



## Vaccine coverage in Italy and assessment of the 2012-2014 National Immunization Prevention Plan

### Coperture vaccinali in Italia e valutazione dell'attuazione del PNPV 2012-2014

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#### Abstract

**Background.** In 2012, the Italian Ministry of Health issued the National Immunization Prevention Plan (*Piano Nazionale Prevenzione Vaccinale*, or PNPV 2012-2014), with the aim of harmonizing immunization strategies across the country and ensuring equitable access to infectious disease prevention to all citizens. The Plan defines the immunization standards all regions should comply with.

**Objective and methods.** As new evidence has accumulated in the field of immunization, and the new National Immunization Prevention Plan is about to be launched, the aim of the current study is to: **i.** present immunization coverage data (2000-2014) for 14 vaccines included in the PNPV to be offered to the general population, **ii.** assess to what extent the PNPV coverage targets and objectives have been met, and **iii.** report on how the PNPV was transposed into regional immunization programs. Data are also available for the eight regions that piloted varicella immunization.

**Results.** The 2012-2014 PNPV first introduced a "lifecourse" approach to vaccination at the institutional level, and has been a milestone for prevention in the Italian health policy agenda. However, infant vaccine coverage rates have been decreasing over the last years, as has influenza immunization in the elderly. HPV vaccine coverage has been increasing for all birth cohorts, but is still far below the targets set in the Plan. Promising preliminary data show that pneumococcal and meningococcal C conjugate vaccines were well introduced in regional immunization schedules.

**Conclusion.** The 2012-2014 PNPV objectives have only been partially met, due to several factors, in particular increase in vaccine hesitancy. Strengthened efforts are needed to promote immunization. The new National Immunization Prevention Plan should introduce new vaccines and extend immunization programs to other target populations on the basis of the most recent scientific evidence available. It is of crucial importance that interventions of proven efficacy be planned and implemented to contrast the growing phenomenon of vaccine hesitancy and ultimately increase immunization uptake.

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**Key words:** vaccine coverage, immunization, immunization programs and policies, National Immunization Prevention Plan, vaccine hesitancy, Italy

#### Riassunto

**Introduzione.** Il Piano Nazionale Prevenzione vaccinale (PNPV 2012-2014) è stato emanato nel 2012 come Intesa in Conferenza Stato-Regioni con l'obiettivo di armonizzare le strategie di immunizzazione in tutto il Paese e di assicurare un accesso equo alla prevenzione delle malattie infettive a tutti i cittadini. Il Piano definisce gli standard di immunizzazione ai quali tutte le Regioni si sono impegnate ad aderire.

**Obiettivo.** A più di tre anni dall'approvazione e nell'imminenza dell'uscita del nuovo Piano, obiettivo del nostro studio è stato quello di: **i.** riassumere i contenuti del PNPV 2012-2014, **ii.** descriverne le declinazioni regionali e **iii.** presentare i più aggiornati dati di copertura (2000-2014), evidenziando gli obiettivi raggiunti e le criticità riscontrate.

**Risultati.** Dall'analisi dei dati raccolti dal Ministero della salute emerge il calo delle coperture in quasi tutte le Regioni per le vaccinazioni dell'infanzia e nella popolazione anziana per quella antinfluenzale; coperture preliminari per le neo-introdotte vaccinazioni antimeningococco C e antipneumococco e per la vaccinazione contro la varicella nelle Regioni che l'hanno introdotta; coperture in aumento per tutte le coorti invitate alla vaccinazione anti-HPV, benché al di sotto dei target stabiliti nel Piano.

**Conclusioni.** I nostri dati sottolineano come gli obiettivi del PNPV 2012-2014 siano stati raggiunti solo parzialmente a causa di

diversi fattori, in particolare l'incremento dell'esitazione sui vaccini. Maggiori sforzi sono necessari per promuovere l'immunizzazione. Il nuovo Piano dovrà considerare i nuovi vaccini e l'estensione dell'offerta di quelli esistenti che già sono stati introdotti in alcune Regioni alla luce delle nuove evidenze scientifiche disponibili. Inoltre, dovranno essere realizzati interventi di informazione e comunicazione di provata efficacia per fronteggiare il fenomeno della esitazione sui vaccini e garantire il raggiungimento degli standard di copertura.

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**Parole chiave:** coperture vaccinali, vaccini, politiche vaccinali Piano Nazionale Prevenzione Vaccinale, vaccine hesitancy, Italia

## BACKGROUND

Immunization programs are key preventive interventions and have largely contributed, over the last century, to reduce the burden of infectious diseases and decrease related morbidity, mortality and healthcare costs.<sup>1-4</sup> International and national health authorities have recently renewed their commitment to promote prevention of vaccine-preventable diseases (VPDs) and strengthen immunization programs. A milestone in the European political agenda for public health, the EU has recently adopted the Council Conclusions on «Vaccinations as an effective tool in public health».<sup>5</sup> Along the same line, the WHO European Region Vaccine Action Plan 2015-2020 (EVAP) – defining immunization priority action areas and targets – calls on countries to implement effective immunization policies and programs.<sup>6</sup>

In Italy, immunization programs are managed within the National Health Service (Servizio sanitario nazionale, or SSN). The SSN provides universal health coverage: the national level sets the health systems' fundamental principles and goals, defines the core benefit package of health services to be guaranteed to all citizens (Livelli essenziali di assistenza, or LEAs), and allocates national funds to the regions. Regions are responsible for planning, financing, and implementing healthcare services.<sup>7</sup> In the field of immunization, this structure translates into each region adopting its own regional immunization plan and schedule.

With the aim of harmonizing immunization strategies between the regions and ensuring to all citizens equity in access to infectious disease prevention, the Ministry of Health issues the National Immunization Prevention Plan (PNPV): a guidance document for immunization policies intended to be of technical support to regions.

The 2012-2014 PNPV was issued by the Ministry of Health in April 2012 after the approval of the State-Regions Conference.<sup>8</sup> It defines the immunization standards all regions should comply with and sets specific objectives to be reached at the national level in terms of target coverage rates, immunization information systems, infectious disease surveillance, quality and safety of immunization programs. The PNPV's crucial points are the following:

- it lists vaccines to be actively offered free of charge to the general population as part of the LEAs and includes them in the National Immunization Schedule (NIS);
- it lists immunization programs for at high-risk subjects and healthcare professionals;
- it makes reference to the need to make vaccines not included in the above-mentioned categories available with co-payment for subjects willing to get immunized.

In accordance with the national health service structure, single regions and autonomous provinces retain the responsibility of implementing and managing immunization programs.

## OBJECTIVE

Since the adoption of the PNPV in 2012, new evidence has accumulated in the field of immunization which has been incorporated in a new and updated Italian National Immunization Prevention Plan about to be launched by the Ministry of Health. Three and a half years after the 2012-2014 PNPV was adopted, and before the new Plan is approved by the State-Regions Conference, the aim of the current study is to:

- present the 2012-2014 legislative process, content, and structure, underlining its most innovative aspects;
- report and analyze how different regions transposed the 2012-2014 PNPV into regional immunization plans and schedules;
- report and analyze the most up-to-date data on vaccine coverage for the immunization programs included in the National Immunization Schedule;
- critically appraise whether 2012-2014 PNPV objectives have been met;
- comment on barriers to effective implementation of immunization programs in Italy that will need to be tackled in the future by the new Plan.

## METHODS

In this paper we present the 2012-2014 PNPV, we list PNPV transpositions into regional immunization plans and programs and we pool and analyze the most up-to-date immunization coverage data for the period 2000-2014.

## Sources of data

Data were provided by the Prevention Directorate-General of the Italian Ministry of Health and from other selected sources, including published papers and reports. We considered the 2000-2014 study period, based on data availability. A detailed list of data sources by year is provided in [Appendix 1](#) (see supplementary material online).

