Childhood vaccination coverage in Italy: results of a seven-region survey

The Italian Vaccine Coverage Survey Working Group[1]

In Italy few data exist on vaccination coverage and timeliness. We therefore carried out cluster surveys on 12–23-month-olds in nine Italian cities and regions using standard Expanded Programme on Immunization methodology. The study areas accounted for 40% of all live births in Italy in 1991. Coverage levels for the third dose of diphtheria and tetanus toxoids and for oral poliovirus vaccine, which are mandatory, exceeded 90% in all but one area. However, less than two-thirds of the children had completed the primary vaccine series by their first birthday. The commonest reason for failure to complete the series in time was that the child had been sick and was not brought for vaccination. For the two optional vaccines (pertussis and measles) coverage was much poorer, ranging from 8% to 71% for pertussis and from 9% to 53% for measles. The commonest reason given by the mothers for pertussis non-vaccination was that they had been advised against it, while for measles the commonest reasons were that the child was sick and that they had been advised against it. These findings suggest that although coverage for the mandatory vaccines is high, coverage for pertussis and measles is very low. Additional education of physicians and mothers is needed concerning the true contraindications for vaccination. Also, in the absence of legislation making pertussis and measles vaccines mandatory, greater efforts are needed to convince physicians and the public about the benefits of their use.

Introduction

Measuring the coverage and timeliness of vaccine delivery to children is important for identifying groups at risk for low coverage. In addition, it provides a useful means of monitoring the coverage and efficiency of the health care system in delivering paediatric preventive services.

In Italy vaccination of all newborns with diphtheria and tetanus toxoids (DT) and with oral poliovirus vaccine (OPV) has been mandatory since the early 1960s (*1*). These vaccines are provided free of charge by local health units. Pertussis and measles vaccines, though recommended, have always been optional. The policy on these optional vaccines varies, even within regions; in some local health units, they are administered free of charge, while in others the parents must purchase the vaccines, which are then administered either by the local health unit or by the child's paediatrician.

The current reporting system on vaccinations in Italy covers only those administered within the national health care system. The available data suggest that coverage in the last few years has been high (Public Health Service Directorate, Ministry of Health, unpublished data). However, only 11 of the 20 Italian regions provided data in 1991 and many of the data were incomplete. Furthermore, the calculation of vaccine coverage using the surveillance data is difficult because accurate information is rarely available on the number of children seeking vaccination through the national health service, and no indication is given of whether the vaccines were administered in accordance with the recommended schedule. The usefulness of surveillance data in evaluating levels of coverage of the optional vaccines is even more limited since such vaccines are often administered in the private sector.

Two large-scale vaccine coverage surveys were conducted in Italy in the mid-1980s. The first, in 1984, focused on the coverage of the optional vaccines, although data were also collected on OPV coverage. The parents of more than 37 000 preschool and elementary school children aged 3–10 years in 80 communities completed a questionnaire on prior vaccination of and illnesses experienced by their children (*2*). The results showed that coverage for OPV was over 98% in all areas of the country. In contrast, pertussis vaccine coverage ranged from 12% in the south to 15% in the north; measles vaccine coverage, from 4% in the south to 13% in the

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north; and rubella vaccine coverage, from 6% in the south to 29% in the north. There were wide variations in coverage between the 80 communities, suggesting that there was considerable variation in the policies of the local health units responsible for deciding local vaccination policy.

The second of the two surveys was conducted in 1985–86 among children born in June 1983 in five Italian cities, four of which were in the south of the country (*3*). This study showed that 60–96% of the children had completed the three-dose polio series; however, even in the cities where coverage was high, less than 70% had been fully vaccinated by their first birthday.

One additional recent study that used vaccine sales data found that pertussis vaccine coverage increased from an estimated 22% for the 1985 birth cohort to 50% for the 1989 birth cohort (*4*). These same data, however, demonstrated a decline in coverage for the 1990 cohort, estimated to be 38%.

Since the last surveys were undertaken, campaigns have been conducted in several parts of Italy to increase optional vaccine coverage, and a greater number of local health units have begun to offer measles and pertussis vaccination free of charge. To assess the current coverage for both mandatory and optional vaccines, the adherence to the vaccine schedule, and the reasons for late or non-vaccination, as well as to evaluate the accuracy of the available data on vaccine coverage, we undertook a vaccine coverage survey. The study, which used standard Expanded Programme on Immunization (EPI) cluster survey methodology, involved nearly 1800 children aged 12–23 months living in seven of the 20 regions of the country. These seven regions accounted for 40% of all live births in Italy in 1991 (*5*).

Methods

Selection of regions, cluster sites, and individual children

In six of the seven study regions, participants in a 2-year field epidemiology training programme sponsored by the Istituto Superiore di Sanità in Rome, and the Centers for Disease Control and Prevention, Atlanta, GA, USA, organized and conducted the survey in their home regions; in the seventh region, residents of a university-based public health specialization programme conducted the survey. Although not randomly chosen, the regions were geographically dispersed; two were in the north (Lombardy and Liguria), three in the centre (Tuscany, the Marches, and Abruzzi), and two in the south (Campania and Molise). In Lombardy and Campania, separate surveys were conducted in the regional capitals (Milan and Naples, respectively) and in the remaining communes of the region, resulting in a total of nine study areas.

