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Editorial

Mandatory vaccination: suited to enhance vaccination coverage in Europe?

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Vaccines are one of the most successful medical measures that save millions of human lives every year. With the implementation of routine immunisation programs, high and maintained vaccination coverages for many vaccine-preventable diseases—such as those against poliomyelitis or diphtheria—have been reached in most European countries and many others [1,2]. Although vaccine acceptance is often high within the general population, even in countries with high vaccination coverage a significant number of children and adults are not sufficiently vaccinated because of missed opportunities or various concerns and misperceptions. The reasons for this 'vaccine hesitancy' are multifactorial, complex and vary across vaccines, time and countries/regions, and are influenced by factors such as complacency (not perceiving disease as high risk and vaccination as necessary), convenience and constraints (practical barriers), and confidence (lack of trust in safety and effectiveness) [3-6]. As a result, vaccination coverages against highly contagious pathogens such as measles virus are not sufficient to prevent outbreaks and infectious disease spread in many countries today.

Despite the World Health Organization (WHO)'s goal to eliminate measles [7,8], a constant increase in measles cases has occurred in recent years. In 2018, more than 82,500 people in 47 of the 53 countries in the WHO European Region were infected with measles, leading to 72 deaths. These numbers were the highest in a decade. They were three times higher than in 2017 and 15 times higher than in 2016, when numbers were at a record low [9-11]. In 2019, the situation seems to be even worse [12,13], indicating that current plans of action in the affected areas are insufficient to stop measles circulation. This is evidenced by the fact that the estimated coverage with the second dose of a measles-containing vaccine is far below the necessary 95% to achieve herd/population immunity in several European countries [13]. In order to maintain or improve the population immunity acquired by vaccination, several countries are currently revisiting their strategies and discussing changes in vaccination policies, with a focus on either educating the population and giving individuals freedom of choice or implementing mandatory vaccination to ensure high coverage rates [14].

With increasing calls to introduce mandatory vaccination programs, intense debates on their effectiveness have also started in several European countries. There are concerns that mandatory vaccination may lead to opposing attitudes and even less vaccine uptake, particularly in those with existing critical attitudes towards vaccines [15]; nonetheless, other studies have disproved that implementation of compulsory vaccination led to opposing attitudes and/or had negative effects [14]. However, it is indisputable that with any changes in vaccination policies, intensified information strategies are necessary to improve trust, rectify perceived risks and improve access and affordability of vaccines [3,15]. Moreover, it is important to note that mandatory vaccination can follow different routes depending on a country's specific social and cultural backgrounds, as well as epidemiological situations. Consideration of these factors can lead to implementing temporary or permanent vaccine mandates for certain vaccines (such as measles/measles-mumps-rubella (MMR) partial compulsory vaccination [15]), for all vaccines included in a national vaccination program [14]] or for selected target groups, such as infants and children before entrance in educational settings or certain occupational groups, such as healthcare workers (HCW) [16].

For example, in France three mandatory vaccines (against diphtheria, tetanus and poliomyelitis (DTP)) co-existed with eight recommended vaccines (against MMR, pertussis, Streptococcus pneumoniae, hepatitis B (HepB), Neisseria meningiditis serogroup C (MenC) and Haemophilus influenza (Hib)) for routine childhood immunisation up until 2017. However, misperceptions in the population, i.e. that non-mandatory vaccines are less valuable, optional or not as safe and effective as the mandatory ones, resulted in insufficient and stagnating vaccine coverages of the recommended vaccines. This growing vaccine hesitancy, as well as large outbreaks and deaths from measles, led to a change in French policy to extend the mandates to all 11 childhood vaccines [17].

Italy has had a similar situation, where four mandatory vaccines were in place already before 2017 (against poliomyelitis, tetanus, diphtheria and HepB). The coverage for vaccination against measles, mumps and rubella dropped country-wide from 90% to 87% between 2000–16 [18,19]. This, together with large measles outbreaks, led the government to extend the existing vaccine mandates to 10 mandatory vaccines (hexavalent vaccine against DTPert (pertussis)-poliomyelitis-Hib-HepB, as well as MMR and Varicella (V) vaccine) in 2017, whereas vaccination against Men C, S. pneumoniae and rotavirus remained recommended vaccines.

The current issue of Eurosurveillance presents articles from France and Italy on approaches and experiences after the extension of mandatory vaccination [19,20]. While an article in last week's issue of Eurosurveillance by Mathieu et al describes the population's general attitude towards mandatory vaccination shortly before implementation of extended vaccination mandates in France [21], the rapid communication by Lévy-Bruhl et al. in this issue evaluates the effects of mandatory vaccination on vaccine coverage 2 years after its implementation [20]. D'Ancona et al., also in this issue, depict challenges in Italy in the year following the introduction of the new mandate and how these are being addressed [19].

Mathieu et al. performed a cross-sectional survey among 3,222 individuals in France, at the time of implementation of the new law, to assess attitudes towards the new vaccination policy and factors associated with a favourable opinion [21]. More than two thirds of survey participants agreed with the extension of the vaccine mandates, considered it as a necessary step and assigned a higher value to these vaccines. However, around 57% deemed the law as authoritarian. The article by Lévy-Bruhl et al. illustrates the impact of the extended mandates on the vaccination coverages of children born in 2018, as well as for vaccines not concerned with the law, such as the HPV vaccine [20]. The legislation stipulates that non-vaccinated children cannot attend any kind of collective institutions, such as nurseries, kindergartens or schools, and no reasons for refusal other than medical exemptions are possible. Regardless of initial debates and concerns regarding whether this compulsory mode of action would foster anti-vaccination stances, already 1 year after implementation the vaccination coverages increased for the mandatory vaccines. The sharp increase in Men C vaccination coverage (36.4%) resulted in a notable decrease of cases of invasive meningococcal C disease. Of particular importance is the finding that vaccination coverages also increased for non-mandatory vaccines, such as the HPV vaccine, as well as in older children not covered by the mandates. The authors conclude that this reflects the commitment and efforts of the government to conduct intensive information campaigns along with the new law. In particular, establishing a governmental website dedicated to vaccination helped to provide answers to common questions on vaccines and vaccination, thereby building trust and improving confidence in safe and effective vaccines [20].

