

## COMMENTARY

# The Italian National Vaccine Prevention Plans, 1999/2020-2023/2025: challenges and obstacles to vaccine coverage goals

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### Abstract

Five consecutive national vaccination plans (from 1999 to 2025) were revised, outlining their objectives, challenges, and results. Vaccination coverage for children consistently approached target levels, though regional differences emerged. In contrast, coverage for adolescents, the elderly, and vulnerable groups, consistently fell short of targets. While vaccination policies in Italy over the past 25 years were ambitious and well-planned, success was primarily limited to newborns immunization, thanks to effective organizational activities. Failure to achieve goals for other population groups was partly due to inconsistent implementation of regional vaccination prevention plans.

### Key words

- national vaccination plan
- Italy
- immunization schedule
- coverage rates

### INTRODUCTION

Italy has consistently been at the forefront of vaccination policies, thanks to its publicly funded “National Health Service” (NHS), which has always prioritized prevention campaigns and offered effective vaccines, free of charge, to target populations. Among the most significant public health successes achieved through mass immunizations, the extensive polio vaccination campaigns in the '50s and '60s [1, 2], the early introduction of universal hepatitis B vaccination (HBV) in 1991 [3, 4], the trial of the acellular pertussis vaccine [5], the introduction of the human papilloma virus (HPV) vaccine for adolescent girls in 2007, extended also to boys in 2017 [6], as well as the more recent introduction of vaccines against meningitis B, rotavirus, and zoster [7] should be mentioned. Since the late 1990s, the Ministry of Health (MoH) aim was not only to extend the offer of vaccines, but also to improve delivery methods, and to support actions finalized at the success of vaccination campaigns, as specified in each vaccination plan.

The first two plans were named “National Vaccination Plan” (NVP). From the third onwards the name was modified into “National Vaccination Prevention

Plan” (NVPP). We think it is extremely important now to revise the main objectives, challenges in implementation, and the results achieved, the five NVPs/NVPPs adopted so far, taking into account the political, legislative, and healthcare contexts of the different historical periods [8], and assessing the output of the plans in terms of vaccination coverage [9, 10].

The time span differed for the five vaccination plans from 2 years (one plan) to four years (one plan), with 3 plans having a 3-years duration. On average, 4.25 years passed between the conclusion of one plan and the adoption of the next one, periods during which the expired plans were always considered, even if there were not specifically extended. Between the first and the second plan, a significant amendment to the Italian Constitution was introduced, with the Constitutional Law 1/2001 [11], which brought “concurrent” legislation to healthcare matters, giving therefore more legislative and administrative power to the 19 regions and the 2 autonomous provinces with regard to the delivery of healthcare services, opening to the era of “Regional Vaccination Prevention Plans” (RVPPs). However, regional plans were approved only by some regions and, usually, after the NVPP had come into action.

The technical support for the development of the national plans was provided by a National Vaccine Committee, which was established within the MoH, but it was abolished in 2012 as part of a legislative effort to reduce public spending [12]. It wasn't until 2017 that Italy, following World Health Organization (WHO) recommendations, established the National Immunization Technical Advisory Group (NITAG), which provides technical advice on vaccination-related decisions, including the NVPPs [13].

### **National Vaccination Plan 1999-2000**

The 1999-2000 plan (Minister: Rosy Bindi; Chief Medical Officer: Fabrizio Oleari) [14] was issued to address the existing disparities in vaccination offer across Italy, to pursue the health objectives set by the WHO, and to overcome the fragmented method of introducing new vaccines through individual ministerial decrees. The increase of measles, mumps, and rubella (MMR) vaccination coverage from below 70% up to 95% was also among the priorities of this plan, as well as changing the polio vaccination schedule from oral to intramuscular to avoid the risk of vaccine-associated paralysis, introducing the *Haemophilus influenzae* type B (HiB) vaccine, and gradually introducing flu vaccination for the elderly population (whose coverage was still below 30%). The plan also included several detailed guidelines on the requirements for vaccination centers and on monitoring the achievement of its goals.