## Analysis

All data retrieved were compiled in a comprehensive database. We present coverage figures by single preventable disease and by vaccine. Based on data availability, we carried out descriptive analysis by region and at the national level. We report on two sets of analyses:

- first, we present current immunization coverage data, ex-

pressed as the most up-to-date coverage rates by preventable disease (cross sectional design analysis);

- then, we present immunization coverage trends over time, expressed as percentage change in vaccine coverage over two different time periods:
- 2000-2014 (the longest study period we can account for, based on data availability);
- 2012-2014 (since the PNPV was adopted).

In both sets of analysis comparisons are made with the vaccine-specific coverage targets established by the 2012-2014 PNPV, to assess whether they have been met, at the regional and national level.

### Outcomes

We focused on immunization programs actively offered to the general population, as defined in the 2012-2014 PNPV. In particular, the following outcomes were considered:

- inactivated poliomyelitis vaccine coverage at 24 months for completed courses – 3 doses (IPV);
- diphtheria, tetanus, and acellular pertussis vaccine coverage at 24 months for completed courses – 3 doses (DTaP);
- diphtheria and tetanus vaccine + diphtheria, tetanus, and acellular pertussis vaccine coverage at 24 months for completed courses – 3 doses (DT-DTaP);
- hepatitis B vaccine coverage at 24 months for completed courses – 3 doses (HepB3);
- *Haemophilus influenzae* type b vaccine coverage at 24 months for completed courses – 1, 2 or 3 doses, based on age (Hib);
- measles, mumps, and rubella vaccine coverage at 24 months / measles, mumps, rubella, and varicella vaccine – first dose (MMR/MMRV);
- measles vaccine + measles, mumps, and rubella vaccine / measles vaccine + measles, mumps, rubella, and varicella vaccine – first dose (M-MMR/M-MMRV);
- pneumococcal conjugate vaccine coverage at 24 months for completed courses – 1, 2 or 3 doses, based on age (PCV);
- meningococcal C conjugate vaccine coverage at 24 months for completed courses – 1, 2 or 3 doses, based on age (MenC);
- influenza vaccine coverage in subjects aged  $\geq 65$  years;
- *Human papillomavirus* vaccine coverage for completed courses and for “at least one dose administered” (HPV);
- varicella vaccine coverage at 24 months – one dose.

## RESULTS

### The 2012-2014 PNPV

The 2012-2014 National Immunization Plan was issued by the Italian Ministry of Health and published on the Ministry of Health website in April 2012<sup>9</sup> after approval of the State-Regions Conference on 22 February 2012<sup>8</sup> and publication in the Italian Official Gazette no. 60, Ordinary Supplement no. 47 on 12 March 2012.<sup>10</sup> The document was issued by the Italian Ministry of Health and composed in close consultation with the High Health Council (Consiglio superiore di sanità, or CSS), experts from the National Institute of Health (Istituto superiore di sanità, or ISS) and the Directorate General for Prevention of the Ministry of Health. The PNPV work-

ing group's methods included comprehensive reviews of the available scientific evidence on vaccines and reference to the most recently updated technical documents of the World Health Organization (WHO) and the European Centre for Disease Control and Prevention (ECDC). The draft was shared with the Italian Medicines Agency (AIFA) and the Interregional Prevention Coordination before final approval by agreement between the government, the regions, and the two autonomous provinces.

General aim of the 2012-2014 PNPV was to harmonize immunization strategies across Italian regions to ensure equity in access to infectious disease prevention to all citizens. Specific objectives were:

- to strengthen infectious disease surveillance systems and serotyping capacity and link them with other SSN and administrative flows;
- to guarantee the active, free-of-charge offer of the immunization programs to the general population included in the National Immunization Schedule (NIS, [table 1](#)) and reach the vaccine coverage targets presented in [table 2](#);
- to guarantee active, free-of-charge offer and promote immunization programs listed in the PNPV for high-risk subjects, healthcare professionals, and hard-to-reach subgroups;
- to implement immunization information systems in the whole country;
- to make vaccines not included in the PNPV available in all local health units in a co-payment regimen for subjects willing to get immunized;
- to plan and implement effective information and communication interventions to promote immunization among healthcare professionals and increase the demand for immunization in the general population.

The 2012-2014 PNPV is structured into eleven main sections. Details on the 2012-2014 PNPV content and structure are presented at page 149 ([box](#)). One of the sections contains the National Immunization Schedule (NIS) ([table 1](#)). Fourteen vaccines are scheduled in the NIS: they are actively offered to the whole population and included in the LEAs.

Previous editions of the PNPV were issued by the Ministry of Health for 1999-2000 and 2005-2007.<sup>11,12</sup> The most innovative aspects of the National Vaccine Schedule as compared to the previous PNPV editions are the following:

- the “lifecourse” approach to immunization with the extension of immunization programs to adults in addition to infant and adolescents;
- the introduction of the pneumococcal conjugate vaccine and meningococcal C conjugate vaccine for infants;
- the planned introduction of the varicella vaccine into the National Immunization Schedule in 2015, after results from regions that piloted its introduction will be available.

### Regional immunization plans

[Appendix 2](#) (see supplementary material online) systematically lists:

- all available legal acts of transposition of the 2012-2014 PNPV at the regional level;

## 2012-2014 PNPV STRUCTURE AND CONTENT

The PNPV is structured into eleven main sections:

- 1. Introduction:** this section outlines the rationale behind the need to have a national guidance document on immunization, namely the need to harmonize immunization offer, policies, and programs between different regions.
- 2. Context:** this section presents the political context in which the 2012-2014 PNPV is grounded; in particular, reference is made to key legal acts and policy documents that preceded the 2012-2014 PNPV and channelled the dialogue between state and regions on prevention.
- 3. The 2012-2014 objectives:** this section outlines the PNPV's general aim and specific objectives (which are presented in detail in the results section).
- 4. Guidelines on how to overcome regional and local differences:** in this section three tools are identified as effective to overcome regional and local differences in immunization program offer, quality standards, and performance: **i)** yearly monitoring of the core benefit package of health services (LEA), **ii)** commitment to meet the 2012-14 PNPV objectives at the regional level, and **iii)** the "solidarity between regions" instrument in its different forms.
- 5. Going beyond compulsory immunization – the conceptual framework:** in this section preliminary arguments are provided regarding legal and administrative pathways, as well as the criteria and requirements needed to go beyond compulsory immunization at the national level (already in place in one Italian region, Veneto).
- 6. Guidelines on how to introduce new vaccines in national and regional immunization schedules:** this section outlines the criteria of efficacy, safety, economic sustainability, and public health prioritization that are needed to support the introduction of new vaccines in the national and regional immunization schedules.
- 7. Guidelines on how to monitor and evaluate immunization programs:** this section presents the main items and associated indicators to be adopted by regions and local health units to monitor and evaluate immunization programs in terms of adequacy, effectiveness, and efficiency.
- 8. National immunization schedule:** this section lists the immunization programs to be actively offered free of charge to the general population in all regions as part of the LEAs and compiled in the National Immunization Schedule (NIS, **table 1**).
- 9. Immunization programs for high-risk subjects:** this section details the immunization programs for high-risk subjects, by vaccine and high-risk subgroup.
- 10. Immunization programs for healthcare professionals:** this section details the immunization programs for healthcare professionals.
- 11. Recommendations for PNPV-implementing technical guidance documents:** this section provides a list of PNPV-implementing technical guidance documents to be issued.

