THE ORGANIZATION AND DELIVERY OF
VACCINATION SERVICES IN THE EUROPEAN UNION

ITALY

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Italy

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Governance

Key agencies

The Italian Ministry of Health is charged with defining the national immunization plan. This document is ratified with an agreement at the State-Regions conference. Since the Italian national health system is decentralized, the 21 regions (19 Regions and two Autonomous Provinces) have the task of establishing their own regional immunization plan and implementing it, based on the national recommendations.

The Italian Ministry of Health has established that all the vaccines included in the national immunization plan should be considered part of the so-called "minimum level of healthcare services" (LEA) that the regional authorities must provide to citizens free of charge. The national immunization plan outlines the objectives of the national immunization strategy for different age and risk groups, and it is ratified by an agreement with the regional authorities (the State-Regions Conference) who are responsible for the implementation of vaccination programmes in their respective regions. Childhood vaccines are usually administered by local vaccination centres, and in some cases by family paediatricians and/or general practitioners.

For influenza vaccination, the Ministry of Health's Directorate-General for Health Prevention provides an annual update of a document ("Circular letter for prevention and control of influenza"), signed by the Minister of Health, shared and agreed with the regions, indicating

the new vaccines' composition and reporting recommendations for the prevention of influenza through vaccination and other measures of hygiene and personal protection. As the influenza vaccine is included in the LEA, it is free of charge for selected target populations. It is administered mainly in vaccination centres and by general practitioners.

The main target of the influenza vaccination campaign is all individuals aged 65 years and over, with a vaccination coverage target of at least 75% and the aim of 95% coverage. Influenza vaccination is also recommended for high-risk individuals aged under 65, with the same target coverage rate.

National and regional level

The Regions are responsible for planning, financing, organizing and implementing health care services, including vaccination services following the national immunization plan recommendations.

Vaccination plan

The current National Immunization Plan 2017–2019 was issued in January 2017. In the past Italy's vaccination schedules had been a patchwork of 21 different regional vaccination schedules; the new plan helped to harmonize the diverse programmes. The plan recommends vaccination for people throughout the entire life-course and sets clear targets for vaccination coverage, but it also identifies the main priorities (e.g. measles and rubella elimination, polio eradication) and considers many actions to reduce disparities among Italian regions.

Mandatory and recommended vaccinations

Until June 2017 there were only four mandatory vaccinations: polio, diphtheria, tetanus and hepatitis B. At the end of July 2017 a new law was approved increasing to 10 the number of mandatory vaccinations for children aged 0–16 years: the previous four plus Hib, pertussis, measles, mumps, rubella and varicella. Regional authorities are required to promote and actively offer all vaccines indicated in the national immunization plan, including mandatory and non-mandatory vaccinations.

Organization of vaccination programmes

The Regions are in charge of implementing the national immunization plan, and the organization of vaccination programmes differs across regions. The national immunization plan requires regions to guarantee free and easy access to all vaccines included in the schedule, in order to achieve individual and population-level protection from vaccine-preventable diseases in line with national objectives. Furthermore, it requires the regions to organize training for health care workers, communication campaigns and the evaluation of their vaccination strategies.

A national electronic immunization register will start to be implemented in the second half of 2018. It will allow vaccination coverage to be evaluated with extreme precision, recalling individuals not yet immunized. So far, there are regional or local electronic immunization registers in more than 90% of Italian Regions and local health services, and they are used for the entire immunization process, from call-out to vaccination, to calculating the vaccination coverage. Regional aggregated coverage data are sent to the Ministry of Health to estimate the national vaccination coverage.

Targeted measures

Specific groups of people benefit from targeted vaccination measures, such as child-bearing women, individuals with specific health conditions at high risk of vaccine-preventable disease, individuals at high risk of professional exposure, individuals at high risk from specific behaviours (e.g. men who have sex with men), or individuals living in specific conditions (living with an immunosuppressed person in the same household).

The objectives of the national immunization plan include the reduction of inequalities through the promotion of vaccination interventions in marginalized or particularly vulnerable groups of the population, including irregular migrants, refugees and asylum-seekers, who may experience difficulties in accessing prevention services. The national immunization plan recommends close collaboration between vaccination services, health care workers, cultural mediators and nongovernmental organizations.

