R.	97.6% (95.7–99.6)
Friuli V.G	97.6% (95.7–99.6)
Liguria	97.6% (95.3–100)
Lombardia	97.6% (95.7–99.6)
Marche	94.8% (90.4–99.1)
Molise	89.1% (82.0–96.3)
Piemonte	98.6% (95.8–100)
Puglia	93.0% (89.1–96.9)
Sardegna	95.2% (92.4–98.0)
Sicilia	91.1% (86.1–96.1)
Toscana	95.2% (92.4–98.0)
Trento	98.1% (96.3–99.9)
Umbria	98.6% (97.0–100)
Val d'Aosta	100
Veneto	97.6% (95.7–99.6)

HBV vaccination coverage in Italy (2000-2023)

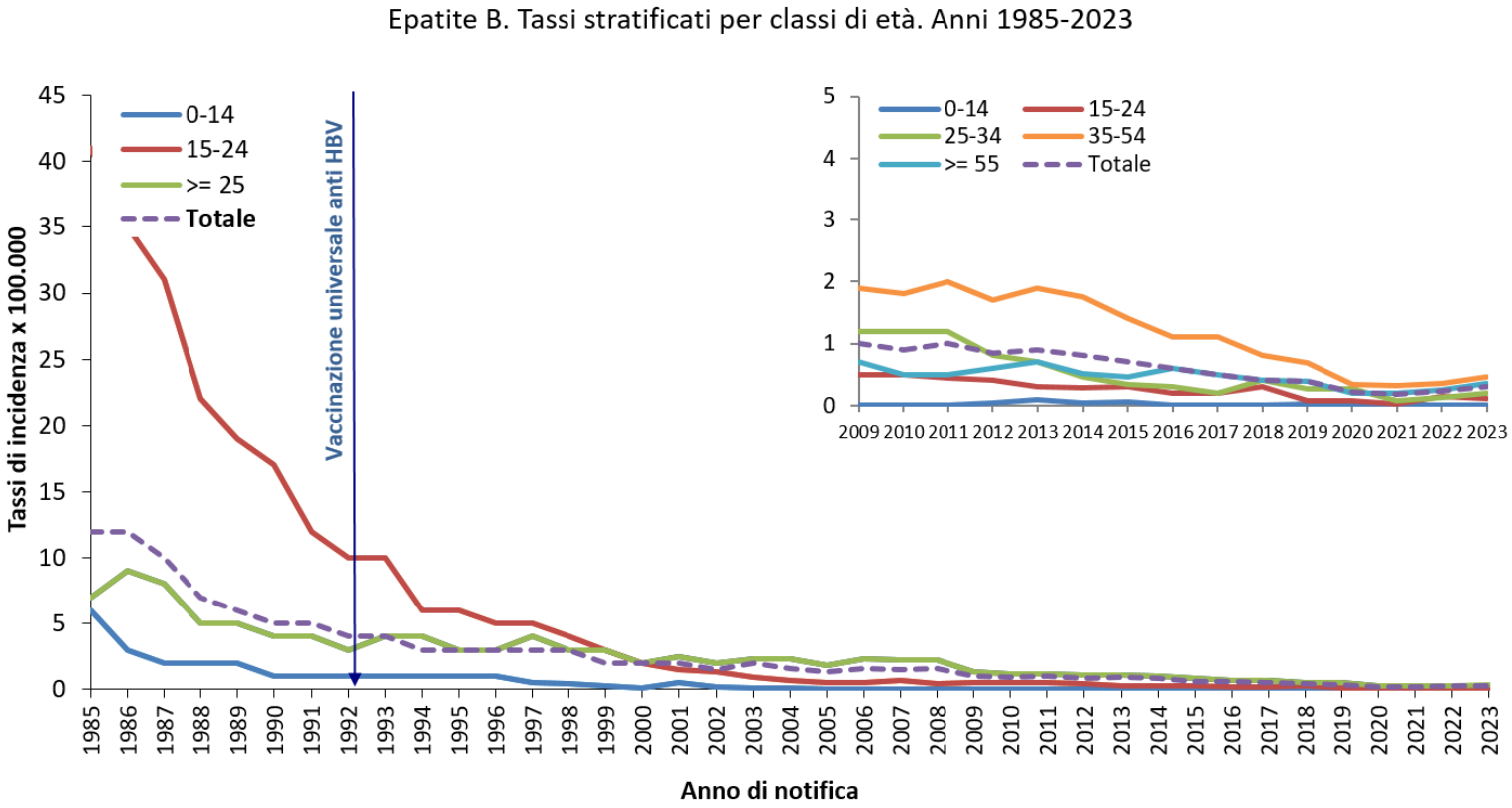


Ministry of Health. Vaccination of children and adolescents – Coverage
https://www.salute.gov.it/portale/documentazione/p6_2_8_1_1.jsp?lingua=italiano&id=38

CLINICAL IMPACT of HB vaccination in Italy

STOP!

Incidence of acute hepatitis B (X 100.000 inhabitants) by age and year of notification (1985-2023) SEIEVA



The incidence rates of hepatitis B have shown a **continuous downward trend** over the years thanks to **improved hygiene conditions and campaigns against HIV infection**. The introduction of mandatory hepatitis B vaccination in 1991 has further consolidated this trend. The most affected age groups have changed over time: adolescents and young adults at higher risk until the 1990s were surpassed by **the adult age group of 35-54 years, not yet fully reached by vaccination**. After the decline in reports, In the two-year pandemic period 2020-2021, incidence rates increased in 2022 and 2023 but did not reach 2019 levels (0.29 x 100,000 in 2023 compared to 0.39 in 2019).