Vaccine	Birth	3 <sup>rd</sup> month	5 <sup>th</sup> month	6 <sup>th</sup> month	11 <sup>th</sup> month	13 <sup>th</sup> month	15 <sup>th</sup> month	5-6 years	11-18 years	>65 years	every 10 years
DTaP <sup>a</sup>		DTaP <sup>a</sup>		DTaP <sup>a</sup>		DTaP <sup>a</sup>		DTaP <sup>a1</sup>	Tdap <sup>d</sup>		Td <sup>h2</sup>
IPV <sup>b</sup>		IPV <sup>b</sup>		IPV <sup>b</sup>		IPV <sup>b</sup>			IPV <sup>b</sup>		
hepatitis B	hepatitis B <sup>3</sup>	hepatitis B		hepatitis B		hepatitis B					
Hib <sup>c</sup>		Hib <sup>c</sup>		Hib <sup>c</sup>		Hib <sup>c</sup>					
MMR <sup>e</sup>							MMR <sup>e</sup>	MMR <sup>e</sup>	MMR <sup>e4</sup>		
PCV <sup>f</sup>		PCV <sup>f</sup>		PCV <sup>f</sup>		PCV <sup>f</sup>					
Men-C <sup>g</sup>							Men-C <sup>g5</sup>		Men-C <sup>g5</sup>		
HPV									HPV <sup>6</sup> (3 doses)		
influenza										influenza	
varicella									varicella <sup>7</sup> (2 doses)		

<sup>1</sup> For children older than 7 years the formulation with diphtheria, tetanus, and acellular pertussis vaccine for adolescents/adults (Tdap) needs to be used.  
<sup>2</sup> Adults with unknown vaccine history need to complete a three dose schedule (Td-Td-Tdap), with the second dose after 4 weeks and the third after 6/12 months. After that, a booster shot every ten years is recommended.  
<sup>3</sup> For children born from HBsAg positive mothers. It has a four-dose schedule: first dose within the first 12-24 hours of life concurrently with specific hepatitis B immunoglobulins, second dose after 4 weeks, third dose after the 8th week of life, fourth between the 11<sup>th</sup> and the 12<sup>th</sup> month of life – even in combination with other vaccinations.  
<sup>4</sup> In case of outbreaks, in addition to catch-up strategies for 11-18 years old subjects, active immunization for susceptible unvaccinated contacts is recommended (mop up strategy).  
<sup>5</sup> Men-C immunization has a one-dose schedule. Administration at 11-18 years old should be considered only in subjects not vaccinated during childhood.  
<sup>6</sup> For 12 year-old girls. Three-dose schedule: at 0, 1 and 6 months for bivalent vaccine (against HPV genotypes 16 and 18) and at 0, 2 and 6 month for quadrivalent vaccine (against HPV genotypes 6, 11, 16, and 18).  
<sup>7</sup> In subjects unvaccinated or with negative history for varicella a two-dose schedule is recommended, with the second dose administered after one month.

<sup>a</sup> diphtheria, tetanus, and acellular pertussis vaccine    <sup>b</sup> inactivated polio vaccine    <sup>c</sup> *Haemophilus influenzae* type b vaccine    <sup>d</sup> diphtheria, tetanus, and acellular pertussis vaccine for adolescents/adults  
<sup>e</sup> measles, mumps, and rubella    <sup>f</sup> pneumococcal conjugate vaccine    <sup>g</sup> meningococcal C conjugate vaccine    <sup>h</sup> diphtheria and tetanus vaccine

**Table 1.** 2012-2014 PNPV National Immunization Schedule (NIS) actively offered to the general population (translated and adapted from ref. 9).

**Tabella 1.** Calendario nazionale delle vaccinazioni offerte attivamente a tutta la popolazione contenuto nel PNPV 2012-2014.

- all available, updated regional immunization prevention plans and schedules adopted in the 19 Italian regions and two autonomous provinces.

For all documents, references to the original documents is provided.

## Immunization coverage rates in Italy

### Immunization for infants

At the national level, polio vaccine coverage in 2014 was 94.7%, the same as for diphtheria. Tetanus vaccine coverage was 94.8%, hepatitis B and pertussis vaccines coverages were 94.6% and Hib vaccine coverage was 94.2%; none of the vaccines reached the 95% coverage target set by the PNPV (figure 1A-F).

At the regional level, 11 regions met the 95% PNPV coverage target for tetanus, 10 regions met the 95% PNPV coverage target for polio and diphtheria, and 9 regions met the 95% PNPV coverage target for hepatitis B and Hib. Regional vaccine coverage ranged from 88% (in particular: 88.5% for polio and tetanus vaccines, 88.4% for diphtheria and pertussis vaccines, 88.0% for hepatitis B vaccine, and 88.7% for Hib vaccine) to 98.8% (figure 1A-F).

In the 2012-2014 period (from PNPV approval in 2012 until the most recent data available) national vaccine coverage decreased for all the above-mentioned immunization programs (figure 2A-C); the percentage decrease was highest for the hepatitis B vaccine (-1.7%) and lowest for Hib (-1.0%). The 2012-2014 percentage change in vaccine coverage at the regional level is reported in Appendix 3A-F (see supplementary material online): for all six vaccines, we report decreasing trends in almost all regions.

When considering the entire 2000-2014 study period, polio vaccine coverage decreased by 2%, diphtheria vaccine coverage by 0.7%, and tetanus vaccine coverage by 0.6%. On the contrary, pertussis vaccine coverage increased by 8.4%, hepatitis B vaccine by 0.5%, and Hib vaccine by 72% (please note that the latter was first introduced into the routine immunization programs in 1999). Figures by region are reported in Appendix 4A-F (available online).

Measles, mumps, and rubella vaccine coverage in Italy in 2014 was 86.6% (figure 1G-I). None of the regions met the 95% coverage target rates set in the PNPV; all but two Regions reached coverage rates greater than 80% for the three vaccines, regional-level range being 68.8% to 90%.

In the 2012-2014 study period, measles vaccine coverage in Italy decreased by 3.7%, with decreasing trends reported in all but one region. In 11 regions, the percentage decrease was greater than 5% (Appendix 3G-I, available online). A similar pattern was observed for mumps and rubella vaccine coverage, for which national level coverage rates decreased by 3% and 2.9% from 2012, with decreasing trends in all but one region, and a percentage decrease that was greater than 5% in 10 regions.

For the measles, mumps, and rubella vaccines altogether, coverage increased as compared to 2000: +16.8% for mumps and rubella and +12.7% for measles (2001-2014). Regional percentage changes in vaccine coverage between 2000 and 2014 are presented in Appendix 4G-I (available online).

Pneumococcal conjugate vaccine coverage at the national level was 87.3% in 2014. Only one region (Basilicata) met the 95% PNPV coverage rate target, nine regions reported coverage rates greater than 90% while – on the other extreme – two regions reported coverage rates lower than 80%. The overall regional range in 2014 was 76.6% to 98.5% (figure 1L).

Overall, pneumococcal conjugate vaccine coverage in Italy decreased by 0.4% in the 2012-2014 study period. Regional patterns are reported in Appendix 5A (available online). Two regions reported opposite peak percentage changes between 2012 and 2014: +68.5% in Abruzzo and -29% in Sardinia. Data on coverage rates earlier than 2012 are scant: they are only available from 2007 and for few regions (Appendix 5B, available online): six regions reported an increase in vaccine coverage greater than 100% since 2007.

Meningococcal C conjugate vaccine coverage rates are only available for the years 2013 and 2014: the most recent figures report an overall national vaccine coverage of 74.9%. No region met the PNPV's 95% coverage target, nine regions reported vaccine coverage rates exceeding 80%, with a regional

Vaccine	Target population	Coverage target
DTaP <sup>a</sup> , IPV <sup>b</sup> , hepatitis B, Hib <sup>c</sup>	newborns	≥95% completed courses (3 doses)
Tdap <sup>d</sup>	adolescents (age range: 11-18 years)	≥90% (1 dose)
MMR <sup>e</sup>	within 2 years of age	≥95% (1 dose)
MMR <sup>e</sup>	age groups: 4-5 and 11-18 years	≥95% (2 doses)
influenza	age group: >65 years	≥75% (minimum) ≥95% (optimal)
PCV <sup>f</sup>	newborns	≥95% completed courses (1, 2, or 3 doses, based on age)
Men-C <sup>g</sup>	newborns and adolescents (age range: 11-18 years)	≥95% completed courses (1, 2, or 3 doses, based on age)
HPV	age group: 12-year-old girls	≥70% completed courses (from 2001 birth cohort) ≥80% completed courses (from 2002 birth cohort) ≥95% completed courses (from 2003 birth cohort)
rubella	child-bearing age women	≤5% of susceptible women

<sup>a</sup> diphtheria, tetanus, and acellular pertussis vaccine  
<sup>b</sup> inactivated polio vaccine  
<sup>c</sup> *Haemophilus influenzae* type b vaccine  
<sup>d</sup> diphtheria, tetanus, and acellular pertussis vaccine for adolescents/adults  
<sup>e</sup> measles, mumps, and rubella  
<sup>f</sup> pneumococcal conjugate vaccine  
<sup>g</sup> meningococcal C conjugate vaccine

Table 2. Immunization program's vaccine coverage; targets set in the 2012-2014 PNPV. / Tabella 2. Target di copertura vaccinale stabiliti nel PNPV 2012-2014

range comprised between 42.7% (Campania) and 88.3% (Emilia-Romagna) (figure 1M).

