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Attitudes towards compulsory vaccination in Italy: Results from the NAVIDAD multicentre study

This is the peer reviewed version of the following article:

Original

Attitudes towards compulsory vaccination in Italy: Results from the NAVIDAD multicentre study / Gualano, Mr; Bert, F; Voglino, G; Buttinelli, E; D'Errico, Mm; De Waure, C; Di Giovanni, P; Fantini, Mp; Giuliani, ANDRES RAMON; Marranzano, M; Masanotti, G; Massimi, A; Nante, N; Pennino, F; Squeri, R; Stefanati, A; Signorelli, C; Siliquini, R Collaborating Group. - In: VACCINE. - ISSN 0264-410X. - STAMPA. - 36:23(2018), pp. 3368-3374. [10.1016/j.vaccine.2018.04.029]

Availability:

This version is available at: 11566/258801 since: 2022-05-27T09:34:19Z

Publisher:

Published

DOI:10.1016/j.vaccine.2018.04.029

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note finali coverage

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Title

Attitudes towards compulsory vaccination in Italy: results from the NAVIDAD multicenter study.

Abstract

BACKGROUND: Vaccine hesitancy is a considerable issue in European countries and leads to low coverage rates. After a long debate, Italy has made vaccination mandatory for admission to its schools.

METHODS: For the NAVIDAD study (a cross-sectional multicenter study), a 63-item questionnaire was administered to 1820 pregnant women from 15 Italian cities. The questionnaire assessed interviewee's opinion on mandatory vaccines, as well as their socioeconomic status, sources of information about vaccines, confidence in the Italian National Healthcare Service (NHS), and intention to vaccinate their newborn.

RESULTS: Information sources play a key role in determining the opinion on restoration of mandatory vaccine, in particular women who got information from anti-vaccination movements websites are less likely to accept it (OR: 0.35, 95%CI: 0.21-0.58, $p < 0.001$). Women who had confidence in healthcare professional information agreed more on mandatory vaccination than the other (OR: 2.66, 95%CI:1.62-4.36, $p < 0.001$), who perceive that healthcare professionals have economic interest in child immunization and who declared that healthcare providers inform only on vaccinations benefits not on risks were less likely to agree on compulsory vaccination (OR: 0.66, CI 95%: 0.46-0.96, $p = 0.03$; OR: 0.66, CI 95%: 0.46-0.95, $p = 0.03$).

CONCLUSION: Information sources and confidence towards health professionals are the main determinants of acceptance of mandatory vaccine restoration. In order to increase the acceptability of the restoration and reduce vaccine hesitancy, these aspects need to be strengthened.

Keywords

Mandatory vaccination; Vaccine hesitancy; attitudes; pregnancy; multicentre survey; Italy

Highlights

- Compulsory vaccination is generally welcome
- Mandatory vaccination are not affected by social determinants
- Confidence in health system determinate trustworthiness of mandatory vaccination

Acknowledgements

The authors declare that no funding or grant was received from other organizations for the conduction of this study.

1 **Introduction**

2 Vaccination appears to be the most effective and cost-effective intervention to reduce the burden of
3 contagious diseases (1–3). Immunization averts an estimated 2 to 3 million deaths every year;
4 however, an additional 1.5 million deaths could be avoided if global vaccination coverage improves
5 (4). Today, several vaccines are available and differently administered all over the world. Moreover,
6 the immunization rates across countries vary considerably and an estimated 19.5 million infants
7 worldwide are still missing out on basic vaccines (5). The Global Vaccine Action Plan (2011-2020)
8 (GVAP) is a framework adopted by all the World Health Organization (WHO) Member States at the
9 Sixty-fifth World Health Assembly in May 2012 to achieve the vision of the Decade of Vaccines
10 (DoV) 2011–2020 of “a world in which all individuals and communities enjoy lives free from
11 vaccine-preventable diseases” (6). The GVAP sets goals, strategic objectives and indicators to achieve
12 the mission, which is “improve health by extending by 2020 and beyond the full benefits of
13 immunization to all people, regardless of where they are born, who they are, or where they live” (6).

14 The European Vaccine Action Plan (2015-2020) (EVAP) developed by the 53 Member States of the
15 Region with the WHO Regional Office for Europe, immunization partners and stakeholders,
16 contributes directly to the goals of the GVAP and the European Region’s overall Health 2020 strategy
17 (7). Despite efforts, the 2015 regional measles and rubella elimination target was missed. The
18 Region’s polio-free status was threatened and several countries saw a resurgence of diphtheria and
19 pertussis, which also exposed the unpredictability of vaccine supply in the Region (4).