In Italy, the extended mandatory vaccination program has been implemented following large measles outbreaks in 2017. Ten vaccines are now compulsory for admission to daycare, kindergarten and schools along with financial sanctions for parents/guardians of children between 6–16 years of age who have not followed the new law. Within 24 months of extended mandatory vaccination, the coverage rates for the mandated vaccines increased between 3–7%. With regard to measles [19], the required coverage rate of 95% has been nearly reached within the past 2 years. Despite this measurable improvement in coverage rates, debates are still ongoing in certain areas of the country because of perceived constraints of individual freedoms and an authoritarian modus operandi in public health aspects [19]. With the recent change of the government, the Italian parliament is now discussing a new legislative proposal, which might reduce mandatory vaccination to measles vaccination only.

These experiences from France and Italy show that mandatory vaccination may even face challenges in countries with a long-standing history of compulsory preventive measures and highlight the need for accompanying activities such as targeted communication and support, e.g. introducing electronic vaccination registries with reminder functions. In view of the high incidence of measles cases in Germany and Austria in recent years, both countries with vaccination programs that do not have vaccine mandates, discussions on the pros and cons of mandatory vaccination are ongoing among experts and in public media. Questions have arisen whether compulsory vaccination (partial or general) might lead to resistance related to people's fear of unwarranted adverse effects, with a further decline in vaccination coverage, rather than helping to increase coverage rates [15,22].

Alternative strategies could focus on mandatory vaccination for children at entrance into collective/public institutions such as childcare centres, kindergartens, schools, etc., but with the possibility to opt-out, leaving the autonomous decision intact [23]. Some countries, such as Finland, achieved high vaccination coverages for recommended vaccines without mandatory vaccination but with the help of comprehensive electronic vaccination registries and recall systems, along with easy access to vaccinations, e.g. physicians proactively addressing patients and applying motivational interviewing skills, vaccination by occupational physicians at work places or by nurses or pharmacists. Focus on mandatory vaccination was only on HCW, which, however, falls under the responsibility of the respective employer rather than the public health authorities [24].

Studies and surveys have consistently shown that the key persons for vaccine uptake, transmission of information and clarifications are physicians and HCW, who act as trusted role models whose advice is followed by parents/guardians and patients. Therefore, profound education of medical students in vaccinology and further training of physicians of all disciplines—as well as of other HCW—is a high priority to improve their knowledge and strengthen their own positive attitudes towards vaccines [16]. Recent outbreaks of vaccine-preventable diseases (such as measles) have on many occasions involved HCW, and infected HCW constitute a particular risk for their patients, both in hospital and ambulatory settings [16]. Thus, medical and ethical obligation of self-protection and prevention of transmission to others, in particular vulnerable population groups, might justify standard guidelines for necessary vaccines according to risk exposure and implementation of mandatory vaccination of HCW, along with the necessary infrastructure and logistics to facilitate compliance with such regulations. Recently published reviews have shown that acceptance of vaccines even increased after the introduction of compulsory vaccinations among HCW [14,16].

In conclusion, mandatory vaccination cannot be implemented under a uniform procedure and might not be a solution for all countries because of different target groups with differing ages and social, cultural, psychological and educational backgrounds within the populations. During continuous large outbreaks it might be necessary, however, to temporarily control disease spread through vaccine mandates for children and highly exposed groups in educational and public health facilities in order close vaccination gaps and stop transmission. As vaccination gaps in adolescents and young adults exist in several European countries, the introduction of mandates for the infant/childhood immunisation programs might, however, not be suited to instantly close the immunity gaps in these age groups [25-27]. Therefore, supplemental immunisation activities are urgently needed to increase the coverages in these age groups. Importantly, these strategies need to be accompanied by advocacy, trust-supporting communication or electronic vaccination registries/recall facilities. With regards to HCW, there is a broad consensus among European experts that mandatory targeted vaccination would minimise risk of infection and transmission of vaccine-preventable diseases within the healthcare setting [14].

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Conflict of interest

None declared.

Authors’ contributions

The authors have equally contributed.

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Rapid communication

Assessment of the impact of the extension of vaccination mandates on vaccine coverage after 1 year, France, 2019

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One year after the extension of the childhood vaccination mandates to the 11 routine vaccinations for children under 2 years old, we estimated vaccination coverage through vaccine reimbursement data. Coverage for children born in 2018 has notably increased. Moreover, vaccine coverage for children and for vaccines not concerned by the law have also shown an increasing trend, supporting a positive impact of the ongoing communication strategy on vaccination, beyond the extension of vaccination mandates.

In December 2017, French parliamentarians passed a law extending the vaccination mandates for children from three (diphtheria, tetanus and poliomyelitis) to the 11 vaccinations included in the routine immunisation schedule of children under 2 years old. Children born from 1 January 2018 onwards are required to receive: three doses of a hexavalent vaccine which includes diphtheria, tetanus, poliomyelitis, pertussis, *Haemophilus influenza b* and hepatitis B antigens at age 2 and 4 months, with a booster dose at 11 months; three doses of the vaccine against invasive pneumococcal diseases with the same schedule; two doses of a vaccine against meningococcal C (MenC) diseases at age 5 and 12 months; and two doses of a vaccine against measles, mumps and rubella (MMR) at age 12 and 16–18 months [1].