### **National Vaccination Plan 2005-2007**

The 2005-2007 plan (Minister: Girolamo Sirchia; Chief Medical Officer: Donato Greco) [15] was approved after the 2001 constitutional modification and the adoption of the 2003 plan for the elimination of measles and rubella [16]. The extensive and well-documented plan (a total of 126 pages) set ambitious goals, including eliminating measles by 2007, reducing the incidence of mumps, pertussis, and HiB to an incidence of less than 1 case per 100,000 population by 2010, and reducing the incidence of chickenpox, meningococcal C invasive disease, and pneumococcal invasive diseases, following the availability on the market of the respective new vaccines. The plan paid particular attention to identifying adverse events and establishing pathways to eliminate the mandatory vaccination requirements, which, at that time, were in place for four diseases (polio, diphtheria, tetanus, and hepatitis B). The latter address was adopted by the Veneto Region which, in 2008, suspended the mandatory vaccinations, even if the final results, evaluated subsequently, were not encouraging [17].

### **National Vaccine Prevention Plan 2012-2014**

The 2012-2014 plan (Minister: Renato Balduzzi, Chief Medical Officer: Giuseppe Ruocco) [18] systematically incorporated the concept of a "life-course vaccination schedule" rather than just a childhood vaccination schedule, partly due to the advocacy of the most relevant scientific societies in the field (public health, pediatrics, family medicine) [19]. It included the introduction of the HPV vaccine for adolescent girls, which

started in 2008, with the goal of gradually achieving 95% coverage. The plan also provided the introduction of universal chickenpox vaccination and acknowledged the need for careful monitoring vaccination coverage following the suspension of mandatory vaccinations in the Veneto Region. Additionally, the plan described the decision-making process for introducing new vaccines, including the use of Health Technology Assessment (HTA), and emphasized the importance of annual local evaluation of the achievements of vaccination programs.

### **National Vaccine Prevention Plan 2017-2019**

The 2017-2019 plan (Minister: Beatrice Lorenzin, Chief Medical Officer: Ranieri Guerra) [20] was considered one of the most innovative in Europe, due to the introduction of five additional vaccines (HPV for boys, menB, zoster, pneumococcal for the elderly and rotavirus) and for implementing strategies aimed at achieving population protection goals in a context increasingly characterized by widespread vaccine hesitancy and a consequent decline in vaccination coverage. The plan included the establishment of a national vaccination registry, a systematic communication and training campaign, the adoption of sanctions against healthcare personnel who did not participate in vaccination campaigns (no-vax) and the potential introduction of new mandatory vaccinations in emergency situations (a measure later adopted by the Parliament in July 2017, when it expanded the number of mandatory vaccines from 4 to 10) [21, 22]. The plan received significant political support (including substantial funding) and involved collaboration with various stakeholders in the decision-making processes. Furthermore, since 2017, vaccines included in the national plan have been automatically considered part of the essential levels of care (*Livelli essenziali di assistenza*, LEA) of the National Health Service (Servizio Sanitario Nazionale, SSN) [23].

### **National Vaccine Prevention Plan 2023-2025**

The 2023-2025 plan (Minister: Orazio Schillaci; Chief Medical Officers: Giovanni Rezza, Francesco Vaia, Maria Rosaria Campitiello) [24] was developed in a context marked by a transition between two different governments and approved by the new – and stable – political majority, characterized by a decline in vaccination coverage, partly due to the COVID-19 pandemic, persistent vaccine hesitancy among the population [25, 26], and a shortage of healthcare personnel within the NHS. This plan maintains the approach of the 4<sup>th</sup> plan, keeping an immunization schedule that is essentially identical to the 2017 plan, but giving the possibility to modify the schedule at the time, based on new epidemiological evidence and the availability of new vaccines. The few new elements include the introduction of the quadrivalent (ACWY) meningococcal vaccine instead of the C-monovalent one, and the recognition of the right to receive free vaccination at any time other than those scheduled in the plan.

The plan also allows the regions to use different providers for vaccine delivery, as it was done during the

