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Historical, Legal and Scientific Issues of Paediatric Vaccine Mandates

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Abstract

This review outlines the scientific and legal foundations for a revision of the regulations concerning mandatory vaccinations, with a particular focus on the situation in Italy. The ten vaccines made mandatory by Italian Law No. 119/2017 (against poliomyelitis, diphtheria, tetanus, pertussis, hepatitis B, *Haemophilus influenzae* type b, measles, mumps, rubella, and varicella) are re-examined, with a particular consideration on their capacity to safeguard public health and, therefore, the interests of the community—a requirement that the Italian Constitution (Article 32) stipulates as a possible justification for mandating a medical treatment. Effects on infection, transmission, and duration of protection differ substantially between vaccines. Their implications regarding the need for vaccination—and the duration of any potential mandate for different segments of the population—must therefore be evaluated separately for each disease. While certain vaccines may be useful in specific epidemiological contexts, there is no justification for a generalized vaccination mandate for children. The analysis further indicates that scientific knowledge gained in recent years through active pharmacovigilance—some of which was not available in 2017—shows that adverse effects of vaccines on children's health are far from negligible, especially when weighed against the low incidence of most of the infectious diseases in question. This invokes the precautionary principle, a cornerstone of medicine, together with the need for truly informed consent, grounded in real-world data.

Keywords: Vaccine mandates; mandatory vaccination; herd immunity; informed consent; constitution; healthcare legislation

Introduction

In the aftermath of the COVID-19 pandemic and amid findings emerging from various commissions of inquiry, calls are growing for greater transparency in health-related decision-making and for political institutions to restore public trust. Against this backdrop, vaccine mandates are increasingly viewed as politically driven measures lacking a sound scientific basis, prompting renewed scrutiny of paediatric vaccination requirements. Italian Law No. 119/2017 requires minors aged 0–16 to receive specific vaccines according to their birth cohort and the applicable vaccination schedule (reported in **Appendix A**). (1) Non-compliance may result in administrative penalties. Access restrictions apply to early-childhood services and preschools, but not to compulsory education, subject to the exemptions and procedures established by law.

Introduced in response to a declared public health emergency during a measles outbreak, the law should now be reassessed in light of current epidemiological conditions and ethical considerations. In fact, article 1(1-ter) of the mentioned law specifically provides a mechanism for discontinuing the requirements for measles, mumps, rubella, and varicella following assessment of epidemiological data, safety reports, and coverage.

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Article 32 of the Italian Constitution provides that no medical treatment may be imposed except "by law," and that such a law is acceptable *only if the mandatory treatment is also intended to preserve the health of others*. Furthermore, any mandate is permissible only within the limits imposed by respect for the human person (**Appendix B**). This balance between individual freedom of treatment and community interests is undermined by a vaccine mandate not firmly anchored to scientific and technical grounds. Judgment No. 5/2018 upheld the challenged vaccination requirements in the circumstances assessed by the Court, while acknowledging that the balance between recommendation and obligation may change with scientific knowledge and epidemiological conditions. The same Court has suggested that the necessity of mandatory vaccination should be re-evaluated, both with regard to vaccines containing live attenuated viruses and those that make up the hexavalent vaccine.

Any decision to impose a vaccination mandate should balance the benefits and risks, both for the individual and for the community, as is the case with all medical and public health interventions. Examples include: abolition of smallpox vaccination; replacement of live attenuated oral polio vaccine with injectable formulations that do not carry a risk of reversion; replacement of the whole-cell pertussis vaccine with a less reactogenic acellular vaccine; and near-complete discontinuation of tuberculosis vaccination. Other vaccines (influenza, rotavirus, pneumococcal disease, herpes zoster, human papillomavirus, meningococcal A, B, C, W, Y, and in some cases hepatitis A) are recommended but not mandated.

The main question is whether mandatory vaccination is necessary to safeguard public health. This depends on whether herd immunity can be achieved: vaccination must produce a sufficiently high percentage of immune individuals—who neither carry nor transmit the pathogen—to halt its spread. It should be recalled that the critical threshold for herd immunity (**Vc**) is the fraction of the target population defined by the formula $\mathbf{Vc = 1 - 1/R_0}$, (2) where $\mathbf{R_0}$ is the basic reproduction number of the pathogen. For example, with an $\mathbf{R_0}$ estimated at around 12 (range 7–18) for measles, (3–5) the **Vc** value is approximately 0.92—meaning that more than 92% of the population would need to be immunized to halt the spread of the infection. The original formula assumes, by definition, a perfect vaccine (100% efficacy). However, various authors (6,7) incorporate a factor related to real-world (field) effectiveness of a vaccine when calculating the critical threshold for herd immunity (**Vc**). If vaccination protects only a proportion "**E**" of those vaccinated, then the critical vaccination threshold must be: $\mathbf{Vc = (1 - 1/R_0) / E}$

Therefore, achieving herd immunity depends both on the type of microorganism in question and on the effectiveness of the vaccine. As shown below, vaccination with purified substances, bacterial extracts or proteins (e.g. vaccines against poliomyelitis, tetanus, diphtheria, pertussis, and hepatitis) may provide individual protection but play no role in generating herd immunity. Even other vaccines based on attenuated viruses cannot generate herd immunity if administered only to children.

Recently, the Italian Independent Medical-Scientific Commission (CMSi) made available to citizens' associations, public authorities, healthcare professionals, politicians, lawyers, educators and journalists a detailed analysis of the ten mandatory vaccines to inform public debate. (8) This article highlights the key points of the issue. It is important to reiterate that the intention here is not to criticise the use of vaccines in childhood, but rather to discuss whether there is a genuine need for mandatory vaccination. For each of the ten products, we address whether the vaccine works, whether it blocks transmission, and, finally, whether a legal mandate remains justified in Italy in 2026.

Adverse Events and Pharmacovigilance

In the debate on mandatory vaccination, the requirement to respect the human person, as stated in Article 32 of the Italian Constitution, is crucial. The Constitutional Court held that a statute imposing a vaccine is compatible with the Constitution **"***provided that it does not adversely affect the health status of the person subjected to it, except for those consequences which, by reason of their temporariness and limited severity, appear normal for any medical intervention and are therefore tolerable." (Judgment* No. 307/1990). Law No. 119/2017 (Article 1(1-ter)) itself includes among the criteria for possible suspension of the mandate "*any adverse reactions reported pursuant to the provisions of law in force".*

If vaccines were completely harmless, there would be no doubt that, for certain serious diseases, mandatory vaccination could be justified in the interest of public health, provided it succeeded in blocking the infection. However, this is not the case, as adverse reactions, including serious ones (SAEs), are unequivocally documented. Regulatory seriousness is defined by outcomes such as death, life-threatening illness, hospitalisation, significant disability,

congenital anomaly, or another medically important event. Symptom severity and regulatory seriousness are distinct concepts. (9) This is not the place to analyse all the adverse effects of numerous paediatric vaccines, but the associated risk is undeniable and must be taken seriously—especially when the State seeks to mandate a potentially risky intervention for healthy individuals, without their consent and in the name of an alleged public interest. Unfortunately, the data suggest that passive pharmacovigilance is completely inadequate to document the true incidence of adverse events following immunization (AEFIs), while pharmaceutical companies' clinical studies and rare studies of active pharmacovigilance provide more comprehensive information. Briefly, for the six vaccines contained in the hexavalent formulation, the overall incidence of SAEs reported by manufacturers is estimated to be at least 1,000 reactions per 100,000 doses. With four doses, one may estimate a minimum of 4,000 reactions per 100,000 children.