Vaccine 40 (2022) 5542–5543

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/vaccine

Commentary

Beyond 30 years of universal anti-hepatitis B vaccination in Italy: Success and areas of improvement

Luisa Romanò [a,*], Maria Elena Tosti [b], Alessandro R. Zanetti [a]

Data collected from our national Surveillance System for Acute Viral Hepatitis (SEIEVA, Sistema Epidemiologico Integrato dell'Epatite Virale Acuta, Istituto Superiore di Sanità, Roma) have shown, after the implementation of vaccination, a dramatic overall decline in the incidence of acute cases from 5 per 100,000 in 1990 to 0.21 per 100,000 in 2020 [9]. This decline was even more dramatic in 15–24 year old individuals where incidence per 100,000 fell from 17 in 1990 to 0.08, and from 1 to 0 in those aged 0–14 years in the same period of time. Of the total 13,874 HBV cases notified to SEIEVA between 1993 and 2020, full information on the vaccination status was available for 12,532 (90.3 %) patients. Of these, 96.6 % (n = 12.112) resulted unvaccinated and 3.4 % (n = 420) vaccinated. Among the vaccinated, 154 (36.7 %) had received a complete vaccination course according to our nationally recommended schedule (3 pediatric doses given at 3, 5, 11 months to infants; 3 doses given at 0, 1, 6 months to adults) and before exposure to HBV. Thus, according to the SEIEVA data, failure of vaccination to protect vaccinated individuals is a rare event, mostly confined to those who did not complete the vaccination schedule, properly. Among the 12,112 unvaccinated cases, 488 (4 %) escaped mandatory vaccination and 3,429 (28.3 %) were not vaccinated despite they were aware of being at increased risk of infection. Intravenous drug use, cohabitation with HBV carriers, and homosexual/bisexual practices were among the most common risk factors associated with the development of acute hepatitis B. Lack of trust in the vaccination, negative attitude, and inaccurate belief followed by lack or poor communication and low perceived severity of the disease were the most frequent reasons for vaccine hesitancy.

Infection (2019) 47:805–810
https://doi.org/10.1007/s15010-019-01308-3

ORIGINAL PAPER

Decreasing role of HCV and HBV infections as aetiological factors of hepatocellular carcinoma in Italy

Tommaso Stroffolini[1] · Evangelista Sagnelli[2] · Caterina Sagnelli[2] · Filomena Morisco[3] · Sergio Babudieri[4] · Caterina Furlan[1] · Mario Pirisi[5] · Maurizio Russello[6] · Antonina Smedile[7] · Mariantonietta Pisaturo[8] · Piero Luigi Almasio[9]

Received: 14 December 2018 / Accepted: 17 April 2019 / Published online: 26 April 2019

Abstract

Background The epidemiology of hepatocellular carcinoma (HCC) is characterized by a dynamical temporal trend of well-established and emerging risk factors.

Methods We evaluated the temporal trend of aetiological factors of HCC over the last two decades in Italy. HCC cases were recruited from two previously published national studies in 1996 and in 2008 and HCC cases were also enlisted from two national surveys in 2001 and in 2014 enrolling consecutive subjects with chronic liver disease (CLD) referring to more than 80 liver units scattered all over the country for a 6-monthperiod.

Results Out of the 9997 subjects with CLD recruited in 2001 and the 2408 recruited in 2014, 3.3% and 5.7% ($P < 0.001$), respectively, had HCC. The temporal trend of HBsAg −/HCV + HCC cases significantly linearly decreased from 71.1% in 1996 to 57.2% in 2014 ($P < 0.001$). Conversely, that of virus-negative cases significantly linearly increased from 12.1% to 28.3% ($P < 0.001$). The proportion of HBV-related HCC cases showed a steady low rate, reflecting the reduced endemicity of the infection in Italy. The proportion of HCC with compensated cirrhosis (i.e., Child–Pugh A) linearly increased over time from 55.6% in 1996 to 76.0% in 2014 ($P < 0.001$) reflecting the growing effectiveness of semi-annual ultrasound surveillance for early detection of HCC.

Conclusion In conclusion, with decreasing viral aetiology, an overall decrease in the incidence of HCC might be expected in the future. The proportion of metabolic diseases is conversely increasing being considered as an aetiology. The growing prevalence of metabolic disorders in the general population may further increase this trend in the years to come.

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ORIGINAL PAPER

Decreasing role of HCV and HBV infections as aetiological factors of hepatocellular carcinoma in Italy

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Table 2 Temporal trend of characteristics of HCC in Italy

Characteristic	1996 Ref. [15] ($N=1083$)	2001 ($N=328$)	2008 Ref. [15] ($N=1733$)	2014 $N=138$	P value
Mean age (years) (mean ± SD)	64.6 (20–87)	67.8 ± 8.6	68.6 ± 9.5	64.6 ± 13.1	< 0.001
Sex ratio	3.3	1.9	2.8	1.4	< 0.001
Underlying cirrhosis, N (%)	1039/1116 (93.1%)[a]	303 (92.4%)	1648/1729 (95.3%)[b]	121 (87.7%)	0.256
Aetiology, N (%)					
HBsAg pos/anti-HCV neg	125 (11.5%)	40 (12.2%)	230 (13.3%)	18 (13.0%)	0.632
HBsAg neg/anti-HCV pos	771 (71.1%)	234 (71.3%)	1,045 (60.3%)	79 (57.2%)	< 0.001
HBsAg pos/anti-HCV pos	55 (5.3%)	11 (3.4%)	47 (2.7%)	2 (1.4%)	< 0.001
HBsAg neg/anti-HCV neg	132 (12.1%)	43 (13.1%)	411 (23.7%)	39 (28.3%)	< 0.001

