

Infant immunization coverage in Italy: estimates by simultaneous EPI cluster surveys of regions

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In 1998, a series of regional cluster surveys (the ICONA Study) was conducted simultaneously in 19 out of the 20 regions in Italy to estimate the mandatory immunization coverage of children aged 12–24 months with oral poliovirus (OPV), diphtheria–tetanus (DT) and viral hepatitis B (HBV) vaccines, as well as optional immunization coverage with pertussis, measles and *Haemophilus influenzae* b (Hib) vaccines. The study children were born in 1996 and selected from birth registries using the Expanded Programme of Immunization (EPI) cluster sampling technique. Interviews with parents were conducted to determine each child's immunization status and the reasons for any missed or delayed vaccinations.

The study population comprised 4310 children aged 12–24 months. Coverage for both mandatory and optional vaccinations differed by region. The overall coverage for mandatory vaccines (OPV, DT and HBV) exceeded 94%, but only 79% had been vaccinated in accord with the recommended schedule (i.e. during the first year of life). Immunization coverage for pertussis increased from 40% (1993 survey) to 88%, but measles coverage (56%) remained inadequate for controlling the disease; Hib coverage was 20%.

These results confirm that in Italy the coverage of only mandatory immunizations is satisfactory. Pertussis immunization coverage has improved dramatically since the introduction of acellular vaccines. A greater effort to educate parents and physicians is still needed to improve the coverage of optional vaccinations in all regions.

Keywords: cluster analysis; diphtheria–tetanus–pertussis vaccine; hepatitis B vaccines; immunization programmes and schedules; Italy; measles vaccine; poliovirus vaccine.

Voir page 849 le résumé en français. En la página 850 figura un resumen en español

Introduction

The circulation of pathogens that cause communicable disease in a population is largely determined by the proportion of susceptible individuals within that population. Neonates constitute the greatest source of susceptible individuals, and the immunization of infants is the most cost-effective means of reducing vaccine-preventable diseases.

In Italy, immunization with oral poliovirus vaccine (OPV), diphtheria–tetanus (DT) and viral

hepatitis B (HBV) vaccines is mandatory; primary immunization consists of three doses of these vaccines, administered at the age of 3, 5 and 11 months. The national health system bears the cost of mandatory vaccinations. These are administered free of charge by vaccination clinics of local health units. The local health unit is responsible for choosing the brand of vaccine and for purchasing a sufficient quantity of doses for each vaccination clinic's catchment population.

Although vaccination for measles, rubella, mumps, pertussis and *Haemophilus influenzae* b (Hib) infection is not mandatory in Italy, national recommendations include the administration of pertussis vaccine combined with DT at 3, 5 and 11 months of age, administration of measles vaccine at 15 months of age, and administration of Hib vaccine at 3, 5, and 11 months or a single dose in the second year of life. Some local health units purchase these optional vaccines and administer them free of charge, or at a minimal cost. In areas where vaccination clinics do not provide this service, parents can purchase the vaccines at pharmacies and have them administered by private practitioners.

In Italy, there is great variation between regions in immunization coverage with mandatory and optional vaccines and in the schedules for giving optional vaccines. A survey in 1993, conducted in seven of the country's 20 geographical regions, showed that coverage was generally high for

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mandatory vaccinations but extremely variable for optional vaccinations, with as low as 8% coverage in some regions for measles and pertussis vaccination (1). After the 1993 survey, a large clinical trial on acellular pertussis vaccines was conducted within the national health service in four regions (2); based on the good level of vaccine safety and efficacy shown by this trial, concerted efforts have been made to disseminate this information and promote all the optional vaccinations. Since 1995, the Italian Ministry of Health has issued several circulars on vaccination strategy and recommended the use of these optional vaccines.

With the aim of (1) obtaining estimates, based on standardized methods, of recent infant immunization coverage in the different regions of Italy, (2) assessing the geographical uniformity of such coverage, and (3) evaluating the reasons for suboptimal results, the Istituto Superiore di Sanità (Italian National Institute of Health) promoted and coordinated a series of regional surveys using the WHO Expanded Programme on Immunization (EPI) cluster sampling technique (3). These surveys (known as the ICONA Study) were targeted at 12–24-month-old children from the 1996 birth cohort, and conducted simultaneously in 1998 in 19 out of the 20 regions in Italy. This article describes the results, with estimates of the overall national immunization coverage for different vaccines.

Materials and methods

Study population

The populations studied were children aged 12–24 months at the time the surveys were conducted (children born between 15 January 1996 and 15 January 1997) and who were resident in 19 of the 20 regions of Italy. All were selected from birth registries.

