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## Overview of adult immunization in Italy: Successes, lessons learned and the way forward

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### ABSTRACT

The exchange of knowledge and best practices in adult immunization are essential to improve vaccination strategies across the European region. Italy has made groundbreaking progress in the field, being one of the first countries to propose a life-course vaccination schedule, broadening the traditional focus on childhood immunization to include adults. All vaccines included in Italy’s vaccination schedule are free of charge. Moreover, the country’s National Immunization Plan sets clear coverage targets, immunization priorities, and actions to reduce disparities. However, the fragmentation of its National Health System following the constitutional reform of 2001 has led to an increased complexity and regional inequalities regarding immunization. Other challenges the country faces include growing vaccine hesitancy, data gaps and underserved populations. This review describes Italy’s adult immunization system, from policy to implementation. The successes, challenges and lessons learned were shared during the first Adult Immunization Board country meeting in Italy, where local experts, healthcare providers, public health representatives, and policymakers engaged in collaborative discussions and shared insights through case studies and presentations (December 2023). These insights are reviewed and discussed in this manuscript.

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## Introduction

In 2021, countries of the World Health Organization (WHO) European Region adopted the European Immunization Agenda 2030,<sup>1</sup> which defines a strategy to ensure lifelong protection from vaccine-preventable diseases (VPDs). Nevertheless, the transition from child-focused immunization campaigns to life-course- strategies remains incomplete and challenging in many European countries.<sup>2</sup> Cross-border exchange of knowledge and best practices in adult immunization is therefore essential to gain insight and leverage successes. Italy is of particular interest, being the first European country to propose a lifetime vaccination schedule for which all included vaccines are available free of charge for any resident of the country. Also, the current country’s National Immunization Plan (PNPV, *Piano Nazionale Prevenzione Vaccinale 2023–25*) sets clear coverage targets, immunization priorities, and actions to reduce disparities.<sup>3</sup> This review presents an overview of Italy’s adult immunization system, including policy-making, financing, purchase and distribution, as well as the monitoring of VPDs, vaccine coverage, vaccine

confidence, and pharmacovigilance. The strengths and weaknesses of the system, including previous successes, responses to challenges, and ways forward are detailed and discussed.

## Adult immunization board (AIB)

The Adult Immunization Board (AIB) is an independent, international, multidisciplinary group of experts in the field of adult immunization, which aims at providing scientific evidence-based reflection and guidance on strategic, technical, and policy issues in the implementation and optimization of European, national and sub-national adult immunization programs.<sup>4,5</sup> The AIB organizes two meetings per year: a technical meeting to discuss technical aspects on adult immunization, and a country meeting to establish a collaborative network of national experts and to address country-specific topics in adult immunization. This review is based on information shared during a dedicated 2-day country meeting held in Florence, Italy, on December 6–7, 2023, during which national and region-specific issues on adult immunization in Italy were discussed together with local experts. Talks and presentations were given by local

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academics, health care providers (HCPs), public health representatives and policymakers, and covered all aspects of Italy's adult immunization, from policymaking and implementation to vaccine acceptance and coverage. Moreover, to illustrate the organization of adult vaccination services at regional level, three case examples were further discussed: Lombardy for Northern Italy, Tuscany for Central Italy, and Puglia for Southern Italy. At the end of the meeting, specific challenges, successes, and the way forward were discussed in small groups and then reported in a plenary session. The complete report of the meeting, the presentations of speakers as well as additional information about the AIB, will be available at [www.adultimmunizationboard.org](http://www.adultimmunizationboard.org).

### Search strategy and selection criteria

References included in this review and used to select speakers for the 2-day AIB country meeting were identified through PubMed Medline and gray literature search using multiple search terms pertaining to adult immunization in Italy. In particular, we used different combinations of keywords related to "Italy," "healthcare system," "vaccinations," and "vaccines for adults" (or other more specific groups such as pregnant women," "migrants," "elderly," "immunocompromised people," etc.). We then further refined our search by identifying relevant articles and potential speakers through backward citation chaining. Articles were further identified by the speakers of the meeting. The final reference list was generated on the basis of relevance to the broad scope of this review. This approach may have limitations, as it might not be sufficiently developed to comprehensively include gray literature and the full breadth of professional expertise in the field. On the other hand, it effectively targeted highly relevant and current literature, ensuring that the review – and ultimately the expert selection – was grounded in the most pertinent and up-to-date evidence available.

### A brief history of Italy's health care system

Following the ratification of the Italian Republic Constitution in December 1947, the first social health insurance system was instituted in the country (1948–1978). Health insurance was originally entitled based on employment, which resulted in major social inequalities regarding health care. In 1978, the national health service (SSN, *Servizio Sanitario Nazionale*) replaced the social health insurance system, allowing health care provision and prevention to be based on residency. The implementation of SSN was associated with an exponential decline in infant deaths and an increase in the country's average life expectancy. With the SSN in place, Italy has been repeatedly classified among the highest rated countries worldwide for life expectancy, and among the lowest in health care spending.<sup>6</sup>

In 2001, Italy's Constitutional Reform led to a major reorganization of the SSN, with an increase in regional competencies with regard to health and prevention. According to reports of Italy's National Observatory on Health, this fragmentation of the SSN has been associated with growing

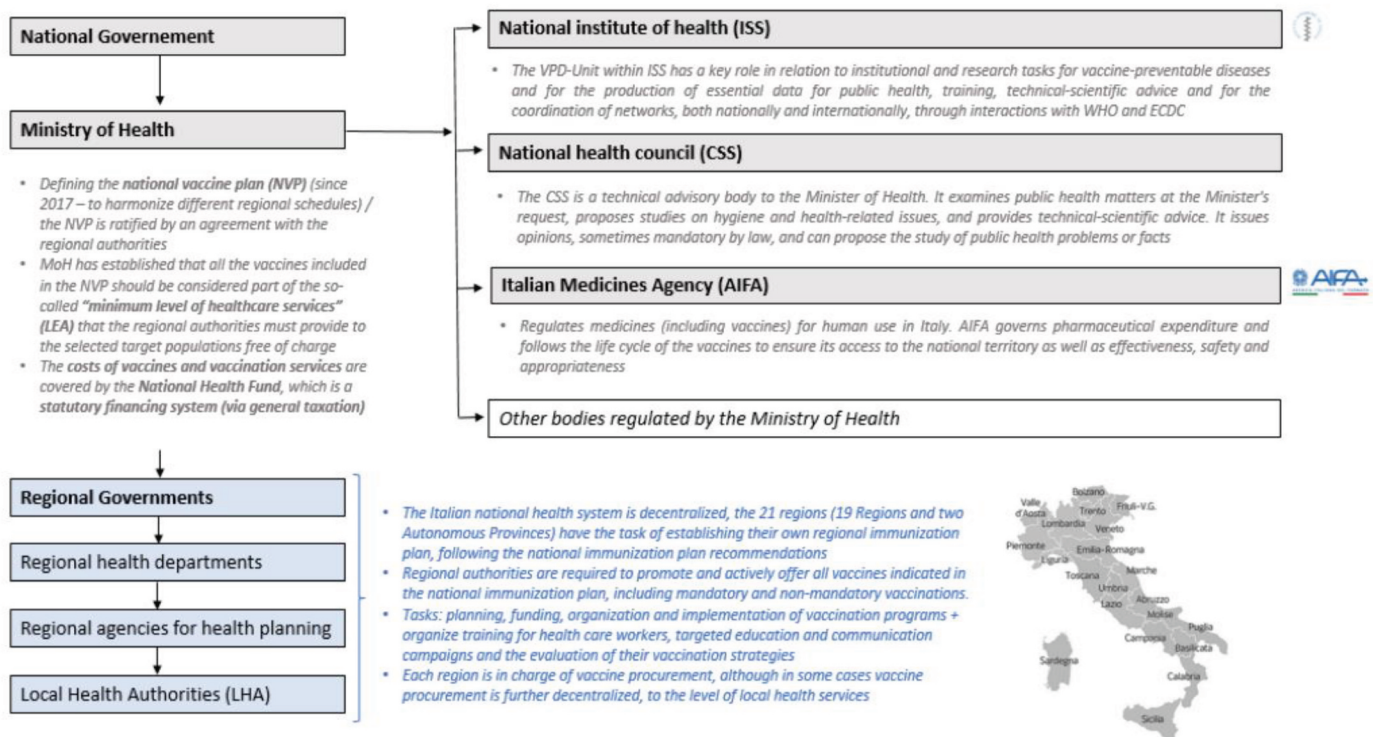
disparities in health care at the regional level, with a notable life expectancy gap between the southern regions and the north of the country.<sup>7</sup> To illustrate the organization of adult vaccination services at the regional level, we selected Lombardy, Tuscany, and Puglia to represent Northern, Central, and Southern Italy, respectively. These regions were chosen due to their distinct healthcare models and the different challenges they faced and may face in implementing immunization programs, and their history of being particularly active in innovating vaccine policies. Lombardy is a highly industrialized and densely populated region that offers insights into managing healthcare in an urbanized setting. Tuscany, with its mixed urban-rural landscape, provides a balanced view of healthcare delivery in Central Italy. Puglia, representing the South, might exemplify the challenges of delivering consistent healthcare in regions with more dispersed populations and varying socio-economic conditions.

