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**In Italy, infant vaccinations are mandatory for four infectious diseases: diphtheria, polio, tetanus and hepatitis B. In the past, there was widespread apprehension in Italy that doing away with obligatory vaccinations would reduce the coverage rate, but the possibility of making vaccinations optional has recently become more popular. The objectives of this study were to investigate parental willingness to vaccinate their children if those vaccinations were no longer mandatory and to evaluate the variables influencing this intention. We conducted face-to-face structured interviews with 1,039 parents at public health vaccination centres in four cities of the Campania region of southern Italy. Most respondents (91.9%) said that they would certainly (69.4%) or probably (22.5%) vaccinate their children if vaccinations were not mandatory. The belief that vaccinations are effective and safe was positively associated with willingness to vaccinate their children, whereas having heard that autism is a possible adverse reaction to vaccination was inversely associated with willingness to vaccinate. Nevertheless, in the context of the relatively low 2012\* vaccination coverage rates in Campania (under the national standard of 95%), our results suggest that eliminating mandatory vaccinations is likely to lead to current coverage rates decreasing to unacceptably low levels, significantly below 90%.**

**Introduction**

In European countries, childhood immunisation is provided in many different ways. There are large differences in whether vaccinations included in the national programmes are recommended or mandatory. At the end of 2010, among the 27 member countries of the European Union, 13 had no obligatory vaccinations, and 14 had at least one vaccination that was mandatory. For example, vaccination against polio is mandatory for children and adults in 12 countries, diphtheria and tetanus vaccination in 11 countries, and hepatitis B vaccination in 10 countries [1].

In Italy, diphtheria [2], polio [3], tetanus [4] and hepatitis B [5] vaccinations are mandatory. Vaccinations against measles-mumps-rubella (MMR), pertussis, *Haemophilus influenzae* type B, invasive pneumococcal disease, and *Neisseria meningitidis* group C are recommended by the current national vaccination schedule and are offered free of charge. In recent years, health authorities, as national policy, have urged vaccination centres to apply the above four vaccines in the form of a hexavalent vaccine that also includes pertussis and *Haemophilus influenzae* type B for infant immunisations. Therefore, the hexavalent vaccine is offered as an alternative to the four mandatory vaccines. So, from a practical point of view, pertussis and *Haemophilus influenzae* type B vaccines are given as if they are mandatory. Furthermore, in Italy there are significant legislative differences, not only between regions but also over time, due to the strong contrast between attitudes favourable and opposed to the mandatory vaccination. Therefore, there is now less distinction between mandatory and recommended vaccinations than in the past, and the concept of 'mandatory' has become ambiguous. For many years, children were not allowed to attend school if they were not vaccinated [6], but this regulation has been abolished [7], and in recent years, all regions have complied with this abolition. Administrative sanctions for failing to vaccinate a child are rarely applied. If a parent refuses to vaccinate their child, the parent will be called to an informative conversation at the local health authority in an attempt to gain compliance. Legislatively, each Italian region is relatively autonomous, so the laws regarding vaccination vary throughout the country. For example, in the Veneto region, vaccinations are not legally compulsory. After the suspension of obligatory vaccinations, this region has maintained high vaccination coverage. The Veneto region, making all vaccinations non-compulsory, appealed to the sense of responsibility of parents, who no longer had to feel 'forced' and could instead make decisions about vaccinations in a 'conscious' manner [8]. In considering a broader suspension of obligatory vaccinations, it is also important to understand which variables influence parental decisions about whether to immunise their children [9–16].

The objectives of this study were (i) to investigate parental willingness to vaccinate their children if vaccinations were no longer mandatory and (ii) to evaluate the variables that influence this intention. We conducted the study in an area of southern Italy with sociocultural characteristics different from the Veneto region of northern Italy.

**Methods****Participants and setting**

In the Campania region of southern Italy, decisions about vaccine types, purchasing, and supply management are centralised at the local health authority and at the regional level. Childhood immunisations are provided at specialised

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- ▶ Effectiveness of trivalent seasonal influenza vaccine in preventing laboratory-confirmed influenza in primary care in the United Kingdom: 2012/13 end of season results

public health vaccination centres (Unità Operative Materno-infantili).

We selected one vaccination centre from each of the four cities with the largest populations in the Campania region (Naples, Salerno, Caserta and Avellino). In Naples, we randomly selected one of the ten vaccination centres. Salerno, Caserta and Avellino each have only one centre. At each centre, two expert healthcare workers interviewed one parent of each child brought for the first, second or third dose of the hexavalent vaccine. When both parents were present at the centre, the workers interviewed only the mother. Written informed consent was obtained from each participant. Interviews were conducted immediately following the vaccinations on one or two days each week between January and April 2013, during all hours that the centres were open to the public.