The epidemiological, legal and societal determinants of such a decision have been described elsewhere [2]. Briefly, the main drivers of the decision were threefold: (i) the confusion created in many parents by the coexistence in the schedule of both mandatory and recommended vaccines, giving the false impression that the latter were less important or even optional [3]; (ii) the growing vaccine hesitancy in the French population, leading to insufficient vaccine coverage for most recommended vaccines [4]; and (iii) the translation of this insufficient coverage into an unacceptable burden of severe morbidity and mortality for some vaccine preventable diseases, including large outbreaks such as the measles epidemic observed in 2008–11 [5,6].

In practice, non-vaccinated children cannot be admitted to any kind of collective institutions such as nurseries, kindergarten, schools or any social activity if they have not complied with the vaccine mandates. No exemption other than medical contraindication is accepted. The law is not retroactive, meaning that only children born since 1 January 2018 are concerned [7].

This decision was highly debated and several experts expressed their concern about a potential counterproductive effect, fearing that it could 'convert vaccine hesitancy into a more extreme anti-vaccination stance' or 'fuel further unfounded resistance to life-saving vaccines' [8,9].

One year later, we present a first assessment of the impact of the law on vaccination coverage (VC) for children born in 2018 and therefore concerned by the measure. We also present data for some vaccinations given to children born before 2018 in order to assess the potential consequences of this change on VC of recommended vaccines.

Table 1

Impact of vaccination mandates on vaccination coverage of children under 1 year old born January–May 2018, France

Vaccine	Vaccination coverage		
	Birth cohort		Gain in coverage (percent point)
	Infants born in January–May 2017	Infants born in January–May 2018	
Hepatitis B, at least 1 dose	92%	98%	6%
Pneumococcal, at least 1 dose	98.0%	99.4%	1.4%
Meningococcal C, first dose	39.3%	75.7%	36.4%

Table 2

Evolution of vaccination coverage at 14 months of age for vaccines scheduled at 12 months, France, 2016–2018

Vaccine	Vaccine coverage				
	Age reached			Gain in coverage 2016–17 (percent point)	Gain in coverage 2017–18 (percent point)
	12 months in 2016	12 months in 2017	12 months in 2018		
MMR, first dose	74.3%	74.7%	77.7%	0.3%	3.0%
Meningococcal C, second dose	55.8%	59.3%	65.0%	3.6%	5.7%

MMR: measles, mumps and rubella.

Source of vaccination coverage data

We used the National Social Security Reimbursement Database, which contains the reimbursement data for all drugs, including vaccines, for more than 99% of the population. Past experience has validated the use of this database to estimate VC through comparison with routine VC estimates obtained by the analysis of the child health certificates mandatorily filled at 24 months [10]. Virtually 100% of reimbursements of vaccines delivered in a given month are available two months later in the database. Data were extracted in March 2019, therefore allowing measurement of vaccination activities for 2018 as a whole.

Vaccination coverage for children concerned by the vaccination mandates

Vaccine coverage for diphtheria, tetanus, poliomyelitis, pertussis and *Haemophilus influenzae b*, as measured by the 24 months child health certificates, has been at least 98% for many years because of the quasi-exclusive use of hexavalent or pentavalent (excluding the hepatitis B component) vaccines for primo vaccination. Estimates of coverage for these antigens cannot be generated through the National Social Security Reimbursement Database because we excluded from the analysis all children in their first year of life with no reimbursement of any DTP-containing vaccine. This was to account for the very low percentage of children (estimated ca 5%) who benefit from free vaccination in the Maternal and Child Health clinics [11]. To estimate the coverage for hepatitis B, we computed the proportion of children vaccinated with a hexavalent vaccine with, as a denominator, the number of children receiving either a pentavalent or an hexavalent vaccine and multiplied this figure by the proportion of children receiving a DTP-containing vaccine, obtained by the analysis of the 24 months health certificates (99%), to account for children who do not receive any vaccine. We compared vaccine coverage between children born January to May 2018 and January to May 2017.

For those same two cohorts of children, we compared vaccine coverage at 7 months of age for at least one dose of pneumococcal vaccine and the first dose of meningococcal C vaccine.

Vaccination coverage for children not concerned by the vaccination mandates and for human papillomavirus (HPV) vaccine

We compared the VC for the first dose of MMR and the second dose of MenC vaccination at the age of 14 months, between children having reached their first birthday in 2018 and aged at least 14 months (children born between January and October 2017) and children born 1 year earlier (between January and October 2016). We also evaluated the number of human papillomavirus (HPV) vaccine doses reimbursed in 2018 for adolescent girls and compared this figure with similar ones for the years 2015–2017.