In a multicentre, double-blind, comparator-controlled, Phase III study conducted in Sweden, Italy, and Finland, healthy infants were randomized 1:1 to receive either A) an investigational hexavalent vaccine (DTaP5-HB-IPV-Hib) or B) the licensed hexavalent vaccine Infanrix-hexa (DTPa3-HBV-IPV/Hib) at 2, 4 and 11–12 months of age. (10) Both groups received the pneumococcal vaccine and the rotavirus vaccine concomitantly—a common practice, including within the Italian vaccination schedule (see **Appendix A** for details on combined vaccinations). Solicited adverse event rates after any dose were similar in both groups, except for higher rates of pyrexia (6.4% difference; 95% CI: 1.5–11.3) and somnolence (5.8% difference; 95% CI: 1.7–9.8) in the DTaP5-HB-IPV-Hib group. Severe fever was reported in 4.0% and 2.7% of children in groups A and B, respectively. The temperature threshold, observation window, and denominator should be reproduced exactly from the study table. Vaccine-related SAEs occurred in 0.3% and 0.5% of children in groups A and B, respectively. These incidence data are much greater than the incidence of SAEs reported by the Italian Medicines Agency (AIFA) mainly based on passive (or mixed) pharmacovigilance. Extrapolating these data to an Italian birth cohort (approximately 400,000 per year), incidences of 2.7% for severe fever and 0.5% for SAEs would affect approximately 10,800 and 2,000 children, respectively, each year.

For the measles–mumps–rubella–varicella vaccine, active surveillance data estimated an adverse-event rate of 46.2%, of which 11.0% were classified as serious (reporting rate = 5.1 × 100). Severe hyperpyrexia, neurological symptoms and gastrointestinal diseases occurred in 38, 20 and 15 cases per 1,000 participants, respectively. These data derive from the report of the Epidemiological Observatory of the Apulia Region. (11–13) A projection of such AEFIs in an Italian birth cohort would yield tens of thousands of serious AEFIs.

A further, more difficult issue concerns adverse reactions that manifest as chronic diseases, particularly autoimmune diseases, which may go unrecognized. A systematic review with meta-analysis found an association between vaccinations and systemic lupus erythematosus and rheumatoid arthritis. (14) Finally, causality assessment should be performed carefully using appropriate techniques for complex, multifactorial post-vaccination conditions, such as those associated with cardiovascular and neurological disorders. (15,16)

Assessment of a mandate should compare compulsory vaccination with realistic recommendation-based alternatives, accounting for uptake, disease incidence, adverse events, and educational access. Current incidence under an established vaccination programme is not automatically the incidence expected under a different policy.

Discussion of the Ten Vaccines Mandated by Law No. 119/2017

To support the constitutionality of a paediatric vaccine mandate, each vaccine must be shown to be genuinely necessary for community health. Alternatively, vaccination coverage below a critical threshold must create a transmission risk not only for unvaccinated individuals, but also for the community. All ten vaccines covered by Law No. 119/2017 are considered below.

Diphtheria

Diphtheria is now very rare in Europe. (17) Diphtheria mortality declined before compulsory vaccination, reflecting improvements in living conditions and clinical care; this does not establish that vaccination made no substantial contribution to later disease control. (18,19) The mortality curve was already declining when compulsory vaccination was introduced in 1939 (**Figure 1A** [20]). During that period, widespread antibiotic use began for respiratory tract infections. Oral hygiene and schooling likely contributed as well.

The improvement in sanitary conditions and healthcare across the population over the course of

the 20th century is also suggested by the trends in the incidence of other, once-widespread diseases for which no vaccine was ever administered (**Figure 1B**). The rate of under-5 mortality in Italy is currently 2.85 per 1,000 live births, among the lowest in the world. (21) The leading causes of death are certain perinatal conditions and congenital malformations, which account for 69% of deaths within the first five years of life. At the beginning of the last century, by contrast, deaths were primarily caused by infectious diseases, with a mortality rate of 108 per 1,000 live births.

A further line of evidence is that, over recent decades, infections caused by non-toxigenic *Corynebacterium diphtheriae* strains have also declined. Because vaccination uses inactivated toxin rather than the bacterium, the disappearance of all *Corynebacterium* strains cannot be attributed to vaccination. A third line of evidence is that protection conferred by diphtheria vaccination wanes over the years, and today at least half of the population lacks diphtheria immunity, (22) yet cases are exceptionally rare. According to a systematic review and meta-analysis, (23) in the 2–6 years since the last dose, approximately 25% of the participants did not achieve seroprotective antibody levels (≥0.1 IU/mL). Finally, the diphtheria toxoid primarily protects against toxin-mediated disease and does not reliably prevent colonisation and transmission. (17)

In summary: a) the diphtheria vaccine works, but immunity wanes over a few decades, leaving large segments of the population unprotected—yet the disease is rare in the current epidemiological setting; b) it does not stop the spread of the disease because vaccinated individuals can become colonized and transmit; c) the disease does not pose a public health problem in Western countries, as it has been extremely rare for decades, and the few cases that do occur can be treated with antibiotics and antitoxins, provided that the diagnosis is made early. Consequently, a generalized vaccination mandate for children is not justified.

Tetanus

Tetanus is a severe disease, but mortality declined before routine childhood vaccination, which was recommended in 1963 and made mandatory in 1968 (**Figure 1C**). Vaccination, wound care, and improved living conditions have all contributed to its present epidemiology. (18,19) In Italy, half of adults no longer have tetanus immunity, (24) yet annual cases remain below one per million, predominantly among people aged over 25 years (**Figure 2** [25]). A similar decline in seroprotection against tetanus, over the decades following vaccination, has recently been reported in a study conducted in China. (26)

In summary: a) the tetanus vaccine is effective, but immunity wanes over the course of several decades; however, the disease is extremely rare even in adults, in a setting shaped by recommended vaccination, hygiene standards, and medical wound care; b) a vaccine mandate might have made sense many decades ago for certain professional groups—given the significant prevalence of the disease, poorer hygiene conditions, and lower public awareness—but the condition no longer poses a public health problem today; c) the vaccine consists of an inactivated toxin and protects the vaccinated individual in the event of an infection, but it does not protect others. Consequently, a generalized vaccination mandate for children is not justified.

Pertussis

In Italy, pertussis mortality declined from about 6,000 children per year at the beginning of the 20th century to one case in 1995, the year in which the DTaP vaccine (diphtheria, tetanus, and acellular pertussis) began to be recommended as a primary three-dose series administered during the first year of life (**Figure 1D**). Pertussis incidence is also relatively low, remaining below 20 cases per 100,000 inhabitants. (27) In recent years, however, pertussis has re-emerged in many countries, including those with very high vaccine coverage (95–98%). In 2024, 209,674 cases of pertussis were reported by 29 EU/EEA countries. The notification rate in 2024 was 54.9 cases per 100,000 population, more than eight times the 2023 rate, and 78 times the 2022 rate. Vaccination status was known for 132,350 cases. Of these cases, 26,872 (20%) were unvaccinated, 10,594 (8%) were vaccinated with one or two doses, 12,124 (9%) with three doses, and 58,385 (44%) with four or more doses. A total of 24,375 cases (18%) were vaccinated, but the number of doses was unknown.