Sampling

Standard EPI cluster survey methodology (3–8), involving systematic sampling from a cumulative population list, was used to select 30 cluster sites in each region, except for Val d'Aosta, where the number of births was too low for this method and simple random sampling of 100 children was used. In the remaining 18 regions, the entire population served as the sampling universe. In Campania, the capital city (Naples) and the rest of the region were considered as separate sampling universes: 30 clusters were chosen from the region and simple random sampling (100 children) was used in Naples. A similar procedure was followed for Lombardy and its capital city (Milan). In Trentino–Alto Adige, 30 clusters were selected for each of the two autonomous provinces (Bolzano and Trento).

In all cases, the population lists for sampling were based on births in 1996 and the mother's place of residence; this information was obtained from the local birth registries. When the number of births was

low, adjacent communities were aggregated prior to sampling. After 30 clusters had been selected within the sampling frame, the local health unit of each community was asked to obtain a list from the local birth registry office of all children who would be 12–24 months of age by the date the study was to begin. Random number tables were used to select seven children in the eligible age group, as well as seven in an alternative list. The sample size allowed for a precision of 10% around the point prevalence estimates of coverage (3).

At least five attempts to contact families of selected children were made (three by telephone and two by home visits), before replacing these children by those in the alternative list.

Sources of information on immunization status

The parents of the selected children, after giving voluntary and informed consent, were interviewed in their homes by trained nurses or doctors from the local health units using a standard questionnaire for EPI cluster surveys that was adapted to the Italian vaccination schedule. The questionnaire included information on immunization status and the dates of administration of doses of DT, pertussis, OPV, HBV, Hib and measles vaccines. The interview also included a review of the children's vaccination cards. Information on measles immunization was collected for children who were at least 15 months old at the time of the interview, since measles vaccination was not recommended for children below this age in Italy. Parents were asked to give the main reason for any missed or delayed vaccinations. The regional surveys were carried out over a 2-month period, during which a toll-free telephone line was set up at the coordination centre at the Istituto Superiore di Sanità in Rome to respond to questions or problems encountered by local staff.

Definitions

Children were defined as "not immunized" against a given disease if, at the time of the interview, they had not received any vaccine dose. Children were classified as "fully immunized" with DT/DTP, OPV, and HBV if they had received at least three doses of these vaccines. They were considered as fully immunized against measles if they had received at least one dose administered at or after the recommended age of 15 months and against Hib if they had received three doses by 12 months of age, or a single dose after this age. Adherence to the recommended schedule for DT/DTP, OPV and HBV was estimated by calculating the proportion of children who had completed primary immunization by 12 months of age.

Data analysis

Data entry and analysis was centralized and performed at the Istituto Superiore di Sanità. Data were analysed using Epi Info version 6.04 (Centers

for Disease Control and Prevention, Atlanta, GA, USA and World Health Organization, Geneva, Switzerland). The C-sample programme was used to compute proportions and confidence intervals (CI), taking into account the design effect. National estimates were computed with C-sample software, adjusting for the size of the population in each region. Val d'Aosta and the cities of Milan and Naples were excluded from the estimation of national coverage because of the different sampling methods used in these areas. The denominators for immunization coverage with DT/DTP, OPV, HBV and Hib vaccines included all the interviewed children. For measles vaccination, only children aged ≥ 15 months at the time of the interview were considered eligible.

Immunization coverage with DT/DTP, OPV, HBV, and Hib vaccines was calculated using two different numerators:

- the overall estimates of coverage included children immunized with three doses, whether or not they had adhered to the recommended schedule;
- the estimates of coverage at 12 months included only those children who had received three doses of vaccine by this age.

Estimates of pertussis immunization coverage included both children who had received DTP and those who had received only the pertussis vaccine.

The effects of maternal sociodemographic characteristics on measles immunization coverage, which has the greatest variability in Italy, were assessed in a logistic regression model using STATA software (9). The association between regional measles immunization coverage and the reported obstacles to vaccination was assessed and expressed using the *r* correlation coefficient (using Epi Info version 6.04).

Results

Study population

The immunization status and home interviews were assessed on samples of an average of 210 children (range: 209–215) in each of the 19 study areas (17 regions and the two autonomous provinces of Bolzano and Trento), as well as on the samples of 100 children in the Val d'Aosta region and the cities of Naples and Milan. The total number of births in these areas represent 90% of the total births in Italy. Overall, 4310 families were interviewed. A total of 397 children (9.2%) were selected from the alternative list because the family initially selected could not be traced or contacted ($n = 218$), or because they declined to participate ($n = 81$); the reason was not determined for the remaining 98 children selected from the alternative list. For nearly all the study children (99.3%), the vaccination card, which was kept by the parents, was used to determine the child's immunization status.