Vaccination coverage comparisons

The proportion of infants, children under 1 year old, receiving a hexavalent vaccine increased from 93.1% in 2017 to 98.6% in 2018, corresponding to an increase of VC against hepatitis B from around 92% in 2017 to

Figure 1

Incidence of invasive meningococcal infections according to age, France, 2006–2018

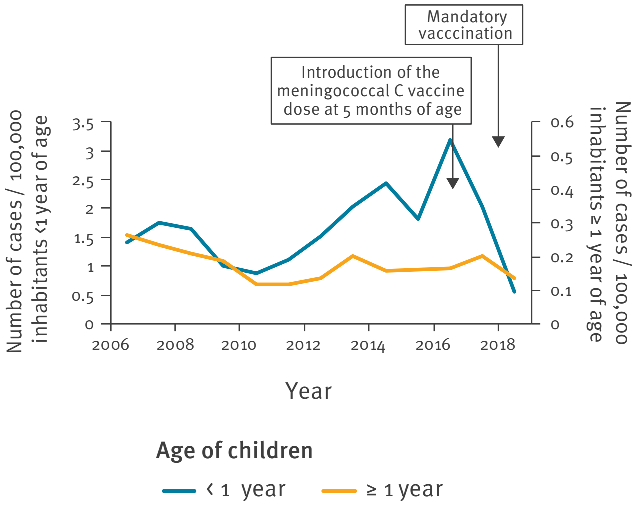
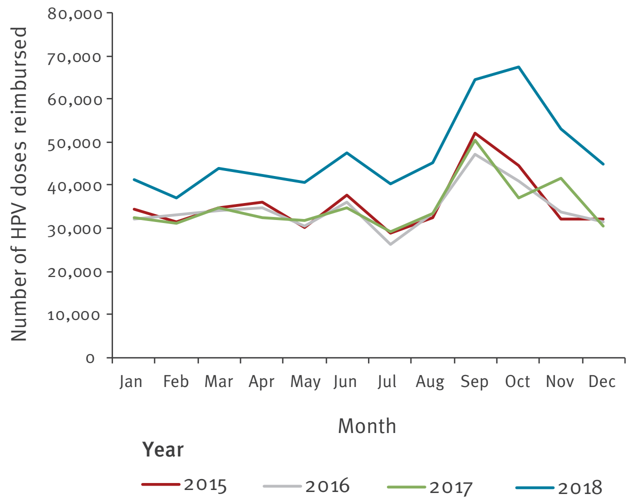


Figure 2

Number of human papillomavirus (HPV) vaccines reimbursed by month, France, 2015–2018



98% in 2018. VC for at least one dose of pneumococcal vaccine increased from 98.0% to 99.4%, and vaccine coverage for the first dose of meningococcal C vaccine increased from 39.3% to 75.7% (Table 1). This sharp increase in MenC VC translated into a dramatic decrease in the number of invasive MenC disease cases notified in infants through the mandatory notification system, from 17 cases on average during the 2012–16 period to four in 2018, all in non-vaccinated individuals. This contrasts with the very limited decrease in incidence in individuals above 1 year of age in 2018 (Figure 1).

The increase in MMR first dose and MenC second dose VC between 2017 and 2018 was 3.0% and 5.7%, respectively. This compared with a 0.3% and 3.6% increase between 2016 and 2017 respectively (Table 2).

The number of doses of HPV vaccines reimbursed show a sharp increase between 2017 and 2018, contrasting with the almost stable volumes during the 2015–2017 period (Figure 2).

Discussion

This first assessment of the impact of the extension of vaccination mandates on vaccination coverage is encouraging. It shows an increase in VC of infants concerned by the extension of the vaccination mandates. VC for the first dose of MenC will most likely continue to increase as time passes, when those children will be registered in a community requiring the completion of the schedule. More remarkable is the increasing trend seen for VC of children too old to have been concerned by the mandates. This suggests that the new law, at least at this stage, had no detrimental effect on vaccine coverage for vaccinations not yet concerned by the mandates or which remain recommended. This is especially true as VC measured at 14 months for the first dose of MMR and the second dose of MenC vaccination, for the sake of the current analysis, underestimate the future VC at 24 months for those children because of the usual catch-up during the second year of life. For the 2015 birth cohort, MMR first dose VC was estimated at 74.3% at 14 months and at 89.6% at 24 months through the health certificates (Table 2) [12]. We also observed a higher increase between 2018 and 2017 in the coverage for the second dose of MMR vaccination in children who reached their second birthday in the second semester of the year (from 75.5% to 78.4%) as compared with the increase in similar cohorts of children between 2016 and 2017 (from 74.0% to 75.5%).

The measles resurgence which started end of 2017 may have contributed to the increase in MMR VC. However, the increasing trend in vaccine coverage for children and vaccinations not concerned by the new mandates is likely to reflect, at least in part, the commitment of the French government in favour of vaccination at a high level, publicly expressed on several occasions by the Minister of Health and the Prime Minister, as well as the implementation, since 2017, by Santé publique France and its partners, of different actions aiming at promoting vaccination and countering vaccine hesitancy. One of the main achievements was the launching of a governmental website dedicated to vaccination (www.vaccination-info-service.fr) during the 2017 European Immunization Week. This site provides answers to most of the general public's questions on vaccines and vaccinations. It has already received more than 6 million consultations. On the occasion of the 2019 European Immunization Week, an additional module of this website, one dedicated to healthcare professionals, was launched. It provides more insights into the various aspects of the National Immunisation Program, safety and effectiveness data, and on the evidence-base supporting the current recommendations.

The results of two surveys based on the same methodology conducted by the Vaccine Confidence Project in 2015 and 2018 were used to assess the improvement in the positive perception of the general public regarding vaccination overall. They show a decreasing proportion of French participants who disagree with the affirmation that vaccines are safe (from 41% to 23.7%) and effective (from 17.3% to 12.5%) [13,14]. However, much remains to be done to control or eliminate vaccine preventable diseases. In particular, the observed increase in MMR VC in young children will have very little impact on the current measles resurgence, which is mainly driven by the immunity gap in young adults who escaped both vaccination and natural infection in childhood. Nevertheless, the current situation is providing a unique momentum to strengthen the current efforts of the various vaccination stakeholders to restore confidence in vaccination, with the ultimate goal to control or eliminate vaccine preventable diseases and to lift the mandates.