**Table 1**  
Vaccination coverage in Italy

Antigen	Uptake indicator	Targets (National Plan 2017-2019) to the year 2019	National coverage (year 2022)
Poliomyelitis	24 months, completed cycle	≥95%	95.15%*
Diphtheria	24 months, completed cycle	≥95%	95.14%*
Tetanus	24 months, completed cycle	≥95%	95.14%*
Pertussis	24 months, completed cycle	≥95%	95.14%*
Hepatitis B	24 months, completed cycle	≥95%	95.05%*
<i>H. influenzae</i> type b	24 months, completed cycle	≥95%	95.08%*
Measles	24 months, 1 <sup>st</sup> dose	≥95%	94.40%*
Rubella	24 months, 1 <sup>st</sup> dose	≥95%	94.39%*
Mumps	24 months, 1 <sup>st</sup> dose	≥95%	94.37%*
Chickenpox	24 months, 1 <sup>st</sup> dose	≥95%	93.35%*
Rotavirus	24 months, completed cycle	≥95%	74.39%*
Meningococcal B	24 months, completed cycle	≥95%	80.91%*
Meningococcal C	24 months, completed cycle	≥95%	85.60%*
Pneumococcus conjugate	24 months, completed cycle	≥95%	91.73%*
Human papilloma virus	12 years, completed cycle	≥95%	♀ 38.78% ♂ 31.81%
Influenza, elderly	≥65 years old, every year	≥75% minimum target ≥95% optimal target	53.3%**§
Pneumococcus	65 years old, one dose	75%	<15%
Zoster	65 years old, one dose	50%	<15%

\*Paediatric vaccinations. Year 2022 (2020 cohort); ♀: girls ♂: boys (2010 cohort); \*\*influenza vaccination 2023-2024; § HCP: healthcare professional -54% (2020-2021); approximately 33% (2019-2020); approximately 23% (2018-2019).

COVID-19 vaccination campaign, with explicit references to hospitals, pharmacies, vaccination hubs, and family doctors.

The major indicator considered in all the five plans was “vaccination coverage for the different vaccine antigens in the target populations”. In childhood, vaccination, uptake levels achieved have consistently been very close to the goals set by the plans, albeit with regional variation. However, for adolescents, the elderly, and “vulnerable” individuals, the results have always fallen significantly below the targets (Table 1).

The plans also included the formulation of specific actions in support to vaccination campaigns, such as communication, training, and the involvement of various stakeholders, although these actions have only rarely been implemented systematically and objectively evaluated. For the 2012-2014 plan, an evaluation made by scientific experts was published [27], while for the 2017-2019 plan, several scientific contributions (mostly published on “grey” literature and non-indexed journals) highlighted the achievement of the objectives, such as target thresholds for measles and rubella, the introduction of mandatory vaccinations as an extreme action to meet the coverage targets and the sanctioning of anti-vax doctors by the National Order of Doctors, Surgeons and Dentists.

In summary, throughout the whole time period considered, the priority has been to introduce updated, effective, and safe vaccines aimed at reducing the impact

of vaccine preventable diseases in the population. The coverage goals set by the plans have been achieved or approached only in childhood and often only after a long period after the introduction of the respective vaccines into the schedules. Examples include the chickenpox vaccine (which only reached 93.3% coverage in 2022 despite being mandatory), the meningococcal B vaccine (introduced in 2017, reaching 80.9% coverage in 2022), and the rotavirus vaccine (also introduced in 2017, with coverage increasing to 74.4% in 2022). It is noteworthy that satisfactory coverage levels were also achieved for non-mandatory childhood vaccines, even during the critical phase of the pandemic. However, coverage goals for vaccinations among adolescence, the elderly, and vulnerable individuals have consistently fallen below the threshold, with variations between different Regions. Furthermore, the data regarding these population are partial or even lacking, and derive from non-official sources of information.

The automatic inclusion of vaccines provided by the national plan into the essential levels of care (LEA) in 2016 [23] was an important milestone in Italian vaccination policies. However, it ties the introduction of new vaccines to specific funding from the Ministry of Economy. This mechanism could slow down the process of updating the national vaccination schedule, encouraging regional initiatives to expand (obviously the law does not permit any reduction) the immunization offer, as it has recently happened with the introduction of the

meningococcal B vaccine for adolescents and prevention/prophylactic tools against respiratory syncytial virus (RSV) infections in the elderly and vulnerable individuals, with one of the three vaccines currently available, and monoclonal antibodies for newborns [28-30].

## CONCLUSIONS

In conclusion, Italian National Vaccination Prevention Plans represented the basis for ambitious vaccination policies over the past 25 years, though innovative planning has not always been matched with adequate achievements in terms of vaccination coverage. Many of the goals and supporting actions have been re-pro-

posed across different plans with the purpose of fitting the expected goals. Finally, the recent availability of monoclonal antibodies for preventive use against RSV in newborns will lead to the definition of an immunization schedule, rather than a vaccination schedule, representing a real paradigm change for the upcoming years.

## Conflict of interest statement

None of the Authors had a conflict of interest.

Received on 7 October 2024.

Accepted on 15 October 2024.

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