Selection of cluster sites and individual children

Except as noted below, standard EPI cluster survey methodology, involving systematic sampling from a cumulative population list, was used to select the 30 cluster sites in each of the study areas.[a] In five regions, the entire population served as the sampling universe. In Campania, Naples and the remainder of the region were each considered as separate sampling universes and 30 clusters were chosen in each. In Milan, a computerized list of births was available, and a random sample was selected directly; in the remainder of Lombardy, 30 clusters were chosen from a cumulative population list. In all cases, the population lists for sampling were based on births in 1991, by commune of residence of the mother, which were obtained from the communal vital record register. When the number of births was small, adjacent communes were aggregated prior to sampling.

After 30 communes had been selected within the sampling universe, the local health unit of the commune was asked to obtain a list from the local birth registration office of all children who would be 12–23 months of age by the date that the study was to begin in the region. Random number tables were used to select seven of the children in the eligible age group as well as a list of seven alternatives.

Survey methods

The standard questionnaire for the EPI surveys[a] was modified to reflect the Italian vaccine schedule and likely reasons for non-vaccination. The resulting questionnaire was pre-tested on a small sample of children in Milan and Tuscany and modifications made prior to training the interviewers.

The background of the interviewers varied by region, but included vaccination nurses and physicians working in the local health units, postgraduate physicians, and the survey organizers themselves. In each region, a training session was held to explain the goals of the survey, the methods, and to review the questionnaire and its completion. The organizers in each area provided telephone back-up during the survey to deal with any questions or problems that developed.

[a] *Training for mid-level managers: the EPI coverage survey.* Unpublished document WHO/EPI/MLM/91.10, 1991.

The interviewers attempted to make telephone contact with the mothers on their list to make an appointment. If the mother could not be contacted after three tries or she did not have a telephone number, a visit was made to the household. If no one was at home, an attempt was made to verify with the neighbours that the family still lived there, and a note was left asking the mother to contact the interviewer to arrange an appointment. Only when a mother could not be reached after three telephone calls and a visit was one of the children on the list of alternatives used. All interviews were conducted in person, usually at the child's home but occasionally in the local health unit.

Definitions

For the analysis, children were considered to be fully immunized against diphtheria, tetanus, poliomyelitis and pertussis if they had received three doses of the corresponding vaccines by the time of the interview. In all regions except Tuscany, coverage for hepatitis B vaccine was considered only for those children born after 16 June 1991, when the law concerning hepatitis B vaccine came into effect. In Tuscany, the corresponding date used was 25 October 1991, when the region sent a circular to the local health units mandating the use of this vaccine. For measles vaccine, coverage was calculated only for those children aged ≥15 months.

The timeliness of vaccination was assessed only for DT and OPV, and only for those children who had a vaccination card. Under the vaccination schedule (Table 1), the first doses of DT and OPV should be administered within the third month of life, with the second dose given 6–8 weeks later, by the fourth or fifth month of life, and the third dose 6 months after the second dose, i.e., by the tenth or eleventh month of life. Interpretations of the age at which vaccinations are to be conducted vary; within the third month, for example, has been interpreted in some areas to mean before 8 weeks of age, while in others the same recommendation is interpreted to mean at or after 12 weeks of age. Because of these ambiguities, the first dose was considered to be delayed if it had been administered after 4 months (16 weeks) of age; for the second and third doses, respectively, the corresponding cut-offs were 6 months (24 weeks), and the child's first birthday.

The mothers of children who had not completed the three doses of the mandatory vaccinations by their first birthday, of those who had not received pertussis vaccine, and of those who were >16 months of age and had not yet received measles vaccine were interviewed to determine why, using a data collection instrument similar to that recommended for use in EPI surveys but modified to reflect the situation in Italy.

Use of routine surveillance for monitoring vaccination coverage

For four of the regions included in the survey, routine surveillance data on the number of first, second, and third doses of DT, OPV, and pertussis vaccines were available for either 1990 or 1991. Using as denominator the number of resident children under 1 year of age, we estimated the vaccination coverage and compared the results with those obtained in the coverage survey.

Health care delivery and the use of optional vaccines

In addition to the coverage survey, we also conducted a brief telephone survey in each region of all the local health units from which clusters had been drawn. The data collected included policies on notifying mothers to bring their children for a first visit, whether they interpreted the regulations to mean that the first dose should be given during or after the third month of life, whether they offered free pertus-

Table 1: **The Italian national vaccination schedule**[a]

Age administered	Vaccine[b]	Interval between doses
3rd month of life	OPV + DT (optional P) + HBV	
4th–5th month of life	OPV + DT (optional P) + HBV	6–8 weeks after first dose
10th–11th month of life	OPV + DT (optional P) + HBV	6 months after second dose
15th month of life	(Optional measles, mumps)	
3rd year of life	OPV	>1 year after third dose
6th year of life	DT	4–5 years after third dose
Pre-puberty	(Optional rubella for females)	
14th year of life	T	Every 10 years

[a] Source: ref. (*1*).
[b] OPV = oral poliovirus vaccine; DT = diphtheria–tetanus; P = pertussis; HBV = hepatitis B vaccine; and T = tetanus.

sis or measles vaccine, and whether they had ever conducted vaccine campaigns and if so for which vaccines. The percentage of local health units engaging in each of these behaviours was plotted against the vaccination coverage for that survey universe, and a regression analysis was carried out using coverage as the dependent variable. When more than one cluster was drawn from a local health unit, the response of the unit was correspondingly weighted such that the total number of responses was 30.