The general sociodemographic characteristics of the sampled population were similar to those of

Table 1. Sociodemographic data for children in the study sample, Italy, 1998

Sample size	4310
Alternates	9.2%
Mean age (months)	18.3
Median age (months)	18
Children aged >15 months	73.9%
Males	52.1%
Breastfed	81.2%
Mean duration of breastfeeding (months)	6.0
Attendance at day-care centre	10.6%
Birth order (median)	1

Table 2. Sociodemographic data for the parents of the children in the study sample, Italy, 1998

	Parent	
	Father	Mother
Mean age (years)	N/A ^a	31.3
Median age (years)	N/A ^a	31
Italian nationality	97.2%	96.4%
Level of education		
Nil/primary school	5.3%	5.4%
Middle school	45.0%	40.4%
High school	38.6%	44.1%
University	10.2%	9.8%
Not known	0.6%	0.3%
Employed	95.1%	49.0%

^a N/A = not applicable.

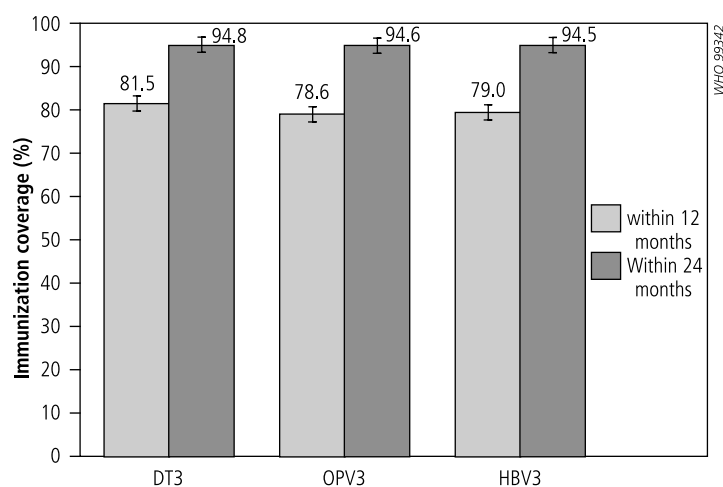
the Italian general population (Table 1 and Table 2): most of the children had no siblings, although the mean age of interviewed mothers was 31 years; approximately 80% of the children had been breastfed for an average of 6 months; and only a few children (10%) were attending day-care centres (10, 11). Approximately 74% of the surveyed children were older than 15 months and therefore eligible for measles vaccination.

Overall estimates of immunization coverage

A total of 8 children, all from regions in southern Italy, had not been immunized against any disease. Another 7 children had not been immunized against poliomyelitis (4 lived in Bolzano in northern Italy), and 12 others had not received HBV (9 in northern Italy).

The overall immunization coverages for DT, OPV, and HBV at 12 months of age and up to 24 months are shown in Fig. 1. For each of these vaccines, approximately 95% of children had been immunized with three doses by 24 months of age at the time of the interview. However, by the age of

Fig. 1. National estimates of immunization coverage for mandatory vaccinations (diphtheria–tetanus (DT3), oral poliovirus vaccine (OPV3), and viral hepatitis B (HBV3)) by 12 months of age and between 12 and 24 months of age for the 1996 birth cohort



12 months, only 79% of children had received the third doses of OPV and HBV; a similar proportion was reported for DT (81%).

Although the pertussis and measles coverages in each region were closely correlated ($r = 0.90$), the observed national coverage between 12 and 24 months of age for the three doses of pertussis vaccine was 87.9% (95% confidence interval (CI): 86.4–89.5), while the coverage for the one dose of measles vaccine was only 56.4% (95% CI: 53.8–59.1). Hib immunization coverage between the ages of 12 and 24 months was 19.8% (95% CI: 17.6–22.0). Approximately 90% of mandatory vaccinations had been administered at the public vaccination clinics of the local health units (ranging from 95.9% for OPV to 89.1% for DT); for the optional vaccinations, this percentage was lower (85.2% for pertussis, 83.4% for measles, and 66.1% for Hib).

Being immunized against measles was positively associated with maternal age, taken as a continuous variable in years (odds ratio (OR)=1.04, 95% CI: 1.02–1.06), and with maternal educational level, grouped into five levels (OR=1.24, 95% CI: 1.11–1.40); in contrast, it was inversely associated with birth order (OR=0.65, 95% CI: 0.57–0.74) and with the father being unemployed (OR=0.46, 95% CI: 0.31–0.69). Associations with breastfeeding, birth weight, and attendance at day-care centres were not statistically significant.