This failure to control pertussis is attributed to limited vaccine effectiveness (**VE**), (28–31) lack of mucosal IgA-mediated defence (30,32,33) and antigenic changes, including the emergence of pertactin-deficient strains. (34–38) A systematic review reported that the efficacy of the acellular pertussis vaccine is initially high (91%) but wanes over time, with a decline of 9.6% per year. (39) At the individual level, the vaccine reduces disease severity, but it does not block transmission, with consequent pertussis outbreaks in vaccinated populations. (40,41)

A recent study reported an increase in the proportion of fully vaccinated cases among individuals aged 0–18 years, from 12.50% in 2016 to 79.24% in 2024. (42)

In summary: a) the pertussis vaccine reduces disease severity, but its effectiveness is limited and short-lived; b) pertussis is most dangerous in young infants, although serious complications occur at other ages; early antibiotics may reduce severity and infectiousness; c) acellular vaccines provide incomplete protection against infection and transmission. Consequently, a generalized vaccination mandate for children is not justified.

Poliomyelitis

The fear of poliomyelitis remains part of the collective imagination, yet the disease has been absent in Europe for decades and the WHO European Region was certified free of indigenous wild poliovirus transmission in 2002. In Italy, mortality from poliomyelitis declined in conjunction with universal vaccination campaigns, well before the introduction of mandatory vaccination (**Figures 3A** and **3B**).

The near-total disappearance of poliomyelitis from Europe may also be due to the introduction of the oral vaccine (Sabin), which provides excellent intestinal immunity and spreads through wastewater. However, this vaccine has caused serious safety concerns—specifically, vaccine-derived paralytic polio—resulting from the emergence of mutated strains. When the current inactivated poliovirus vaccine (IPV) was introduced, polio had already disappeared from Europe. Consequently, there is no field evidence of the effectiveness of the current vaccine where the virus is circulating. In addition, since poliomyelitis is caused by an enterovirus, an injectable vaccine cannot confer intestinal immunity and therefore cannot block transmission.

In summary: a) the efficacy of the inactivated poliovirus vaccine (IPV)—currently in use—has never been demonstrated in the field in Europe, due to the absence of cases; b) poliomyelitis is absent from the European epidemiological landscape—barring the possibility of an occasional imported case—and does not constitute a public health issue; any cases of polio that might occur in the coming years (likely vaccine-derived or imported) would be strictly contained through hygiene measures, the isolation of cases, and "ring vaccination," and would pose no risk of an epidemic; c) the IPV is unable to prevent the spread of the virus, nor can it confer herd immunity, as it does not provide protection at the intestinal level. Consequently, a generalized vaccination mandate for children is not justified.

Hepatitis B

Hepatitis B is transmitted through exposure to infected blood (transfusions or injection drug use), tattooing performed under unhygienic conditions, or bodily fluids such as semen and vaginal secretions. In Italy, incidence has been steadily declining since 2010, and the decline continued after 2017 until 2025. (43) Those most affected were aged 35–64 years; since 1990, no fatal cases have been recorded among the paediatric population (**Figure 3C**). Following vaccination, anti-HBs antibody levels gradually decline; only one-third of vaccinated individuals maintain protective levels after 15 years. (44,45) Given the decrease in the incidence of the disease, this suggests that long-term protection may persist thanks to immune memory, or that the opportunities for transmission—even among adults—have changed.

Autoimmune conditions have been reported after hepatitis B vaccination, and several mechanisms have been proposed. (46–48) Concerns regarding the advisability of exposing the entire population to mandatory hepatitis B vaccination have been raised by authoritative experts. (49) These authors conducted a literature review to evaluate the benefits of hepatitis B vaccination in individuals not previously exposed to HBV. Based on four available studies, the hepatitis B vaccine showed no clear effect on the risk of becoming positive for viral antigens.

In summary: a) the hepatitis B vaccine is effective in protecting high-risk individuals, but there is no evidence that it is effective in healthy newborns; b) hepatitis B is extremely rare, and vaccinating infants who are only a few months old and not at risk is unnecessary from a public health perspective; c) unvaccinated children cannot infect vaccinated ones due to hepatitis B-specific transmission pathways and the immunity of vaccinated individuals. The argument concerning hepatitis B in Italian children should address their absolute risk and the performance of targeted alternatives to avoid infection. Consequently, a generalized vaccination mandate for children is not justified.

Haemophilus influenzae type b

Haemophilus influenzae includes encapsulated and non-encapsulated strains. Colonisation and common respiratory infections should be distinguished from invasive type b disease (*Hib*), which is the target of

mandatory vaccination. However, the vaccine's efficacy is not 100%: Of 44 cases of invasive *Hib* disease that occurred during the three-year period 2021–2023, 9 cases involved vaccinated children who met the criteria for defining vaccine failure (disease occurring two weeks after the administration of a single dose in a child over one year of age, or, alternatively, one week after two doses in a child under one year of age). (50) In Italy, after the introduction of the vaccine in 1995 (without a mandate), the number of invasive *Hib* disease cases declined in children. No public health emergency exists: Invasive disease caused by serotype b—the only vaccine-preventable form—is now very rare: 17 in 2021, 16 in 2022, 11 in 2023, 8 in 2024, with no deaths recorded. Yet invasive *Haemphilus influenzae* disease caused by non-b strains has increased steadily since 2007, raising concern among central public health authorities. (51) The frequency of cases of non-encapsulated *Haemophilus influenzae* associated with meningitis is increasing in Italy, and diverse and heterogeneous clones are circulating. (52)

In summary: a) invasive diseases due to serotype b—the only vaccine-preventable form—are very rare; b) the bacterial disease, if diagnosed in time, can be treated with antibiotics; c) non-b and non-encapsulated strains now account for much of the invasive disease burden. Consequently, a generalized vaccination mandate for children is not justified.

Measles

Measles, a disease widespread in the early 20th century, declined in its incidence over time—in terms of both mortality and morbidity—independently of vaccination. However, the disease has not disappeared and is resurfacing even in regions from which it had seemingly been eliminated. Given the importance attributed to measles by the mass media and health authorities—as well as its role as a proxy indicator of how well a vaccination system is functioning—we will devote greater attention to this disease here.

Data reported by Pezzotti (27) indicate that the introduction of the recommended monovalent measles vaccine in the mid-1970s had a limited impact on the downward trend in morbidity, which was already occurring spontaneously. The effect of universal MMR vaccination on mortality is even less apparent (measles–mumps–rubella), introduced from 1999 onward (**Figure 4**).

In Italy, measles mortality was 3 per 1,000 live births in 1930, fell to 0.2 in 1961 and approached zero around 1980, well before widespread MMR vaccine adoption. Over the past 25 years, measles cases (ranging from a few hundred to a few thousand per year) are mostly sporadic or occur in short transmission chains; they have never generated epidemics. Mortality is much higher in low-income countries and fragile, conflict-affected settings with high levels of malnutrition and vulnerability.