Data entry and statistical analysis

Data entry and analysis were performed using Epi Info version 5.0 (*6*). For each variable, 95% confidence intervals that took into account the cluster design of the survey were calculated using an experimental Epi Info routine and verified using Epi Table software (Médecins sans Frontières, Paris).

Results

Study population

A total of 210 mothers were interviewed in each of the eight study universes where cluster sampling was used; in the remaining study universe where random sampling was employed, 100 mothers were interviewed. Table 2 shows the the proportion of children in each cluster drawn from the alternative list, and the sex, maternal age, and maternal education levels for the study populations. The proportion drawn from the alternative list ranged from 8.7% in Lombardy to 20.0% in Milan. Most replacements occurred because the mother had moved or could not be contacted; the vast majority of those contacted agreed to participate. The characteristics of the mothers in the study did not differ significantly from those obtained from birth records from each of the regions for 1990 (ISTAT, unpublished data).

Mandatory vaccines

Vaccine coverage. Coverage, by region, for the first and third doses of DT and OPV for the entire cohort and for the first and third doses of hepatitis B vaccine for those born after this vaccine became mandatory, is shown in Table 3. The coverage was virtually universal (≥98%) for the first dose of DT and OPV in all areas studied. By contrast, the levels of the third dose varied considerably, ranging from a high of 99% in the Marches to a low of 77% in Campania. For the newly mandatory hepatitis B vaccine, the coverage for the third dose ranged from 63% in Abruzzi and Naples to 92% in Lombardy.

Adherence to vaccine schedule. The proportions of children whose first, second, and third doses of OPV and DT (or diphtheria–tetanus–pertussis (DTP)) vaccines were delayed are shown in Table 4. The proportion of vaccinated children receiving a third dose of DT within the recommended period ranged from 33% in Naples to 69% in Lombardy. For OPV the proportions were similar. In general, the proportion who were vaccinated late increased with the dose number of the series.

Reasons for incomplete vaccination. In all the regions studied, the commonest reason given for the delay in completing the primary DT and OPV sched-

Table 2: **Characteristics of the study population, by region, Italian vaccination coverage survey, 1993**

Characteristic	Abruzzi	Campania		Liguria	Lombardy		Marches	Molise	Tuscany
		Naples	Other		Milan	Other			
Sample size	210	210	210	210	100	210	210	210	210
% drawn from alternate list	14.7	14.8	10.0	15.2	20.0	8.7	13.3	11.9	11.0
% male	50.5	51.9	52.4	51.9	58.0	49.5	54.3	55.2	50.0
Maternal age (years)									
Mean ± SD	30.0 ± 4.4	29.6 ± 5.2	29.5 ± 5.1	31.4 ± 4.6	32.0 ± 4.9	30.6 ± 4.6	30.8 ± 4.9	30.3 ± 4.9	31.4 ± 5.0
Median	29 (18–44)[a]	29 (18–44)	29 (16–45)	31 (18–44)	32 (19–42)	31 (20–42)	30 (19–47)	30 (18–44)	31 (19–42)
Maternal education level (%)									
None	0	1.9	0.5	0.5	1.0	0	0.5	0	0.5
Elementary	5.7	28.6	17.6	1.4	7.0	3.8	4.8	7.6	5.2
Middle school	41.9	31.4	42.4	36.8	20.0	36.7	35.7	42.9	39.0
High school	44.3	33.3	29.5	49.8	53.0	49.0	47.6	42.9	42.9
University	8.1	4.8	10.0	11.5	19.0	10.5	11.4	6.7	12.4

[a] Figures in parentheses are the range.

Table 3: **Percentage coverage of first and third doses of diphtheria–tetanus, poliovirus, and hepatitis B vaccines, by region, for children aged 12–23 months**[a]