20 Nowadays, Europe faces many challenges including issues with access to vaccine supply and
21 affordable pricing, sustainable domestic financing and resource mobilization, as well as a growth of
22 anti-vaccination sentiment and visibility (6). Indeed, many Countries and communities are dealing
23 with groups refusing available recommended vaccinations for themselves and/or their children (8–10).

24 The factors underlying these decisions are different and there is no single intervention strategy that
25 can solve the problem (11,12). Vaccines are losing public confidence and several international
26 organizations (WHO, EU, ECDC) warn against the growing phenomenon of vaccine hesitancy and its
27 impact on decreasing vaccine coverage trends (13,14). This has created a need for national
28 immunization programs to find approaches and strategies to address vaccine hesitancy.

29 In Italy for each vaccine included in the National Immunization Schedule (NIS), it has provided the
30 coverage targets fixed considering herd immunity thresholds needed to break infectious diseases
31 transmission throughout the population. The 24 months coverage target defined in PNPV (Piano

32 Nazionale Prevenzione Vaccinale) was set at $\geq 95\%$ for the following vaccines: DTPa (Diphtheria,
33 Tetanus, Acellular Pertussis), Hepatitis B, Hib (Haemophilus influenzae type b), first dose of MPR
34 (Measles, Mumps, Rubella), Pneumococcal, Meningococcal C, Chicken pox, Rotavirus (15). The
35 HPV vaccine in females and in males should achieve a coverage $\geq 70\%$ at 12 years old. In 2016
36 available data on infant vaccines reported that the 24 months of age coverages were all beneath the
37 95% threshold (16). These percentages were a long way off the PNPV published targets and the
38 WHO's recommendations on GVAP. Furthermore, it is important to note that vaccine coverages have
39 been in decline for some years. From 2013, the only coverage that has shown an increase in national
40 data was Meningococcus (17). Negative trend coverage has been reported for all the other vaccines, as
41 Pneumococcal (88.7% in 2015 vs 88.4% in 2016), Measles and Rubella (90.4% in 2013 vs 85.3% in
42 2015 and then look slightly up in 2016 but still far from achieving the coverage needed to eliminate
43 the virus) (17). The general negative trend was also confirmed by the national 36-months vaccination
44 coverage for 2016 (relating to children born in 2013). This data is especially useful for monitoring the
45 share of children who were in default of the previous year's vaccination survey and were recovered.
46 The 36-month coverages showed slightly higher values than those found for the same birth cohort at
47 24 months the previous year. Recuperation is limited and 95% is only achieved for Hib (18) .
48 The national low immunization levels and their negative trend led to the introduction of compulsory
49 vaccination in Italy on 31th July 2017 for ten infectious diseases. Compulsory vaccination has been
50 introduced in order to guarantee public health safeguard and to reach coverage targets of the PNPV
51 (19). Preliminary data from five regions show that, compared with 2016, this strategy lead to an
52 increase in vaccine coverage from June to October, 2017 of 1,0% for the hexavalent vaccine against
53 diphtheria, tetanus, pertussis, poliomyelitis, *H influenzae* type b, and hepatitis B and of 2,9% for the
54 measles, mumps, and rubella vaccine (20).

55 In this context, a study named NAVIDAD (Nozioni e Attitudini sui Vaccini dell'Infanzia nelle Donne
56 in Attesa e loro Decisioni), started in 2016 and lasted for about a year, has been conducted with the
57 aim of analysing the influence of many determinants (21–24) on Italian pregnant women's decision on
58 routine vaccinations of their children (25). This paper focuses on pregnant women's attitude towards
59 compulsory nature of infant vaccinations and its relationship with some vaccine hesitancy
60 determinants: sociodemographic data, information sources, trust on institution, knowledge and
61 perceptions on vaccines and preventable infectious diseases (26,27). The main objective of this paper
62 is to describe pregnant women's attitudes and behaviours towards compulsory nature of paediatric

63 vaccinations, assessing their trustworthiness and acceptability. In particular we wanted to analyse its
64 possible determinants, considering social determinants, source of information and trust in National
65 Health System. In fact, these information can play a role in future public health policies.