Varicella immunization coverage rates are reported for the year 2014 in the regions that piloted varicella universal immunization program<sup>14</sup> and are shown in figure 3. They vary between 51.1% in Calabria and 84.2% in Veneto. Detailed data on varicella immunization programs in selected regions since its introduction are provided by the Interregional Group on Varicella Vaccination (IGVV).<sup>13</sup>

### Immunization for adolescents

Figure 4 reports national HPV vaccine coverage rates by birth cohort, as reported in the most recent 2014 update of the National Institute of Health.<sup>14</sup> At the national level, coverage rates for completed courses in 11-year old girls were 70.8% for the 1997 birth cohort, 70.9% for the 1998 birth cohort, 72.1% for the 1999 birth cohort, and 71.1% for the 2000 birth cohort. Coverage rates by region are reported in Appendix 6A-D (available online). Data for “at least one administered dose” by region are also available by birth cohort for the same study period and show similar patterns over time (Appendix 7A-F, available online). On average, 4% of girls did not complete the whole HPV immunization course. Regional data show large heterogeneity, with completed vaccine courses of 27%-86% in the 1997 birth cohort, 27%-84% in the 1998 birth cohort, 28%-82% in the 1999 birth cohort, and 31%-82% in the 2000 birth cohort.

For the 2001 and 2002 birth cohorts – for which the offer has not yet been completed in all regions – overall coverage rates were 67% and 52.4%, respectively. However, data from the two latter birth cohorts cannot be considered definitive. The 70% PNPV coverage rate target for the 2001 birth cohort was met in 9 regions, while no region has yet met the 80% coverage target for the 2002 birth cohort (Appendix 6E-F, available online).

### Immunization for the elderly

In the last (2014-15) influenza season, national influenza vaccine coverage in subjects aged  $\geq 65$  was 48.6% – the lowest reported since the 2000-2001 season (figure 5A).

At the regional level, vaccination coverage equal or exceeding 50% was reported in six regions, but no region met the minimum (75%) or optimal (95%) coverage targets set in the 2012-2014 PNPV. The highest rates were reported in Umbria (61.8%) and Veneto (53.4%), the lowest in the autonomous province of Bolzano (36.6%) and in Abruzzo (38.5%).

Although we report an overall 17% increase in vaccine coverage as compared to the 1999-2000 influenza season (figure 5B and Appendix 8B), since 2011-2012, influenza vaccine coverage in Italy has decreased by 22% (Appendix 8A). The decreasing trend observed at the national level is consistently mirrored in all regions, with reductions exceeding 25% in 7 regions.

## DISCUSSION

Overall, the 2012-2014 PNPV has been a milestone for prevention in the Italian health policy agenda for a number of reasons:

- in the ongoing epidemiologic transition and changing demographic structure, it introduced for the first time at the institutional level a “lifecourse” approach to vaccination;
- it provided technical guidance for regions to prepare and implement regional immunization plans;
- it provided ground for fruitful debate and consultation between the Ministry of Health, its technical agencies, and others stakeholders;
- it raised awareness about the need to harmonize immunization policies across the country, and, more importantly:
- it greatly contributed to disseminate the culture of immunization among national and local health authorities, as well as the general public.

Three and a half years after the adoption of the 2012-2014 PNPV we present a comprehensive overview of vaccine coverage rates in Italy, focusing on infant, adolescent, and adult immunization programs included in the National Immunization Schedule. Overall, in Italy, apart from a few exceptions, coverage rates have been decreasing since 2012 and, to date, are still below the targets established in the Plan. We report a high degree of heterogeneity between the various Italian regions and vaccines.

With regard to infant immunization (polio, TDP, hepatitis B and Hib), nearly one third of Italian regions reached the 95% coverage target set in the Plan. However, in other regions, coverage remained under 90% for compulsory vaccines. The recent decreasing trends reported at the national level are mirrored in virtually all regions. Scant data are available on the two vaccines included in the National Immunization Schedule for the first time in 2012: the pneumococcal and meningococcal C conjugate vaccines. Preliminary data suggest that – although far from meeting PNPV targets – both vaccines were well introduced in infant immunization schedules, reaching, respectively, over 87% and 74% coverage at the national level. In addition, promising trends are reported for the conjugate pneumococcal vaccine.<sup>15</sup> Its coverage rates have increased since 2007 in all regions for which we have data. HPV vaccine coverage is below the target but has been increasing for all birth cohorts invited so far, showing a relatively successful catching up of unvaccinated girls. Influenza vaccine uptake is low in the elderly and has been decreasing over the last years, with a dramatic decreasing peak reported in the last flu season, likely to be associated to the «Fluad case».<sup>16</sup>

We systematically recorded PNPV transpositions at the regional level and referenced all available Regional Immunization Prevention Programs and Plans. As emerges from the data, the immunization offer varies widely across the country. As new evidence accumulates in the field of vaccination and new vaccines are made available – in a context of a decentralized health system – regions are implementing different immunization strategies. For example, some regions extended HPV vaccine offer to other age cohorts (7 regions offer HPV vaccine to two age cohorts and 1 offers it to four age cohorts); since 2015, five Italian regions have extended active offer of the HPV vaccine to males.<sup>14,17</sup> With regard to the pneumococcal conjugate vaccine, three Italian regions offer it to all subjects older than 65

**Figure 1 (A-M)**

Immunization coverage rates for infant vaccines scheduled in the National Immunization Schedule. 2014 updated data by region and at the national level.

Notes: Sardegna - data not available.

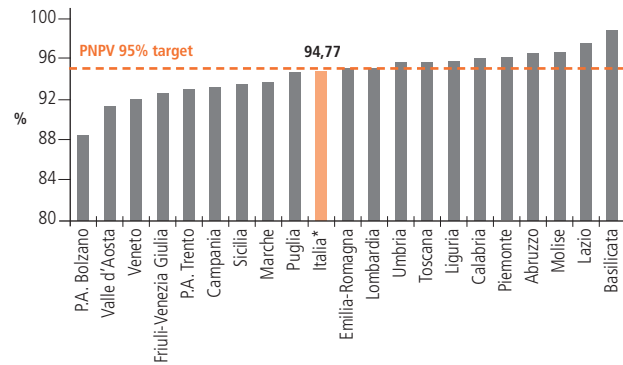
Legend: \* average.

**Figura 1 (A-M)**

Coperture vaccinali per le vaccinazioni pediatriche offerte attivamente a tutta la popolazione (PNPV 2012-2014). Dati aggiornati al 2014 per regione e a livello nazionale.

Note: Sardegna - dati non pervenuti.