#### **Sample size**

The target sample size of approximately 1,000 subjects was obtained by assuming a 95% prevalence of the main outcome, a precision of  $\pm 1.2\%$ , a 95% confidence level and a power of 80%. A total of 1,039 questionnaires were completed (329 in Naples, 254 in Avellino, 251 in Salerno and 205 in Caserta). Using univariate analysis and chi-square tests, we analysed the parents' responses by demographic characteristics and location of vaccination centre. A value of  $p < 0.05$  was considered statistically significant.

#### **Questionnaire**

A questionnaire was developed, pilot tested in a full day of interviews in the Naples centre, and consequently modified. The aim was to investigate parents' vaccination intentions, the main outcome variable, by asking, 'Would you immunise your child if vaccinations were not mandatory?' Parents' intentions were scored on a five-point Likert scale, with values of 'certainly', 'probably', 'I don't know', 'probably not' and 'certainly not'. The 95% confidence interval (CI) for proportions was calculated for this outcome. In the analysis, the responses were dichotomised by distinguishing those answering 'certainly' and 'probably' from those giving any other response.

The parents were then invited to give their level of agreement with the following statements: 'I am favourable toward vaccination', 'Vaccinations are effective in reducing the risk of disease' and 'Vaccinations are safe' on a five-point Likert scale. The response categories were 'strongly agree', 'somewhat agree', 'I don't know', 'somewhat disagree' and 'strongly disagree'. For analysis, the responses were dichotomised to distinguish agreement ('strongly agree' and 'somewhat agree') from disagreement (all other response categories). Respondents were also asked to express their views on whether vaccinations should be mandatory or optional (response categories of 'entirely mandatory' and 'entirely optional') and on whether vaccinations can cause adverse reactions (response categories of 'never', 'rarely', 'frequently' and always were dichotomised as 'never/rarely' vs 'frequently/always').

The source of information on the possible adverse effects of vaccination was operationalised by asking, 'In which way have you been informed about the possible adverse reactions after vaccination?' Responses were dichotomised as physician vs other sources. Respondents were also asked whether any of their children had experienced adverse reactions after vaccination. Finally, two questions were asked concerning knowledge about the debate on autism as an adverse reaction and vaccines containing mercury. These questions were placed at the end of questionnaire to avoid influencing the responses to other items. First, respondents were asked, 'Have you ever heard of possible adverse reactions or diseases associated with the administration of vaccines containing mercury?' The second question was modified as a result of the pilot test. Initially, the question was, 'Have you ever heard of autism as a possible adverse reaction after the administration of vaccines?' As some parents were alarmed by this question, it was modified in the final questionnaire: 'Although this hypothesis was disproved, have you ever heard of autism as a possible adverse reaction after the administration of vaccines?'

Sociodemographic data were collected for each respondent: age, education level, marital status, occupation and number of children.

#### **Statistical analysis**

Bivariate tests were used to assess the univariate associations between each of the independent variables and the main outcome. Only those variables associated with the outcome at the  $p \leq 0.25$  level in the bivariate analysis were subsequently included in the multivariate regression model. Logistic regression models were then estimated to evaluate the association between the independent variables and the main outcome. Backward stepwise procedures were applied, and the final model included only variables contributing significantly to the explanation of the outcome. Variables were selected for the multivariate model using  $p < 0.2$  for entry and  $p < 0.4$  for exclusion. Analyses were carried out using Stata 10 [17].

The final logistic model predicted parents' vaccination intentions 'Would you immunise your child if vaccination was not mandatory?' (no=0; yes=1). Based on the results of the univariate analysis, independent variables measuring attitudes towards vaccination and knowledge of potential adverse reactions following vaccination were included in the model. Specifically, the included independent variables were: being favourable toward vaccination (no=0, yes=1); believing that vaccinations are effective (no=0, yes=1); believing that vaccinations are safe (no=0, yes=1); believing that vaccinations should be mandatory (entirely optional=0, entirely mandatory=1); believing that vaccinations can cause adverse reactions (no=0, yes=1); source of information about possible adverse reactions after vaccination (physician=0, others=1); children's previous experience with adverse reactions after vaccination (no=0, yes=1); having heard of possible adverse reactions or diseases associated with the administration of vaccines containing mercury (no=0, yes=1) and having heard of autism as a possible adverse reaction after the administration of vaccines (no=0, yes=1).

The Ethics Committee of the Second University of Naples approved this study (reference number 41/2012).