Although the elimination of measles is considered an ideal goal for all vaccination programmes, it has proven much more difficult than anticipated due to a number of critical factors, (53) most notably the following: a) the extremely high contagiousness of the virus, which requires vaccination coverage of over 95% to achieve herd immunity; b) international travel has increased significantly in recent decades, leading to a rise in "imported" cases; c) the imperfect efficacy of current vaccines, which necessitates two doses and catch-up vaccination schedules to address immunity gaps resulting from low viral circulation and some secondary vaccine failures; d) growing public indifference toward measles, contrasted with heightened concern regarding chronic degenerative diseases and adverse reactions to vaccines; e) the challenges associated with modern vaccination campaigns that rely on mandatory paediatric immunisation rather than fostering informed consent and public support among the population, including young adults; and f) technical and organisational issues in clinical, epidemiological, and virological surveillance. In short, attributing the resurgence of measles in regions where it had seemingly been eliminated to a supposed decline in paediatric vaccination coverage seems like an incomplete explanation.

Given the high contagiousness of the disease, the threshold for herd immunity against measles was estimated by Fine to be between 83% and 94% of immunized individuals. (54) In 2014, coverage of 90% obtained without mandates was considered acceptable. Nevertheless, WHO sought to increase paediatric coverage to 95%, relying on mandates and sanctions for non-compliance. Even this approach failed to eliminate the disease, and in 2024 cases increased to more than 1,000. A similar phenomenon occurred in 2025 in the United States: as of 14 October 2025, 1,596 confirmed measles cases were reported across 44 outbreaks. Despite high childhood vaccination coverage, measles has once again become an endemic disease in the USA. (55) From a technical perspective, it is essential to recognize that the 95% value often indicated as an ideal target for all vaccines has not been supported by scientific studies. (56)

The measles vaccine is effective, although vaccine-induced immunity gradually wanes over time (57) and outbreaks occur even in highly vaccinated settings. (58) The effectiveness of the measles vaccine in the major outbreak of 2017 in Italy can be estimated from epidemiological data. By cross-referencing data on vaccination coverage with the number of measles cases among individuals aged 1–39 years—the age group in which nearly all cases occurred, excluding infants under one year of age, who are not yet eligible for vaccination—the **VE** is calculated to be slightly less than 80% (the vaccine effectiveness was calculated using the formula $\mathbf{VE = [1 - (I_v/I_{uv})] \times 100}$ (59) (**Table 1**).

This incomplete vaccine effectiveness certainly has implications for the stated goal of eliminating measles by relying on herd immunity. Considering the situation in Italy described above, with an $\mathbf{R_0}$ of 12 and a **VE** of 79.02%, the required vaccination coverage (**Vc**) is 0.92/0.79 = 116%, which clearly indicates that achieving herd immunity through immunisation alone is impossible. This impossibility becomes even more apparent when one considers that it would be difficult to carry out mass vaccination among the adult population as well—unless a mandate were imposed on them, too, the feasibility of which for measles is highly questionable. Similar conclusions have been reported elsewhere. In an analysis of a measles outbreak in Japanese schools, (3) $\mathbf{R_0}$ and **VE** were estimated at 7.40 and 76.55%, respectively. Because of the lower **VE**, measles virus transmission could not have been stopped even if all students received the vaccine.

In Italy, paediatric measles vaccination coverage was approximately 90% well before Law No. 119/2017 introduced mandatory vaccination. After the law entered into force, coverage among birth cohorts from 2016 onwards rose by 2–4 percentage points and remained between 91% and 94.8% until 2025. Yet, after a few relatively quiet years, there were 1,084 cases in 2024, 529 cases in 2025, and 472 cases in the first five months of 2026. These trends suggest that the mandatory vaccination policy has not yielded the results claimed by its proponents and that factors other than paediatric vaccine coverage are at play.

Also in European countries, the increase of measles vaccination coverage during years from 2000 to 2023 was not followed by significant decrease of incidence. (60) A recent review examined the risk of measles re-establishment as endemic transmission in countries where it had previously been eliminated. (61) Risk ratios were then calculated for 10% reductions in first- and second-dose coverage across coverage categories <90%, <80%, and <70%. First-dose coverage <70% was the only significant finding (95% CI 1.09–1.31). Only when coverage falls below 70% is there a significant increase in measles re-establishment risk in countries that had previously eliminated measles. (61) Vaccination confers weaker immunity than natural infection, as also supported by seroprevalence studies (62,63) and by mathematical models. (64) This suggests that, when measles circulates within a population, it acts as a "natural booster" even for vaccinated individuals, who would otherwise lose immunity over time. (65)

A key feature of measles epidemiology, increasingly evident over time, is that in Western countries the disease mainly affects adults and young adults. (66) Many cases also occur during the first year of life, before the age of vaccine eligibility (15 months). In Italy, from 2017 onward, 80% of cases occurred in age groups outside the scope of the paediatric mandate (**Figure 5** [67]). Since the vast majority of cases involve young adults, it would be incorrect to attribute this unfavourable trend seen in recent years to a supposed decline in paediatric vaccination coverage during the pandemic.

Breakthrough infections are increasingly frequent among individuals aged 15 years or older who have received two vaccine doses. (64) Similarly, a recent study conducted in Serbia (68) documented a marked decline in the number of immune individuals in the 30–49-year age group, whereas older adults maintained full protection. A significant measles immunity gap exists among younger adults in Türkiye, with measles IgG seropositivity declining from 78.4% in 2014–2019 to 62.6% in 2022, consistent with a cohort effect whereby vaccine-era cohorts exhibit lower protection than older adults with naturally acquired immunity. (69) Rubella immunity, by contrast, remained close to the 95% elimination benchmark throughout.

Another important issue is that, in an epidemiological setting approaching elimination, but in the absence of eradication, the lack of exposure to the endemic wild-type virus means that natural immune boosting no longer occurs. (70) Consequently, measles-specific IgG levels in the population follow a trajectory of steady decline over time following vaccination, gradually expanding the pool of susceptible young people and young adults and creating a persistent risk of outbreaks. (71) In Taiwan in 2025, an imported case of measles triggered an outbreak in a healthcare setting, resulting in 19 confirmed cases—a consequence of a significant decline in immunity among the healthcare workers involved. (72)

In summary: a) measles had been on the decline for many decades—both before and after the introduction of large-scale vaccination—yet the goal of eradication has not been achieved, due to both the high infectivity of the virus and the fact that artificial immunity is shorter-lived than natural immunity; b) while the vaccine is effective in protecting children for a few years, elimination remains a distant prospect, as the disease most frequently affects infants under the age of vaccination eligibility (<1 year old) as well as young adults (teachers, nurses, parents, etc.); c) given the dynamics of the disease over time, and the fact that it has not been eliminated even in populations with very high vaccination rates, a vaccination policy focused on children does not appear to have offered any public health advantage. Consequently, in the current epidemiological context, a generalized vaccination mandate for children is not justified; furthermore, for the reasons mentioned, it will be necessary to carefully assess the risk that intensive vaccination within the paediatric population could paradoxically prove counterproductive to public health, by shifting the age of disease onset to later stages of life, when the clinical risk is greater.

Irrespective of whether a legal mandate is justified, the idea remains valid that vaccination could be useful on a voluntary basis—particularly if available in a monovalent formulation. Moreover, a single-component vaccine could be highly useful for outbreak containment by vaccinating close contacts within 72 hours after exposure ("ring vaccination" or "cocoon strategy" when aimed at protecting newborns within a household). Unfortunately, manufacturers have converged on producing and marketing only more commercially profitable combined vaccines (MMR and MMRV).