Vaccine[b]	Abruzzi	Campania		Liguria	Lombardy		Marches	Molise	Tuscany
		Naples	Other		Milan	Other			
DT1	99.5 (98.6–100)[c]	98.6 (97.0–100)	99.1 (97.8–100)	99.5 (96.6–100)	100	100	100	100	100
DT3	95.2 (91.1–99.3)	77.1 (71.0–83.2)	87.2 (82.5–91.9)	96.7 (94.1–99.2)	91.0 (85.4–96.6)	94.8 (88.8–100)	98.6 (97.0–100)	95.2 (92.2–98.3)	95.2 (91.6–98.9)
OPV1	99.5 (98.6–100)	98.6 (97.0–100)	98.1 (96.3–99.9)	99.5 (98.6–100)	100	100	100	99.5 (98.6–100)	100
OPV3	97.6 (95.7–99.6)	77.6 (71.5–83.7)	88.2 (83.7–92.6)	96.7 (94.1–99.2)	91.0 (85.4–96.6)	97.6 (95.3–100)	98.6 (97.0–100)	94.3 (90.9–97.7)	95.2 (91.6–98.9)
HBV1	89.2 (80.9–97.4)	84.4 (76.4–92.4)	79.3 (67.5–91.1)	94.0 (88.7–99.3)	96.6 (91.8–100)	99.2 (97.7–100)	95.7 (89.8–100)	82.3 (71.6–93.9)	98.3 (90.7–100)
HBV3	62.5 (51.3–74.8)	62.3 (53.9–70.7)	63.1 (50.4–75.7)	85.9 (78.7–93.2)	79.3 (68.8–89.8)	92.2 (87.9–96.0)	87.1 (78.7–95.6)	68.3 (56.3–80.2)	81.0 (68.3–93.8)

[a] For hepatitis B vaccine only for children born after 16 June 1991, when vaccine was made mandatory (25 October 1991 for Tuscany).
[b] DT = diphtheria–tetanus; OPV = oral poliovirus vaccine; HBV = hepatitis B vaccine.
[c] Figures in parentheses are the 95% confidence intervals.

ule was that the child was sick and was not brought for vaccination, although the proportion of mothers who gave this reason varied from 37% in Milan to 69% in Molise. Other reasons included the following: lack of awareness that the vaccination should be completed by a certain deadline; the child was sick and brought in, but vaccination was deferred; and they were not notified by the local health unit to come or the appointment given for the third dose was after the child's first birthday. It was not possible to determine whether the decision not to bring a sick child for vaccination was made in consultation with the child's paediatrician. However, for those regions that collected data on the illnesses reported when the child should have been vaccinated, many were not true contraindications to vaccination.

When we examined the health care factors associated with delayed vaccination, little correlation was seen between the following: the timely completion of the third dose and the percent of the local health units that sent out letters for the first visit ($r = 0.22$); whether these units considered that the first dose should be given during or after the third month of life ($r = 0.11$); or whether they performed active follow-up of the children who did not come for their first visit ($r = -0.21$).

Table 4: **Percentage of children receiving first, second, and third doses of diphtheria–tetanus and poliovirus vaccines within one month of the deadline, by region, for 12–23-month-olds**[a]

Vaccine[b]	Abruzzi	Campania		Liguria	Lombardy		Marches	Molise	Tuscany
		Naples	Other		Milan	Other			
DT1	87.1 (80.6–93.6)[c]	54.1 (45.1–63.1)	68.4 (60.8–76.1)	90.4 (87.1–93.8)	83.7 (74.7–90.7)	93.2 (90.0–96.5)	89.1 (83.9–94.2)	87.6 (82.2–93.0)	87.6 (83.0–92.2)
DT2	81.8 (75.0–88.7)	49.0 (41.3–56.7)	59.2 (50.3–68.1)	87.0 (83.0–90.9)	72.4 (62.4–81.4)	87.8 (81.8–93.8)	81.8 (74.3–89.2)	72.5 (62.4–82.6)	81.4 (76.4–86.5)
DT3	54.5 (43.3–65.6)	33.3 (26.4–40.2)	43.1 (34.2–52.3)	63.4 (56.7–70.0)	54.4 (44.1–64.7)	68.7 (58.9–78.5)	55.3 (45.9–64.6)	51.8 (40.8–62.7)	56.5 (48.0–65.0)
OPV1	86.6 (80.1–93.1)	54.6 (45.7–63.5)	69.6 (61.9–77.4)	90.0 (86.6–93.3)	83.7 (74.7–90.7)	92.7 (89.5–95.9)	87.5 (81.6–93.4)	84.7 (78.8–90.7)	88.1 (83.8–92.4)
OPV2	81.3 (74.0–88.7)	50.5 (42.5–58.4)	59.3 (49.8–68.8)	87.9 (84.0–91.9)	77.3 (67.3–85.3)	87.8 (81.0–92.6)	80.7 (73.1–84.4)	71.3 (61.1–81.6)	83.8 (79.0–88.6)
OPV3	55.6 (45.3–66.0)	34.6 (27.2–41.9)	44.8 (34.9–55.4)	62.1 (56.2–67.9)	56.7 (46.5–66.9)	65.2 (55.6–74.8)	55.3 (46.2–64.3)	52.4 (41.2–63.6)	55.6 (45.3–66.0)

[a] In Italy the following deadlines are specified by law: 4 months of age for the first dose; 6 months for the second; and 12 months for the third dose.
[b] DT = diphtheria–tetanus; OPV = oral poliovirus vaccine.
[c] Figures in parentheses are the 95% confidence intervals.