## **Results**

#### **Sociodemographic characteristics**

In total, 1,039 parents answered the questionnaire, and 34 (3.2%) refused to participate. Most of the respondents (89.5%) were mothers. Compared with the fathers interviewed, more of the mothers were between 20 and 39 years of age (80.4% of the mothers vs 59.6% of the fathers) and fewer were married (87.2% of the mothers vs 93.5% of the fathers). Respondents with more than one child made up 53.1% of the sample. Only half of the mothers were employed (50.2% compared with 92.6% of the fathers) (Table 1).

**Table 1.** Selected characteristics of the study population, Italy, 2013 (n=1,039)

**Intention to vaccinate**

Among the 1,039 interviewed parents, 955 (91.9%) stated that they would certainly (n=721; 69.4%) or probably (n=234; 22.5%) vaccinate their children if vaccination were not mandatory. On the other hand, 84 parents (8.1%) stated that they would certainly (n=30; 2.9%) or probably not (n=35; 3.4%) vaccinate their children or that they did not know what they would do (n=19; 1.8%) (Table 2).

**Table 2.** Parents' intentions to vaccinate their children, Italy, 2013 (n=1,039)

**Attitudes and beliefs**

Parents who intended to vaccinate their children if vaccination was not mandatory were generally more favourable toward vaccination and more likely to state that vaccinations are effective, safe (Table 3) and rarely or never cause adverse reactions (data not shown). Moreover, they thought that all vaccinations should be mandatory. In the bivariate analysis, all five included attitudinal variables were significantly associated with the main outcome (Table 4).

**Table 3.** Parents' attitudes and beliefs about vaccinations, Italy, 2013 (n=1,039)

**Table 4.** Factors associated with intention to vaccinate, Italy, 2013 (n=1,039)

**Knowledge about adverse reactions**

Physicians were the main source of information about adverse effects, and intention to vaccinate was positively associated with this source of information. In the bivariate case, parents who had knowledge about potential adverse reactions of vaccines containing mercury or about autism as a consequence of vaccination reported the intention to vaccinate their children less often than those lacking this knowledge. Finally, having a child who had experienced an adverse reaction to vaccination did not affect the intention to vaccinate (Table 4). All data were disaggregated by centre location and by sociodemographic characteristics, but there were no statistically significant associations with the main outcome.

**Multivariate analysis**

In the multivariate analysis, the associations between the intention to vaccinate and the three variables on positive attitudes toward vaccinations remained statistically significant. These variables were: being favourable toward vaccination, believing that vaccinations are safe, and believing that vaccinations are effective. The association between not being favourable toward vaccination and knowledge about autism as an adverse effect after vaccination also remained significant (Table 5).

**Table 5.** Multivariate logistic regression analysis predicting the intention to vaccinate children if vaccination was not mandatory, Italy, 2013 (n=1,039)

**Discussion**

The ongoing debate about obligatory vaccination involves two opposing considerations. On the one hand, the main arguments in favour of obligatory vaccination are that it maintains a high coverage rate. On the other hand, arguments against obligatory vaccination claim that it goes against the principles of self-determination and freedom of choice in health matters [18-24]. Moreover, an additional reason for not making vaccines mandatory is that, psychologically, it invites opposition, because individuals object to being told what to do.

In the past, there was strong concern in Italy that making vaccination non-compulsory would result in lower coverage rates. However, the possibility of an optional vaccination scheme has recently gained popularity. The natural experiment undertaken in the Veneto region beginning in 2008 was both informative and reassuring, as the region's vaccination

coverage has remained above the National Prevention and Vaccination Program standard of 95% after the suspension of obligatory vaccinations (Piano Nazionale Prevenzione Vaccinale 2012–2014) [25]. Based on this experience, the Italian health authorities have frequently declared their intention to make vaccinations non-compulsory nationwide. However, this intention has never been realised because of fear of reducing coverage rates. These fears are driven by the knowledge that the significant sociocultural and economic differences between Italian regions make it impossible to use the experience from one region to make an accurate prediction for others. Indeed, sociodemographic statistics indicate that the population in southern Italy is poorer, less industrialised, has lower employment, and is less educated than northern Italy. These characteristics, known as 'the southern question', exist where this work was carried out, and contribute to the contrast with the Veneto region in northern Italy. In the most recent Italian report on vaccination coverage rates from 2012\* [26], the Campania region had the lowest rate (with the exception of the autonomous province of South Tyrol), whereas the Veneto region, even in absence of obligatory vaccination, had a rate that was higher than Campania's and just below the median value for all regions (Table 6).