66

67 **Methods**

68 A cross-sectional multicenter study was conducted by involving patients in the following Italian cities:

- 69 - Bologna, Ferrara, Milan, Parma and Turin that were considered from the North of Italy;
- 70 - Ancona, Perugia, Roma and Siena were considered from the Centre of Italy;
- 71 - Catania, Chieti-Pescara, L'Aquila, Messina and Naples were considered from the South of
72 Italy.

73 The execution of this study was approved by the Ethics Committee of the Hospital "A.O.U. Città della
74 Salute e della Scienza di Torino".

75 Study subjects (pregnant women over the age of 18 who were able to understand the protocol
76 information and the questionnaire) were enrolled from September 2016 and May 2017 among patients
77 waiting for a gynecological, ultrasound or hematological examination, in the reference hospitals of the
78 cities involved in the study.

79 Informed consent was obtained after the full explanation of the nature and possible consequences of
80 the study.

81 Trained resident doctors through the submission of a non-self-compiling paper questionnaire
82 subjected the women to a 25-minutes interview.

83 The questionnaire was composed of seven sections for a total of 63-item. Each section was
84 investigating:

- 85 1. the socio-economic framing (patient age, qualification, occupation, ...).
- 86 2. whether she intended to vaccinate her child and for which pathologies.
- 87 3. the sources through which the women had sought and obtained information about
88 vaccinations
- 89 4. the degree of confidence of the women in healthcare workers
- 90 5. the perception of the frequency and severity of the major preventable pathologies with
91 vaccinations
- 92 6. an assessment of her vaccine knowledge

93 7. the interviewee's opinion on the restoration of mandatory vaccines

94 This study focuses on the section number 7, interviewee's opinion on the restoration of mandatory
95 vaccines and how it is influenced by socio-economic framing, willingness to vaccinate the newborn,
96 information sources and confidence in healthcare service (section 1, 2, 3 and 4).

97

98 *Population and sample size calculation*

99 Two different letter were sent to all Italian Public Health Schools' Director. 15 of them agreed to
100 participate in the study. For each city, the sample was defined based on demographic data of the
101 resident population, considering the number of the newborns in the cities included (28).

102 Considering the MPR vaccine coverage of 86,7% (17), it was possible to provide an estimation of the
103 number of interviews necessary in order to get valid data (29–31). We considered a -10% of MPR
104 vaccine coverage as “Worst Acceptable” for results, in order to find a very conservative value. The
105 confidence level was set at 95% and the power of the study was considered to be 80%. The sample
106 size was then calculated through the statistical software "EPI INFO". To be more conservative, it was
107 required a number of cases in the range between the sample size calculation results and the same
108 increased by 30%.

109 The final sample size was expected to be in the range between 1764 and 2296 subjects involved, for
110 each city the number of questionnaire required ranged like follows: Ancona (116-151), Bologna (133-
111 172), Catania (132-172), Chieti-Pescara (124- 161), Ferrara (120-160), L'Aquila (111-144), Messina
112 (129-168), Milan (138-178), Naples (136-177), Parma (128-176), Perugia (125-163), Rome (150-
113 180), Siena (99-129) and Turin (123-175) .

114

115 *Statistical analyses*

116 After the data collection, all the participating centers mailed the original paperwork of the
117 questionnaires filled in anonymous way to the Department of Public Health and Pediatrics at the
118 University of Turin.

119 A total of 1,820 questionnaires were processed by using SPSS 24 Statistical software for Windows.

120 At first, a descriptive analysis of all the variables was conducted. The major outcome was the
121 interviewee's opinion on the restoration of mandatory vaccines. The variables included in the analysis
122 were: the socio-demographic data, any previous pregnancies, the pregnancy quarter, the willingness to

123 vaccinate the newborn, the different ways of obtaining the information and the degree of trust in
124 healthcare workers.

125 A logistic regression was conducted to estimate the impact of some variables on the above-described
126 outcomes. The covariates included in the final model have been selected using a stepwise forward
127 selection process, with the criterion of a P value at univariate <0.25 (32). These associations are
128 expressed as Odds Ratios (OR) with 95% Confidence Interval (CI) and the p value ≤ 0.05 was
129 considered significant for all analyses.