Regional estimates of immunization coverage

The estimated regional coverage for mandatory vaccinations, though variable, was found to be relatively high in almost all regions (Table 3). For OPV coverage between 12 and 24 months of age, a point prevalence below 90% was observed in four study areas: Campania region (87%), the city of Naples (86%), Molise region (89%), and the province

of Bolzano (88%). The same areas also had the lowest HBV coverage (88%, 84%, 89%, and 86%, respectively), while Campania and Naples had the lowest DT coverage (89% and 86%, respectively). The immunization coverage for OPV, DT and HBV by the age of 12 months ranged from 50% (Naples) to 98% (Val d'Aosta).

With regard to optional vaccinations (Table 4), the highest coverage in all regions was for pertussis, ranging from approximately 70% in Campania to 97% in each of the regions of Veneto, Friuli–Venezia Giulia, and Umbria, for children between 12 and 24 months of age. Nearly 96% of the children who had been immunized against pertussis had received the acellular vaccine, and 85% of pertussis immunizations were performed in public vaccination clinics.

Regional immunization coverage for measles was observed to be low, with southern Italy showing lower coverage than northern and central Italy; the lowest coverage (25.5%) was found in Calabria and the highest (87.7%) in Emilia Romagna (northern Italy). A positive correlation ($r = 0.66$) was observed between the regional immunization coverage for measles and the proportion of vaccinations administered in public vaccination clinics. Of the children immunized against measles, 94.1% had received the combined vaccine for measles, mumps, and rubella.

Regional Hib immunization coverage between 12 and 24 months of age ranged from 1.9% (Calabria) to 41.4% (Friuli–Venezia Giulia).

Obstacles to vaccination

No medical contraindications to vaccination were reported for any of the unvaccinated children. Among the 981 children with a missed ($n = 27$) or delayed ($n = 954$) mandatory vaccination, the most frequent reason given (53.6%) was an intercurrent illness, such as common cold or other respiratory tract infection (Table 5). For 70 children (7.1%), the reason given was due to a modification of the regional vaccination schedule (i.e. the third dose of DTP provided at seven months of age and, six months later, the third doses of OPV and HBV administered at the same time as the fourth dose of DTP). Logistic problems, such as the working hours of the vaccination clinic and the distance to the clinic, and family constraints (i.e. illness of mother, working mother, etc.) were reported for 214 (21.8%) children, while lack of information was reported for only 27 (2.8%) children.

With regard to optional immunizations, missed or delayed pertussis vaccination was primarily attributed to an intercurrent illness ($n = 312/894$ unvaccinated children; 34.9%) and to lack of appropriate information ($n = 220/894$; 24.6%). Among the 1413 children not vaccinated against measles, lack of information was the most frequently reported obstacle ($n = 658$, 46.6%), followed by intercurrent illness ($n = 398$, 28.2%). Regional measles coverage was directly related ($r = 0.79$) to the proportion of children whose immunization was

Table 3. Percentage immunization coverage for the three doses of mandatory vaccinations in children born in 1996 and aged 12–24 months (A) and the proportion of children immunized by 12 months of age (B), by region in Italy

Region/ city/province	Oral poliovirus vaccine		Diphtheria–tetanus toxoids		Hepatitis B vaccine	
	A	B	A	B	A	B
North						
Piedmont	98.6 (95.8–100) ^a	87.1	97.6 (94.6–100)	87.1	98.6 (95.8–100)	87.6
Val d'Aosta	100	98.0	100	98.0	100	98.0
Lombardy	98.6 (97.0–100)	89.5	98.6 (97.0–100)	90.0	97.6 (95.7–99.6)	88.6
Milan	91.8 (84.5–96.4)	78.6	92.9 (85.8–97.1)	80.6	92.9 (85.8–97.1)	77.1
Bolzano	88.0 (84.0–92.0)	65.6	90.9 (87.2–94.6)	69.2	85.6 (80.6–90.7)	62.7
Trento	99.0 (97.8–100)	93.8	99.0 (97.8–100)	93.8	98.1 (96.3–99.9)	92.9
Veneto	97.6 (95.7–99.6)	90.0	96.2 (92.9–99.5)	88.5	97.6 (95.7–99.6)	90.0
Friuli–V. Giulia	97.6 (95.7–99.6)	90.5	98.1 (96.3–99.9)	90.0	97.6 (95.7–99.6)	90.0
Liguria	98.6 (97.0–100)	85.2	99.0 (97.8–100)	89.0	97.6 (95.3–100)	82.4
E. Romagna	98.1 (96.3–99.9)	83.8	94.3 (87.6–100)	79.5	97.6 (95.7–99.6)	83.3
Centre						
Tuscany	95.7 (93.0–98.4)	68.9	98.1 (96.3–99.9)	87.1	95.2 (92.4–98.0)	68.9
Umbria	98.6 (97.0–100)	86.7	99.0 (97.8–100)	86.7	98.6 (97.0–100)	87.1
Marches	94.8 (90.0–99.5)	83.3	95.2 (91.1–99.3)	83.8	94.8 (90.4–99.1)	82.4
South						
Abruzzi	94.8 (91.4–98.2)	76.4	93.9 (89.7–98.0)	70.8	94.8 (91.4–98.2)	75.9
Molise	89.1 (81.9–96.2)	77.1	91.5 (86.9–96.0)	77.6	89.1 (82.0–96.3)	77.1
Campania	87.1 (80.8–93.5)	66.2	88.6 (82.7–94.5)	69.0	87.6 (81.3–93.9)	67.1
Naples	86.0 (77.9–91.9)	49.5	86.0 (77.9–91.9)	49.0	84.1 (75.8–90.5)	49.5
Puglia	92.5 (88.7–96.4)	79.0	92.5 (88.7–96.4)	84.1	93.0 (89.1–96.9)	79.5
Basilicata	94.8 (96.5–100)	85.8	99.1 (99.7–100)	89.6	99.1 (97.8–100)	85.8
Calabria	94.8 (91.9–97.6)	79.2	93.4 (89.6–97.0)	76.9	94.8 (91.7–97.9)	79.2
Sicily	90.6 (85.7–95.6)	63.8	93.0 (88.7–97.2)	74.2	91.1 (86.1–96.1)	67.1
Sardinia	95.2 (92.4–98.0)	75.6	95.2 (92.1–98.3)	77.6	95.2 (92.4–98.0)	77.5