### Immunization within the Italian health care system

Since 2001, immunization-related mandates have been split between Italy's central health authority and regional health authorities (Figure 1). The central health authority, Italy's Ministry of Health (MoH), defines the objectives to improve population health status and is responsible for national health planning. Immunization policies are defined by the MoH through laws, decrees, plans, and circular letters (*Circolari*). Those currently in place are summarized in Table 1. The immunization policies are ratified by an agreement with the regional authorities during state-regional conferences.<sup>8</sup>

There are 21 regional health authorities in Italy, 19 regions and two autonomous provinces. The regional health authorities are autonomous in immunization operating strategies. They are responsible for planning, financing, organizing, implementing vaccination services in accordance with the national immunization policies, and for promoting both mandatory and non-mandatory vaccines. Notably, the organization of the regional health systems differs between regions, and certain competencies can be further decentralized. In Lombardy, for example, governance and control are managed by eight separate ATS (Health Protection Agencies, *Agenzie di Tutela della Salute*) further divided into 27 Local Health Authorities (*Aziende Socio Sanitarie Territoriali – ASST*),<sup>9</sup> while in Tuscany the local health entities are divided into three geographical clusters (*Area Vasta*: North-West, Central, and South-East) that include three AUSLs (Local Health Authority, *Azienda Unità Sanitaria Locale*), and 4 AOU (University Hospitals, *Azienda Ospedaliero-Universitaria*).<sup>10</sup>

Other key immunization stakeholders include Italy's medicine agency AIFA (*Agenzia Italiana del Farmaco*)<sup>11</sup> and the country's National Immunization Technical Advisory Group (NITAG).<sup>12</sup> AIFA is responsible for market authorizations of drugs and vaccines, for the definition of the reimbursement and supply regimes for authorized medicines, and for pharmacovigilance. AIFA operates under the guidance and supervision of the MoH and supervision of the Ministry of Economy and Finance. The NITAG is an independent board, appointed by the MoH,



**Figure 1.** Organisation of immunization within the Italian health care system. AIB figure based on Ricciardi et al. Lancet 2021(1); European Observatory on Health Systems and Policies, WHO 2018(2).

**Table 1.** National immunization policies in place, Italy, December 2023.

**Mandatory vaccination in children (Law):** Ministero della Salute. Conversione in legge, con modificazioni, del decreto-legge 7 giugno 2017, n. 73, recante disposizioni urgenti in materia di prevenzione vaccinale. (17G00132). Legge 31 luglio 2017, n. 119. (G.U. Serie Generale, n. 182 del 05 agosto 2017). Available online at: <https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=60201&completo=true>.

**List of authorized yellow fever vaccination centers (Decree):** Ministero della Salute. Centri autorizzati a praticare la vaccinazione contro la febbre gialla ed al rilascio del relativo certificato – 2023. DECRETO 2 agosto 2023. (23A05095) (GU Serie Generale n.215 del 14-09-2023). Available online at: [https://www.gazzettaufficiale.it/atto/serie\\_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2023-09-14&atto.codiceRedazionale=23A05095&elenco30giorni=false](https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2023-09-14&atto.codiceRedazionale=23A05095&elenco30giorni=false).

**COVID-19 national strategic vaccine plan for the prevention of SARS-CoV-2 (Decree):** Ministero della Salute. Approvazione del Piano strategico nazionale dei vaccini per la prevenzione delle infezioni da SARS-CoV-2 costituito dal documento recante «Elementi di preparazione della strategia vaccinale», di cui al decreto 2 gennaio 2021 nonche’ dal documento recante «Raccomandazioni ad interim sui gruppi target della vaccinazione anti SARS-CoV-2/COVID-19» del 10 marzo 2021. (21A01802). Decreto 12 marzo 2021. (G.U. Serie Generale, n. 72 del 24 marzo 2021). Available online at: <https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=79430&completo=true>.

**2023-2025 National Vaccination Plan (Plan):** Presidenza del Consiglio dei Ministri Conferenza permanente per i rapporti tra lo stato le regioni e le province autonome. Intesa, ai sensi dell’articolo 8, comma 6, della legge 5 giugno 2003, n. 131, tra il Governo, le regioni e le Province autonome di Trento e di Bolzano, sul documento recante «Piano nazionale di prevenzione vaccinale (PNPV) 2023-2025» e sul documento recante «Calendario nazionale vaccinale». (Rep. atti n. 193/CSR del 2 agosto 2023). (23A04685). Intesa 02 agosto 2023, n. 193. (G.U. Serie Generale, n. 194 del 21 agosto 2023). Available online at: <https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=95963&completo=true>.

**2019 National preparedness and response plan for a polio epidemic (Plan):** Ministero della Salute. Piano nazionale di preparazione e di risposta a una epidemia di poliomielite. Aprile 2019. Available online at: [https://www.salute.gov.it/imgs/C\\_17\\_pubblicazioni\\_2843\\_allegato.pdf](https://www.salute.gov.it/imgs/C_17_pubblicazioni_2843_allegato.pdf).

**2010-2015 National plan for the elimination of measles and congenital rubella (Plan):** Ministero della Salute. Piano nazionale per l’eliminazione del morbillo e della rosolia congenita 2010-2015. Available online at: [https://www.salute.gov.it/imgs/C\\_17\\_pubblicazioni\\_1519\\_allegato.pdf](https://www.salute.gov.it/imgs/C_17_pubblicazioni_1519_allegato.pdf).