Conflict of interest

None declared.

Authors' contributions

LF made the extraction and the analysis of the data under the supervision of SV, ASB provided the epidemiology data, and DLB wrote the first draft. DA, IB, DC, SQ, BC have contributed to the final version of the submitted manuscript.

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Promoting vaccination in maternity wards – motivational interview technique reduces hesitancy and enhances intention to vaccinate, results from a multicentre non-controlled pre- and post-intervention RCT-nested study, Quebec, March 2014 to February 2015

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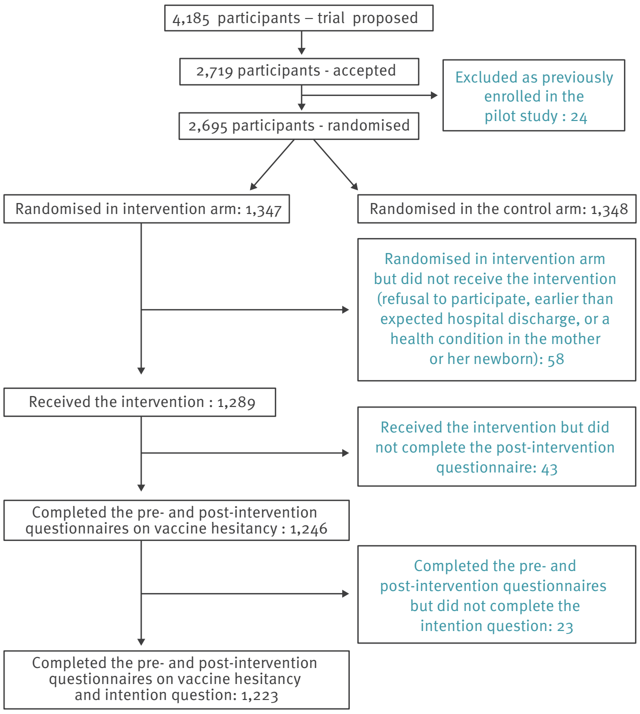
Background: Many countries are grappling with growing numbers of parents who delay or refuse recommended vaccinations for their children. This has created a need for strategies to address vaccine hesitancy (VH) and better support parental decision-making regarding vaccination. **Aim:** To assess vaccination intention (VI) and VH among parents who received an individual motivational-interview (MI) based intervention on infant immunisation during post-partum stay at a maternity ward between March 2014 and February 2015. **Methods:** This non-controlled pre-/post-intervention study was conducted using the results from parents enrolled in the intervention arm of the PromoVaQ randomised control trial (RCT), which was conducted in four maternity wards across the Province of Quebec. Participants (n = 1,223) completed pre- and post-intervention questionnaires on VI and VH using Opel's score. Pre-/post-intervention measures were compared using McNemar's test for categorical variables and Wilcoxon signed-rank test for continuous variables. **Results:** Pre-intervention: overall VI was 78% and significantly differed across maternity wards (74%, 77%, 84%, 79%, p = 0.02). Post-intervention: VI rose significantly across maternity wards (89%, 85%, 95%, 93%) and the overall increase in VI was 12% (78% vs 90%, p < 0.0001). VH corroborated these observations, pre- vs post-intervention, for each maternity ward (28% vs 16%, 29% vs 21%, 27% vs 17%, 24% vs 13%). Overall, VH was curbed post-intervention by 40% (27% vs 16%; p < 0.0001). **Conclusions:** Compared with pre-intervention status, participants who received the MI-based intervention on immunisation displayed lower hesitancy and greater intention to vaccinate their infant at 2 months of age.

Introduction

According to data from the World Health Organization (WHO), 19.5 million children worldwide failed to receive routine life-saving vaccinations in 2016 while ca 90,000 children died from measles, a vaccine-preventable disease [1]. These figures suggest that vaccination, long recognised as instrumental to human health, still faces complex and multi-factorial barriers leading many families to forego or delay childhood immunisation [2]. Despite past and ongoing campaigns to promote childhood vaccination, including efforts to facilitate vaccination, current worldwide vaccine coverage against diphtheria-tetanus-pertussis (DTP3) is ca 85%, which

Figure 1

Study flowchart showing the number of participants receiving the intervention, number that completed the pre- and post-intervention questionnaires, Quebec, March 2014–February 2015 (n = 1,223)



is less than the expected threshold of 90% for herd immunity [3]. In the Province of Quebec (Canada), the latest survey conducted by the National Institute of Public Health of Quebec showed that, as of 2016, complete vaccine coverage (including against rotavirus and hepatitis B) was reached for 82% of children aged 24 months [4]. The Quebec immunisation schedule can be seen in supplement S1. Only 50% of children aged 24 months received all recommended vaccinations (excluding rotavirus and hepatitis B) within 1 month after the recommended age for each dose [4].

A reason for falling vaccine coverage is parental vaccine hesitancy (VH); a concept first recognised by the WHO Strategic Advisory Group of Experts (SAGE) on Immunisation in 2012, with a clear definition published in 2015 [5]. In response to this definition, an online survey was conducted among Canadian parents to explore the degree/level of VH in Canada in 2015 by the Canadian Immunization Research Network. A total of 2,013 parents/caregivers of at least one child (aged 24–59 months) participated. They reported that 85% of the children under their care had received all of the recommended vaccines according to the schedule [6] and there was an overall positive attitude towards immunisation. Further, the levels of parental vaccination awareness and trust in institutions associated with VI was positive [6]. In the Province of Quebec, higher VH was associated with low household income and low education level [7].