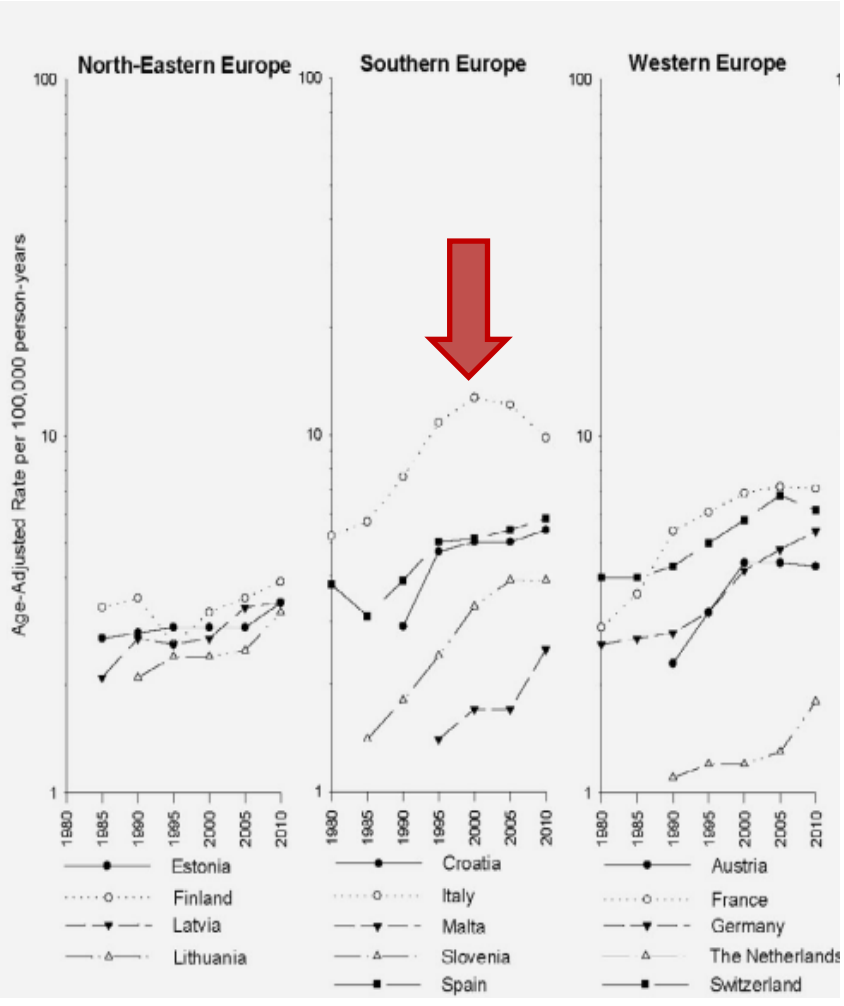
[a]For the other listed variables, information was lacking in 33 cases

[b]For this variable, information was missing in 4 cases

IJC
International Journal of Cancer

International trends in hepatocellular carcinoma incidence, 1978–2012

Jessica L. Petrick[1,2], Andrea A. Florio[1], Ariana Znaor[3], David Ruggieri[4], Mathieu Laversanne[3], Christian S. Alvarez[1], Jacques Ferlay[3], Patricia C. Valery[5], Freddie Bray[3] and Katherine A. McGlynn[1]



Trends in liver cancer incidence rates by country, 1978–1982 through 2008–2012. Rates are per 100,000 person-years and age adjusted to the world standard population.

In Italy, rates have not significantly decreased, but a decline is noted for the most recent time period (2000–2012 APC = –2.6%).

