



## Current immunization policies for pneumococcal, meningococcal C, varicella and rotavirus vaccinations in Italy

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### ABSTRACT

**Objectives:** As Italian Regions can implement different policies for immunizations that are not already recommended “across the board” in the country, the present study aimed to describe Regional recommendations and strategies concerning pneumococcal, meningococcal C, varicella and rotavirus vaccines.

**Methods:** In July 2010, a self-administered cross-sectional questionnaire was mailed to the Regional coordinators for infectious diseases and vaccinations. Data were analysed and compared with the results of previous surveys conducted two and four years before.

**Results:** To date, a universal vaccination programme is implemented free of charge in 18 out of 21 Regions (86%) and 17 out of 21 Regions (81%) for pneumococcal and meningococcal C vaccine, respectively. Varicella immunization policies still differ widely among Regions: seven Regions (33%) have adopted a universal free of charge programme, while in the remaining 14 varicella vaccination is offered only to at risk groups. Nine of these Regions also provide immunization to susceptible adolescents. Rotavirus vaccination has not been identified as a priority in Italy, and only 5 Regions have officially introduced it in their schedule.

**Conclusions:** Italian Regions are moving towards a common vaccination strategy concerning pneumococcal and meningococcal C vaccine. The debate on a common varicella and rotavirus vaccination strategy is still on-going.

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### 1. Introduction

In Italy the National Health Service (NHS) has been decentralized since 2001. This endows all 21 Italian Regions with the responsibility of organizing, delivering and allocating budget for all health services, with the strategic support of the Ministry of Health. Concerning vaccinations,

a National Vaccination Committee has been established. This Committee is composed of representatives of the Regional Health Authorities (RHAs), Ministry of Health (MoH), National Institute of Health (Istituto Superiore di Sanità, ISS) and scientific societies and has the task of elaborating the National Immunization Plan (NIP). Within the current NIP, nine vaccines are universally recommended. Of those diphtheria, tetanus, poliomyelitis and hepatitis B are mandatory, while pertussis, Haemophilus influenzae type b, measles, mumps and rubella are recommended. Both mandatory and non-mandatory vaccinations are included in “essential health interventions” and must by law be provided to all children free of charge across Italy in order to guarantee an equal access irrespective of socioeconomic status or area of residence [1]. A parent's refusal

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of a mandatory vaccination results only in administrative sanctions. Other vaccinations, such as anti-pneumococcal conjugate vaccine (PCV), anti-meningococcal C conjugate vaccine (Men C) and anti-varicella vaccine, although recommended at the national level only for at risk groups, can be offered also to other targets based on individual Regional vaccination policies [2]. Finally, other licensed vaccines such as anti-rotavirus vaccine, still lack national recommendations. Their administration is therefore totally dependent on Regional policies. This normative framework has been conducive to the implementation of very diverse immunization strategies across the country, both in terms of target populations and of the delivery of immunizations.

In 2006 [3] and 2008 [4] two surveys were conducted to describe the different policies adopted at Regional level for vaccines not universally recommended at the national level. Both studies identified a heterogeneous offer across the 21 Italian Regions. Since then, many new combined vaccines (e.g. vaccine against measles, mumps, rubella and varicella – MMRV) and new products (e.g. 10- and 13-valent pneumococcal conjugate vaccine; vaccine against rotavirus) were introduced on the market.

This study was performed to assess the current regional immunization policies for pneumococcal invasive disease, meningococcal C disease, varicella and rotavirus vaccines, and to compare the current scenario with the ones described in 2006 and 2008.

## 2. Methods

### 2.1. Immunization policies

In July 2010, a self-administered questionnaire was mailed to the 21 Regional coordinators for infectious diseases and vaccinations, in order to update knowledge on vaccination policies in Italy. The survey was aimed at collecting information on: the presence of Regional deliberations for the 7-, 10-, 13-valent PCV, Men C, varicella, MMRV and rotavirus vaccines; the date of their approval; the target population; the immunization schedule, the type of delivery (i.e. free of charge, in co-payment, or paid by patient at manufacturing price), the type of offer (i.e. active call, on parents/paediatrician request, or other), availability of coverage data and educational/informative campaigns conducted or planned.

Three types of Regional vaccination policies were identified: (1) Regions offering vaccination only to disease-specific risk groups (Table 1); (2) Regions offering vaccination other target groups in addition to disease-specific risk groups; (3) Regions offering vaccination to all newborns (universal vaccination). Each Region was classified in one of the aforementioned categories according to the strategy adopted for at least 3 years during the period 2006–2010.

### 2.2. Incidence data

In Italy, meningococcal and pneumococcal diseases and varicella are subject to mandatory notification and data are routinely collected from the Italian infectious diseases surveillance system [5].

**Table 1**

Specific groups for whom PCV, MEN-C, varicella (according to the Italian National Immunization Plan, 2005–2007) vaccinations are recommended.

|  |
|--|
| <i>PCV</i>   |
| All children ages <5 years with:<br>splenic dysfunction, immunodeficiency, HIV infection, chronic pulmonary diseases, chronic cardiovascular diseases, chronic liver disorders, chronic renal failure, diabetes mellitus, cerebrospinal fluid leakage, cochlear implant                  |
| <i>MEN-C</i>   |
| Any person presenting splenic dysfunction or immunodeficiency  |
| <i>Varicella</i>   |
| Susceptible individuals who present one of the following conditions:<br>household of individuals with immunodeficiency, acute lymphatic leukaemia in complete remission, chronic renal failure, HIV infections, with CD4 $\geq$ 25%, child-bearing age women, health and school workers. |

We calculated the annual incidence rates for the period 2006–2010 both nationally and by Region, based on mandatory notifications, using as reference the 2008 Italian population estimated by Italy's National Census Bureau (ISTAT). For varicella, we also calculated the trend in incidence for the period 2006–2009. Data for 2010 were excluded from the analysis because provisional.

### 2.3. Vaccination coverage

Vaccination coverage data for PCV, Men C and varicella is not routinely collected by all Regions, therefore no reliable national vaccination coverage estimates are available. However, an EPI cluster sampling survey was conducted in 2008 among children aged 12–24 months to assess immunization [6].

As a proxy of coverage data we used the number of vaccine doses sold provided by the Italian National Drug Utilisation Monitoring Centre (OsMed) for the period 2007–2010 [7].

### 2.4. Statistical analysis

Statistical analysis was performed using Epi Info version 6.04 (Centres for Disease Control and Prevention, Atlanta, USA). Data were analysed stratifying by type of Regional vaccination policy. All differences in cumulative incidence were assessed by the chi-square test with  $p < 0.05$  indicating statistical significance, and incidence over the study period was assessed by the chi-square for trend test.

## 3. Results

Questionnaires were completed and returned by all the 21 Italian Regions. By 2008, all Regions had issued recommendations on the offer of PCV, Men-C and varicella vaccines (Tables 2–4). Between 2008 and 2010 some of those policies were revised and four Regions issued recommendations on Rotavirus vaccination.

As of July 2010, pneumococcal vaccine (Table 2) was offered universally free of charge in 18 out of 21 Regions (86%), a geographical area that hosts 85% of the national population. Children are actively called for vaccination in 14 (78%) out of those 18 Regions, while the vaccine is

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