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

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### 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:** In the NAVIDAD study (a cross-sectional multicentre study), a 63-item questionnaire was administered to 1820 pregnant women from 15 Italian cities. The questionnaire assessed the 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 vaccines; in particular, women who obtained information from anti-vaccination movements are less likely to accept the vaccines (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 did the other women (OR: 2.66, 95% CI: 1.62–4.36,  $p < 0.001$ ); those who perceived 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,  $p = 0.03$ , respectively).

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

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### 1. Introduction

Vaccination appears to be the most effective and cost-effective intervention to reduce the burden of contagious diseases [1–3].

Immunization averts an estimated 2 to 3 million deaths every year; however, an additional 1.5 million deaths could be avoided if global vaccination coverage improved [4]. Today, several vaccines are available and differently administered all over the world.

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Moreover, immunization rates across countries vary considerably, and an estimated 19.5 million infants worldwide are still not receiving basic vaccines [5]. The Global Vaccine Action Plan (2011–2020) (GVAP) is a framework adopted by all the World Health Organization (WHO) Member States at the Sixty-fifth World Health Assembly in May 2012 to achieve the vision of the Decade of Vaccines (DoV) 2011–2020 of “a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases” [6]. The GVAP sets goals, strategic objectives and indicators to achieve the mission, which is to “improve health by extending by 2020 and beyond the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live” [6].

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

Currently, Europe faces many challenges, including issues with access to vaccine supply and affordable pricing, sustainable domestic financing, resource mobilization, and a growth of anti-vaccination sentiment and visibility [6]. Many countries and communities are dealing with groups refusing available recommended vaccinations for themselves and/or their children [8–10]. The factors underlying these decisions are different, and there is no single intervention strategy that can solve the problem [11,12]. Vaccines are losing public confidence, and several international organizations (WHO, EU, ECDC) warn against the growing phenomenon of vaccine hesitancy and its impact on decreasing vaccine coverage trends [13,14]. This issue has created a need for national immunization programmes to find approaches and strategies to address vaccine hesitancy.

In Italy, for each vaccine included in the National Immunization Schedule (NIS), officials have provided fixed coverage targets considering herd immunity thresholds needed to break infectious disease transmission throughout the population. The 24-months of age coverage target defined in PNPV (Piano Nazionale Prevenzione Vaccinale) was set at  $\geq 95\%$  for the following vaccines: DTPa (diphtheria, tetanus, acellular pertussis), hepatitis B, Hib (Haemophilus influenzae type b), first dose of MPR (measles, mumps, rubella), pneumococcal, meningococcal C, chicken pox, and rotavirus [15]. The HPV vaccine in females and in males should achieve coverage  $\geq 70\%$  at 12 years old. In 2016, available data on infant vaccines reported that the 24-months of age coverage rates were all beneath the 95% threshold [16]. These percentages were a long way off from the published PNPV targets and the WHO's recommendations on GVAP. Furthermore, it is important to note that vaccine coverage rates have been declining for several years. Since 2013, the only coverage that has shown an increase in national data was meningococcus [17]. A negative coverage trend has been reported for all the other vaccines, including pneumococcal (88.7% in 2015 vs 88.4% in 2016), measles and rubella (which was 90.4% in 2013 vs 85.3% in 2015 and slightly up in 2016 but still far from achieving the coverage needed to eliminate the virus) [17]. The general negative trend was also confirmed by the national 36-months of age vaccination coverage for 2016 (relating to children born in 2013). These data are especially useful for monitoring the share of children who were in default of the previous year's vaccination survey and were recovered. The 36-months of age coverage rates showed slightly higher values than those found for the same birth cohort at 24 months of age in the previous year. Recuperation is limited, and 95% is only achieved for Hib [18].

The national low immunization levels and their negative trends led to the introduction of compulsory vaccination in Italy on 31 July 2017 for ten infectious diseases. Compulsory vaccination has been introduced to guarantee public health safeguards and to reach the coverage targets of the PNPV [19]. Preliminary data from five regions show that compared with 2016, this strategy has led to an increase in vaccine coverage from June to October of 2017 of 1.0% for the hexavalent vaccine against diphtheria, tetanus, pertussis, poliomyelitis, *H influenzae* type b, and hepatitis B and 2.9% for the measles, mumps, and rubella vaccine [20].

In this context, a study named NAVIDAD (Nozioni e Attitudini sui Vaccini dell'Infanzia nelle Donne in Attesa e loro Decisioni), which was started in 2016 and lasted for approximately one year, was conducted with the aim of analysing the influence of many determinants [21–24] on Italian pregnant women's decisions regarding routine vaccinations of their children [25]. This paper focuses on pregnant women's attitudes towards the compulsory nature of infant vaccinations and its relationship with some vaccine hesitancy determinants as follows: socio-demographic data, information sources, trust in the institution, and knowledge and perceptions on vaccines and preventable infectious diseases [26,27]. The main objective of this paper is to describe pregnant women's attitudes and behaviours towards compulsory nature of paediatric vaccinations, assessing their trustworthiness and acceptability. In particular, we wanted to analyse its possible determinants, considering social determinants, source of information and trust in the National Health System. This information could play a role in future public health policies.

## 2. Methods

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

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

Each city was considered in Northern, Central or Southern Italy according to European Parliament constituencies. In particular, North-West and North-East constituencies were considered as North.

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

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

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

The interviews were conducted by two different trained resident doctors from each centre involved. The interviewers were recognizable as researchers, and the interviews were conducted by a doctor who was not directly involved in the patients' care team.

A non-self-compiling paper questionnaire was used during the 25-min interview of the women involved. The questionnaire was composed of seven sections for a total of 63 items. Each section was investigating the following topics:

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