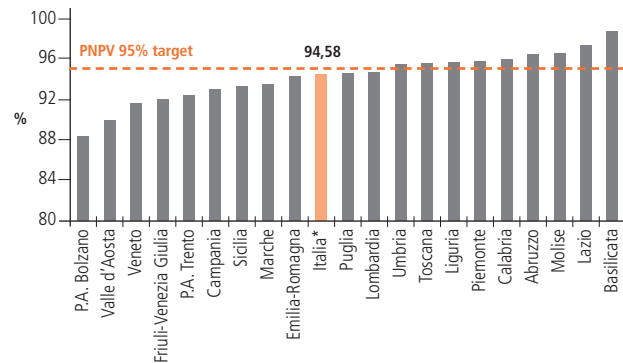
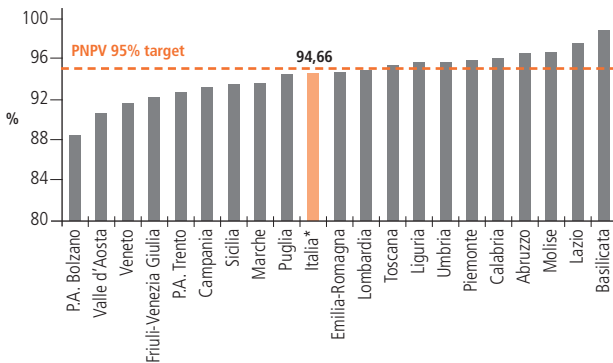
Legenda: \*media nazionale.

**Figure 1C. Tetanus**

Diphtheria and tetanus vaccine (DT) + diphtheria, tetanus, and acellular pertussis vaccine (DTaP) coverage at 24 months for completed courses (three doses).

**Figura 1C. Tetano**

Coperture vaccinali al 24° mese per vaccini difterite-tetano (DT) + difterite-tetano-pertosse acellulare (DTPa) - ciclo di base completo (3 dosi).

**Figure 1A. Poliomyelitis**

Inactivated polio vaccine (IPV) coverage at 24 months for completed courses (three doses).

**Figura 1A. Poliomieltite**

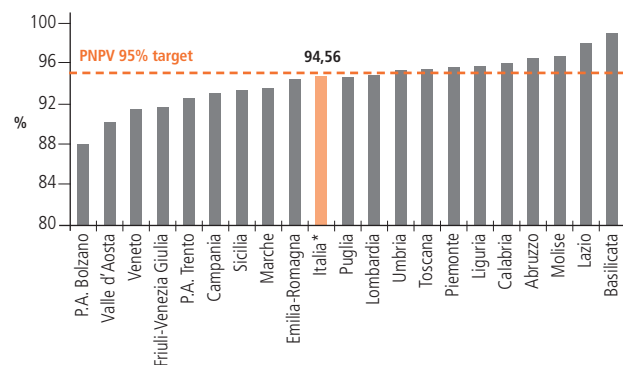
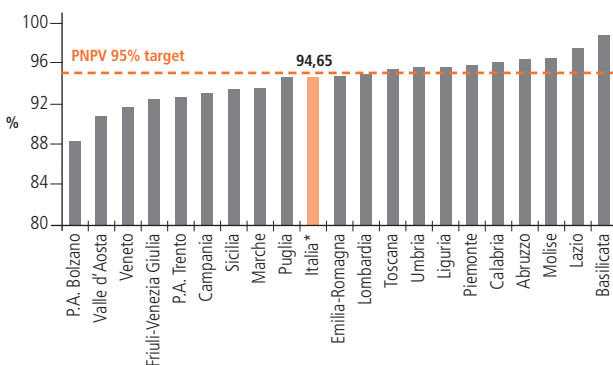
Coperture vaccinali al 24° mese per vaccino antipolio inattivato (IPV) - ciclo di base completo (3 dosi).

**Figure 1D. Pertussis**

Diphtheria, tetanus, and acellular pertussis vaccine (DTaP) coverage at 24 months for completed courses (three doses).

**Figura 1D. Pertosse**

Coperture vaccinali al 24° mese per vaccino difterite-tetano-pertosse acellulare (DTPa) - ciclo di base completo (3 dosi).

**Figure 1B. Diphtheria**

Diphtheria and tetanus vaccine (DT) + diphtheria, tetanus, and acellular pertussis vaccine (DTaP) coverage at 24 months for completed courses (three doses).

**Figura 1B. Difterite**

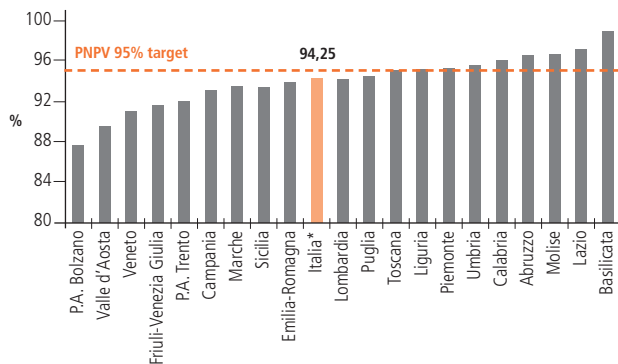
Coperture vaccinali al 24° mese per vaccini difterite-tetano (DT) + difterite-tetano-pertosse acellulare (DTPa) - ciclo di base completo (3 dosi).

**Figure 1E. Hepatitis B**

Hepatitis B vaccine (HepB) coverage at 24 months for completed courses (three doses).

**Figura 1E. Epatite B**

Coperture vaccinali al 24° mese per vaccino anti-epatite B (HepB) - ciclo di base completo (3 dosi).

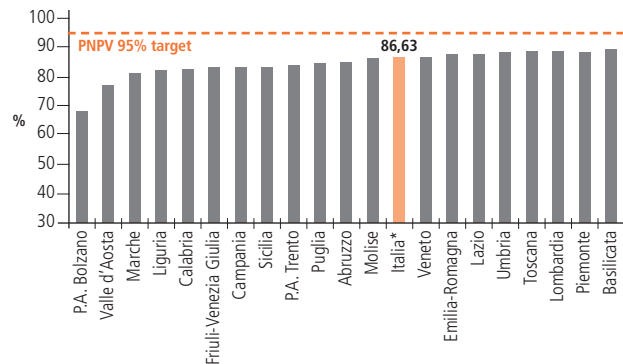


**Figure 1F. *Haemophilus influenzae* type B (Hib) disease**

*Haemophilus influenzae* type b (Hib) coverage at 24 months for completed courses (1, 2 or three doses, based on age).

**Figura 1F. Patologia da *Haemophilus influenzae* tipo B**

Coperture vaccinali al 24° mese per vaccino anti-*Haemophilus influenzae* tipo B (Hib) - ciclo di base di 1, 2 o 3 dosi secondo l'età.

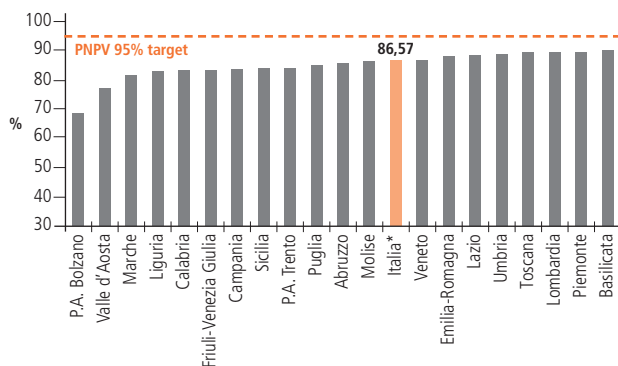


**Figure 1I. Measles**

Measles (M) vaccine + measles, mumps, and rubella vaccine / measles, mumps, rubella, and varicella vaccine coverage at 24 months - first dose (M-MMR / M-MMRV).

**Figura 1I. Morbillo**

Coperture vaccinali al 24° mese per vaccini anti-morbillo + anti-morbillo-parotite-rosolia / morbillo-parotite-rosolia-varicella (M-MPR / M-MPRV) - prima dose.