^a Figures in parentheses are 95% confidence intervals.

delayed because of an intercurrent illness, and inversely related to the proportion of children not vaccinated because of lack of information. Lack of information was also the leading cause of missed Hib immunizations ($n = 2644/3826$, 69.1%).

Discussion

Immunization coverage needs to be closely monitored because it is the best indicator of an immunization programme's ability to reach its desired targets. The Italian Ministry of Health monitors the coverage in each region by collecting data every six months on the number of vaccine doses administered in public vaccination clinics and comparing these figures with the number of target children living in the area. However, the data are often incomplete for optional vaccinations, which are not offered by all public clinics, and because privately administered vaccinations are rarely recorded. The results are also difficult to interpret because of lack of individual information and the impossibility of accurately calculating the proportions of fully immunized children or the age-appropriate coverage.

Moreover, in areas with suboptimal coverage, information is not available on the reasons for missed or delayed immunization.

An improved system for continuous monitoring of immunization coverage in the whole country is needed, especially in view of the WHO objectives of eradicating poliomyelitis and eliminating diseases like diphtheria, neonatal tetanus and measles. Until an improved system is developed, periodic standardized regional surveys, like those described here, can provide some data on immunization coverage and information on obstacles to vaccination.

EPI surveys using cluster-sampling techniques have been developed and widely applied, not only in developing countries, where birth and/or vaccination records may not be available (3), but also in industrialized countries to validate existing figures. Compared with the standard EPI design, the use of total number of births as the sampling frame in each region permitted the accurate selection of clusters with the appropriate sampling weights. The inclusion of children randomly selected from birth registration lists in each cluster further ensured representativeness.

Table 4. Immunization coverage (by region) for optional vaccinations in children born in 1996 and aged 12–24 months

Region/city/province	Pertussis (3 doses)	Hib (3 doses/1 dose) ^a	Measles (age ≥ 15 months)
North			
Piedmont	91.4 (86.3–96.6) ^b	17.1 (11.42–22.9)	60.4 (50.4–70.3)
Val d'Aosta	89.2 (81.5–94.5)	2.0 (0.2–6.9)	43.3 (31.2–56.0)
Lombardy	97.1 (95.1–99.2)	32.9 (22.2–43.5)	75.9 (68.1–83.7)
Milan	89.8 (82.0–95.0)	32.7 (23.5–42.9)	74.6 (62.5–84.1)
Bolzano	73.2 (64.8–81.6)	39.2 (28.4–50.1)	28.1 (18.7–37.4)
Trento	94.3 (90.6–98.0)	11.4 (6.2–16.7)	58.0 (48.2–67.7)
Veneto	96.7 (94.5–98.9)	31.1 (21.5–40.4)	81.2 (75.4–87.0)
Friuli–Venezia Giulia	96.7 (94.5–98.9)	41.4 (29.9–53.0)	77.3 (68.9–85.7)
Liguria	95.2 (92.4–98.0)	33.8 (25.9–41.7)	62.1 (52.9–71.4)
Emilia Romagna	95.2 (92.1–98.3)	31.6 (24.4–38.5)	87.7 (81.1–94.3)
Centre			
Tuscany	95.2 (92.4–98.0)	9.6 (5.0–14.0)	64.8 (55.5–74.2)
Umbria	97.6 (95.3–100)	8.6 (4.6–12.5)	72.3 (64.6–81.0)
Marches	91.4 (85.8–97.0)	9.5 (2.6–16.4)	58.7 (48.7–68.7)
South			
Abruzzi	90.6 (86.7–94.4)	20.3 (13.3–27.2)	45.5 (38.5–51.9)
Molise	82.5 (76.0–89.0)	5.2 (0–10.1)	40.5 (29.6–51.4)
Campania	70.5 (62.9–78.1)	3.8 (0–7.1)	26.5 (17.3–35.7)
Naples	77.6 (68.5–85.1)	14.0 (8.1–22.1)	39.8 (29.2–51.1)
Puglia	82.7 (76.7–88.7)	14.0 (8.6–19.4)	50.6 (41.0–60.2)
Basilicata	85.8 (78.0–93.6)	4.7 (1.6–7.8)	44.7 (33.2–56.1)
Calabria	71.6 (60.3–82.8)	1.9 (0–4.1)	25.5 (17.0–33.9)
Sicily	86.3 (81.0–91.8)	2.8 (0–6.1)	44.6 (34.3–54.8)
Sardinia	90.5 (85.6–95.4)	35.7 (25.7–45.7)	56.3 (46.8–65.7)