Optional vaccines

Vaccine coverage. The coverage for the optional vaccines was considerably lower than that for the mandatory vaccines (Table 5). For pertussis vaccine, the coverage for the third dose ranged from 7.6% in Molise to 71% in Lombardy. For measles vaccine, the coverage was also low, ranging from 8.6% in Naples to 53% in Lombardy.

Reasons for non-use of measles and pertussis vaccines. The reasons given by mothers for not having had their children vaccinated against measles and pertussis are given in Table 6. For pertussis, the commonest reasons included the following: they had been advised against it; the vaccine had undesirable side-effects; they did not know the vaccine existed; it was better to get the disease; and the disease was not dangerous. In the areas with higher coverage, the first two of these reasons were commoner; in those with lower coverage, the lack of knowledge about the vaccine's existence was more dominant. The reasons for not vaccinating against measles were more varied. The commonest, however, included that the child was sick and was not brought for vaccination, that they had been advised against it or told to wait until the child was older, that it was better to get the disease, and that the vaccine had undesirable side-effects. Except in Naples and Campania, the cost of vaccine was rarely cited as a reason for non-vaccination for either pertussis or measles. Of note is that 14% of mothers in Naples and 7% of those in Campania stated that their child had already had measles; in the other areas, the corresponding values were 0–3.5%.

A strong correlation was observed between the proportion of local health units in each study universe providing pertussis vaccine free of charge and the actual coverage (r = 0.95; 95% CI = 0.77–0.99; P = 0.001). Because so few of the local health units had conducted pertussis vaccine campaigns (0–23%, depending on the region), we did not examine the correlation of vaccine coverage with such campaigns.

As was the case for pertussis vaccine, the correlation between the proportion of local health units in each study universe that provided measles vaccine free of charge and the actual coverage was high, but not as high as for pertussis (r = 0.75; 95% CI = 0.17–0.94; P = 0.02). Although many of the local health units stated that they had carried out vaccine campaigns, there was no correlation between the proportion offering measles vaccine campaigns and the coverage (r = 0.16; 95% CI = –0.56 to 0.75).

Use of routine surveillance for monitoring vaccination coverage. Data from routine surveillance were available for four of the seven study regions for either 1990 or 1991 (Table 7). For the mandatory vaccines, the surveillance system appears to have underestimated the coverage in two of the regions, with the surveillance estimates being less than the lower 95% confidence limit of the survey value. In the Marches, the number of each dose of DT and OPV administered exceeded the number of 1-year-olds, resulting in coverages greater than 100%. In the remaining regions, the survey and surveillance coverages were similar. For pertussis vaccine, the coverage obtained from the surveillance system differed substantially from that obtained in the survey in all four regions.

Discussion

Although the EPI cluster survey methodology has been more commonly applied in developing country settings, the present study confirms the feasibility of using it to obtain timely information on the vaccination status of children in a developed country, rapidly and at reasonably low cost, using existing health care personnel. In countries such as Italy that have a more extended vaccine schedule than that used in developing countries, consideration should be given, however, to performing such surveys on slightly

Table 5: **Percentage coverage of first and third doses of pertussis vaccine and of measles vaccine, by region**[a]

		Campania			Lombardy				
Vaccine	Abruzzi	Naples	Other	Liguria	Milan	Other	Marches	Molise	Tuscany
Pertussis 1	25.7 (16.2–35.2)[b]	15.2 (9.1–21.4)	19.4 (18.1–26.7)	43.8 (31.4–56.2)	62.0 (51.0–72.0)	79.0 (70.9–87.2)	55.7 (45.0–66.4)	11.0 (5.1–16.8)	30.5 (19.4–41.5)
Pertussis 3	21.4 (18.1–29.8)	12.4 (7.2–17.5)	15.2 (10.2–20.2)	37.6 (26.3–49.0)	56.0 (45.0–66.0)	71.0 (61.9–80.0)	51.0 (40.7–61.2)	7.6 (3.7–11.6)	26.2 (15.1–37.3)
Measles	18.7 (11.6–25.9)	8.6 (3.1–14.2)	16.1 (8.3–23.8)	32.3 (24.5–40.2)	43.3 (30.3–56.3)	52.6 (42.8–62.5)	35.8 (26.8–44.9)	11.0 (5.6–16.4)	44.4 (35.2–53.5)

[a] The data for measles vaccine are for children >15 months of age.
[b] Figures in parentheses are the 95% confidence intervals.

Table 6: **Distribution of the reasons given by the mothers for non-vaccination with pertussis and measles vaccine, by region**