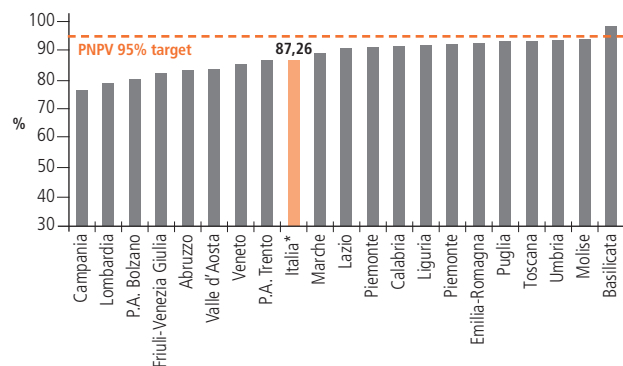


**Figure 1G. Mumps**

Measles, mumps, and rubella vaccine / measles, mumps, rubella, and varicella vaccine coverage at 24 months - first dose (MMR/MMRV).

**Figura 1G. Parotite**

Coperture vaccinali al 24° mese per vaccino anti-morbillo-parotite-rosolia / morbillo-parotite-rosolia-varicella (MPR/MPRV) - prima dose.

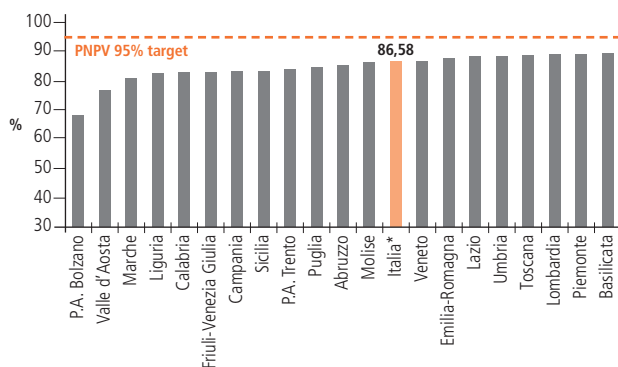


**Figure 1L. Pneumococcal disease**

Pneumococcal conjugate vaccine coverage at 24 months (birth cohort: 2012) for completed courses (1, 2, or 3 doses, based on age).

**Figura 1L. Patologia pneumococcica**

Coperture vaccinali al 24° mese per vaccino anti-pneumococco coniugato - ciclo di base di 1, 2 o 3 dosi secondo l'età.

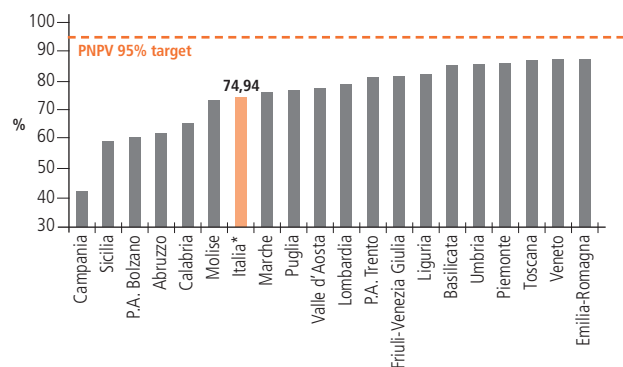


**Figure 1H. Rubella**

Measles, mumps, and rubella vaccine / measles, mumps, rubella, and varicella vaccine coverage at 24 months - first dose (MMR/MMRV).

**Figura 1H. Rosolia**

Coperture vaccinali al 24° mese per vaccino anti-morbillo-parotite-rosolia / morbillo-parotite-rosolia-varicella (MPR/MPRV) - prima dose.



**Figure 1M. Meningococcal disease**

Meningococcal C conjugate vaccine (Men-C) coverage at 24 months (birth cohort: 2012) for completed courses (1, 2, or 3 doses, based on age) [data not available for Lazio].

**Figura 1M. Patologia meningococcica**

Coperture vaccinali al 24° mese per vaccino anti-meningococco C coniugato (Men-C) - ciclo di base di 1, 2 o 3 dosi secondo l'età [dati non pervenuti per il Lazio].

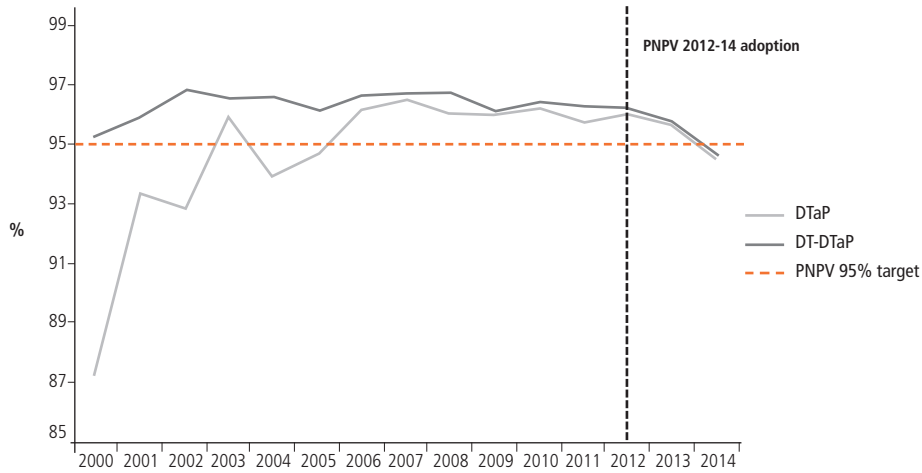


**Figure 2 (A-C)**

Immunization coverage rates over time for selected vaccines(2000-2014).

**Figure 2 (A-C)**

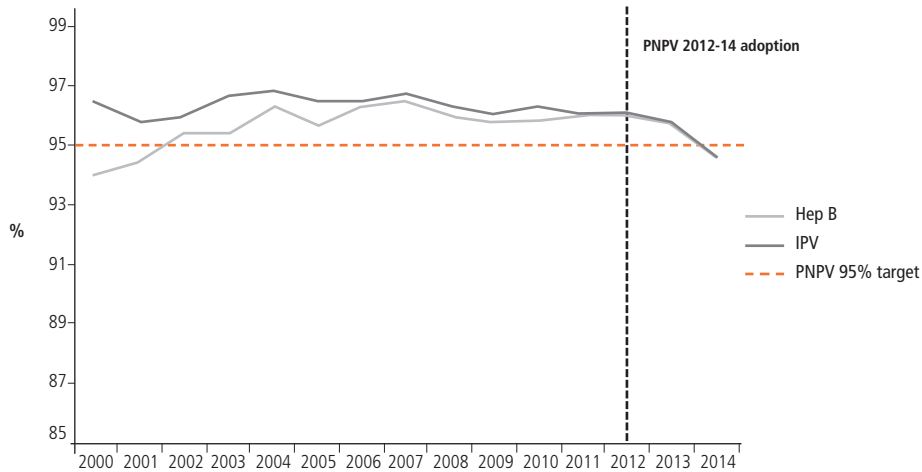
Coperture vaccinali: trend temporali per alcuni vaccini (2000-2014).

**Figure 2A.****Diphtheria - Tetanus - Pertussis**

Diphtheria and tetanus vaccine (DT) + diphtheria, tetanus, and acellular pertussis vaccine (DTaP) coverage at 24 months for completed courses (three doses).

**Figura 2A.****Difterite - Tetano - Pertosse**

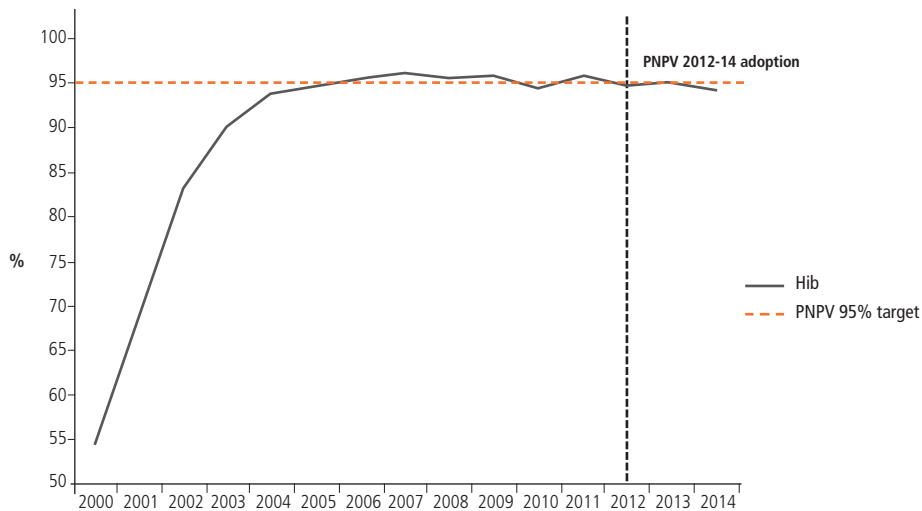
Coperture vaccinali al 24° mese per vaccini difterite-tetano (DT) + difterite-tetano-pertosse acellulare (DTPa) - ciclo di base completo (3 dosi).