^a Three doses within 12 months of age, or one dose after age of 12 months.

^b Figures in parentheses are 95% confidence intervals.

Table 5. Reasons reported by parents for missed or delayed vaccinations and percentage of children not immunized or immunized late

Reason	Mandatory Vaccinations (%) (n = 981)	Pertussis vaccination (%) (n = 894)	Measles vaccination (%) (n = 1413)	Vaccination against Hib (%) (n = 3826)
Intercurrent illness	53.6	34.9	28.2	3.6
Local vaccination schedule	7.1	0.0	0.0	9.8
Logistic and family constraints	21.8	19.2	20.0	13.4
Lack of information	2.8	24.6	46.6	69.1
Not known/missing	14.7	21.3	5.2	4.1
Total	100	100	100	100

The results in the present survey can be compared with those from the 1993 survey, which used a similar methodology to study the 1991 birth cohort in seven regions (1, 12). In the 1993 survey, the immunization coverage for DT and OPV of children aged 12–24 months ranged from 77% in the city of Naples to 99% in the Marches region.

Immunization coverage for pertussis ranged from 8% to 71%, and for measles from 9% to 53%.

Compared with the 1993 survey, the present (1998) survey showed higher coverage for all vaccines in the same seven regions: for mandatory vaccinations, coverage ranged from 86% (Naples) to 99% (Lombardy and Liguria); optional immunization coverage ranged from 71% to 98% for pertussis and from 26% to 88% for measles. Although very few children in both surveys were totally unimmunized, their spatial clustering suggests that the effectiveness of immunization programmes needs to be improved in specific geographical areas.

Overall, 95% of the present survey's sample received three doses of the mandatory vaccines, but only 80% were immunized during the first year of life in accord with the recommended vaccination schedule. However, the timing of vaccinations had improved: thus, in the seven regions included in both surveys, 49–90% of the children in the present survey were fully immunized with mandatory vaccines during the first year of life, compared with 33–69% in 1993. Delay in vaccine administration is not only a marker of the performance of the vaccination programme, but also an indicator of the size of the population temporarily left partially immunized, which could potentially create pockets of susceptible individuals. Although the circulation of wild poliovirus in Italy was very probably interrupted some years ago (13), the presence of large numbers of non-immunized children could allow imported infections to be transmitted. In some areas of Italy, such as the port city of Naples and the province of Bolzano, which is located on the Austrian border, only half the child population was fully immunized against poliomyelitis by the age of 12 months. This missed or delayed vaccination could have an even greater impact in the near future when, to reduce the incidence of vaccine-associated paralytic poliomyelitis (VAPP), OPV will be completely replaced by inactivated poliovaccine (IPV), and the benefits of the circulation of the viral vaccine strain will thus disappear.

Intercurrent childhood illnesses still appear to be the leading cause of delays in performing mandatory vaccination. However, since primary health care delivery and prevention activities are the responsibility of local health authorities, there exist differences in vaccination schedules, which could also account for regional variations in adherence to national recommendations. For example, in the regions of Tuscany and Veneto, delays in completing immunization with the three primary doses of OPV and HBV were due to changes in the local schedule, with the administration of the third doses being deferred to coincide with that of the fourth dose of DTP.

Immunization coverage for pertussis in the seven regions included in both surveys increased in the period between the two surveys: from 40% for the 1991 birth cohort to 87% for the 1996 cohort. This improvement can largely be attributed to restored confidence in acellular pertussis vaccines.