**Table 6.** Vaccination coverage by region, Italy, 2012

The present study investigated parents' willingness to vaccinate their children even in the absence of compulsory vaccinations. We found that 91.9% of the respondents reported that they would certainly or probably vaccinate their children. At first glance, and considering the confidence interval, this result seems quite positive. However, if we consider that 6.3% of parents stated that they would certainly or probably not vaccinate their children and that the coverage rates in Campania in 2012 are under the national standard of 95%, it seems likely that the suspension of obligatory vaccination would result in the current coverage rates declining to significantly below 90%. This would represent an unacceptably low level of coverage. These considerations support the caution with which the Italian health authority is addressing this issue.

As expected, and as shown by previous research, the intention to vaccinate is significantly associated with the belief that vaccines are safe and effective [27–31]. However, negative attitudes toward vaccinations were not associated with a significant decrease in the intentions of parents to vaccinate their children. In terms of knowledge about potential adverse effects of vaccination, having heard of autism as a possible side effect after the administration of vaccines was most strongly negatively associated with intention to vaccinate [32]. The effect of this variable is more consistent than the effect of believing that mercury contained in vaccines causes damage [33]. The results were consistent across the four studied cities and for individuals with varying sociodemographic characteristics, potentially providing evidence of homogeneous attitudes toward vaccination throughout the region.

Our results should be interpreted carefully because the willingness to vaccinate children is not the same as the actual behaviour of bringing children for vaccinations. For example, a well-known critical point is that the interviewee may be influenced to respond according to the perceived wishes of the interviewer. Therefore, it is likely that, in the absence of obligatory vaccination, both those who intended to vaccinate their children and those who did not intend to do so might reconsider their positions. Another limitation of the study was the underestimation of the fathers' opinions (i.e. we interviewed only the mothers even when both parents were present). Taking the decision to vaccinate is a complex process that presumably involves a discussion between both parents, but this process was too difficult to detect with a short interview. Moreover, the interviews were conducted in a health centre immediately after the administration of the child's vaccination, and this setting probably encouraged a greater amenability to vaccinations. Our population was also older, more urban, more educated, and more likely to be employed than the average regional population because the sample units were the four vaccination centres in the cities with the largest populations in the Campania region. Finally, the sample excluded all parents who did not bring their children for vaccination. These individuals belong to two main groups: parents who have difficulty accessing health services (passive absentee) and parents who decide not to vaccinate their children (active absentee) [11]. Future research should explore the motivations of parents who do not vaccinate their children, especially as the vaccination coverage rates in the Campania region are among the lowest in Italy. Understanding which of these two groups is prevalent in the region (passive or active absentee) is crucial for designing appropriate interventions.

#### \* Authors' correction

At the request of the authors, the date was corrected from 2011 to 2012 on 5 September 2014.

#### Conflict of interest

None declared.

#### Authors' contributions

FA: principal investigator, designed the study, wrote the article. CPP: responsible for organization, coordinator of data collection and data entry, contributed to statistical analysis and interpretation. SM and AJVA: data collection and data entry. GS: statistical analysis and interpretation.

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**TABLE 1**

Selected characteristics of the study population, Italy, 2013  
(n=1,039)

Characteristic	Mother		Father	
	n	%	n	%
Age (years)	927	100	109	100
15–19	12	1.3	0	0
20–29	229	24.7	15	13.8
30–39	516	55.7	50	45.9
40–49	165	17.8	39	35.8
50–59	5	0.5	5	4.6
Marital status	925	100	108	100
Married	807	87.2	101	93.5
Other	118	12.8	7	6.5
Education	927	100	109	100
Primary school	30	3.2	2	1.8
Middle school	215	23.2	18	16.5
High school	370	39.9	38	34.9
College degree	312	33.7	51	46.8
Occupation	926	100	108	100
Employed	465	50.2	100	92.6
Unemployed	461	49.8	8	7.4
Other children	926	100	109	100
Yes	492	53.1	60	55
No	434	46.9	49	45
<b>Total<sup>a</sup></b>	<b>930</b>	<b>89.5</b>	<b>109</b>	<b>10.5</b>

Numbers for each item may not sum to the total study population because of missing values.

**TABLE 2**

Parents' intentions to vaccinate their children, Italy, 2013  
(n=1,039)

Would you immunise your child if vaccination were not mandatory?	n	%	95% CI
Certainly	721	69.4	66.6–72.2
Probably	234	22.5	20.0–25.1
Probably not	35	3.4	2.2–4.4
Certainly not	30	2.9	1.8–3.9
I don't know	19	1.8	1.0–2.6
Total	1,039	100	

CI: confidence interval for proportions.



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I don't know	19	1.8	1.0–2.6
Total	1,039	100	

CI: confidence interval for proportions.