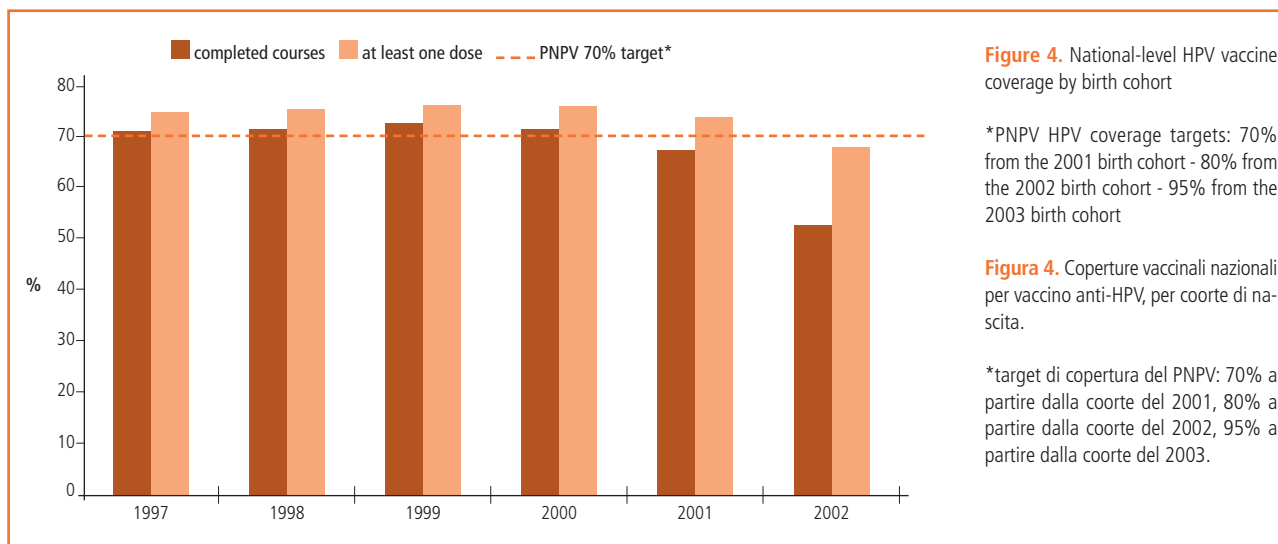
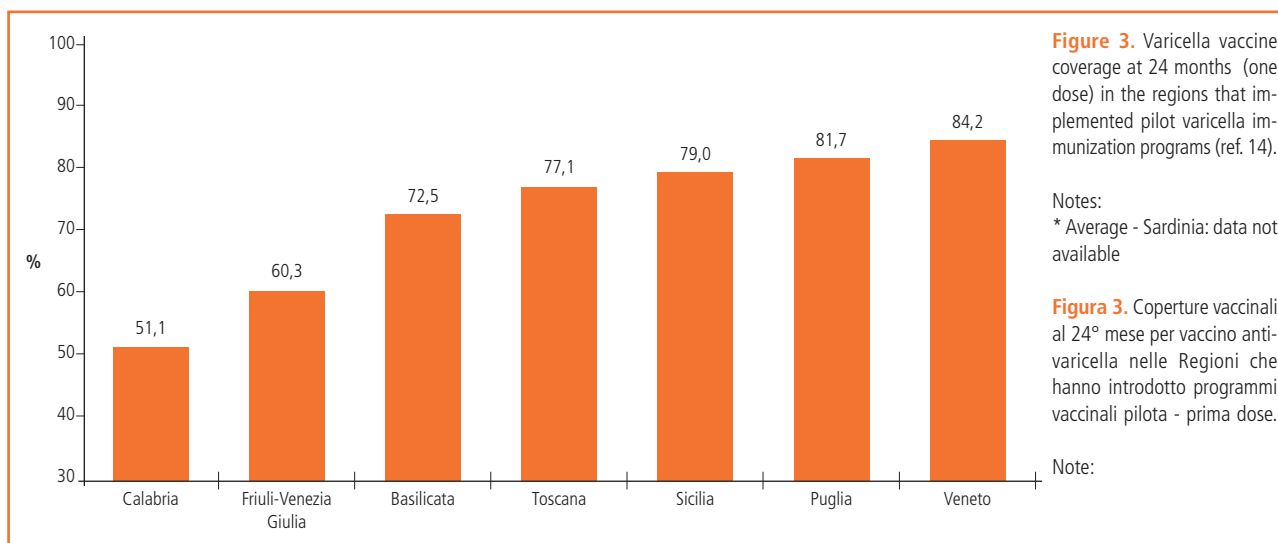
**Figure 2B.****Poliomyelitis - Hepatitis B**

Inactivated Polio vaccine (IPV) and hepatitis B vaccine (HepB) coverage at 24 months for completed courses (three doses).

**Figura 2B.****Poliomielite - Epatite B**

Coperture vaccinali al 24° mese per vaccini antipolio inattivato (IPV) e anti-epatite B (Hep B) - ciclo di base completo (3 dosi).

**Figure 2C.****Haemophilus influenzae type B (Hib) disease***Haemophilus influenzae* type B (Hib) coverage at 24 months for completed courses (1, 2, or 3 doses, based on age)**Figura 2C.****Patologia da Haemophilus influenzae tipo B**Coperture vaccinali al 24° mese per vaccino anti-*Haemophilus influenzae* tipo B (Hib) - ciclo di base di 1, 2 o 3 dosi secondo l'età.



years, others to selected older birth cohorts, others only to at-risk subgroups. Since serogroup B meningococcal (Men B) vaccine was licensed in Europe and became available in Italy, eight Italian regions and one autonomous province have introduced it in their regional immunization schedules for children under one year of age.<sup>18</sup> Furthermore, over the past few years, eight regions have implemented a two-dose schedule varicella immunization program; preliminary vaccine coverage data over time are available and will inform the introduction of universal varicella vaccination at the national scale.<sup>13</sup>