		Campania			Lombardy				
	Abruzzi	Naples	Other	Liguria	Milan	Other	Marches	Molise	Tuscany
Pertussis vaccine	*n* = 165	*n* = 184	*n* = 178	*n* = 65[a]	*n* = 41	*n* = 52	*n* = 103	*n* = 99[b]	*n* = 155
Were advised against it (%)	26.7	20.7	16.3	69.2	39.0	48.1	35.9	22.2	14.5
Undesirable side-effects (%)	26.7	10.9	13.5	0	14.6	15.4	16.5	10.1	15.5
Didn't know there was a vaccine (%)	7.3	21.2	20.8	1.5	2.4	5.8	10.7	29.3	19.4
Better to get the disease (%)	10.9	8.7	12.4	0	7.3	0	1.9	2.0	3.9
Disease not dangerous (%)	2.4	5.4	4.5	0	2.4	1.9	2.9	1.0	1.3
Measles vaccine	*n* = 118	*n* = 140	*n* = 130	*n* = 59[c]	*n* = 37	*n* = 71	*n* = 105	*n* = 141	*n* = 86
Sick, not brought in (%)	13.6	9.3	6.9	18.6	10.8	23.9	29.5	12.1	26.7
Were advised against it (%)	7.6	17.9	10.0	37.3	21.6	11.3	23.8	6.4	9.3
Better to get the disease (%)	15.3	12.9	15.4	0	13.5	2.8	3.8	10.6	5.8
Undesirable side-effects (%)	19.5	5.0	16.2	0	8.1	4.2	12.0	5.7	2.3
Physician suggested waiting (%)	0.8	0.7	1.5	10.2	2.7	2.8	3.8	0.7	31.4

[a] Data for 65 of the 131 unvaccinated or incompletely vaccinated.
[b] Data for 99 of the 194 unvaccinated or incompletely vaccinated.
[c] Data collected for 59 of the 123 unvaccinated.

older children to avoid problems with incomplete denominators for measles vaccination and to determine more accurately the duration of delays in receiving the final dose of the three-dose vaccines without resorting to the use of more complicated person–time denominators.

Our study may have overestimated the rate of vaccine coverage. The percentage of mothers drawn from the alternative list in most areas was relatively low, and we had virtually a 100% response rate among those mothers who were contacted successfully. None the less, for practical reasons, our sampling was based on birth registration data for the communes included in the survey. Although registration is obligatory within 10 days of birth in order to receive health benefits and for school attendance, undocumented immigrants, who may also be less likely to be immunized, were not included in the study sample. Also excluded were any families who had moved into the area after the child was born, although geographical mobility in Italy is low (*5*). These deficiences would most probably have had the greatest effect on the coverage estimates for Milan and Lombardy, since most immigration and in-country migration are to the more heavily industrialized north (*5*). It is difficult to estimate the impact of this exclusion, but it is unlikely that it dramatically affected the reported coverage levels.

Although the use of several interviewers might have affected the consistency of the data collection, information on the vaccination dates was obtained directly from vaccination cards, minimizing any difficulties with interviewing technique and with maternal recall. However, use of several interviewers might have caused some inconsistencies in recording the reasons for non-vaccination.

The high coverage levels against diphtheria, tetanus, and poliomyelitis are reflected in the virtual

Table 7: **Comparison of the percentage vaccination coverage for the third doses of diphtheria–tetanus (DT), oral poliovirus (OPV), and pertussis vaccines from the vaccination survey and from routine surveillance**

Region	Source of surveillance data	Year	DT 3 (%)		OPV 3 (%)		Pertussis 3 (%)	
			Survey	Surveillance	Survey	Surveillance	Survey	Surveillance
Lombardy (except Milan)	Regional health authority	1990	94.8	97.8	97.6	97.8	71.0	58.1
Marches	Ministry of Health	1991	98.6	>100	98.6	>100	51.0	42.6
Molise	Regional health authority	1990	95.2	89.9	94.3	76.0	7.6	1.3
Tuscany[a]	Ministry of Health	1991	95.2	90.7	95.2	96.4	26.2	13.4

[a] Based on 6 months of data.

absence of these diseases among young children in Italy. In 1992, no cases of tetanus or diphtheria were notified among under-5-year-olds, and the last documented case of poliomyelitis in a child was an imported one in 1988 (Ministry of Health, unpublished data). The levels of vaccine coverage in all the areas studied except Campania and its capital city, Naples, approach or exceed the district-specific goals set by WHO for 1997;[b] they also compare favourably with coverage rates elsewhere in Western Europe (*7*)[c] and are higher than the levels reported for many parts of the USA (*7, 8*).[d]

Although vaccination coverage was high, there were some delays in vaccine delivery, especially for the third dose. The rates of failure to adhere to the vaccine schedule were particularly high in the commune of Naples, where two-thirds of the children had not received the third dose of DT and OPV by their first birthday. At least part of the delay in some of the study areas appears to have been due to late initiation to the entire vaccination series. Such delays may have resulted from the failure of the local health unit to receive a list of recent births from the communal birth register, failure of the health unit to notify the parents in time to appear for the first appointment, or delays in parents bringing their child once they had been notified. Another important factor leading to delays was the postponing of vaccination due to intercurrent illness by either the mother or health personnel, which may have varied from area to area depending on the local health policies. Frequently, further questioning of mothers revealed that many of the children had illnesses that were not truly contraindications for vaccination. Thus it appears that improving the system of notifying the mother about the first vaccination visit, combined with providing physicians and vaccination staff, as well as mothers, with clear guidelines about true contraindications would probably increase the timeliness of vaccination coverage. Educating physicians and vaccination staff may perhaps be best accomplished via circulars, the medical literature, and scientific meetings. For educating mothers, it may be helpful to develop an information sheet to accompany the vaccination booklet and to have paediatricians and vaccination staff discuss contraindications with mothers during routine health care visits and vaccination sessions.