**Annual circular letter for prevention and control of influenza**, indicating the new vaccines’ composition and reporting recommendations for the prevention of influenza through vaccination and other measures of hygiene and personal protection (Circolari)<sup>1</sup>

**Circular letters on COVID-19 vaccine recommendations** (Circolari)<sup>1</sup>

<sup>1</sup>Circular letters are technical recommendations or explanations of a law, decree or plan. These are not legally binding but allow for flexibility and rapid response.

that has an advisory role on immunization policies, including the National Immunization Plan (*Piano Nazionale Prevenzione Vaccinale*; PNPV). The last country’s NITAG

has been in place since 2021 and it is currently composed of 29 core members from different medical and/or immunization-related fields.<sup>12</sup>

**Table 2.** The ten objectives of the national immunization plan, 2023–2025, Italy.

Maintain polio-free status
Eliminate measles & congenital rubella
<i>Reduce HPV-related diseases<sup>1</sup></i>
Reach vaccination coverage targets, <i>using pandemic settings in vaccination campaigns</i>
<i>Vaccinate high-risk groups (e.g., chronic conditions) and highly vulnerable groups for social and economic conditions</i>
Reduce inequalities in vaccination offer
Implement the national digital vaccination registry
Improve surveillance of VPI
<i>Improve communications on vaccines</i>
Promote vaccine education in HCPs

Abbreviations: HCP: Health Care Providers; HPV: Human papilloma virus; VPI: Vaccine preventable infections.

<sup>a</sup>Objectives in italics are those added to the latest version of the National Immunization Plan, 2023–2025.

## The national immunization plan (PNPV) and immunization schedule

Italy's PNPV recommends vaccination for people throughout the entire life course and sets clear priorities and vaccination coverage targets. The last PNPV is composed of two documents, the National Immunization Plan and the National Immunization Schedule.

The objectives of the National Immunization Plan are shown in Table 2. These objectives have been updated in the latest 2023–2025 PNPV (ratified in August 2023) to address the critical issues of the previous 2017–2019 PNPV.<sup>13,14</sup> Issues included the failure to meet vaccine coverage targets in adults and growing regional disparities in organization and coverage rates.

The current National Immunization Schedule is shown in Figure 2. Since 2023, the vaccination schedule can be updated on an annual basis, without modification of the PNPV, and work on a new schedule for 2024 is currently ongoing. The original backbone of the schedule was a proposal from the Board of the Lifetime Immunization Schedule, a unique alliance of four scientific societies and professional associations that was established to propose 'ideal' vaccination schedules, based on scientific evidence of efficacy, effectiveness, and safety. Their 2016 schedule was one of the first European initiatives to propose a life-course approach to immunization,<sup>15,16</sup> a success story that shows the major role that scientific societies and professional associations can play in the improvement of (adult) immunization.

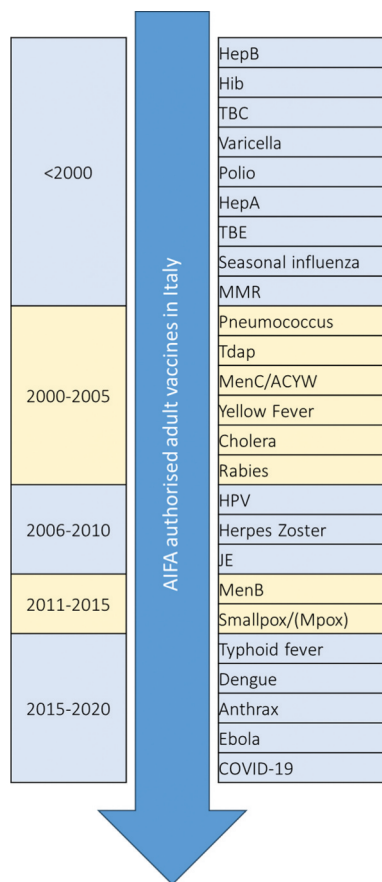
## Market authorisation of vaccines

Market authorization of vaccines in Italy and the European Union (EU) can go through three different regulatory pathways: a centralized procedure, a mutual recognition procedure (authorization of a medicine in one EU member state is recognized by another), or a de-centralized (national) procedure. The centralized procedure is obligatory for a series of products, including those produced through biotechnological processes such as recombinant DNA technologies. To enter the Italian market, all vaccines authorized for use in the EU will also require positive advice from AIFA. The mutual recognition procedure applies when a vaccine already authorized in one EU member state is recognized by others, streamlining access across multiple countries; the decentralized procedure is used

Age (months/years)	2 months	3 months	4 months	5 months	6 months	10 months	12 months	13/14 months	5 years	6 years	11 years	12-18 years	19-59 years	50-64 years	60 years	65 years	>66 years
Hexavalent vaccine: Tetanus, Diphtheria, Pertussis, Hepatitis B, Haemophilus influenzae type b, Polio (TDaP-IPV-HBV-Hib)	■		■			■											
Rotavirus (RV)	■	■		■													
Pneumococcal conjugate vaccine (PCV)	■		■			■										■	
Meningococcal B vaccine (MenB)	■	■		■			■										
Measles, Mumps, Rubella, Varicella (MMRV or MMR+V)							■		■								
Meningococcal ACWY vaccine (MenACWY)							■					■					
Tetanus, Diphtheria, Pertussis, Polio (Tdap-IPV/Tdap-IPV)									■			■					
Papillomavirus vaccine (HPV)											■						
Tetanus, Diphtheria, Pertussis (Tdap)													■	■	■	■	■
Influenza vaccine (Flu)					■	■	■	■	■	■					■	■	■
Herpes zoster vaccine (HZ)																■	■

■ Recommended vaccination by age

**Figure 2.** Italy's life-course immunization schedule, August 2023. Italy's Life-course Immunization Schedule, as published in the 2023–2025 National Immunization Plan, translated to English NB: months and years are considered completed. Examples: the first dose of TDaP-IPV-HBV-Hib can be offered from 2 months of age, or from 61 days of life; the booster dose TDaP-IPV-HBV-Hib at 10 months, or from 301 days of life.



**Figure 3.** Vaccines authorized for use in Italy, December 2023. Years indicate year of first approval of current vaccine platform in use. Year of approval may differ from the year of effective implementation in the different Italian regions. Abbreviations: Hep: hepatitis; Hib: Haemophilus influenzae; HPV: Human papilloma virus; JE: Japanese encephalitis; Men: meningococcal; MMR: measles-mumps-rubella; Mpox: Monkeypox; RSV: Respiratory syncytial virus; TBC: tuberculosis; TBE: tick-borne encephalitis; Tdap: Tetanus-diphtheria-acellular pertussis.

when a vaccine has not been authorized in any EU member state, and this allows simultaneous submission to several countries with one acting as the reference for assessment. **Figure 3** shows all vaccines authorized for use in Italy as of December 2023.

### Financing of immunization

Vaccines included in the PNPV are considered Essential Levels of Healthcare (LEA, *Livelli Essenziali di Assistenza*) for those identified as the recipients of the vaccine recommendations. LEA are health services and benefits that the SSN is required to provide to all residents, uniformly throughout the whole national territory, free of charge or upon payment of a fee (*ticket*). The ticket (co-payment) is, however, not required for LEA vaccines.<sup>17</sup> LEAs cover not only Italian citizens but also EU residents and migrants, including those without regular status, for essential vaccinations. Travellers from other countries who are not residents, on the other hand, must generally pay out of pocket for these services.<sup>18,19</sup> LEA are determined by the MoH in agreement with the Ministry of Economy and Finance, and are centrally financed by the National Health Fund, a statutory financing system based on general taxation. In addition, regional health authorities are free to determine

further health services to be provided uniformly at regional level, so that vaccines or preventive mAbs (monoclonal antibodies) that are not included in the PNPV may be locally procured and financed.