Incentive schemes

No monetary incentives exist for vaccinators, except for general practitioners in the case of influenza vaccination. Since September 2017 proof of vaccination has been required for children up to 6 years of age to attend kindergarten and nurseries. Lack of vaccination in older children does not impede their access to school, but financial sanctions are applied to parents refusing vaccination (with a maximum fine of €500 if all vaccinations are missing). The financial sanctions are also applied to parents of children up to 6 years of age if their parents refuse vaccinations.

Vaccination coverage

Vaccination coverage for all childhood vaccinations included in the national immunization schedule is measured annually for the following categories:

- at 24, 36 and 48 months old (for all vaccines);
- children in their 7th year of life and those in their 8th year of life (booster: DTP, polio; second dose: MMR, Var);
- adolescents aged 11–18 years (first dose and full course of HPV vaccine);
- adolescents aged 16 and 18 years (DTP, IPV, MMR, Men C, Men ACWT);
- individuals aged 65 years and over, pregnant women and general population (only for influenza)
- individuals aged 65 years (Zoster and pneumococcal vaccines).

Vaccination coverage for each vaccine is calculated by the Ministry of Health dividing the number of persons fully vaccinated by age in the target population by the total number of persons in the target population. The denominator is the critical point: some regions provide statistical population data, whereas others provide the number of people resident in their territory, and others the number of people registered in the local health system register.

In addition, epi-cluster surveys were conducted in 1998, 2003 and 2008 to validate administrative coverage data and to collect information regarding reasons for non-vaccination; however, further surveys are not planned.

Provision

All vaccinations, except against influenza, are mainly administered by the vaccination services in the local health units. Involvement of family paediatricians is being piloted in some regions.

Adult vaccinations against influenza are administered in almost all regions by general practitioners. Each region is free to decide on its own organization and is in charge of vaccine procurement, although in some cases vaccine procurement is further decentralized, to the level of local health services. Data are collected by public health services.

Financing

All compulsory and recommended vaccinations included in the National Immunization Plan 2017–19 are offered to the target population free of charge. The costs of vaccines and vaccination services are covered by the National Health Fund, which is a statutory financing system (via taxation) which covers the entire resident population.

Influenza vaccination is offered free of charge to all risk groups for which it is recommended, including:

- all individuals aged 65 years and above;
- clinical risk groups, such as individuals with treatment-induced and/or disease-induced immunosuppression, metabolic disorders, chronic pulmonary, cardiovascular or renal disease, hepatic disease, people living with HIV/AIDS, individuals with morbid obesity defined as body mass index >= 30kg/m2;
- all pregnant women in the second and third trimesters of pregnancy;
- all health care workers; for them vaccination is voluntary – it is an individual choice, and there is no penalty for not being vaccinated;
- selected occupational groups, such as military service personnel and poultry industry workers; staff

working in laboratories, e.g. in the non-medical academic or environmental sector; police and fire-fighters; veterinary service workers; and

- residents of long-term care facilities and household members of immunosuppressed individuals.

The system covers the entire resident population, including non-EU citizens with a regular residence permit and their dependent family members legally residing in Italy. Irregular immigrants are also entitled to receive vaccinations free of charge.

Key barriers and facilitators

Concerns about adverse events following immunization (e.g. autism or other chronic conditions) and underestimation of the potential severity of vaccine-preventable diseases are the main barriers to effective vaccination coverage against measles. Facilitators include targeted education and communication campaigns, training for health care workers, identification and vaccination of the most susceptible, and the update of the measles and rubella elimination plan.

The measles outbreak that started in Italy in 2017, with more than 7,000 cases and eight deaths in less than two years, has contributed to raising awareness among the population on the importance of vaccination.

With regard to influenza, concerns about perceived vaccine safety and effectiveness and the perceived low severity of influenza are the most commonly reported barriers to vaccination. Low influenza vaccination coverage among health care workers is also considered an obstacle.

Targeted education and communication campaigns and training for health care workers can facilitate influenza vaccination uptake.