In contrast to the high levels of vaccine coverage for the obligatory vaccines, the levels for the optional vaccines were very low. Although caution is required in generalizing our results to the entire country, the levels of pertussis and measles vaccination in Italy appear to be the lowest in industrialized Europe.[d] Reported levels of pertussis vaccine coverage range from 54% in Germany to 100% in San Marino; for measles vaccine, coverage ranges from 38% in Austria to 100% in San Marino.[d] Not surprisingly, pertussis and measles remain common illnesses in the face of the relatively low coverage rates, with the mean annual number of notified cases among under-5-year-olds for the period 1985–89 being as follows: 7731 for pertussis (range: 3680–10 732; rate: 266 per 100 000) and 12 022 for measles (range: 2892–22 737; rate: 414 per 100 000) (*9–13*).

The experience in Italy with the optional vaccines contrasts sharply with that in several other European countries in which some or all of the childhood vaccines are optional rather than mandatory, but the coverage is none the less quite high (*14*). The low coverage in Italy appears to be multifactorial and involves the following factors: the access to free vaccine on site; the willingness of local physicians to recommend the optional vaccines when their administration is not legally mandated (*15*); the attitudes of the mothers themselves about the safety of the vaccines and the perceived severity of the diseases; absence of ongoing educational efforts; and perhaps the importance of autonomy and independent choice in the Italian culture (*16*).

Mothers of children who elected not to have their children vaccinated against measles and pertussis frequently cited as a reason that the family paediatrician had not recommended such a course or, for measles vaccine, that such action should be delayed until the child was older. However, two recent surveys of paediatricians, vaccination doctors, and general practitioners suggest that, although their lack of advocacy may play a role in this respect, it does not fully explain the low coverage. A random sample telephone survey of the knowledge, attitudes, and practices of 132 paediatricians and 48 vaccination doctors conducted in nine regions of Italy in 1991 showed that only two out of three paediatricians and four out of five vaccination doctors recommended that children in their practices be vaccinated against pertussis (*17*). A similar level (65%) was found in a mail survey of paediatricians and general practitioners throughout the country conducted in 1991 (*15*). A greater proportion recommended measles vaccination: in the nine-region telephone survey, 96% of paediatricians and 100% of vaccination doctors reported advising mothers to have their children vac-

[b] Meeting of the Expanded Programme on Immunization, WHO Regional Office for Europe, Milan, 23–25 June 1992.

[c] *Expanded Programme on Immunization Information System. Summary for the WHO European Region.* Unpublished document, WHO/EPI/CEIS/93.2, 1993.

[d] **Stoltenow CL et al.** Early childhood vaccination in two rural Nebraska counties. Paper presented at: *EIS (Epidemic Intelligence Service) conference, Atlanta, GA, USA, 19–23 April 1993.*

cinated against measles (*17*); in the national mail survey, 95% of paediatricians and 73% of general practitioners favoured the use of measles, mumps, and rubella vaccine (*15*). In both surveys, however, physicians may have overstated their advocacy role, and in the mail survey, the low response rate (21%) may have influenced the results. Furthermore, neither of the surveys determined whether physicians were actively counselling their patients or providing their opinions only when specifically asked.

Among the physicians who did not recommend use of the optional vaccines, misconceptions about their efficacy and adverse effects as well as about the severity of the diseases they prevent appeared to be common. In the telephone survey, both paediatricians and vaccination physicians tended to underestimate the efficacy of pertussis vaccination and more than half were worried about adverse reactions associated with the vaccine (*17*); in the mail survey, physicians reported that the potential post-vaccination complications of pertussis and measles vaccines were worse than those associated with the diseases themselves (*15*). Physicians also seem to be concerned about the medico-legal consequences of administering optional vaccines. Recently, legislation was passed in Italy that provides for compensation for severe adverse events resulting from the administration of the mandatory vaccines, but no provisions are made for the optional vaccines.

The vaccination campaigns conducted at the local health unit or regional levels appear to have had somewhat limited results. There may be several reasons for this. First, the number of local health units that have launched campaigns may not have been enough to have had a substantial effect, particularly for pertussis, where only 26% of the local health units participating in the national survey have carried out campaigns (*15*). Second, in some areas, the campaigns have been limited to sending letters to parents and/or physicians, which may have restricted their effectiveness. Finally, the measles campaigns conducted to date have been largely aimed at providing complete coverage for children aged 1–8 years and much of their efforts have focused on reaching children in the school setting. This strategy was adopted to increase rapidly the vaccine coverage in the country, and thereby decrease measles transmission, and also to prevent development of a susceptible pool of older children and adolescents. Although it does appear to have decreased the transmission of measles (*18*), this strategy has not resulted in substantially higher coverage among the age group included in our survey, perhaps because of the lack of continuity implicit in a campaign and the lack of institutionalization of immunization for young children in the local health units.