Face-to-face interventions have been proposed as a strategy to address VH and to increase vaccination awareness among parents. A scoping review and meta-analysis, published in 2015, concluded that while there is no strong evidence to support the use of any specific intervention to address VH [8], interventions directly tailored at vaccine-hesitant parents were scarce. In 2018, a Cochrane Review concluded that low to moderate evidence suggested that face-to-face interventions might improve parental VI if adapted to the target population and provide accurate information on vaccines [9].

Traditional educational methods (e.g. information pamphlets, communication interventions aiming to provide information) have proven inefficient in addressing VH [10]. It is known that merely providing additional factual information to vaccine-hesitant parents is counterproductive [11]. Our group developed a vaccination promotion programme, called PromoVac, based on a face-to-face intervention with parents conducted post-partum in maternity wards. We further refined the intervention using a standardised information session and motivational-interview (MI) techniques [12,13]. Our novel face-to-face intervention strategy is patient-oriented, tailored to welcome parents at their individual level of knowledge and with respectful acceptance of their personal beliefs [14]. Our first quasi-experimental regional pilot study ('PromoVac') using this MI-based intervention was conducted in the Eastern Townships region of the Province of Quebec between March 2010 and February 2011. Locally, results demonstrated both an increase in parents' VI (15%) and in the vaccine coverage (7%) of infants aged 7 months [12,13], suggesting potential benefits. Results on the long-term impact of our MI-based post-partum intervention show that the children of participant parents who received it were 9% more likely to display complete vaccine coverage at 0–2 years [15].

The 'PromoVaQ' study aimed to scale-up our regional pilot, monocentric, quasi-experimental study ('PromoVac' March 2010–February 2011) to a Province-wide multicentric study, conducted in four university hospital maternity wards between March 2014 and February 2015, in order to measure how our MI-based post-partum intervention impacted post-intervention VI and VH in participant parents of newborns.

Methods

Design

To assess the post-intervention impact on VI and VH, we designed a nested non-controlled pre-/post-intervention study using data from consenting parents enrolled in the intervention arm of a pragmatic, unblinded, parallel-randomised controlled trial (RCT) (NCT02666872); this study design is recognised as being suitable to determine the impact of an experimental intervention in a single arm study [16].

This study was a pragmatic, unblinded, parallel-randomised controlled trial (RCT) powered to compare the impact of our MI-based intervention to the standard of care provided to parents of 2-day-old newborns on the overall vaccine coverage for children aged 24 months (refer to the study protocol for additional details [17]).

Setting

The RCT was conducted in four university hospital maternity wards of the Province of Quebec, collectively accounting for over 20% of all births province wide. The hospitals were located in Sherbrooke (CIUSSS de l'Estrie - CHUS), Montreal (in a French- and an English-language maternity ward at the CHU Ste-Justine Hospital and the McGill University Health Centre, respectively) and Québec city (CHU de Quebec). These hospitals were selected in order to increase external generalisability of results, characterise feasibility issues and determine efficacy of the intervention, irrespective of regional disparities in maternity ward organisation and/or socioeconomic and cultural diversities. However, it was beyond the scope of this study to further dissect sites differences.

Study period, population and eligibility criteria

Enrolment took place between March 2014 and February 2015. Mothers were eligible to participate in the study if their newborn was delivered in one of the four participating university hospital maternity wards and they had not yet been discharged. Mothers were excluded if: (i) they were aged 18 years or younger, (ii) did not speak either French or English, (iii) participated in the pilot study conducted at the CIUSSS de l'Estrie - CHUS between 2010 and 2011, (iv) if their newborn presented an unstable condition requiring intensive care management, or (iv) if interviewing was incompatible with the mother's health. If the father was also at the maternity ward, he was invited to receive the intervention and answer the questionnaires jointly with the mother.

Parents who consented to participate in the study were randomised through a web-based system (Dacima). Randomisation was conducted using a block size strategy (eight participants/block) and was stratified by maternity ward using a 1:1 allocation ratio to ensure proportionate allocation among sites and groups.

Parents enrolled on the standard of care arm of the RCT did not complete post-intervention questionnaires, as it has been shown that providing parents with a copy of the public health vaccine brochure (standard of care), does not alter parental VI or VH [18].

Ethics

This study was reviewed and approved by the institutional research ethics review board at each site ((CIUSSS de l'Estrie – CHUS: 2014-609, 13-074; McGill University Health Centre: 13-084 (3262); CHU Ste-Justine: 2014-601, 3793; CHU de Québec: 2014-1742, B13-07-1742)). Written informed consent was obtained from all participants before study inclusion and participation as required by law.

Intervention

The study intervention has been described previously [12,17]. Briefly, the intervention merges the MI framework [14] to Prochaska's stages-of-change model as the conceptual backbone [19]. According to this model, stepwise changes [19] must occur in order to increase an individual's awareness and internal motivation to change by exploring/resolving his/her own ambivalences [14]. The rationale underlying the study intervention was to accompany parents, in a non-judgmental manner, from their own stage of VI to the next stage by tailoring the intervention accordingly. The intervention covered five main areas: (i) vaccine-preventable diseases and their consequences, (ii) vaccines and their effectiveness, (iii) the importance of the immunisation calendar in infants, (iv) reluctance to vaccinate and vaccination side-effects [20], and (v) vaccination services and facilities in each of the study regions. Local research assistants were trained to provide a standardised intervention and a 2-week trial period was conducted at each maternity ward before the study launch. The MI-based intervention was administered individually to consenting parents 24–48 hours after delivery in their maternity ward room. The intervention lasted ca 20 min. Based on the pragmatic nature of this RCT, co-interventions were allowed and maternity staff interacted with the participants based on their clinical judgement.