Pointing out the limited effectiveness of a vaccine or a mandatory childhood vaccination programme does not mean discrediting efforts to eradicate a disease; rather, it serves to identify critical or missing factors that must be considered in pursuit of the ideal goal: combating the disease through methods that are both collectively agreed upon and ethically acceptable to all. Instead of imposing rigid measures to reach the elusive "measles-free" status, an alternative perspective suggests it would be more appropriate to "contain" the disease within acceptable limits, allocating resources in proportion to the actual level of risk. Achieving this desirable objective would require: a) striving to develop more effective vaccines; b) identifying other factors affecting infectivity—specifically those that influence the $\mathbf{R_0}$ value; c) establishing "ring vaccination" plans to swiftly interrupt any outbreaks; d) ensuring the availability of rapid diagnostic tests; e) identifying and strengthening non-pharmacological measures to prevent transmission or reduce the clinical severity of the infection; and f) making a single-component measles vaccine available, which might encourage those segments of the population who are hesitant to vaccinate due to fears of adverse effects.

Mumps

Until the 1960s, mumps was very common, affecting almost all school-age children through recurrent epidemics, and conferring lifelong immunity. The persistence of naturally acquired immunity was due both to an efficient immune response to the wild-type virus and to repeated exposures of adults to infected children over the life course, which acted as natural boosters. Vaccination against mumps (**Figure 4B**)—typically administered alongside vaccines for measles and rubella (MMR) and, since 2017, following the introduction of mandatory vaccination, with the addition of the varicella component (MMRV)—may have contributed to a reduction in mortality; however, the extent of this effect remains unclear, given that the vaccine was introduced at a time when mortality was already near zero and morbidity was also in decline. (27) The efficacy of the vaccine is only partial and short-lived; numerous reports document mumps outbreaks among vaccinated young adults, suggesting primary vaccine failure or waning of vaccine-induced immunity. (73,74) In 2015, among 20,496 students at the University of Iowa, mumps affected 259 students, 98.1% of whom had received at least two MMR doses. (75) Five years after the second MMR dose, fewer than half of vaccinees retained sufficient antibody protection. According to ECDC data, 193 cases of mumps were recorded in Italy and 2,963 in Europe in 2023. (76) Information on vaccination status was available for 1,938 cases (65%). Of these, only 564 (29%) were unvaccinated, 390 (20%) had received one dose of the MMR (measles-mumps-rubella) vaccine, 624 (32%) had received two doses, and 12 (0.6%) had received three or more doses. The majority of fully vaccinated individuals (those who had received at least two doses) were in the 5–14 age group. Given this limited **VE** over the medium to long term, it is entirely impossible to rely on mandatory childhood vaccination and herd immunity to eradicate the virus.

In summary: a) small outbreaks occur within communities of young people and adults with high vaccination coverage, which demonstrates that vaccine-induced immunity wanes; b) childhood mumps disease is mild and no epidemic emergency exists; c) it

is even possible that the net balance is unfavourable for vaccinated individuals, by increasing the risk of more dangerous mumps in adulthood and older age, thereby failing the constitutional requirement that the measure not negatively affect individual health. Consequently, a generalized vaccination mandate for children is not justified.

Rubella

Rubella is extremely mild and often asymptomatic, except when it affects a pregnant woman, in which case it can cause foetal malformations (congenital rubella syndrome). To prevent this outcome, a vaccine was introduced in 1972 and offered to preadolescent girls not already immunized by natural infection in childhood (**Figure 4C**). Given the occurrence of only sporadic cases and no outbreaks for at least 36 months, the disease may be considered eliminated. This success suggests low contagiousness and indicates that a recommendation-based policy alone (pre-2017) was effective. In 2012, 93.8% of pregnant women in Italy possessed IgG antibodies against rubella, (77) but some (0.4%) also tested positive for IgM antibodies—suggesting that the virus continues to circulate, even in asymptomatic cases, which may be one of the reasons for the high level of population immunity.

No cases of congenital rubella syndrome were identified in 2019–2021. The Serbian study cited above (68) confirms the absence of reported rubella cases in that country, attributing it to high vaccination effectiveness. Unlike measles and mumps, rubella IgG levels were consistently high across all ages, with a mean seropositivity of 94.8%. According to the authors, this indicates that epidemic risk is minimal.

In summary: a) the rubella vaccine is effective and, since 1972, has been recommended for preadolescent girls to prevent congenital rubella syndrome, with good results; b) in children, rubella follows a very benign course; c) there is robust population immunity—potentially bolstered by the asymptomatic circulation of the virus—and, in the current context, there is no risk of an epidemic. Consequently, although the recommendation to vaccinate seronegative preadolescent girls is not in question, a generalized vaccination mandate for children is not justified.

Varicella

Varicella (chickenpox) is a contagious exanthematous disease caused by the varicella-zoster virus (VZV), a DNA herpesvirus. The vaccine is effective, although protection is incomplete. Protection is estimated to last 13–20 years, less than naturally acquired immunity. As vaccination increases, reduced viral circulation (without eradication) provides fewer opportunities for natural boosting, leading to waning protection that is likely to manifest in many individuals in later life. Therefore, universal paediatric vaccination risks shifting cases to older ages—a concern already raised for measles and mumps, but more serious for varicella. (78) Varicella is very rarely fatal in children (1 death per 100,000 cases, see also **Figure 4D**), but it is more severe in adults. Mortality risk increases with age: in adolescence it is already 5–7 times higher than in childhood; in adults 10–15 times higher; and in older age 100 times higher. Moreover, if immunity wanes over time, mothers may become immunologically unprotected and therefore unable to transfer passive immunity to newborns.

Varicella vaccination introduces a live attenuated virus that persists latently in neural cells, with potential reactivation as herpes zoster, whether due to transient immunosuppression or age-related immune decline. While this also occurs after natural infection, the claimed necessity of varicella vaccination to reduce future herpes zoster is not supported by data; in fact, the opposite is highly likely. (78) If a vaccinated person develops blisters, they may, in rare cases, transmit varicella to a susceptible individual—that is, someone who has not been immunized and has never had the infection. Because the vaccine contains a live virus, this possibility is particularly dangerous for pregnant women; for this reason, it is advised that pregnant women avoid contact with recently vaccinated children for a period; furthermore, a vaccinated person who develops a rash should cover the rash and avoid contact with susceptible people until the rash scabs or heals.

The addition of the varicella component to the MMR vaccine at least doubles the risk of seizures compared to the MMR vaccine alone or the MMR vaccine administered separately from the varicella vaccine. (78–80) MMRV vaccination causes serious adverse effects and febrile seizures more frequently than other vaccines, including MMR alone. (81) Among 30 European countries, only Italy, Hungary and Latvia impose a vaccination mandate for varicella. (82) By contrast, 12 countries recommend the vaccine, while 15 do not include it even among recommended vaccinations.

In summary: a) the varicella vaccine is effective, but it has high reactogenicity and carries a theoretical risk of transmitting the live virus to pregnant women; b) varicella typically follows a very mild

course in children, but it could prove more dangerous in adults and the elderly if the protection provided by the vaccine is not as long-lasting as that conferred by a natural infection; c) it is even possible that the overall outcome for the population could be unfavourable, by increasing the risk of contracting a more severe form of varicella in adulthood or later life—a scenario that would contravene the constitutional requirement that any public health measure must not negatively affect the health of the population. Consequently, a generalized mandatory vaccination policy for children is not justified.