Financing of the immunization programmes (costs related to distribution, administration, promotion, infrastructure) and non-LEA vaccines falls upon the regional health authorities. Overall, an estimated 5% of the regional health budget is dedicated to prevention,<sup>20</sup> with inequalities in levels of investment when comparing regions. Some regions apply citizen co-payment systems for non-LEA vaccines as in Lombardy or Tuscany, others strictly assure financing of program costs related to LEA vaccines and do not cover non-LEA vaccines as is the case in Puglia. Although the National Health Fund has included, since 2017, a supplementary budget item for each region to support reimbursement and purchasing of vaccines, this closed envelope is considered insufficient due to the high expenditure costs and the high-priced new vaccines arriving on the market. Moreover, this budget is not solely dedicated to vaccines, but also to the competitive purchase of innovative (oncology) drugs.<sup>20</sup>

Of note, health insurances and employers play a limited role in the financing of vaccines in Italy, with the latter sometimes covering costs related to influenza vaccines or work travel-related vaccines of their employees. Travel-related vaccines are categorized as non-LEA vaccines, and this is something to take into account for the future, especially as climate change may lead to an increased demand for these vaccines due to higher travel-related health risks.

### Purchase, assessment of demand, procurement and delivery

Vaccine purchase is a mandate of the regions. Regions organize local public tenders, each through different agencies e.g., ARIA S.p.A, in Lombardy (Regional Company for Innovation and Purchasing), ESTAR in Tuscany (Tuscan Regional Administrative Technical Support Body) or InnovaPuglia S.p.A. in Puglia. Assessment of demand is usually estimated by the regions using historical numbers of procurement and uptake, the PNPV uptake targets, and population data issued by the National Institute of Statistics (Istat, *Istituto Nazionale di Statistica*). It can be particularly tricky in high-risk populations or when historical data do not match with the vaccine coverage targets, and privacy concerns can limit the ability to stratify citizens based on specific risk factors, which could otherwise improve the precision of vaccine distribution and targeting. Organization of procurement also differs across regions. For example, in Tuscany, ESTAR distributes the vaccines directly to the administration sites. In Lombardy, administration sites can directly order the vaccines from the vaccine company that wins the public tender; while in Puglia, vaccines are ordered from a regionally procured stock.

Multiple administration sites and vaccine administrators are used in Italy's immunization programmes. Vaccines are administered in numerous vaccination centers of local health authorities located across the country, by general practitioners (GPs) and pediatricians, by specialist doctors and occupational doctors, in (university) hospitals and at pharmacies, with the

involvement also of pharmacists as vaccine administrators. Contribution differs by region and by vaccine type. In Puglia, for example, GPs remain the main vaccinators for influenza, while vaccination centers of the Local Health Authorities are the main administration sites for pneumococcal conjugate vaccine (PCV) and herpes zoster (HZ) vaccines.

To increase delivery for adults, various outreach programs and vaccine promotion initiatives are organized by the Italian regions. Successful examples from Lombardy include outreach programs for homeless, vaccination in community homes and long-term care facilities (LTCF),<sup>21</sup> hospital campaigns (e.g., vaccination against HZ in cancer wards), and target-group-specific outreach such as the vaccine project for diabetic patients.<sup>22</sup> Moreover, multiple immunization success stories amidst the COVID-19 pandemic have been identified. Lombardy successfully integrated pharmacists as vaccine administrators, who ultimately were responsible for 46% of COVID-19 vaccine administrations (versus 28% by ASST and 17% by GPs).<sup>23,24</sup> In Tuscany, vaccination centers guaranteed extended openings, even on weekends, the booking system was simplified with a dedicated web portal, and the workflow was designed to ensure low waiting times and manage a large number of people. Puglia successfully reached its highest vaccine coverage for primary COVID-19 schedule ever (99.9% in 60 years and older).

### Surveillance of VPDs

Italy's national surveillance of infectious diseases is a responsibility of the MoH, supported by the regional health authorities and the National Institute of Health (ISS, *Istituto Superiore di Sanità*), and it falls under the EU and European Centre for Disease Control (ECDC) umbrella and regulations. The surveillance system is defined by the decree law of March 7, 2022 “*Revisione del sistema di segnalazione delle malattie infettive (PREMAL)*.”<sup>25</sup> It includes over 50 infections or groups of diseases,<sup>26,27</sup> and uses two main surveillance pathways, *mandatory notification* and complementary *special surveillance systems* that are coordinated by the ISS.<sup>28,29</sup> Although mandatory notification is based on a pre-defined list of infectious diseases that are compulsory to declare to the country's health authorities, the system allows for flexibility, with the addition of new elements when necessary (e.g., outbreak response). The special surveillance systems are enhanced systems implemented when disease surveillance requires additional infrastructure and/or data besides that which is obtained through the mandatory notification system (e.g., further laboratory testing). One representative example is RespiVirNet,<sup>30</sup> which collects epidemiological and virological data on influenza-like illness (ILI), using a network of GPs and pediatricians. This sentinel surveillance has an estimated national coverage of four percent and is complemented by a sentinel hospital-based severe acute respiratory infection (SARI) surveillance. Other VPDs that are targeted by a special surveillance system include vaccine-preventable invasive bacterial diseases (IBD), measles and rubella, and SARS-CoV-2/COVID-19. Results are available through EpiCentro,<sup>31</sup> an online tool created to improve access to Italy's epidemiological information.

## Epidemiology and disease burden of a selection of VPDs

### *Influenza and ILI (RespiVirNet)*<sup>30</sup>

The last three years have been characterized by atypical ILI waves, going from the near absence of circulation during the 2020–2021 season (COVID-19–related measures) to a high disease burden in the 2022–2023 season. During the 2022–2023 season, 14 million ILI cases were recorded, and a higher peak incidence was reached compared to pre-pandemic seasons. Causal pathogen distribution varied according to age group, with influenza, SARS-CoV-2 and Respiratory syncytial virus (RSV) paying a heavy tribute to ILI in the adult population. Overall, influenza was identified in 22% of the positive samples (80% influenza type A, with 92% subtype H3N2).

### *SARS-CoV-2/COVID-19 (COVID-19 integrated surveillance data in Italy)*<sup>32</sup>

With 16 million infections and more than 160,000 SARS-CoV-2-related deaths recorded between March 2020 and April 2022, Italy was one of the most affected countries by the pandemic in the EU, especially during its first phase.<sup>32</sup> Overall, more than 8 million SARS-CoV-2 infections, 260,000 hospital admissions 31,000 intensive care unit (ICU) admissions, and 150,000 deaths were averted between January 2021 and January 2022 thanks to the COVID-19 immunization campaign in Italy.<sup>33</sup> Results from the ISS national SARS-CoV-2 surveillance system and a modeling study by Marziano et al. have shown a progressive decline in the proportion of severe COVID-19 cases between early 2020 and end of 2023.<sup>32,34</sup> However, despite the reduction in disease severity, the weight of COVID-19 on the Italian public health system remains substantial as high disease incidence persists.

### *Respiratory syncytial virus*

A high RSV burden was reported for the 2021–2022 season in Lombardy. A marked increase in the population-level susceptibility to RSV during the COVID-19 pandemic (~60% increase in the proportion of the RSV infection-naïve population), particularly in the very young population, presumably contributed to the observed increase in RSV primary infections.<sup>35,36</sup>

### *Invasive pneumococcal disease*

Vaccine-preventable IBD, including invasive pneumococcal disease (IPD), are monitored through a special surveillance system of the ISS. As with other respiratory pathogens, a drop in IPD incidence was observed during the COVID-19 pandemic. This was a result of the interruption of possible pathogen transmission pathways by the restriction measures in place (e.g., social distancing, face masks) and of an indirect negative impact on the quality and rate of reporting of non-COVID-19 diseases due to an overburdened health system. In the pre-pandemic years, an increase in the number of IPD cases reported through the ISS's special surveillance system was recorded in Italy.<sup>37</sup> Comparing results to hospital records

revealed that this trend was related to an improvement of the surveillance system with increasing reporting rates, rather than a change in the underlying epidemiology of IPD.<sup>38</sup>

### Herpes zoster

According to data published in 2010 and 2017, the incidence of HZ in Italy is aligned with current EU/EEA incidences, with 5–10 cases per 1,000 person-years.<sup>39,40</sup> This incidence translates into an estimated 150,000 to 300,000 cases per year, with 1% requiring hospital admission. HZ and its complications, including post-herpetic neuralgia, disproportionately affect older adults from 50 years onwards.