IJC
International Journal of Cancer

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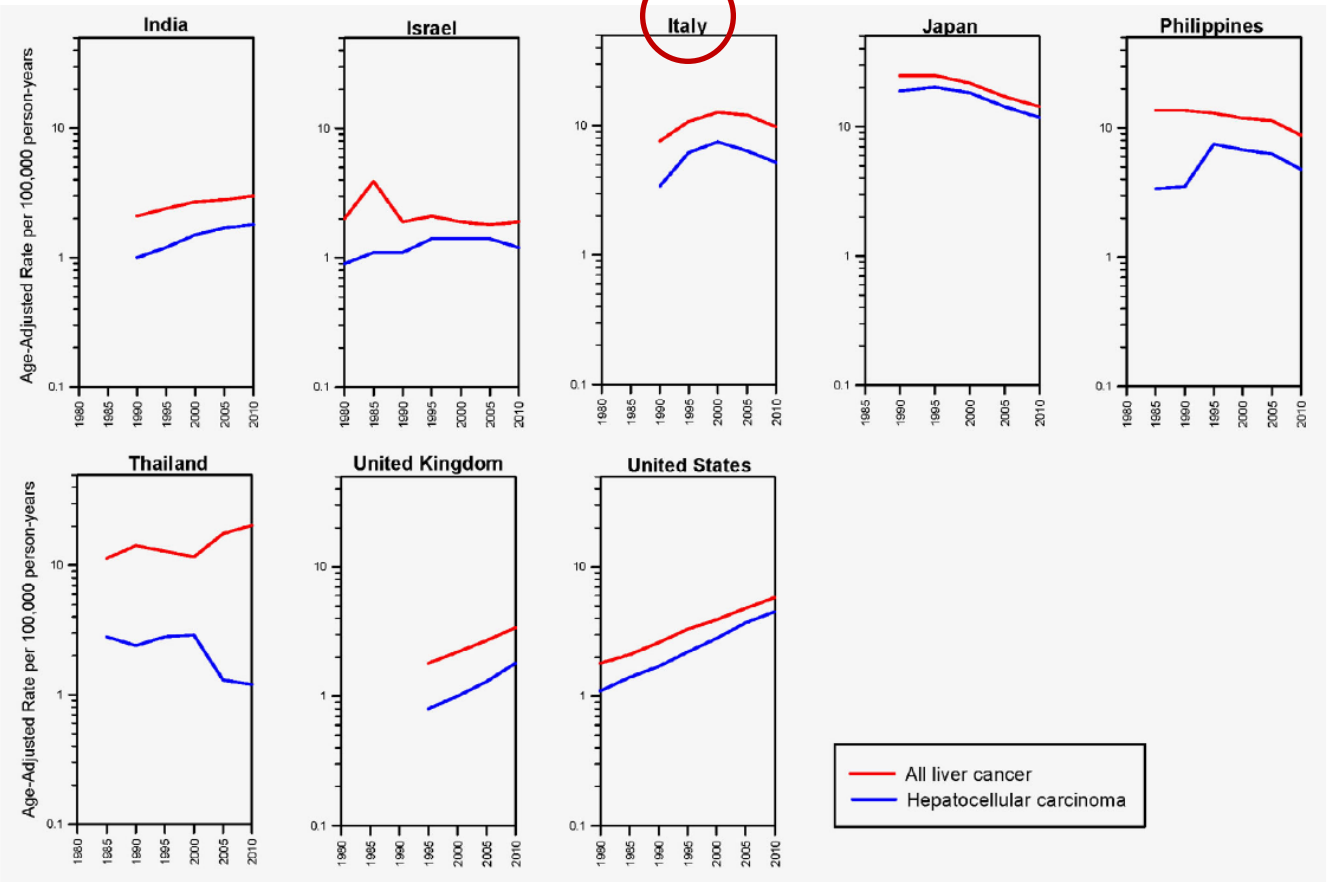
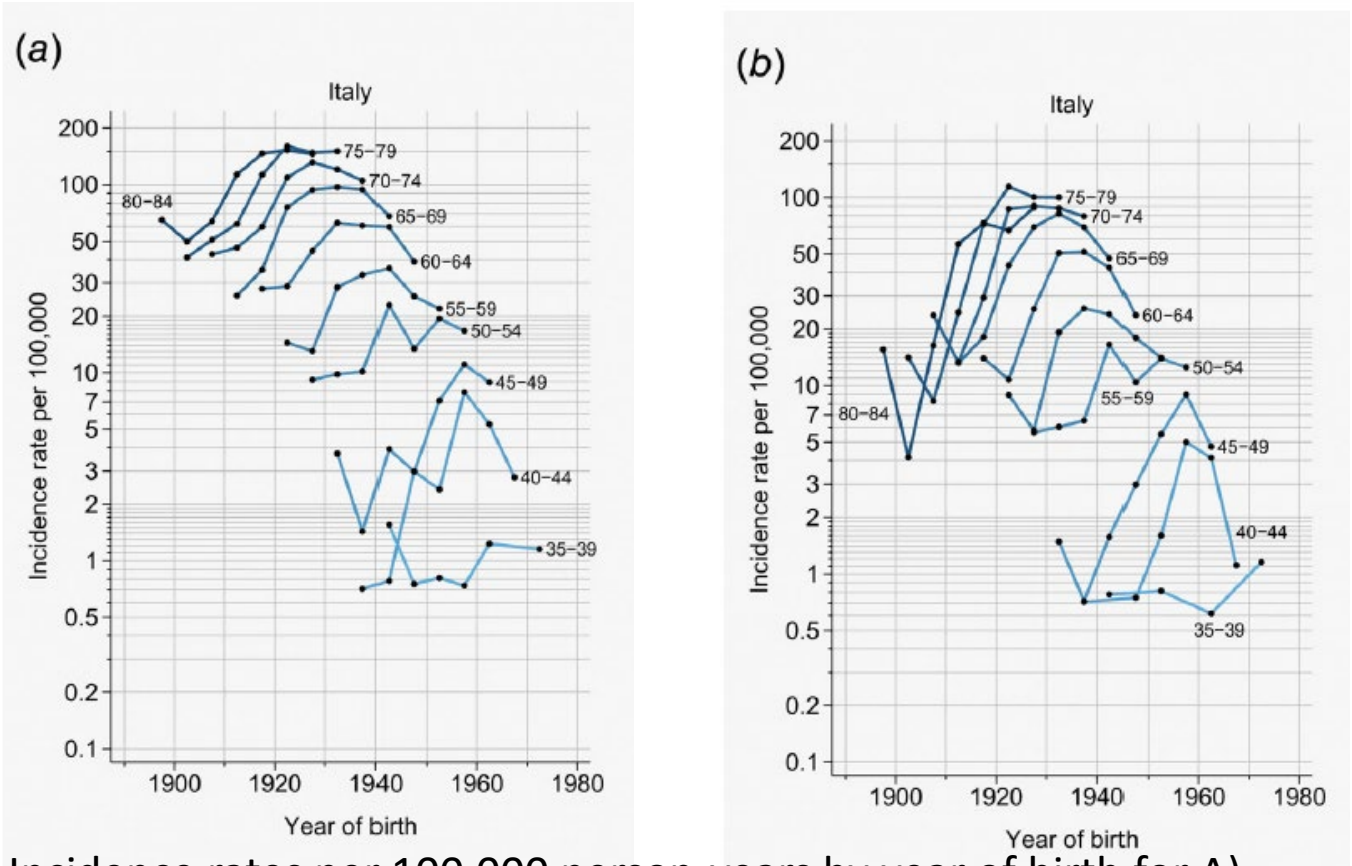


Trends in liver cancer incidence rates by calendar period for primary liver cancer and hepatocellular carcinoma, 1978–2012

IJC
International Journal of Cancer

International trends in hepatocellular carcinoma incidence, 1978–2012

Jessica L. Petrick[1,2], Andrea A. Florio[1], Ariana Znaor[3], David Ruggieri[4], Mathieu Laversanne[3], Christian S. Alvarez[1], Jacques Ferlay[3], Patricia C. Valery[5], Freddie Bray[3] and Katherine A. McGlynn[1]



Rates of HCC generally decreased in younger birth cohorts but began to plateau in the most recent birth cohorts.

Incidence rates per 100,000 person-years by year of birth for A) **primary liver cancer** and B) **hepatocellular carcinoma** from selected countries.

ECONOMIC IMPACT 6 years after implementation (1996)?

ELSEVIER

Vaccine 17 (1999) 1734–1738

Immunization programme against hepatitis B virus infection in Italy: cost-effectiveness

G. Da Villa *, A. Sepe

Italian Institute for Prevention of Liver Diseases, WHO Collaborating Center, Via Generale Orsini, 42, 80132 Naples, Italy

Saving of assistance and social expenditure associated with AVH in Italy from 1991 to 1996

	1985–1990	1991–1996	Saving
No. cases	35,614	17,608	18,006
Assistance cost	400,658,000	198,090,000	202,568,000
Social cost	82,558,000	40,818,000	41,740,000

Thousand USD.

In the light of these preliminary results, the saving of costs due to the fall in AVH cases amounts to 2/3 of expenditure on vaccination. Moreover, observing the incidence trend of new infections in the last few years, we can estimate a progressive further increase in savings. But the main economic goal of vaccination will be reached starting from 2006, after 15 years of immunization, when we will begin to save money in the treatment of cirrhosis and HCC too.

Da Villa, 1999

Economic impact 20 years after the implementation (2010)?