Conclusions

Vaccines are useful tools for the prevention of infectious diseases and should be recommended within the framework of clinical counselling that presupposes genuine, informed consent. However, imposing ten vaccines on the paediatric segment of the population is open to criticism on several scientific and technical grounds, since it may prove unnecessary for the protection of the community and potentially even counterproductive.

Because the Italian Constitution safeguards both individual health and the collective interest, what must be verified in concrete terms is, first, whether the imposition of a given medical treatment is truly necessary for the recipient and *others*; and, second, whether the treatment entails consequences which—by virtue of their persistence over time and/or their magnitude—exceed what is ordinarily "normal and tolerable." Legislation that imposes on children the risk associated with administering so many vaccines—without scientific evidence that such coercive intervention is necessary to protect public health—violates the principles of proportionality and precaution.

Herd immunity is meant to interrupt transmission chains and constitutes the only potentially relevant collective interest argument. If vaccine protection is limited, the vaccinated child is protected for a few years, but the virus may continue to circulate among teachers, school staff, passengers, physicians and parents, who may infect unvaccinated children, and subsequently vaccinated ones as immunity wanes. This type of assessment concerns the balance between the benefits and risks of vaccination; it does not, however, justify the imposition—on a single age group—of an obligation to receive injections of pharmaceutical products that certainly cannot be described as harmless. The current vaccination framework therefore requires revision and updating.

What has been set out here makes clear that no technical or scientific argument supports maintaining a vaccination mandate (particularly one that entails the severe sanction of exclusion from preschool). It is therefore necessary to consider legislative or administrative measures, including implementing circulars or targeted amendments, to shift toward a recommendation-based regime, as is done for all other products included in the vaccination schedule. Informed consent requires adequate and truthful information from the paediatrician and vaccinating physician.

Replacing coercion with proactive, accurate, evidence-based information should be accompanied by the effective operation of vaccination registries nationwide and by strengthened surveillance of the general and vaccine-specific health status of the paediatric population. Working groups free from conflicts of interest should prepare updated information leaflets containing evidence-based data on the benefits and risks of the various vaccines, using quantitative estimates wherever possible. Conflict-of-interest clauses should be introduced for medical commissions dealing with vaccination policy.

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Conflicts of interest

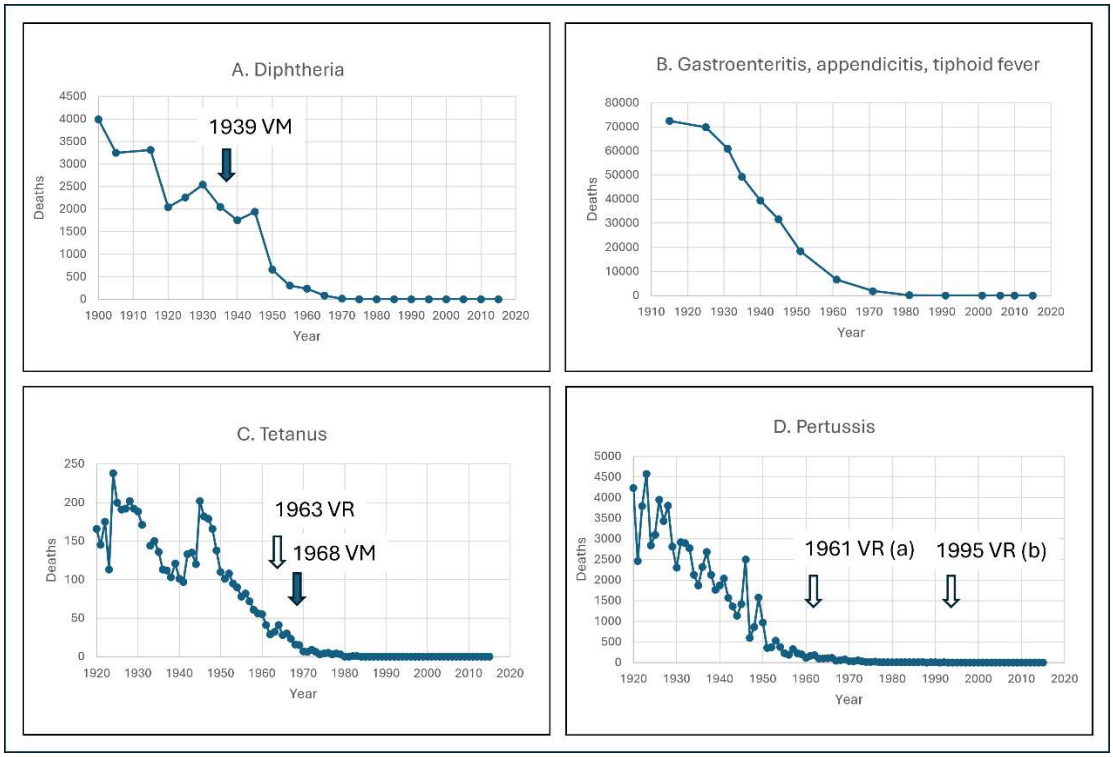
The authors declare the complete absence of conflicts of interest with respect to the matters addressed herein.

Table 1. Estimation of the effectiveness of measles vaccination (**VE**) in Italy in 2017, based on the incidence among vaccinated and unvaccinated individuals aged 1–39 years

	Vaccinated	Unvaccinated
Population	11,517,988	13,080,990
Measles cases	586	3175
Incidence per 100,000	5.09 (I_v)	24.27 (I_{uv})
VE	79.02	

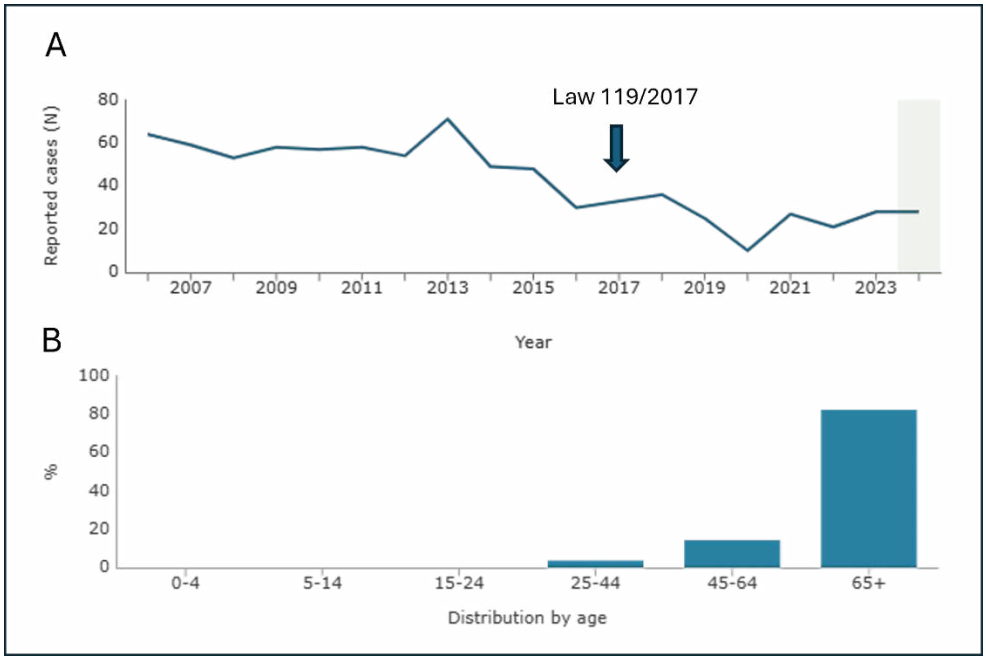
Legend: Population data are from the National Institute of Statistics (ISTAT), while data on case incidence are from the Italian National Institute of Health (Istituto Superiore di Sanità).