### Tetanus

Between 2017 and 2021, Italy accounted for ~40% of all tetanus cases reported by EU/EEA countries to ECDC.<sup>41,42</sup> Such disproportionate contribution to overall notified cases in Europe could be attributed to the use of a case definition for tetanus different from the EU case definition.<sup>41</sup> Overall, 90% of the Italian cases occurred in persons 65 years or older.

### Diphtheria

During the multi-country 2022–2023 European outbreak of diphtheria related to migrant populations, three cases were detected in Italy in 2022.<sup>42,43</sup> They occurred in male adults (two cases in the age group 25–44 years and one case in the age group 45–64 years); two cases were travel associated. No further cases have been notified in Italy in 2023.<sup>44</sup>

### Pertussis

Data shows a strong decrease of pertussis notified cases in 2020–2021, likely due to the COVID-19 pandemic.<sup>42</sup> When compared to the epidemiologic data of other EU/EEA countries, Italy shows a different age distribution: the proportion of cases reported in adults 30 years or older is lower than the European average. This observation may be the result of underreporting, rather than an epidemiological trend.<sup>45</sup>

## Monitoring of vaccine coverage and vaccine effectiveness

Italy's national vaccination registry (NVR) was created in 2017, in parallel with the implementation of new childhood mandatory vaccinations. The registry was built to track vaccinations, vaccinated people, target populations, doses and administration times, side effects, and exempted individuals. The data are also used to calculate vaccine uptake, for assessment of the country's immunization programmes, and are shared with international institutions such as the WHO or ECDC. The data collected within the NVR is fed by the regions and autonomous province registries, every quarter. Although regional vaccine databases communicate with the NVR, the different systems are not yet fully integrated. This results in multiple challenges, such as difficulties in obtaining the vaccine history if a person is being treated outside the region of

residence. Moreover, regional vaccine databases use different software and access rights. Accuracy and completeness are ensured in the regional databases through alerts and mandatory fields.

Other specific databases and surveillance systems used for vaccine coverage uptake include the *influenza vaccination coverage data collection*, a register coordinated by the National Institute of Health that produces detailed vaccine coverage data by vaccine type, brand, risk group, and age group for every season; the Istat multipurpose *survey on households*,<sup>46</sup> which collects self-reported vaccinations from a sample population; and population surveillances *PASSI and PASSI d'Argento*.<sup>47,48</sup> PASSI is a population surveillance system monitoring health in Italy's adult population, while PASSI d'Argento monitors health in the older population. Besides the specific indicators of vaccination compliance among the general population living in Italy and its specific subgroups (e.g., people with chronic conditions or HCPs), these Italian surveillance systems allow further analysis by sociodemographic or other modifiable lifestyle risk factors.

For the COVID-19 pandemic, a fully integrated National COVID-19 Data vaccine registry was put in place, with daily updates, allowing for a vaccination uptake dashboard and close monitoring.<sup>49</sup> The linking of the COVID-19 vaccine registry with the national SARS-CoV-2 surveillance system through individual fiscal codes allowed for successful surveillance of COVID-19 vaccine effectiveness, generating brand-specific and age-group-specific results using retrospective cohort designs.<sup>50,51</sup> Other methods for vaccine effectiveness evaluations have been used in Italy, including the screening method to evaluate the meningococcal C conjugate vaccine during a serogroup C/cc11 *Neisseria meningitidis* outbreak in Tuscany.<sup>52</sup>

## Mandatory vaccination

At the end of July 2017, a law increasing the number of mandatory vaccines for children aged 0–16 years from four (poliomyelitis, diphtheria, tetanus, and hepatitis B) to ten (original list plus *Haemophilus influenzae* b, pertussis, measles-mumps-rubella (MMR), and varicella) to attend kindergarten and the primary/secondary schools up to 16 years of age, was ratified in Italy. This decision was driven by worrisome declines in vaccine coverage, the relative ineffectiveness of the “light” obligation strategies in place (without penalties), and the measles epidemic of 2017–2018, which severely hit Italy and resulted in the country being put under trial by the WHO for its low MMR coverage. The new law also applies to catch-up vaccinations in previously unvaccinated children and enforces specific penalties in the event of noncompliance with the legislation, with fines ranging between 100 and 500 Euros.

The making of the law met multiple challenges, leading to both political and public discussions and antivax-driven obstacles (e.g., disinformation, judicial proceedings). Nevertheless, a favorable impact on vaccine coverage was observed. Between 2016 and 2022, the vaccine uptake for polio went from 93% to 95%, and, more markedly, from 87% to 94% for MMR. Additionally, an increase in vaccine uptake for non-



mandatory vaccines was also registered, such as an increase in PCV coverage from 88% to 91%.<sup>53</sup> Currently, there are no adult compulsory vaccination laws in Italy at the National Level. However, for HCPs, some Regions have instituted compulsory vaccinations (especially influenza) in their Regional Laws. Mandatory vaccination as a tool to increase vaccine coverage was also applied during the COVID-19 pandemic, with compulsory vaccinations to perform recreational and social activities and for workers in selected settings (schools and health care facilities).

## Pharmacovigilance

Monitoring the safety of medicines, including vaccines, is a mandate of Italy's medicines agency, AIFA. The Italian pharmacovigilance system<sup>54</sup> is based on the National Pharmacovigilance Network (RNF) which can be accessed by health providers or citizens registered on the AIFA Services Portal, who have a username and password, a digital identity, a National Service Card (CNS) or an Electronic Identity Card (CIE). All suspected adverse reaction reports collected in the RNF are regularly sent to Eudravigilance and from Eudravigilance to the global database of the World Health Organisation, so basically after a short time since the report was made it becomes available to all international regulatory authorities competent in pharmacovigilance.<sup>55</sup> Italy's pharmacovigilance system was considered robust by the group of discussants during the meeting. Based on AIFA data, adverse event following immunization (AEFI) rates with non-COVID-19 vaccines reach 78 events per 100,000 doses. Most AEFI are classified as mild, with severe AEFI rates in Italy estimated at 3-6 events per 100,000 doses.<sup>56</sup> AEFI rates for COVID-19 vaccines have been slightly higher, with 97 events per 100,000 doses, mainly related to the most widely used mRNA vaccines.<sup>57</sup>

During the COVID-19 pandemic, AIFA participated in additional pharmacovigilance collaborations, such as the CovidVaccineMonitor.eu project.<sup>58,59</sup> This project is an EMA-funded prospective and multi-country European pharmacovigilance surveillance study. Sixteen EU countries were involved, with 12 actively participating in the prospective monitoring. The study used active surveillance via a smartphone web app, collecting both solicited and unsolicited safety events. In total, 2982 persons participated in Italy. Local events and non-severe systemic AEFI were all higher with mRNA vaccine produced by Moderna. Unsolicited events were the same across vaccine types. Special cohort monitoring was also performed within the project, with the University of Verona coordinating safety monitoring in special cohorts, including pregnant and breastfeeding women.