Outcomes and measurement tools

The primary outcome was VI measured using a validated questionnaire [12,17,21] based on the health belief model [22], where answers were provided according to a four-category Likert scale (certainly not, probably not, probably and certainly). The secondary outcome was parental VH measured using Opel's validated questionnaire [12]. Briefly, VH questions were scored in an adapted Opel approach [23] as follows: 2 points for hesitant-related responses; 1 point for 'I don't know or not sure' responses and 0 for non-hesitant responses. Scores were summed unweighted to a 0–100 range using simple linear transformation and accounting for missing data. According to the methodology of Opel [23] and Dube [24], categories were defined as follows: 0–29 score = low level VH; 30–49 = moderate level VH; 50 and higher = high level VH. Questionnaires were self-administered and distributed to parents before and immediately following the end of the MI-based intervention. The post-intervention questionnaire was collected at discharge from the maternity ward.

Statistical analyses

As this study is nested within a larger RCT's objective, no sample-size calculation was defined a priori to answer this study's primary outcome. Based on our previous study evaluating a 77.5% baseline VI in parents [24] and a sample size of 1,300 participants, a significant difference of 6.5% in VI will be observable

Table 1a

Study flowchart showing the number of participants receiving the intervention, number that completed the pre- and post-intervention questionnaires, Quebec, March 2014–February 2015 (n = 1,223)

Characteristics	Maternity hospital								Total (n = 1,223)	
	CIUSSS de l'Estrie-CHUS (n = 373)		McGill University Health Centre (n = 290)		CHUS Ste-Justine (n = 265)		CHU de Quebec (n = 295)			
	n	%	n	%	n	%	n	%	n	%
Newborn										
Week of delivery										
< 37	16	4.3	11	3.8	17	6,4	11	3.7	55	4.5
≥ 37	352	94.4	277	95.5	246	92.8	284	96.3	1,159	94.8
Unknown	5	1.3	2	0.7	2	0.8	0	0	9	0.7
Rank in the family										
First	179	48.0	131	45.2	128	48.3	135	45.8	573	46.9
Second	126	33.8	110	37.9	87	32.8	116	39.3	439	35.9
Third or more	68	18.2	48	16.6	47	17.7	44	14.9	207	16.9
Unknown	0	0	1	0.3	3	1.1	0	0	4	0.3
Presence of a disease at birth needing medical follow-up										
Yes	9	2.4	5	1,7	7	2.6	3	1.0	24	2,0
No	361	96.8	278	95.9	255	96.2	292	99.0	1,186	97,0
Unknown	3	0.8	7	2.4	3	1.1	0	0	13	1.1
Mother										
Language[a]										
French	343	92.0	110	37.9	200	75.5	264	89.5	917	75.0
English	14	3.8	74	25.5	8	3.0	2	0.7	98	8.0
Both French and English	7	1.9	51	17.6	36	13.6	16	5.4	110	9.0
Other	9	2.4	49	16.9	19	7.2	13	4.4	90	7.4
Unknown	0	0	6	2.1	2	0.8	0	0	8	0.7
Country of birth[a]										
Canada	338	90.6	155	53.4	164	61.9	257	87.1	914	74.7
Other	29	7.8	126	43.4	94	35.5	34	11.5	283	23.1
Unknown	6	1.6	9	3.1	7	2.6	4	1.4	26	2.1
Age at delivery (years)[a]										
< 20	3	0.8	1	0.3	7	2.6	0	0	11	0.9
20–29	198	53.1	78	26.9	88	33.2	113	38.3	477	39.0
30–39	167	44.8	196	67.6	158	59.6	173	58.6	694	56.7
≥ 40	5	1.3	14	4.8	12	4.5	9	3.1	40	3.3
Unknown	0	0	1	0.3	0	0	0	0	1	0.1

[a] $p < 0.05$ (Missing value not included). At least one site is different from the other. Statistics present overall differences in socioeconomic factors between maternity wards as a whole. As per the study objectives, no further test was applied to distinguish which site was different from the others.

Table 1b

Study flowchart showing the number of participants receiving the intervention, number that completed the pre- and post-intervention questionnaires, Quebec, March 2014–February 2015 (n = 1,223)