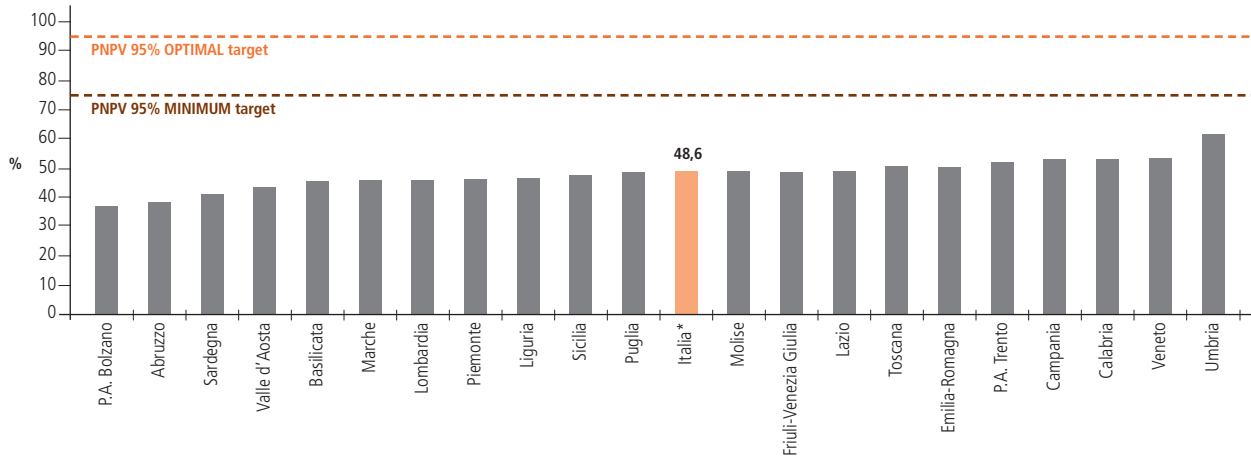
It is worth underscoring that the wide variability of coverage among regions is not a new phenomenon and has historical reasons, such as dissimilar organizational models in the offer of vaccinations by Local Health Units, different attention and commitments from politicians and decision-makers at the local level, different vaccine culture in the population. In any case, there is no doubt that the decreasing coverage for several vaccines reflects an international trend recorded in the past few years and is mainly due to what is known as «vaccine hesitancy». A more complete, comprehensive vaccination of-

fer does not hamper the attainment of coverage targets for other vaccines, rather it could convey a stronger message of trust in active immunization. Such consideration is supported by data on measles and rubella coverage rates in regions that already introduced a universal varicella vaccination program compared to regions who did not. The 4 regions with the lowest MMR coverage in 2014 were not in the pilot group of universal varicella vaccine implementers. Three out of the 8 pilot regions have MMR coverage rates higher than the national average, an additional 4 were only slightly under the national average (data for Sardinia not available). Furthermore, among the 5 regions that registered the worse percent decrease in coverage for MMR in the last 3 years, only one (Puglia) offered universal varicella vaccination between 2012 and 2014. In other words, MMR coverage rates and trends are not negatively influenced by a simultaneous offer of universal varicella vaccination.

Our study has a number of limitations. First, more data would have been useful to further explore immunization coverage rates in Italy: whereas certain vaccine coverage rates are routinely collected by the Ministry of Health for other vaccines,

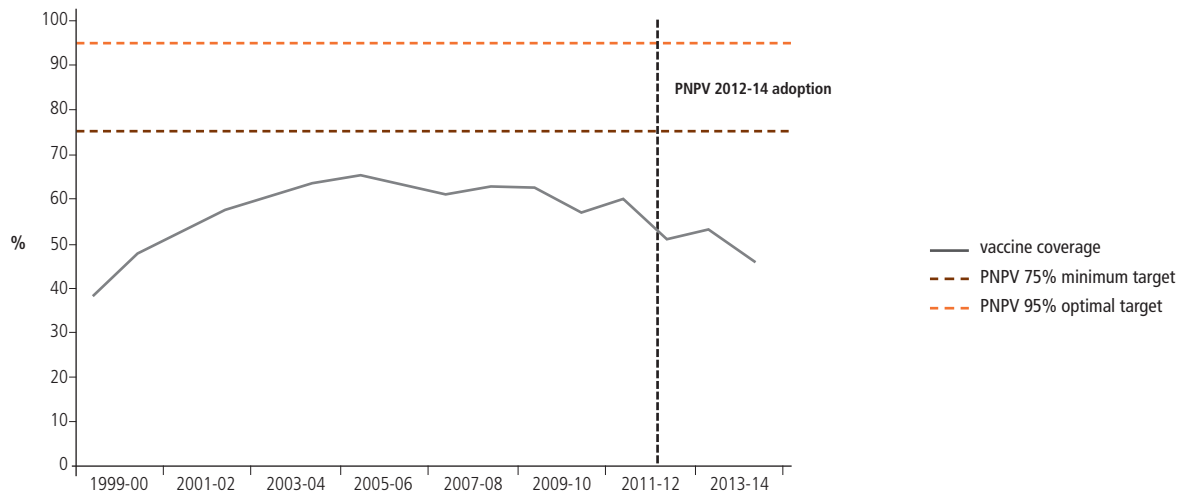
**Figure 5.** Influenza immunization coverage rates in subjects aged  $\geq 65$  years by region and at the national level.

**Figura 5.** Coperture vaccinali per vaccino antinfluenzale nei soggetti  $\geq 65$  anni, per Regione e a livello nazionale.



**Figure 5A.** Influenza vaccine coverage by region for flu seasons 2014-2015.

**Figura 5A.** Coperture vaccinali per la stagione influenzale 2014-2015, per Regione.



**Figure 5B.** National-level influenza vaccine coverage over time (from 1999-2000 to 2014-2015).

**Figura 5B.** Coperture vaccinali nazionali: trend temporali (stagioni influenzali da 1999-2000 a 2014-2015).

namely the pneumococcal, meningococcal, and varicella vaccines, no routine coverage surveillance system has been in place in recent years and coverage data are only collected in *ad hoc* projects.<sup>19</sup> Pneumococcal and meningococcal vaccines routine coverage started in 2014. Influenza immunization data are collected and transmitted to the ministerial level mostly by general practitioners while HPV data were routinely collected by ISS and, as stated in the Ministerial Circular of 24 April 2014, will be routinely collected by Ministry of Health starting from 2015.<sup>14</sup> In addition, the data we presented did not allow us to distinguish between different available

conjugate meningococcal, conjugate pneumococcal, and HPV vaccines or between two- and three-dose HPV vaccine schedules. Last but not least, the available data are not sufficient to monitor all the PNPV coverage targets and objectives. Another limitation is our descriptive approach. Although we acknowledge that accounting in our analysis for environmental factors that might have an impact on vaccine uptake over time and in different regions in an analytic approach might have provided us with elements that would help us understand how vaccine coverage could be increased, that was not the aim of this study. Our objective was to describe immunization

coverage rates in Italy in a comprehensive, transparent way, and assess whether PNPV objectives have been met.

Finally, we did not present the VPD burden in terms of notifications and hospitalization, nor did we speculate on the extent to which the VPD burden was prevented through immunization – the most important indicators to assess immunization program effectiveness – as this would have broadened the scope of our work too much. Further studies will explore these issues in depth.

### CONCLUSION

Overall, the 2012-2014 PNPV objectives have been only partially met. We have already discussed the coverage target goals. With regard to the other PNPV objectives, a great deal still needs to be done to improve surveillance systems and serotyping capacity, link VPD notifications and immunization coverage data with other administrative data flows, and implement immunization information systems across the country. Of crucial importance, in times where vaccines are losing public confidence and the World Health Organization warns against the growing phenomenon of vaccine hesitancy,<sup>20</sup> renewed efforts should be devoted to plan and implement effective information and communication interventions to promote immunization among healthcare professionals and increase the demand for immunization in the general population. In particular, the potential offered by information and communication technologies and new media should be leveraged by in-

stitutions and the public health community to inform and educate the general public on the benefits of vaccination.<sup>21-25</sup>

This is no time to decrease our preventive efforts, but rather to rekindle trust in all immunizations of proven efficacy, effectiveness, and public health impact.

The new National Immunization Prevention Plan is about to be launched. It has been drafted in consultation with representatives of several scientific societies. In particular, the “lifetime immunization schedule” recommended by the Italian Society of Hygiene, Preventive Medicine, and Public Health (SIIt), the Italian Society of Paediatrics (SIP), the Italian Federation of Paediatricians (FIMP), and the Italian Federation of General Practitioners (FIMMG) constituted a solid basis for discussion.<sup>26</sup> Taking into consideration the most recent scientific evidence available, the new National Immunization Schedule will include new vaccines of proven efficacy and extend vaccine offer to additional target populations. Several lessons have been learned in the last three and a half years, and the data we presented and the findings we derived have greatly informed the definition of the new Plan’s objectives and strategies. As we praise the work done so far to strengthen and harmonize immunization policies in Italy, we need to roll up our sleeves and prepare for the work ahead.

**Conflicts of interest:** none declared

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