Figure 1. Trends in childhood mortality (<5 years of age) for certain infectious diseases over time in Italy, with an indication of the year in which mandatory vaccination (VM) was introduced or vaccination was recommended (VR)



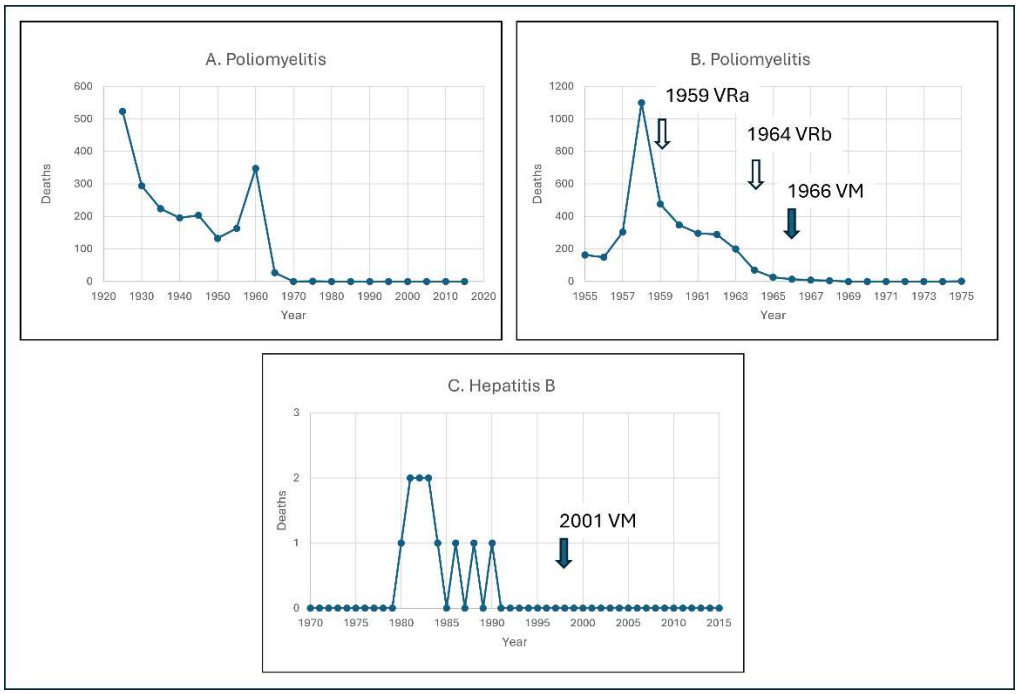
Legend: A: Diphtheria; mandatory vaccination was introduced in 1939 for children aged 2–10 years. B: Cumulative incidence of gastroenteritis, appendicitis, and typhoid fever. C: Tetanus; the tetanus vaccine was introduced in 1963 for high-risk occupational groups and became mandatory for children in 1968. D: Pertussis (whooping cough); the first vaccinations against pertussis (using a whole-cell vaccine) were implemented in 1961, but vaccine coverage increased (rising from less than 30% to over 90%) only following the introduction of an acellular vaccine in 1995, alongside those for diphtheria and tetanus (DTPa). Data are from Italian Institute of Statistics (ISTAT). (20)

Figure 2. Cases of tetanus in Italy from 2007 to 2024 and their distribution by age



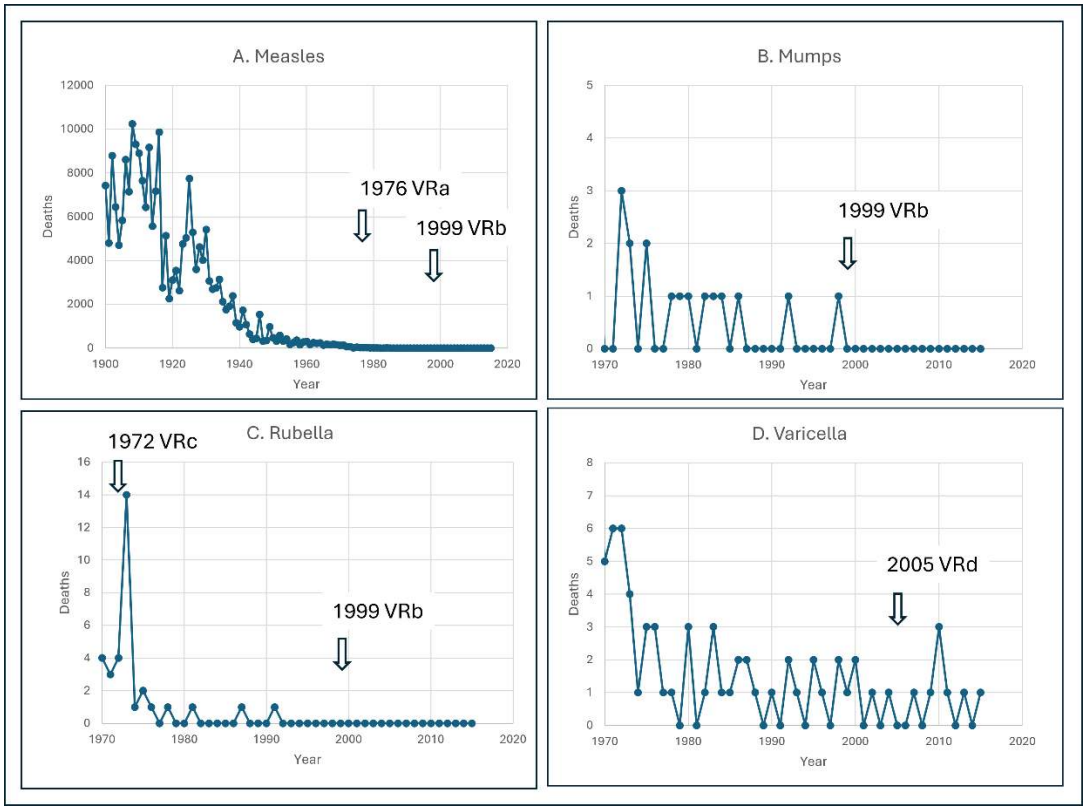
Legend: Data from the European Centre for Disease Prevention and Control (ECDC) surveillance of infectious diseases. (25)

Figure 3. Trends in under-five mortality from poliomyelitis (panels A and B) and hepatitis B (panel C) over time in Italy, with an indication of the year in which vaccination was either recommended (VR) or made mandatory (VM)