In addition to the monitoring of safety, communication over vaccination safety is also fundamental. Projects such as Progetto MAGNOLIA (a multilayer framework to enhance pharmacological knowledge among women in reproductive age, pregnancy, and post-partum) and dedicated studies, have shown that both pregnant and breastfeeding women are requesting more information on the vaccine safety to allow informed decision-making,<sup>60-62</sup>

## Vaccine confidence

Vaccine confidence is a quantitative predictor of vaccine uptake and is therefore essential to monitor.<sup>63</sup> In 2018, the European Commission engaged the Vaccine Confidence Project to create the first "State of Vaccine Confidence in the EU" report. Since then, the Vaccine Confidence Project had conducted bi-annual surveys on public attitudes to vaccines. According to results of 2022, vaccine confidence in Italy remains high in both the general population and in HCPs.<sup>64</sup> However, by comparison of the 2018, 2020, 2022 results in the general population, vaccine confidence tends to be lower toward Human papillomavirus (HPV) and MMR vaccines, and HCPs show lower vaccine confidence for the vaccination of pregnant women against influenza and COVID-19. In a mixed-methods study of HCP attitudes toward vaccination in 15 European countries, Italy was among the four countries with the lowest vaccine confidence, alongside Hungary, Romania, and Switzerland.<sup>65</sup> A lack of trust among HCP in health authorities and in the information they provide was identified as one of the drivers of this low vaccine confidence. In 2016, parental vaccine hesitancy in Italy was investigated by the ISS. Overall, across 3130 completed questionnaires, 83.7% of parents were in favor of vaccines, 15.6% were classified as hesitant, and <1% were classified as anti-vaccine.<sup>66</sup>

In the aftermath of the COVID-19 pandemic, vaccine hesitancy has been rising, particularly among young adults of reproductive age, and a growing vaccine confidence age gap has been detected in the EU by the Vaccine Confidence Project, with signals indicating higher confidence in age groups 45 years and older. In 2022, the Italian Society of Public Health recommended ten actions to counteract vaccine hesitancy (see Table 3).<sup>67</sup> These recommendations were successfully incorporated in the 2023-2025 PNPV. Moreover, a specific chapter detailing a framework for improved vaccine communication was included in the new plan. The successful translation of this framework into action will require dedicated tools, such as reliable references for the general population (e.g., VaccinarSi)<sup>68</sup> and identification of determinants of vaccine confidence through social media in order to convey targeted communication strategies.

## Immunization strategies in specific adult population groups: challenges, opportunities and examples of success stories

To provide additional insight into Italy's adult immunization, the country's specific recommendations, vaccine strategies, vaccine coverage rates, success stories, challenges, and opportunities are reviewed for seven adult population groups, namely older adults, pregnant women, HCPs, immunocompromised, migrants, young adults, and travelers (Table 4). Despite a detailed description of various best practices for adult immunization, the information reported here may present some limitations and not be fully representative of the general situation in Italy. Nonetheless, the initiatives and success stories provided can serve as potential examples for other countries.

**Table 3.** The Italian society of public Health's ten actions to counteract vaccine hesitancy, 2022.

Establishment of a National Multidisciplinary Working Group on Vaccine Hesitancy
Activation of a National Monitoring/Surveillance System on Vaccine Hesitancy
Identification and Dissemination of Tools and Methods to Measure and Understand Vaccine Hesitancy
Identification, Testing, and Dissemination of Local and National Good Practices to Counteract Vaccine Hesitancy
Widespread and Interdisciplinary Training on Vaccine Hesitancy
Training on Risk Communication, Community Engagement and Infodemiology
Inclusion of Effective Interventions to Counteract Vaccine Hesitancy within the National Immunization Plan
Promoting the Establishment and Growth of a Community of Practice and Research in the Field of Vaccine Hesitancy
Promoting Collaborations between Scientific Societies
Promoting Knowledge from the Behavioural Sciences

The future prospects and potential solutions to overcome barriers and enhance adult immunization efforts in Italy that are described in Table 4 were identified during the 2-day AIB country meeting by the AIB advisors and experts. Improvements and opportunities suggested include an increased prioritization of adults within the national vaccination plan and targeted communication campaigns tailored to high-risk adult population with clear and simple messages. Additionally, lessons learned from best practices embraced during the COVID-19 pandemic can contribute to improve vaccination data collection and facilitate integration of the regional registries into the NVR, which is essential to better define the effectiveness of the preventive measures adopted. Another opportunity to increase vaccination coverage in adults is to ease accessibility to vaccinations with the expansion of vaccine administration sites (e.g. pharmacies, hospital's wards, outpatients' clinics). Moreover, since in Italy only 5% of the National Health Fund is dedicated to prevention (not for

vaccinations alone) it is necessary to advocate for better funding of prevention. Scientific societies can play a role in engaging specialists in the vaccination pathways for specific high-risk groups and organize trainings and educational courses to improve knowledge and vaccine literacy of HCPs, including information on vaccine safety based on data provided by the pharmacovigilance surveillance system. Finally, a key consideration for future adult immunization strategies is the possible involvement of citizen and patient associations in the planning and decision-making process. Their inclusion could help prioritize new target groups and vaccines, while also promoting alliances to address challenges such as vaccine hesitancy and vaccine fatigue.<sup>87-90</sup>

## Conclusions

Italy has made groundbreaking measures in the field of adult immunization strategies within Europe. The country was one of the first to propose a life-course vaccination schedule, broadening the historical focus on children to include all adults. Moreover, Italy's PNPV sets targets for vaccination coverage, identifies the main immunization priorities, and considers multiple actions to reduce disparities among Italian regions. The vaccines included within the PNPV are categorized as LEA and are consequently free of charge for all individuals residing in the country. In 2017, significant gaps in vaccine coverage, particularly for the MMR vaccine that prompted a severe measles outbreak, were positively countered by the expansion of childhood mandatory vaccines for school attendance from four to ten different vaccines up to the age of 16 years. In addition, Italy has a strong vaccine vigilance system and established a successful post-marketing surveillance system for COVID-19 vaccines, for both effectiveness and safety. The COVID-19 pandemic imposed unprecedented resourcefulness, with new

**Table 4.** Italy's vaccine strategies and programs in older adults, pregnant women, health care providers, immunocompromised, migrants, young adults, and travelers.

Older adults	
Specific recommendations	PNPV: Influenza vaccine, PCV, HZ vaccine and Tdap are recommended. Specific Circular 2023/24: High-dose or adjuvanted influenza vaccines are to be used for seasonal flu vaccination of older adults.
Vaccine strategies	Multiple strategies are implemented across Italy's regions and in various settings (LTCF, hospitals, pharmacies etc.) mostly concerning influenza vaccination and some for PCV and HZ vaccine. <sup>69</sup> One example comes from the Veneto region where an active call, information letter, and set appointments for co-administration are given to residents 65 years of age (1 <sup>st</sup> dose HZ and PCV; 2 <sup>nd</sup> dose HZ and Tdap).
Vaccination coverage (in 65y+)	Coverage varies according to targeted pathogen and region. Decreasing trends have been recorded in recent years. Coverages tend to be higher in patients with frailty. <sup>70</sup> Vaccine coverage estimates are estimated at 56% for seasonal Influenza vaccine, 3-18% for COVID-19 5 <sup>th</sup> dose, <30% for PCV (no official national coverage data available), and 5-12% for HZ (no official national coverage data available).
Success stories/Examples of awareness activities on EU level	Calls to action through a Manifesto, <sup>71</sup> with the Italian Society of Gerontology and Geriatrics among its authors. Establishment of a Parliamentary intergroup on Healthy aging in March 2023. PROVAX programme: integrated vaccination programmed with information, vaccination, and follow-up during and after a hospital stay Emilia-Romagna region: mandatory to include specific recommendations for vaccinations in all hospital's discharge letters PNRR-Age-It: proposal for vaccination in all LTC residence and specific guidelines for admission to nursing home residents
Challenges	Lack of training of HCPs on vaccination of older adults and the benefits of the life-course approach. Lack of awareness of (preventable) disease burden in older adults, among HCPs and general population. Regional disparities in adherence to national guidelines. Absence of evaluation of the different vaccine strategies used. National coverage data lacking for pneumococcal and HZ vaccines Lack of coordination in the access to the digital vaccination records.