- *Which were the **costs incurred** and **avoided** due to the Italian vaccination strategy in the first 20 years of implementation?*

- *Was it **clinically/economically justified**?*

Economic analysis "ex post"

- **Vaccination program in Italy (1991-2010)**

versus

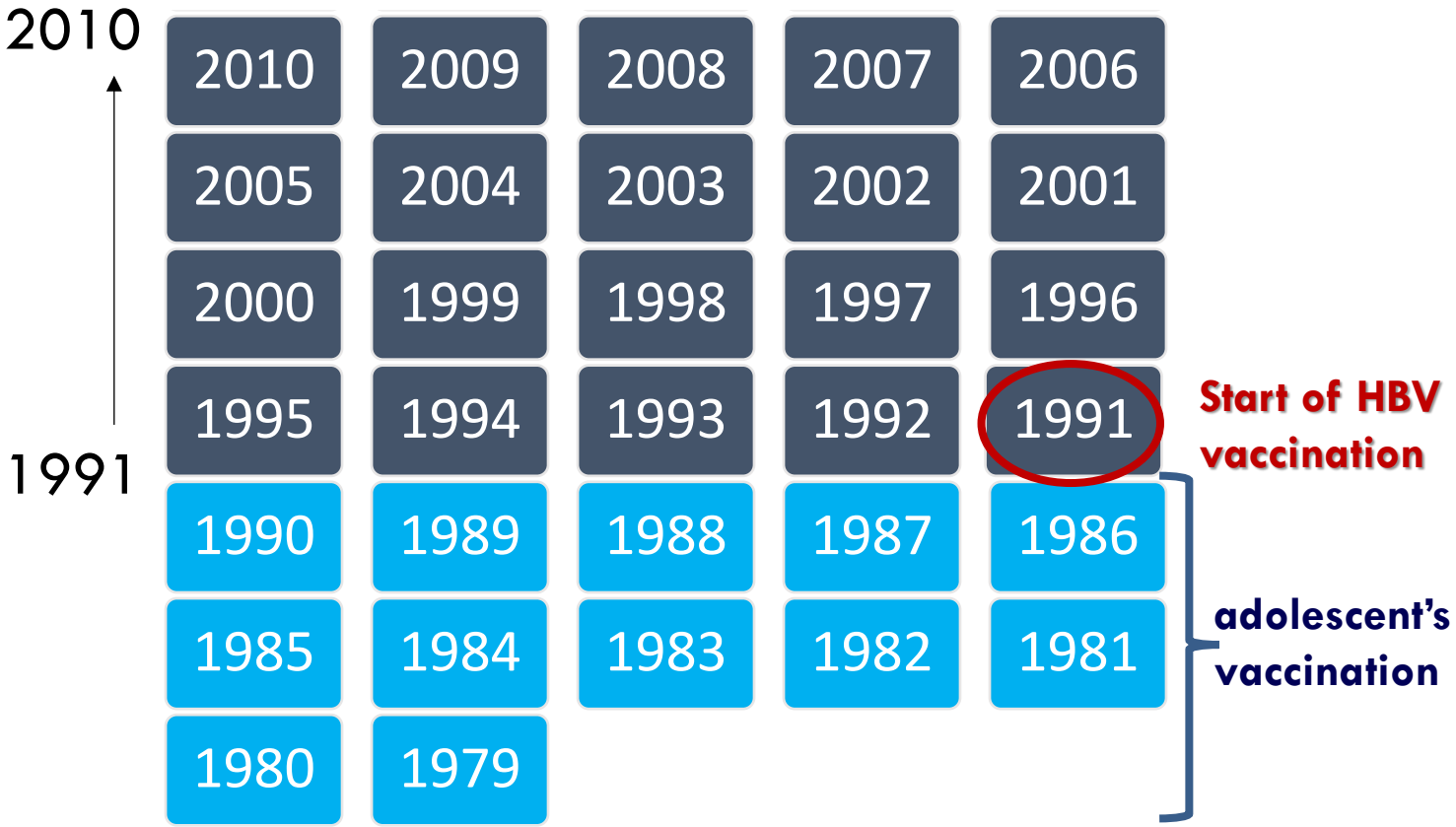
- **No vaccination program (1991-2010):** in the scenarios of slowly decreasing hepatitis B incidence due to some impact of other preventive interventions

Table 5. Methodology for the calculation of the annual number of acute hepatitis B cases, by age group, in the no-vaccination scenario

No-vaccination scenario: slow decrease of acute hepatitis B incidence
0–14 y ***(reduction of incidence mainly due to adoption of preventive interventions other than vaccination)***
75% of calculated cases = same incidence of vaccination period
25% of calculated cases = incidence of 1991
15–24 y
50% of calculated cases = same incidence of vaccination period
50% of calculated cases = incidence of 1991 *(intermediate importance of sexual transmission)*
≥ 25 y
25% of calculated cases = same incidence of vaccination period
75% of calculated cases = incidence of 1991 *(maximal importance of sexual transmission)*

20 years of HBV vaccination:

32 VACCINATED COHORTS



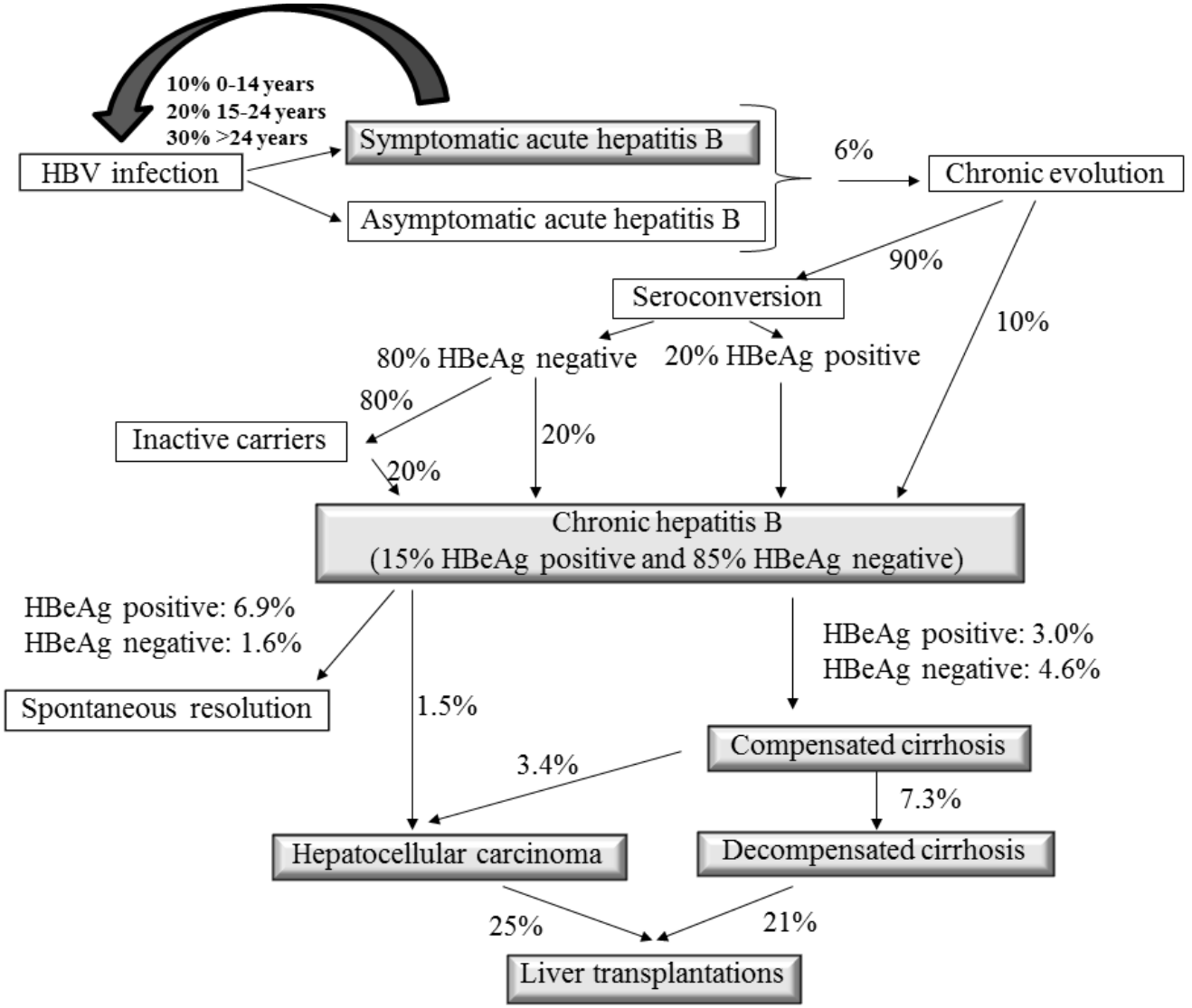
Outcomes

32 vaccinated cohorts in 20 years

- avoided HBV acute cases
- avoided HBV chronic cases that would need a long lifetime treatment (up to 2059, based on patient survival)

…… and related costs

From literature research to reconstruction of the natural history of hepatitis B to develop the mathematical model



RESEARCH PAPER

Human Vaccines & Immunotherapeutics 9:5, 1119–1128; May 2013; © 2013 Landes Bioscience

Economic analysis of the first 20 years of universal hepatitis B vaccination program in Italy

An a posteriori evaluation and forecast of future benefits

Sara Boccalini,[1] Cristina Taddei,[1] Vega Ceccherini,[1] Angela Bechini,[1] Miriam Levi,[1] Dario Bartolozzi[1,2] and Paolo Bonanni[1,*]

Table 1. Total number of clinical cases related to HBV infection in Italy

Clinical Cases	No-vaccination	Vaccination	Avoided cases	% reduction
HBV infection	168,930	42,038	126,892	75
AHB	43,140	28,520	14,621	34
CHB	5,465	1,360	4,105	75
CC	129	59	70	54
DC	9	4	5	54
HCC	86	22	64	74
LT	24	7	17	72

The implementation of the immunization program **reduces largely the overall burden of hepatitis B disease**. Particularly, **the number of HBV infections was decreased by 75%.**

Table 2. Clinical costs during the period 1991–2010, 2011–2059 and 1991–2059 according to NHS and Societal perspective in the no-vaccination and vaccination scenario (continued)

TOTAL COSTS (1991–2059)				
NHS perspective				
	No-vaccination	**Vaccination**	**Avoided costs**	**% reduction**
AHB	572,051,723	362,160,953	209,890,771	37
CHB	2,056,293,355	522,377,222	1,533,916,133	75
CC	37,632,849	17,434,276	20,198,573	54
DC	1,989,007	918,681	1,070,326	54
HCC	70,324,386	19,364,927	50,959,459	72
LT	8,991,040	2,588,844	6,402,196	71
Total	***2,747,282,361***	***924,844,902***	***1,822,437,459***	***66***
Societal perspective				
	No-vaccination	**Vaccination**	**Avoided costs**	**% reduction**
AHB	689,926,159	436,786,229	253,139,930	37
CHB	2,419,376,011	614,614,115	1,804,761,896	75
CC	44,277,735	20,512,671	23,765,064	54
DC	2,340,208	1,080,893	1,259,315	54
HCC	83,324,461	22,953,529	60,370,932	72
LT	10,227,996	2,936,098	7,291,898	71
Total	***3,249,472,570***	***1,098,883,535***	***2,150,589,035***	***66***

Note: costs assessed during 2011–59 are limited to those that acquired HBV during the 1991–2010 period.

The implementation of vaccination against HBV infection compared with the no-vaccination scenario implies a **reduction in clinical costs of 53% during the past period (1991– 2010), 77% during the future period (2011–2059) and 66% in the overall analyzed period**.

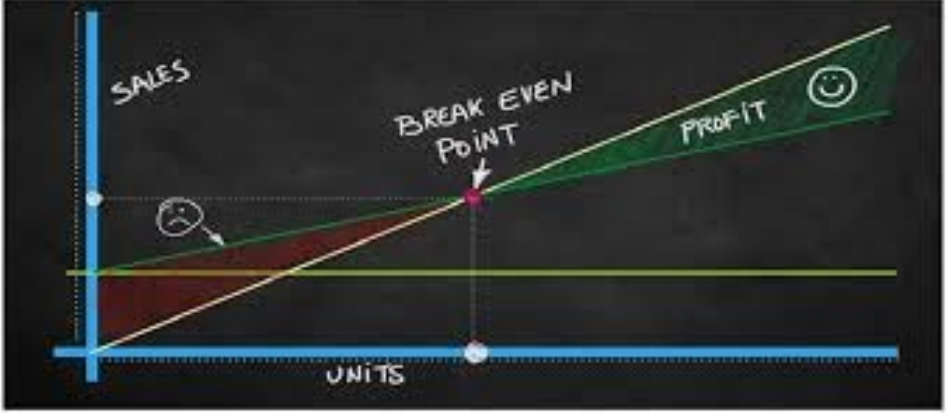
The predominant clinical costs avoided are due to **treatment of prevented chronic hepatitis B cases and acute hepatitis B related costs**.