130

131 **Results**

132 A total of 1,820 pregnant women were interviewed. In particular, the number of women that
133 participated for each city was: Ancona 120, Bologna 172, Catania 160, Chieti-Pescara 139, Ferrara
134 140, L'Aquila 123, Messina 81, Milan 203, Naples 140, Parma 29, Perugia 125, Rome 127, Siena 90
135 and Turin 171. The mean age of the sample was 32.5 years (SD \pm 5.2). The youngest patient was 18
136 years old, while the oldest 48. Most women declared to be Italian (90.8%), to be married or living
137 with a partner (91.9%), primiparous (63.4%) and at the third trimester of pregnancy (71.9%). Around
138 the half of the sample affirmed to be educated at least to university degree level (46.8%). The majority
139 of women declared to be employed (71.8%): 39.9% were office workers or teachers, 14.7% were
140 entrepreneurs or private professionals, 9.3% were labourers or artisans. Moreover, 7.9% of the sample
141 had an occupation in the healthcare field.

142 Of the entire sample, 1.9% of women declared they would not vaccinate their next child. As regards to
143 information sources, in the overall sample, only 41.8% of the women obtained information about
144 vaccines from healthcare professionals; the 56.9% declared to have gained information autonomously.
145 The most frequently used information sources were web sites (65.7%), of that a half (50.4%) were
146 non-institutional web sites. The second most used information source was the word of mouth (47.7%).
147 Paediatricians were the third source of information as frequency (37.3%).

148 Furthermore, the results showed that 92% of our sample had confidence in healthcare professionals
149 and 86.5% declared that they are experienced and knowledgeable; only 18.7% of the interviewed
150 women trusted more private healthcare professionals than the ones engaged by the Italian National
151 Health System. Nevertheless, the 31.6% stated that healthcare providers have economic interest in

152 child immunisation and the 35.5% declared that healthcare professionals inform only on vaccinations
153 benefits not on risks. Moreover, the Italian vaccination schedule was considered too inflexible to adapt
154 to changing parents' needs in 42.8% of questionnaires and the 38% of the women claimed that people
155 who do not vaccinate are blamed by healthcare service. Concerning vaccines, 21.7% of the sample
156 thought that they are an imposition and 44.6% that they are more useful for the society than for the
157 individual. Furthermore, the majority of interviewed women (81.6%) was in favour of compulsory
158 vaccination. Most women of the sample (81.6%) declared to be in favour of mandatory vaccinations,
159 13.8% were against them and 4.5% did not answer to the question.

160 *Univariate analysis*

161 In Table 1 the main demographic, occupational and social features of the sample are resumed,
162 stratified by the propensity towards compulsory vaccinations. Women from the North of Italy had a
163 higher propensity for mandatory vaccination (90.1% of them) comparing to the women from the
164 Centre and the South (83.1% and 82.1% respectively; $p<0.001$). Women older than 33 agreed more on
165 mandatory vaccination than the younger ones (87.2 vs 83.7%; $p=0.04$), as well as women who were
166 married or lived with a partner when compared with single or divorced women (86.3% vs 76.3%;
167 $p=0.04$). Moreover, women who wanted to vaccinate their next child were more inclined towards
168 compulsory vaccination (87%) compared with the rest of the sample (19.4%; $p<0.001$).

169 Table 2 shows the main differences regarding the information sources between women who agreed
170 and disagreed with mandatory vaccination. Women that used institutional information leaflets had a
171 higher propensity for compulsory vaccination than women who did not use this kind of information
172 source (88.5% vs 84.2%; $p=0.03$), as well as women who went to vaccination clinics to obtain
173 information (88.6% vs 84.6%; $p=0.05$). Conversely, women who went to a private healthcare
174 professional were less inclined towards compulsory vaccination than the other ones (80.9% vs 86%;
175 $p=0.05$), as well as people who got information from anti-vaccination movements (69.7% vs 86.8%;
176 $p<0.001$).

177 Table 3 describes the association between the trust in health care system and the propensity towards
178 compulsory vaccination. The analysis shows that women who had confidence in healthcare
179 professional information agreed more on mandatory vaccination than the rest of the sample (87.7% vs
180 55%; $p<0.001$), as well as women who declared that healthcare professionals are experienced and

181 knowledgeable (87.2% vs 70.2%; $p<0.001$) and who considered the Italian vaccination schedule
182 flexible (87% vs 82.5%; $p=0.02$).

183 On the contrary, women who trusted more private healthcare professionals than the ones engaged by
184 the Italian NHS agreed less to mandatory vaccination (79.6% vs 87.1%; $p<0.001$). The propensity
185 towards compulsory vaccination was lower among women who stated that healthcare providers have
186 economic interest in child immunization (77% vs 89.8%; $p<0.001$) and among the ones who declared
187 that they inform only on vaccinations benefits not on risks (78.3% vs 90.1%; $p<0.001$). Furthermore,
188 the women that claimed that people who do not vaccinate are blamed by healthcare service were less
189 inclined towards mandatory vaccination compared with the rest of the sample (82.9% vs 87.1%,
190 $p<0.001$), as well as women who thought that vaccines are an imposition (79% vs 87.6%; $p<0.001$).