Specifically, the results of the Italian Pertussis Trial (2) were widely publicized in 1995, and contributed to increasing the level of acceptance of pertussis vaccination. However, as pointed out above, the reintroduction of pertussis vaccination combined with DT significantly affected the timing of administration of the third dose of OPV and HBV; the logistics of vaccinations should therefore be evaluated when additional vaccines are included in immunization programmes.

Although the coverage for measles vaccination has improved slightly since 1993, it is still too low for interrupting transmission. In some regions (Lombardy and Emilia Romagna), the coverage was close to the level required to interrupt transmission, but in many regions only one-third of the eligible children had been immunized. This partially controlled circulation of measles virus may result in many adolescents or young adults remaining susceptible to this virus, consequently increasing the risk of acquiring the disease at an older age when the clinical presentation tends to be more severe. Thus, improving the immunization coverage for measles should be a national priority, not only for reaching the WHO targets for the control and eventual elimination of the disease, but also for preventing the onset of severe cases, which could further reduce the level of confidence in immunization programmes. Regional coverage for measles was directly related to the proportion of total vaccinations performed in public vaccination clinics. Lack of information was the most frequently reported reason for missed measles vaccination. At the recommended vaccination age of 15 months, no other routine visits to the local vaccination clinics are scheduled. As a result, parents may remain unaware of the need and the timing of measles vaccination. This is supported by the observation that the children of older and better

educated mothers are more likely to be immunized against measles, which agrees with findings in other countries (14). However, in 1999 these considerations led to a change in the recommended vaccination schedule for measles — the vaccine is now administered simultaneously with the third doses of mandatory vaccines (i.e. at 12 months of age).

With the strengthening of individual immunization programmes, the most commonly reported obstacle to timely vaccination is not “lack of information” (as observed for measles and Hib) but “intercurrent illness”. Thus, efforts to increase the level of knowledge about the available vaccinations must include education of parents and health care providers about appropriate reasons for deferring vaccination.

The present survey shows that, within a dual system of mandatory and optional infant vaccinations, the programme for optional vaccinations must be strengthened. The striking difference between the improved coverage for pertussis and the consistently low coverage for measles confirms that formal recommendations for vaccination have only a limited impact. A greater effort is needed to educate parents and doctors on the value of optional vaccinations. Although, in a decentralized health care system, vaccinations are a local responsibility, infectious diseases cannot be controlled unless synergistic initiatives are undertaken and effectively coordinated at the national and international level. This coordination will help to overcome some striking regional differences in immunization coverage in Italy, and promote efforts towards reaching the goal of disease prevention. ■

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Résumé

La couverture vaccinale de l'enfant en Italie : estimations par des sondages en grappe régionaux simultanés

Entre janvier et mars 1998, une série de sondages en grappe régionaux (connus collectivement sous le nom d'Étude ICONA) ont été entrepris simultanément dans 19 des 20 régions de l'Italie pour estimer la couverture vaccinale des enfants âgés de 12 à 24 mois par les vaccins obligatoires — antipoliomyélitique oral (VPO), antidiphthérique-antitétanique (DT) et anti-hépatite virale B (HVB) —, par les vaccins facultatifs contre la coqueluche, la rougeole et *Haemophilus influenzae* b (Hib), et aussi pour évaluer les vaccinations manquées ou retardées.

Les enfants de l'étude sont nés en 1996 et ont été choisis dans des registres de naissances utilisant la technique de sondage en grappe du programme élargi de vaccination. Cette méthode a été appliquée dans 18 des 19 régions étudiées; l'échantillonnage randomisé simple a été utilisé dans deux grandes villes (Milan et Naples) ainsi que dans une région ayant enregistré moins de

1000 naissances en 1996. L'état vaccinal des enfants a été déterminé par des visites à domicile, avec interrogatoire des parents et vérification des cartes de vaccination. On a également demandé aux parents les raisons des vaccinations manquées ou retardées comparativement au calendrier recommandé.

On considérait l'enfant comme pleinement vacciné i) par DT/DTC, VPO et HBV s'il avait reçu au moins trois doses, ii) par le vaccin antirougeoleux s'il avait reçu au moins une dose à l'âge recommandé de 15 mois ou après, et iii) par le vaccin anti-Hib s'il avait reçu 3 doses à l'âge de 12 mois ou une dose unique après cet âge. Ces résultats ont été comparés à ceux d'une enquête précédente effectuée en 1993 dans sept régions de l'Italie.