**TABLE 3**

Parents' attitudes and beliefs about vaccinations, Italy, 2013 (n=1,039)

	I am favourable toward vaccination		Vaccinations are safe		Vaccinations are effective in reducing the risk of disease	
	n	%	n	%	n	%
Agree strongly	617	59.4	500	48.1	729	70.2
Agree somewhat	370	35.6	466	44.9	278	26.8
I don't know	12	1.1	15	1.4	11	1
Disagree somewhat	32	3.1	37	3.6	13	1.2
Disagree strongly	8	0.8	21	2	8	0.8
Total <sup>a</sup>	1,039	100	1,039	100	1,039	100

<sup>a</sup> Numbers for each item may not sum to the total study population because of missing values.

ctors associated with intention to vaccinate, Italy, 2013  
=1039)

	Intention to vaccinate			
	Yes		No	
	n	%	n	%
<b>Attitude toward vaccination</b>				
Dislike	933	94.5	54	5.5
Like	22	42.3	30	57.7
$\chi^2=181.3$ , df=1, p<0.001				
RR=10.54, CI: 7.44–14.94				
<b>Belief that vaccinations are effective in reducing the risk of disease</b>				
Dislike	941	93.5	66	6.5
Like	14	43.8	18	56.2
$\chi^2=103.07$ , df=1, p<0.001				
RR=8.58, CI: 5.54–12.61				
<b>Belief that vaccinations are safe</b>				
Dislike	913	94.5	53	5.5
Like	42	57.5	31	42.5
$\chi^2=124.89$ , df=1, p<0.001				
RR=7.74, CI: 5.33–11.25				
<b>Belief that vaccinations should be mandatory</b>				
Completely mandatory	378	96.9	12	3.1
Partially mandatory	577	88.9	72	11.1
$\chi^2=21.07$ , df=1, p<0.001				
RR=3.61, CI: 1.98–6.56				
<b>Belief that vaccinations can cause adverse reactions</b>				
Dislike	393	87.9	54	12.1
Like	562	94.9	30	5.1
$\chi^2=16.85$ , df=1, p<0.001				
RR=0.42, CI: 0.27–0.64				
<b>Source of information about possible adverse reactions after vaccination (n=802)<sup>a</sup></b>				
Physician	453	93.6	31	6.4
Others	277	87.1	41	12.9
$\chi^2=9.9$ , df=1, p=0.002				
RR=1.45, CI: 1.1–1.89				
<b>Child has experienced adverse reactions after vaccination (n=913)<sup>b</sup></b>				
Dislike	268	93.7	18	6.3
Like	572	91.2	55	8.8
$\chi^2=.64$ , df=1, p=0.2				
RR=1.39, CI: 0.83–2.33				
<b>Worried about adverse reactions associated with vaccines containing mercury (n=1,038)<sup>c</sup></b>				
Dislike	130	84.4	24	15.6
Like	824	93.2	60	6.8
$\chi^2=13.64$ , df=1, p<0.001				
RR=0.44, CI: 0.28–0.68				
<b>Worried about autism as a possible adverse reaction to vaccinations</b>				
Dislike	199	83.3	40	16.7
Like	756	94.5	44	5.5
$\chi^2=31.3$ , df=1, p<0.001				
RR=0.33, CI: 0.22–0.49				

95% confidence interval; df: degrees of freedom; RR: relative risk.

<sup>a</sup> A third response option was 'None'.

<sup>b</sup> A third response option was 'I don't know/I don't remember'.

<sup>c</sup> One answer was missing.

multivariate logistic regression analysis predicting the intention to vaccinate children if vaccination was not mandatory, Italy, 2013 (n=1,039)

Variable	OR	SE	95% CI	p value
log likelihood: -149.78, $\chi^2=123.01$ (df=7), $p<0.0001$				
avourable toward vaccination	11.7	5.2	4.9-27.9	<0.001
belief that vaccinations are effective in reducing the risk of disease	9.4	5.4	3.04-29.21	<0.001
belief that vaccinations are safe	4.2	1.73	1.86-9.4	0.001
heard about autism as a possible adverse reaction to vaccinations	0.47	0.15	0.25-0.88	0.02
belief that vaccinations should be entirely mandatory	1.97	0.79	0.9-4.3	0.09
informed about adverse reactions after vaccination by a physician (n=802) <sup>a</sup>	0.64	0.2	0.34-1.2	0.17
belief that vaccinations can cause adverse reactions	0.67	0.22	0.35-1.3	0.24

95% confidence interval; OR: odds ratio; SE: standard error.  
The option "None" has been excluded.