(Continued)

**Table 4.** (Continued).

Future goals/Opportunities	To reach coverage targets of PNPV: 75% for influenza & PCV; 50% for HZ vaccine. Insert vaccination in specialist guidelines and local diagnostic and treatment pathways for each chronic disease. Geriatric specialists to be included in NITAG membership. Expand involvement of SSN and its facilities. Involve hospitals and community pharmacies in vaccine administration, and improve access to pharmacy networks. Give access to the regional registry to all actors involved in the vaccination process, in order to feed databases with complete data.
<b>Health care providers</b>	
Specific recommendations	PNPV: HBV, influenza, MMR, Varicella, Tdap, (BCG for specific exposure risks). Specific Circular: Seasonal COVID-19 During the pandemic, COVID-19 vaccination was mandatory for HCP.
Vaccine strategies	Variable across regions and institutions. Can be offered at the workplace or local vaccination units/centers. Alternatively, by the HCP's general practitioner.
Vaccination coverage	No official national coverage data are available for all HCP-recommended vaccines. Influenza vaccine uptake in HCP is available through the population surveillance PASSI, showing low coverage rates of < 50%. <sup>72</sup> Additional vaccine coverage data comes from regional and local initiatives. <sup>73</sup> In general, vaccine coverage rates in HCPs are low, fluctuate, generally mirror those found in the general adult population, and tend to be higher for vaccines preventing diseases with an individual perceived risk (e.g., COVID-19 during pandemic).
Success stories/Examples of awareness activities on EU level	COVID-19 vaccine uptake, reaching 94% for primary schedule
Challenges	Lack of coordination, no uniformity of offer at regional or national level. Lack of awareness of benefits
Future goals/Opportunities	Incentives (e.g., paid vacation days; inter-department competition for best rates). Increase accessibility through proximity vaccination (on-site, mobile teams in hospitals). Increase and/or improve vaccination training for HCP.
<b>Pregnancy</b>	
Specific recommendations	PNPV: Tdap is recommended during the 3rd trimester, for each pregnancy. Influenza vaccine recommended (any trimester, according to seasonality).
Vaccine strategies	Specific Circular: COVID-19 vaccine during 2nd or 3rd trimester Vaccines are offered by obstetrics departments and hospital birth centers, as well as family clinics, prevention department clinics, vaccination centers, and GPs. Vaccines are administered by public health specialists, midwives, gynecologists, nurses, and to a lesser extent by GPs. Direct and free access to vaccines is possible at the prevention departments and vaccination centers, and appointments can be made via a unified booking center (centralized computerized system). Vaccinations are offered free of charge. Promotion of vaccination during and after pregnancy is part of birth support and/or antenatal programmes. Informative material for women, training of HCPs, and dedicated agenda slots are used to promote vaccination.
Vaccination coverage	No official national data available. Indeed, although collected in NVR, the data are not validated. Pregnancy status is not an obligatory variable in the registry, leading to denominator issues in correctly calculating vaccine coverage. According to regional data (Tuscany): the highest vaccine coverage in pregnancy is reached for Tdap: 43-47%. <sup>74</sup> This does not reflect national data.
Success stories/Examples of awareness activities on EU level	In Palermo, implementation of vaccination educational interventions, including counseling by HCP during childbirth courses, improved vaccination adherence. <sup>75</sup>
Challenges	Absence of dedicated vaccine pathways for pregnant women.
Future goals/Opportunities	Creation of a dedicated vaccine pathways, with better monitoring. Increase HCP awareness. Improve accessibility, extend free access to vaccination centers, implement (multilingual) outreach campaigns.
<b>Immunocompromised</b>	
Specific recommendations	PNPV: defines specific recommendations for Asplenia, Immunocompromised, HIV patients, solid organ transplant and Haematopoietic stem cell transplantation candidates, and household members of immunocompromised patients.
Vaccine strategies	PNPV 2023-2025: RZV and HPV vaccine (for persons living with HIV). Specific Circular: Seasonal COVID-19 The PNPV 2023-2025 details a framework to promote interventions in high-risk populations. Vaccine strategies are to be integrated within the immunocompromised patient's clinical care pathway. Moreover, immunization requires a proactive approach, both at the hospital and local level.
Vaccination coverage	No national-level coverage data or denominator data are available. Only local or regional studies in specific subgroups provide estimates. <sup>76,77</sup>
Success stories/Examples of awareness activities on EU level	The operational proposal for the vaccination of fragile/immunocompromised persons by a collective of Italian scientific societies. <sup>78</sup>
Challenges	Specific challenges were exposed during the COVID-19 pandemic. These included the ever-evolving epidemiology, vaccine hesitancy, and communication challenges. <sup>79</sup>
Future goals/Opportunities	Involvement of Specialists and scientific societies in immunization. Increase awareness (e.g., vaccine recommendations in discharge letter) and facilitate access (e.g., appointment booking options). Authorise access to NVR by professionals involved in patient care to improve and facilitate vaccination pathways.
<b>Young adults (example of HPV)</b>	
Specific recommendations	PNPV: HPV vaccination in adolescents, both females and males (targeted age: 11–12-year-olds); 2 or 3 doses according to age: 2-dose vaccination cycle (0 and 6 months) up to 14 years of age and 3-dose vaccination cycle at times 0, 2, 6 months from 15 years. New: Free of charge for women who have been treated for CIN2+ or higher-grade lesions. Vaccination may be administered before or after treatment, up to a maximum of three years after treatment. Free catch-up vaccination is recommended for women at least up to 26 years of age, also using the appropriate opportunity of the call to the first screening for the prevention of cervical cancer (25 years) and for men at least up to 18 years, if they have not been previously vaccinated or have not completed the vaccination course. Vaccination is also recommended and free of charge for subjects with HIV infection and MSM.

(Continued)

Table 4. (Continued).