Our study findings showed that the availability of free measles and pertussis vaccine was positively correlated with vaccine coverage. Although the costs of vaccine at the time of the study were not high (6000 lira (US$ 4) for a three-dose DTP series; 11 000 lira (US$ 7.30) for measles vaccine alone; and 17 000 lira (US$ 11.30) for measles, mumps, and rubella vaccine (*19*)), the inconvenience and time spent in buying the vaccines at a pharmacy and visiting the paediatrician or local health unit to have them administered may be substantial. Caution, however, is required in attributing our findings entirely to the availability of free vaccine, since those health units that provide vaccines free of charge may also advocate their use more actively.

Whether high pertussis and measles vaccine coverage can be achieved in Italy without making these vaccines mandatory is an open question. Certainly this is one solution, as evidenced by experience in Italy with hepatitis B vaccine. For the children in our cohort born prior to 16 June 1991, when hepatitis B vaccine was still optional, the levels of coverage were considerably lower than those born after this date when its administration became mandatory. The coverage will probably increase even further, since in some of the regions, it took time to implement the new policy and obtain adequate supplies of vaccines. Indeed, the government has deliberated for many years about the advisability of making the currently optional vaccines mandatory, and if the efficacy of the new acellular pertussis vaccines can be demonstrated, and the safety issues related to pertussis vaccine are no longer an obstacle, the current policy may change.

In the meantime, it would appear worthwhile to implement several measures to improve vaccine coverage for the optional vaccines similar to those that have worked successfully elsewhere. These might include the following: provision of vaccines free of charge; provision of adequate continuing education and guidelines for paediatricians and vaccination centre physicians and nurses; and provision of financial incentives for paediatricians and vaccination centre staff (*20*). In addition, it may be helpful to carry out broad-based publicity campaigns that are aimed at emphasizing the benefits of vaccination and dispelling unrealistic concerns about the risks. It may also be helpful to set up an outreach programme similar to that in England and Wales, where mothers are counselled at antenatal visits about the benefits of vaccination and a visit is made to each mother shortly after the birth of her child to encourage her to seek vaccination (*20*). Mothers' focus groups might prove useful for determining in greater depth why they are not having their children vaccinated and thus for developing new approaches and educational materials to deal with these perceptions.

One of the secondary goals of our survey was to determine whether the existing surveillance system provides data of sufficient accuracy for monitoring coverage levels of the mandatory vaccines. In some of the regions where routine reporting was available, we found that the levels were similar to those obtained through our survey, implying that the surveillance data may be useful for monitoring vaccination trends. In others, however, the surveillance system either overestimated or underestimated the coverage. If surveillance rather than periodic surveys is to be used for monitoring the use of mandatory vaccines, it may be useful to modify vaccination reporting forms to provide more accurate denominators and to obtain information on whether the vaccine schedule had been completed on time. Furthermore, efforts are needed to improve both the timeliness and completeness of the system if it is to be used for routine monitoring, especially since only 11 of the 20 regions provided data for 1991 and even fewer have reported in 1992. For the optional vaccines, periodic surveys are likely to remain necessary since many are administered in the private sector, and establishing a reliable reporting system would be difficult.

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Résumé

Couverture vaccinale chez l'enfant en Italie: résultats d'une enquête réalisée dans sept régions

En Italie, il n'existe que peu de données sur la couverture vaccinale et le respect du calendrier de vaccination. C'est pourquoi nous avons réalisé des enquêtes par sondage chez des enfants âgés de 12 à 23 mois dans neuf zones d'étude couvrant sept régions d'Italie, en utilisant la méthodologie normalisée du Programme élargi de vaccination. Les zones étudiées couvraient 40% de l'ensemble des naissances vivantes recensées en Italie en 1991. Les taux de couverture pour la troisième dose des anatoxines diphtérique et tétanique et pour le vaccin antipoliomyélitique oral, qui sont obligatoires, dépassaient 90% dans toutes les zones d'étude sauf une. Toutefois, moins des deux tiers des enfants avaient reçu la série complète de vaccins avant l'âge d'un an. La raison la plus fréquente de la non-vaccination était que l'enfant avait été malade et n'avait pas été conduit au centre de vaccination. Pour les deux vaccins facultatifs (contre la coqueluche et la rougeole), le taux de couverture était beaucoup plus faible, allant de 8% à 71% pour la coqueluche et de 9% à 53% pour la rougeole. Dans le cas du vaccin anticoquelucheux, la raison la plus souvent avancée par les mères pour la non-vaccination était qu'on la leur avait déconseillée; pour la rougeole, la raison la plus fréquente était que l'enfant était malade et, également, qu'on leur avait déconseillé la vaccination. D'après les résultats des enquêtes, la couverture pour les vaccins obligatoires est forte, mais elle est très faible pour les vaccins anticoquelucheux et antirougeoleux. Il est nécessaire d'améliorer l'information des médecins et des mères quant aux contre-indications vraies à la vaccination. De plus, en l'absence d'une législation rendant obligatoire la vaccination contre la coqueluche et la rougeole, il faudra intensifier les efforts visant à convaincre les médecins et le public de ses avantages.

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