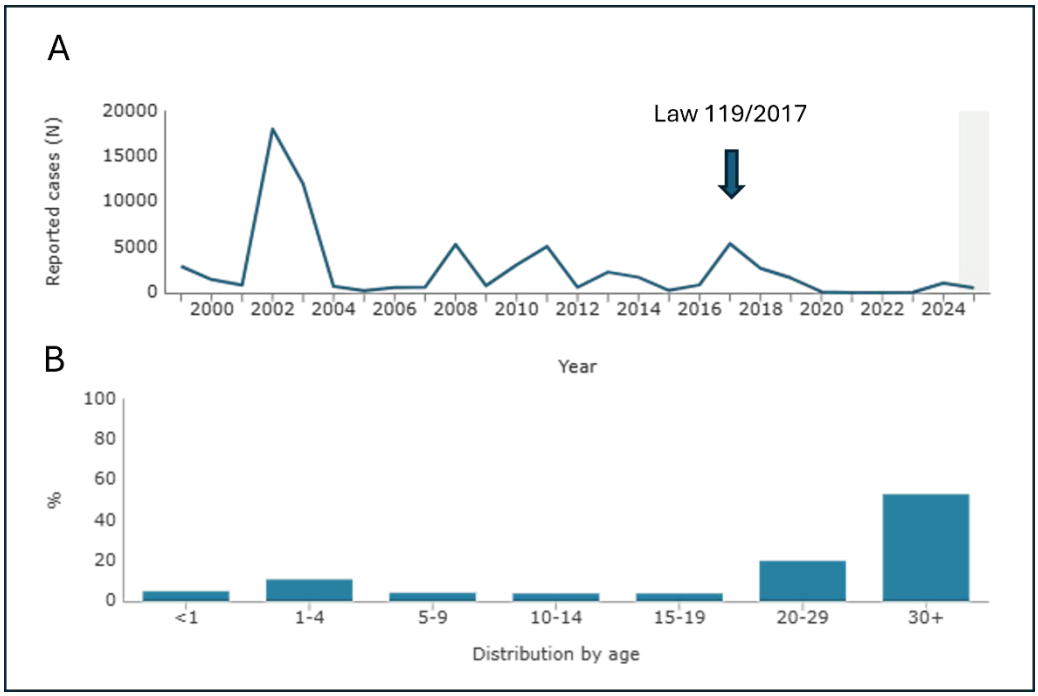
Legend: VRa: In 1959–1960, following a severe epidemic in 1958 that resulted in over 8,000 cases of paralysis, vaccination with the Salk vaccine (IPV) was recommended; however, voluntary uptake of the Salk vaccine remained very low overall. VRb: True mass coverage was not achieved until 1964, with the introduction of the oral Sabin vaccine (OPV). In Italy, polio vaccination became mandatory in 1966. Data are from ISTAT as in **Figure 1**.

Figure 4. Trends in childhood mortality (<5 years of age) for measles (A), mumps (B), rubella (C), and varicella (D)



Legend: A: In 1976, a live attenuated measles vaccine was recommended (1976 VRa), but the vaccine coverage sharply increased only after 1999, when the combined MMR vaccination was included in the national immunisation plan (1999 VRb). C: In 1972, a live attenuated rubella vaccine was offered to preadolescent girls (1972 VRc), but the vaccine coverage increased only after 1999, when the combined MMR vaccination was included in the national immunisation plan (1999 VRb). D: The 2005 National Vaccine Prevention Plan recommended the varicella vaccine for high-risk individuals and susceptible adolescents (2005 VRd). In 2017, vaccination against all four diseases using live attenuated viruses became mandatory for children, with doses administered at 12 months of age and during the fifth year of life. Data are from ISTAT as in **Figure 1**.

Figure 5. Cases of measles in Italy from 1999 to 2024 (A) and their distribution by age (B)



Legend: Data from the European Centre for Disease Prevention and Control (ECDC) surveillance of infectious diseases. (67)

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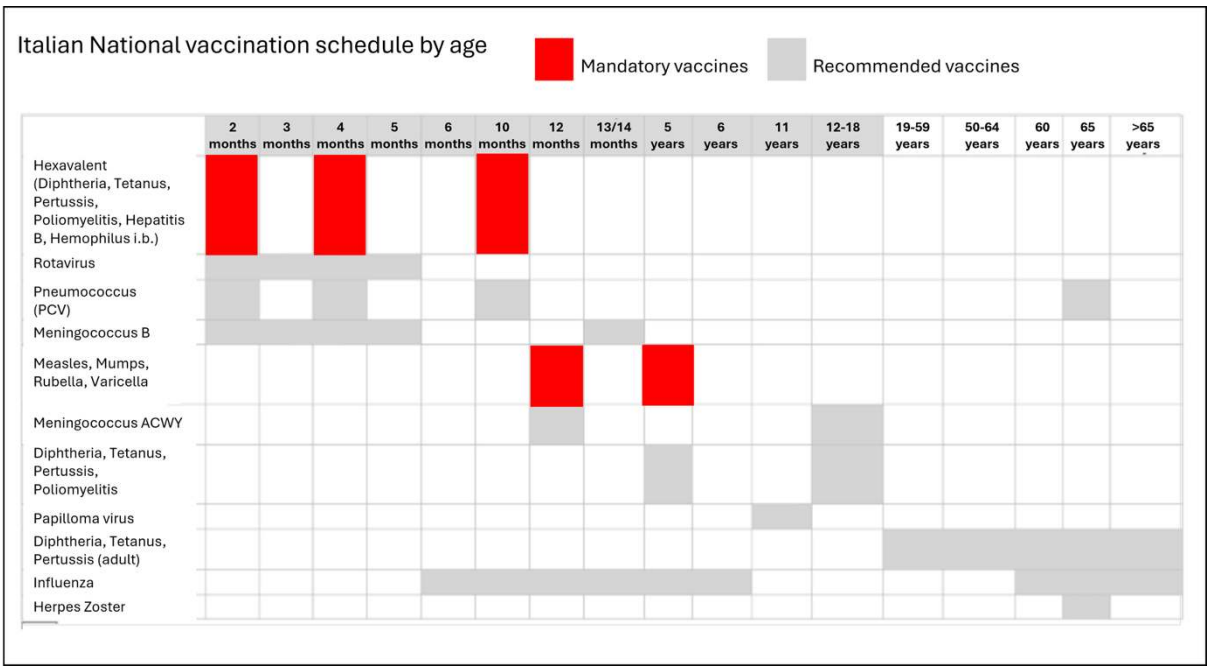
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Appendix A – Italian Vaccination Schedule

Figure A-1. The Italian vaccination schedule, part of the 2023–2025 National Vaccine Prevention Plan (PNPV), approved by the State-Regions Conference on 2 August 2023, and published in the Official Gazette (General Series, No. 194, 21 August 2023)



It has been extended until the end of 2026. The varicella requirement applies only to those born in 2017 or later. The national schedule provides for co-administration of hexavalent and pneumococcal vaccines, while the timing of meningococcus B and rotavirus vaccination depends on the schedule and product used.

Appendix B – Article 32 of the Italian Constitution

«La Repubblica tutela la salute come fondamentale diritto dell'individuo e interesse della collettività, e garantisce cure gratuite agli indigenti.
Nessuno può essere obbligato a un determinato trattamento sanitario se non per disposizione di legge.
La legge non può in nessun caso violare i limiti imposti dal rispetto della persona umana.»

Official English translation by the Senate:
«The Republic shall safeguard health as a fundamental right of the individual and as a collective interest, and shall ensure free medical care to the indigent.
No one may be obliged to undergo any health treatment except under the provisions of the law.
The law may not under any circumstances violate the limits imposed by respect for the human person.»