Return on Investment

Table 3. Savings during the first 20 y of the vaccination program (1991–2010) and overall saving (1991–2059)

Savings during the first 20 y of the vaccination program (1991–2010)		
	NHS perspective	**Societal perspective**
Clinical savings	666,696,195	790,600,281
Vaccination cost	655,675,042	872,002,316
Net costs	*-11,021,153*	*81,402,035*
ROI/BCR	**1.02**	**0.91**
Overall savings (1991–2059)		
	NHS perspective	**Societal perspective**
Clinical savings	1,822,437,459	2,150,589,035
Vaccination cost	655,675,042	872,002,316
Net costs	*-1,166,762,417*	*-1,278,586,719*
ROI/BCR	**2.78**	**2.47**

- Comparing vaccination costs with clinical savings, the immunization program results slightly in savings for the NHS perspective but not for the Societal perspective during the period 1991–2010, with a Return of Investment (ROI) value of **1.02** and **0.91** respectively.
- Instead, the preventive intervention becomes **cost saving in both perspectives during the overall analyzed period** with an overall ROI of **2.78** and **2.47**, respectively, in the long-time horizon.



Break-even point … achieved!

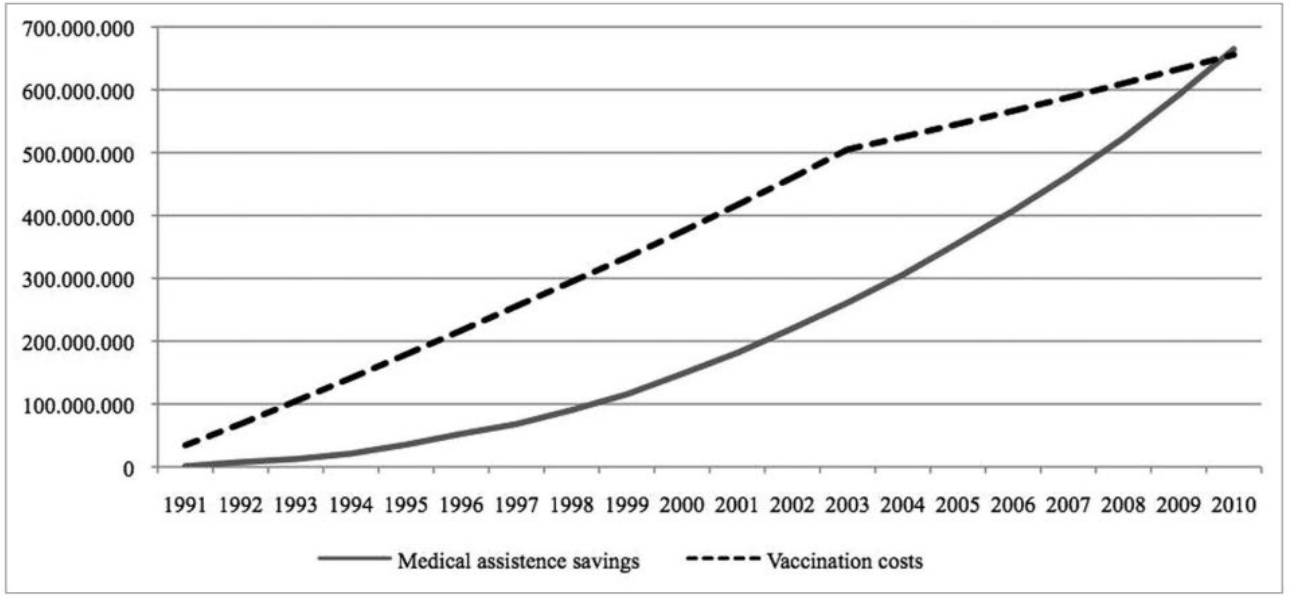


Figure 2. Cumulative clinical savings and vaccination costs in the NHS perspective during the period 1991–2010.

Analyzing the cumulative costs during the period 1991–2010, clinical savings exceeded vaccination costs in **2010** in the NHS perspective, while the break-even occurred in **2012** in the Societal perspective.

Conclusions (at 20 years)