191 *Multivariate analysis*

192 These results were partially confirmed in the logistic regression model (Table 4): women who want to
193 vaccinate their next child were more inclined towards compulsory vaccination compared with the rest
194 of the sample (OR: 11.83, 95% CI: 3.74-37.45, $p<0.001$). Moreover, women who went to vaccination
195 clinics to obtain information had a higher propensity for mandatory vaccination (OR: 1.90, 95% CI:
196 1.22-2.95, $p=0.01$), as opposed to women who got information from anti-vaccination movements
197 comparing to the others (OR: 0.35, 95% CI: 0.21-0.58, $p<0.001$). Furthermore, women who had
198 confidence in healthcare professional information agreed more on mandatory vaccination than the
199 other women did (OR: 2.66, 95% CI: 1.62-4.36, $p<0.001$). On the contrary, people who stated that
200 healthcare professionals have economic interest in child immunisation and who declared that
201 healthcare providers inform only on vaccinations benefits not on risks were less likely to agree on
202 compulsory vaccination (OR: 0.66, 95% CI: 0.46-0.96, $p=0.03$; OR: 0.66, 95% CI: 0.46-0.95,
203 $p=0.03$).

204 **Discussion**

205 The implementation of a compulsory vaccination program represents a turning point in vaccination
206 plan in Italy (19). Ethical, political and scientific debate on mandatory vaccinations is an interesting
207 topic. The major aim of this study is to assess pregnant women's attitude toward compulsory nature of
208 paediatric vaccination and identify the main factor influencing it.

209 The results show an interesting association between information sources and attitudes towards
210 compulsory vaccination. In fact, mandatory vaccination is more easily accepted among who seek for
211 information in vaccination clinics. With no surprise, the few women obtaining information from anti-
212 vaccine associations are less prone to accept mandatory vaccination plan. A paper published on
213 Vaccine in 2015 by SAGE Working Group on Vaccine Hesitancy proposed the “3Cs” model (12). In
214 this model, a key role in determining the acceptance of vaccination was played by the confidence in
215 the health system and in the reliability and competence of the health services and health professionals.
216 Comparable results are shown in the NAVIDAD study. In fact, women who stated that healthcare
217 professionals have economic interest in child immunisation and who declared that healthcare
218 providers inform only on vaccinations benefits were less likely to agree on compulsory vaccination.
219 To be clear, vaccine hesitancy, defined as a delay or refusal in accepting vaccination (12), is slightly
220 different from attitudes towards compulsory vaccination. Nevertheless, results from NAVIDAD study
221 show how there is a strong association between acceptance of mandatory vaccination and intention to
222 vaccinate the next child. Furthermore, different studies shows how decision about vaccination is made
223 during pregnancy (33,34) and, in particular, first time mother are more vaccine hesitant and undecided
224 about childhood vaccination (35). For these reason, multicomponent and dialogue-based interventions
225 should be considered considering that strategies should be carefully tailored according to the target
226 population, their reasons for hesitancy, and the specific context (36).

227 A cross-sectional study has some limitation due to the study design. No causality can be proven.
228 Therefore this survey is an assessment tool with some limitations (37).

229 On the other hand, to our knowledge, there is no other study that evaluate which are the factors that
230 can have an influence on the acceptance of compulsory vaccine plan. Furthermore, the results can be
231 easily generalized to Italian population due to the wide sample size and the number of centres
232 involved. It has to be stated that this study has been performed before the Italy's law 119/2017 that
233 makes ten vaccines mandatory for infants. As reported on The Lancet Infectious Disease by Signorelli
234 et al. (20) mandatory vaccine seems to be an effective tool to increase vaccine coverage and the results
235 are encouraging. For this reason, policy makers should consider the results from NAVIDAD study. In
236 particular, the effect on the reliability of health system and professionals should be considered, not
237 only when talking about vaccine.

238

239 **Ethical standards**

240 The authors assert that all procedures contributing to this work comply with the ethical standards of
241 the relevant national and institutional committees on human experimentation and with the Helsinki
242 Declaration of 1964 and its later amendments.

243

244 **Conflict of interest**

245 The authors declare that they have no conflict of interest.

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