La population d'étude comprenait 4310 enfants âgés de 12 à 24 mois. Le nombre total de naissances dans les 19 régions étudiées représentait 90% du

nombre total de nacimientos en Italia. La cobertura global por los vacunos obligatorios (VPO, DT et HBV) dépassait 94%, mais seuls 79% des enfants avaient été vaccinés conformément au calendrier recommandé (c'est-à-dire avant l'âge d'un an). La couverture vaccinale anticoquelucheuse de cette classe d'âge est passée de 40% (enquête de 1993) à 88%, mais la couverture antirougeoleuse (56%) restait insuffisante pour lutter contre la maladie; la couverture anti-Hib était elle de 20%.

La cause la plus fréquemment indiquée pour les vaccinations obligatoires manquées ou retardées était la

maladie; les parents et ceux qui s'occupent des enfants doivent donc être rendus bien attentifs aux raisons pouvant justifier un report de la vaccination. La raison la plus souvent indiquée de la non-vaccination antirougeoleuse était le manque d'information. Ces résultats confirment qu'en Italie la couverture n'est satisfaisante que pour les programmes de vaccination obligatoires. La couverture anticoquelucheuse a toutefois augmenté de manière spectaculaire après l'introduction des vaccins acellulaires. Un effort accru d'éducation des parents et des médecins reste nécessaire pour améliorer la couverture par les vaccins facultatifs dans toutes les régions.

Resumen

Cobertura inmunitaria de la población infantil en Italia: estimaciones regionales simultáneas mediante la técnica de muestreo por conglomerados del PAI

Entre enero y marzo de 1998 se llevaron a cabo simultáneamente en 19 de las 20 regiones de Italia una serie de encuestas regionales por grupos (conocidas colectivamente como el estudio ICONA) a fin de estimar la cobertura de los niños de 12 a 24 meses de edad en lo que respecta a la inmunización obligatoria con la vacuna antipoliomielítica oral (OPV), contra la difteria-tétanos (DT) y contra la hepatitis B (VHB), así como en relación con la vacunación optativa contra la tos ferina, el sarampión y *Haemophilus influenzae* del tipo b (Hib); se aprovechó para evaluar al mismo tiempo la inobservancia de los calendarios de vacunación.

Los niños estudiados habían nacido en 1996 y fueron seleccionados a partir de los registros de nacimientos mediante la técnica de muestreo por conglomerados del PAI (Programa Ampliado de Inmunización). Este método se aplicó en 18 de las 19 regiones estudiadas; se efectuó un muestreo aleatorio simple en dos ciudades grandes (Milán y Nápoles) y en una región en la que en 1996 se registraron menos de 1000 nacimientos. El estado de vacunación de los niños se determinó mediante visitas domiciliarias en las que se entrevistaba a los padres y se examinaban las fichas de vacunación. Cuando se descubría que faltaba alguna vacuna o que había sido administrada con retraso, se preguntaba a los padres las razones de ello.

Se consideraba que los niños habían sido plenamente inmunizados i) con DT/DTP, OPV y VHB, cuando habían recibido como mínimo tres dosis, ii) con la vacuna antisarampión, cuando habían recibido al menos una dosis a la edad recomendada de 15 meses o más tarde, y iii) con la vacuna anti-Hib, cuando habían

recibido tres dosis a la edad de 12 meses o una sola dosis más tarde. Los resultados se compararon con una encuesta anterior llevada a cabo en 1993 en siete regiones italianas.

La población estudiada estaba constituida por 4310 niños de 12-24 meses de edad. El número total de nacimientos en las 19 regiones estudiadas representaba el 90% de los nacimientos totales registrados en Italia. La cobertura inmunitaria global con las vacunas obligatorias (OPV, DT y VHB) superó el 94%, pero sólo el 79% había sido vacunado de acuerdo con la pauta recomendada (esto es, durante el primer año de vida). La cobertura con vacuna antitosferínica de los niños de este grupo de edad aumentó de un 40% (encuesta de 1993) a un 88%, pero la cobertura antisarampión (56%) seguía siendo insuficiente para controlar la enfermedad; la cobertura vacunal contra Hib fue del 20%.

La razón más frecuente del retraso o la no administración de vacunas obligatorias fue la existencia de una enfermedad intercurrente; es preciso, por tanto, educar a los padres y a los dispensadores de atención sanitaria respecto a las razones válidas para retrasar la vacunación. La razón más frecuentemente notificada de no haber vacunado contra el sarampión fue la falta de información. Estos resultados confirman que en Italia sólo es satisfactoria la cobertura proporcionada por los programas de vacunación obligatoria. Sin embargo, la cobertura inmunitaria contra la tos ferina ha mejorado espectacularmente tras la introducción de las vacunas acelulares. Es necesario un mayor esfuerzo para educar a los padres y los médicos con miras a mejorar la cobertura inmunitaria optativa en todas las regiones.

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