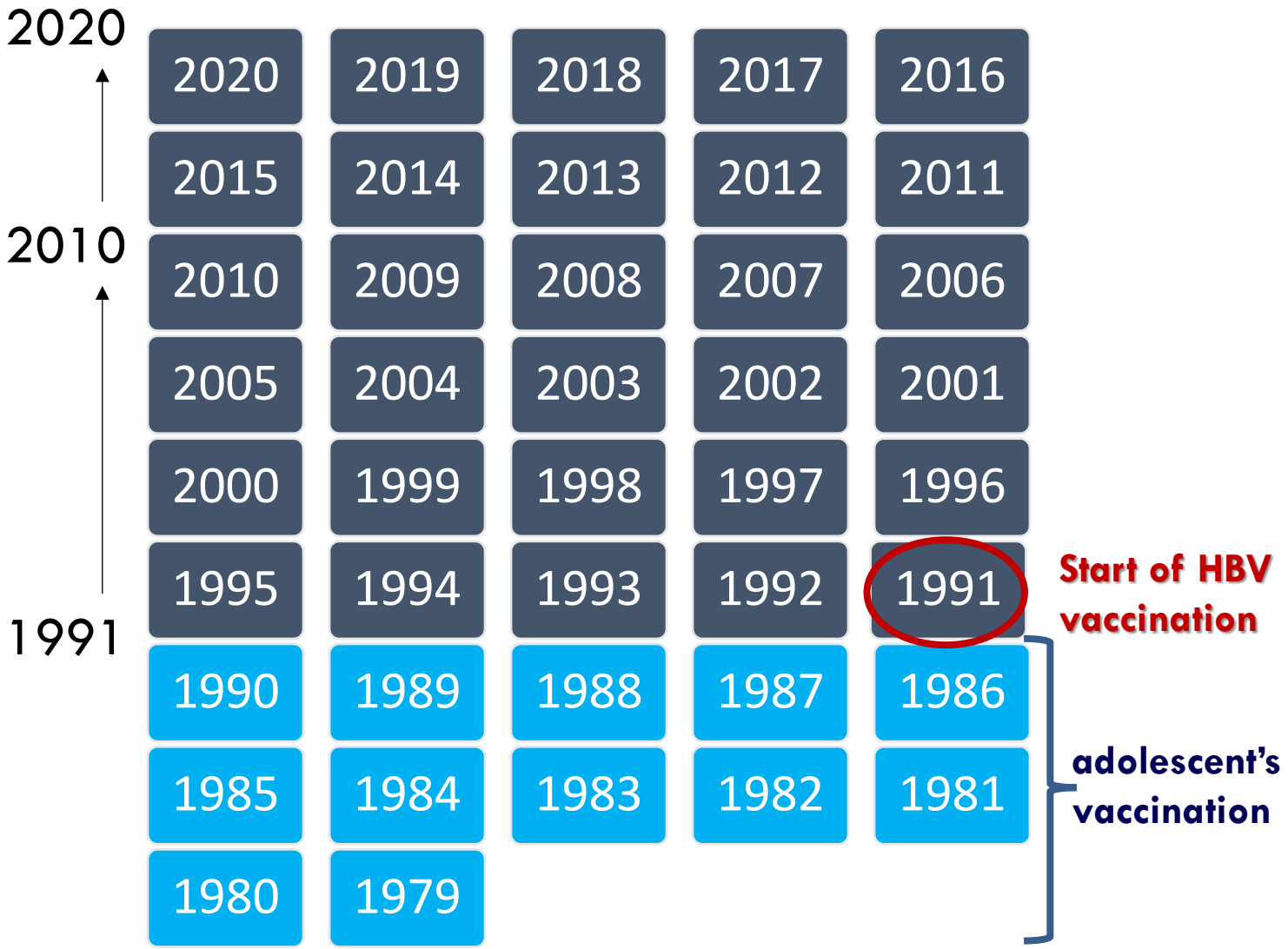
- The introduction of universal hepatitis B vaccination in Italy was **clinically and economically favourable** during the first 20 years of adoption.

- Further clinical and economic benefits for this first period of vaccination will be **increasingly evident in the future** (chronic hepatitis, cirrhosis, hepatocellular carcinoma cases avoided and no longer requiring treatment).

- In the payer perspective, we certainly already reached the **break-even point**, and we are now progressively saving more and more money.

Economic impact 30 years after implementation (2020)

30 years of HBV vaccination:
42 VACCINATED COHORTS



International Journal of
Environmental Research and Public Health

MDPI

Article

The First 30 Years of the Universal Hepatitis-B Vaccination-Program in Italy: A Health Strategy with a Relevant and Favorable Economic-Profile

Sara Boccalini [1,*], Benedetta Bonito [1], Beatrice Zanella [1], Davide Liedl [2], Paolo Bonanni [1] and Angela Bechini [1]

Table 3. Total number of clinical cases related to HBV infection in Italy (AHB: Acute Hepatitis B; CHB: Chronic Hepatitis B; CC: Compensated Cirrhosis; DC: Decompensated Cirrhosis HCC: Hepatocellular carcinoma; LT: Liver Transplantation).

1991–2020	No Vaccination	Vaccination	Prevented Cases	Reduction Rate (%)
HBV infection	237,074	43,701	193,373	82
AHB	61,329	30,931	30,397	50
CHB	7670	1414	6256	82
CC	143	62	81	57
DC	10	4	6	57
HCC	120	23	97	81
LT	32	7	25	79

The first thirty years of the HBV vaccination program in Italy (1991–2020) reported **a marked reduction rate in the different clinical stages of the disease**, compared to a hypothetical no-vaccination scenario (projected till 2070):

- HBV infections and CHB cases showed a reduction rate of 82%,
- the reduction of the health consequences of CHB was also particularly relevant (-81% for HCC, -79% for LT, -57% for CC and DC),
- moreover, the number of AHB cases was halved compared to the already occurring decreasing trend.

Table 5. Costs/Savings (in EUR) and ROI/BCR during the first 30 years of the vaccination program (1991–2020) and in the overall period (1991–2070).

	Period 1991–2020	
	NHS Perspective	Societal Perspective
Clinical savings (EUR)	1,967,370,576	1,967,370,576
Vaccination costs (EUR)	1,263,247,830	1,484,792,906
Net costs (EUR)	−396,494,926	−482,577,670
ROI/BCR	1.31	1.33
	Overall Period 1991–2070	
	NHS Perspective	Societal Perspective
Clinical savings (EUR)	3,462,510,182	4,088,377,071
Vaccination costs (EUR)	1,263,247,830	1,484,792,906
Net costs (EUR)	−2,199,262,351	−2,603,584,165
ROI/BCR	2.74	2.75

- These first thirty years of the HBV immunization-program resulted in a ROI of **1.31** and **1.33** for the NHS and from societal perspectives, respectively, **leading to a relevant cost-saving profile**.
- ROI is predicted to be higher in the whole period 1991–2070 (**2.74** and **2.75**, respectively), implying **net savings** of **EUR 2,199,262,351** from the NHS perspective and EUR **2,603,584,165** from the societal perspective.

Conclusions: an **effective investment** in health value

- The study confirms how the universal hepatitis-B-vaccination-program implemented in Italy , **in addition to the wide reduction of HBV infections and chronic cases**, cut direct and indirect costs in the short- and long-term, **generating savings**, which can **be reinvested in other public-health activities**.

- It should be emphasized that **this universal preventive-program continues to be favorable in Italy**, where **the current incidence of HBV is very low**, and the specific impact of vaccination is therefore paradoxically reduced by the immunization program itself.

Take home messages

- *What key lessons can other countries learn from Italy's universal HBV vaccination strategy?*
  - ***Universal HB vaccination is an effective preventive strategy, with relevant clinical impact***

- *How has vaccination coverage correlated with changes in liver cancer incidence?*
  - ***HB vaccination strategy with high vaccine coverage reduced acute HBV infection but also chronic cases of disease***

- *What has been the economic impact of hepatitis B vaccination in Italy?*
  - ***HB vaccination resulted in an effective investment not only in health, but also in economic value***