Vaccine strategies	Not a mandatory vaccine. WHO launched in 2020 the first global health strategy for the elimination of cancer addressed as a public health problem. In Italy the strategy aims at strengthening prevention of cervical cancer and other related HPV diseases. The main identified actions to be taken in Italy are (1) Strengthening the national vaccination campaign against HPV with the active involvement of GPs, pediatricians, specialists (gynecologists, oncologists), family counseling centers, scientific societies and civil society, (2) Promotion of vaccination by expanding access to vaccination services, organizing open days and catch-up activities, the maintenance of gratuity over time for the target cohorts (up to 26 years for females and up to 18 years for males), the adoption of flexible informatic tools and technologies to support the active call and the management of the reservation to reduce the probability of non-presentation, (3) Analysis of the determinants of HPV vaccine hesitancy and development of an extensive communication and information campaign in support of the national vaccination campaign against HPV, committed on several fronts: schools, meeting points for adolescents and young people, all media (including social media).
Vaccination coverage	Vaccine coverage: varies by region. In 2021, coverage by 15y in males (birth cohort 2006), last dose, estimated at 54.2%, in 15-year-old females it was estimated at 69.4% at the national level. <sup>80</sup>
Success stories/Examples of awareness activities on EU level	SPERANZA: project on HPV vaccination after surgical treatment for HPV-related diseases. The study showed HPV vaccination to be beneficial as an adjuvant to surgical treatment for relapse prevention. <sup>81</sup>
Challenges	Remaining low coverage and specific vaccine hesitancy toward HPV vaccine, compared to other vaccines
Future goals/ Opportunities	Research on ideal timing for vaccination after (pre-) cancer lesions: international RCT trial NOVE and HOPE9 (RCT trial involving nine Italian centers). Reach PNPV HPV vaccine coverage target of 95%.
<b>Migrants, including refugees and asylum seekers</b>	
Specific recommendations	PNPV, Children: (catch-up) vaccination according to PNPV immunization schedule, and Hep.A in risk groups. PNPV, Adults: (catch-up) vaccinations against poliomyelitis, MMR, varicella, Tdap, and Hepatitis B. Italian guidelines further detail immunization of migrants. <sup>82</sup>
Vaccine strategies	The PNPV 2023-2025 now includes a strategy to reduce inequalities with regard to immunization. The strategy will now need to be translated into action.
National vaccination coverage	No national-level coverage data or suitable denominator are data available. Specific studies such as influenza in high-risk patients, rubella in women (PASSI study), or COVID-19 uptake studies have shown lower coverage rates in the migrant population. <sup>83,84</sup>
Success stories/Examples of awareness activities on EU level	AcToVax4NAM: access to vaccination for newly arrived migrants, including Co-creation of tools and training sessions with and for Professional For Health. <sup>85</sup>
Challenges	Although the right to access vaccinations is guaranteed for all migrants from a legislative perspective, this is not always the case in practice. Challenges are multiple and include cultural and linguistic barriers, difficulties to identify by health registries, and contact through usual channels (e.g., invitation letters). Difficulties in health service accessibility and mistrust of local authorities are additional constraints.
Future goals/ Opportunities	Drawing lessons from the COVID-19 pandemic. <sup>86</sup> Multidisciplinary approach, including civil society and social services. Enhancing professionals' knowledge about migrants' rights to health care/prevention. Improving reachability through updated data sources and collaboration. Promoting adherence through culturally sensitive health campaigns and strategies. Achieving vaccination coverage through flexible services and better documentation. Evaluating interventions to measure effectiveness. Strengthen NVR, essential for immunization follow-up of 'on-the-move' populations
<b>Travellers</b>	
Specific recommendations	Hep A in children visiting friends and relatives (free of charge). All: (catch-up) vaccinations for HBV, MMR and TdPaP (in children) or Tdap (in adults). Vaccination depending on destination, type of travel, and patient specificities. These (e.g., yellow fever, rabies) are not included in PNPV and therefore not LEA.
Vaccine strategies	Consultations of travelers in dedicated travel medicine clinics within many ASL.
National vaccination coverage	No national-level coverage data or denominator data are available (NVR does not include a "traveler" item). Roughly 50% of travelers are seen pre-travel, but this drops to < 20% if travelers visit friends and relatives.
Success stories/Examples of awareness activities on EU level	Good pre-travel counseling results in higher vaccine acceptance (e.g., rabies) Opportunity for catch-up vaccination
Challenges	The COVID-19 pandemic resulted in a total disruption of this preventive medicine. Travel medicine is not a recognized discipline in Italy.
Future goals/ Opportunities	Vaccinology formally taught. Travel medicine recognized as a discipline. Improvement of NVR with regard to denominators.

Abbreviations: BCG: Bacillus Calmette-Guérin; HCP: Health care providers; Hep: hepatitis; HIV: Human immunodeficiency virus; HPV: Human papilloma virus; HZ: herpes zoster; LEA, Essential levels of assistance, *Livelli Essenziali di Assistenza*; LTCF: long term care facility; HBV: Hepatitis B Virus; MMR: measles-mumps-rubella; NVR: national vaccine registry; PNPV: National Immunization Plan, *Piano nazionale prevenzione vaccinale*; PCV: pneumococcal conjugate vaccine; RSV: Respiratory syncytial virus; RZV: Recombinant zoster vaccine; SSN: National Health Service, *Servizio Sanitario Nazionale*; Tdap/TdPaP: Tetanus-diphtheria-acellular pertussis; NITAG: National Immunization Technical Advisory Group; ASL: Local Health Unit, *Azienda Sanitaria Locale*; GPs: General practitioners; HIV: Human Immunodeficiency Virus; HPV: Human Papilloma Virus; MSM: Men having Sex with Men.

vaccine campaign organization and strategies that can be leveraged, including the use of novel vaccine administration sites such as hospital settings and pharmacies. However, the fragmentation of Italy's SSN following the constitutional reform of 2001, has led to an increased complexity and regional disparities regarding immunization. Indeed, although LEA vaccines are financed centrally by the National Health Fund, the

organizational costs of immunization fall upon the regional authorities. As Italy's regions are not financially equal, decentralization has led to inequalities in vaccine campaign rollout and ultimately vaccine uptake. Other immunization challenges identified include the changing demographics with an aging population, an increase in vaccine hesitancy in the aftermath of the COVID-19 pandemic, the lack of targeted vaccine

campaigns and communication even toward HCPs, and specific issues related to underserved populations, such as migrants and pregnant women. Additionally, the lack of complete integration of the regional vaccine registries to the NVR leads to issues on the field (absence of vaccine history of patients) and vaccine coverage data gaps, particularly for high-risk groups that lack appropriate denominator data (e.g., travelers, immunocompromised, pregnancy, HCPs). Gaps in vaccine coverage data as well as the absence of certain VPDs in the national surveillance system (e.g., herpes zoster) impede vaccine campaign monitoring and evaluation. While Italy is often regarded as one of the leading examples in Europe for adult immunization, barriers to vaccination in Italy are well known and multiple future prospects and potential solutions have been identified by the involved Italian stakeholders to enhance adult immunization efforts. At present, the largest challenge remains the effective translation of recommendations into actions.

### Further reading

- Adult Immunization Board: [www.adultimmunizationboard.org](http://www.adultimmunizationboard.org).
- Italy's Board of Lifetime Immunization schedule: [www.vaccinarsi.org/notizie/2019/07/%E2%80%8Bcalendario-vaccinale-per-la-vita-2019](http://www.vaccinarsi.org/notizie/2019/07/%E2%80%8Bcalendario-vaccinale-per-la-vita-2019).
- Italy's National Observatory on Health: <https://osservatorioiosullasalute.it/>.
- Istituto Superiore di Sanità, EpiCentro: [www.epicentro.iss.it](http://www.epicentro.iss.it).
  - a. Respirirnet: [www.epicentro.iss.it/influenza/respirirnet](http://www.epicentro.iss.it/influenza/respirirnet).
  - b. PASSI: [www.epicentro.iss.it/passi/](http://www.epicentro.iss.it/passi/).
  - c. PASSI d'Argento: [www.epicentro.iss.it/passi-argento/](http://www.epicentro.iss.it/passi-argento/).
- Ministero della Salute COVID-19 vaccine uptake dashboard: [www.governo.it/it/cscovid19/report-vaccini/](http://www.governo.it/it/cscovid19/report-vaccini/).
- Vaccine Confidence Project: [www.vaccineconfidence.org](http://www.vaccineconfidence.org).

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### Authors' contributions

Supported by Chloé Wyndham-Thomas (AIB medical writer). All authors contributed to writing and reviewing the current version of the manuscript. All authors read and approved the final edited version. The views and opinions expressed in this manuscript are those of the authors and do not necessarily reflect the official policy or position of Italy's Ministry of Health.

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