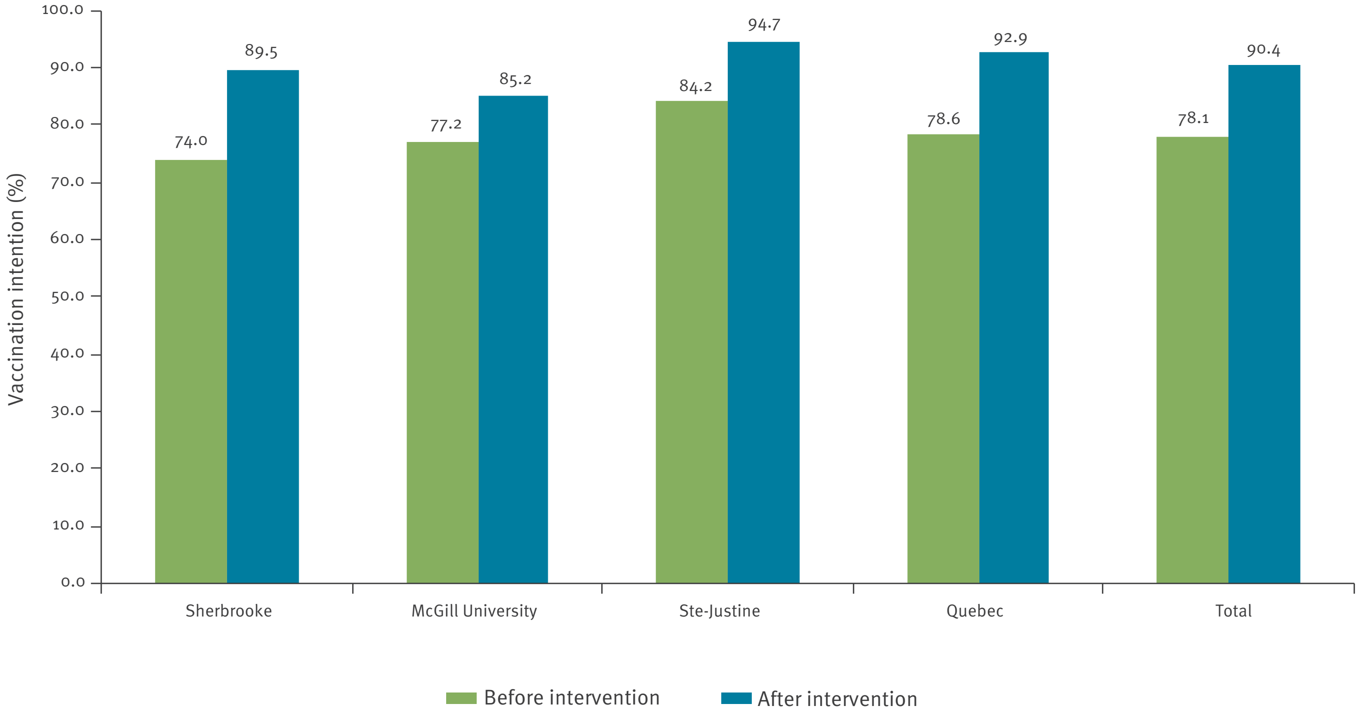
Characteristics	Maternity hospital								Total (n = 1,223)	
	CIUSSS de l'Estrie-CHUS (n = 373)		McGill University Health Centre (n = 290)		CHUS Ste-Justine (n = 265)		CHU de Quebec (n = 295)			
	n	%	n	%	n	%	n	%	n	%
Mean ± SD	29.1 ± 4.7		31.8 ± 4.9		31.1 ± 5.1		30.8 ± 4.6		30.6 ± 4.9	
Median (min-max)	29.0 (18–43)		32.0 (18–50)		32.0 (18–43)		31.0 (20–48)		31.0 (18–50)	
Education level[a]										
High school: incomplete	17	4.6	7	2.4	15	5.7	7	2.4	46	3.8
High school: completed	110	29.5	32	11.0	53	20.0	38	12.9	233	19.1
College	95	25.5	50	17.2	41	15.5	67	22.7	253	20.7
University	148	39.7	192	66.2	150	56.6	182	61.7	672	54.9
Unknown	3	0.8	9	3.1	6	2.3	1	0.3	19	1.6
Civil status[a]										
Single	17	4.6	16	5.5	18	6.8	9	3.1	60	4.9
Common-law partners	268	71.8	104	35.9	128	48.3	190	64.4	690	56.4
Legally married	84	22.5	161	55.5	111	41.9	95	32.2	451	36.9
Separated or divorced	2	0.5	0	0	4	1.5	0	0	6	0.5
Unknown	2	0.5	9	3.1	4	1.5	1	0.3	16	1.3
Healthcare professional involved in pregnancy management[a]										
Family physician	122	32.7	35	12.1	3	1.1	109	36.9	269	22.0
Gynaecologist-obstetrician	213	57.1	237	81.7	257	97.0	154	52.2	861	70.4
Midwife	9	2.4	5	1.7	0	0	2	0.7	16	1.3
None	0	0	1	0.3	0	0	0	0	1	0.1
Both family physician and gynaecologist-obstetrician	20	5.4	3	1.0	3	1.1	30	10.2	56	4.6
Unknown	9	2.4	9	3.1	2	0.8	0	0	20	1.6
Annual family income[a]										
< CAD 40,000 (EUR 27,000)	78	20.9	63	21.7	65	24.5	33	11.2	239	19.5
CAD 40,000–79 999 (EUR 27,000-54,000)	133	35.7	81	27.9	72	27.2	61	20.7	347	28.4
≥ CAD 80,000 (EUR 54,000)	159	42.6	125	43.1	117	44.2	194	65.8	595	48.7
Unknown	3	0.8	21	7.2	11	4.2	7	2.4	42	3.4

SD: standard deviation.

[a] $p < 0.05$ (Missing value not included). At least one site is different from the other. Statistics present overall differences in socioeconomic factors between maternity wards as a whole. As per the study objectives, no further test was applied to distinguish which site was different from the others.

FIGURE 2

Participants who 'certainly' intended to vaccinate their infant at age 2 months before and after the intervention, Quebec, March 2014–February 2015 (n = 1,223)



post-intervention, using an alpha set at 5%, a beta at 20% and a proportion of discordant pairs of 0.17, i.e. the percentage of participants expected to alter their score in relation to the principal outcome at the post-vs pre-intervention stage.

Analyses were performed under the intention-to-treat principle, i.e. with all participants enrolled in the intervention arm of the pilot PromoVac RCT, with the aim to provide descriptive data for the four study sites. Results were not adjusted for study site baseline criteria. Categorical variables are presented as frequencies (percentages) with a chi-squared Pearson test used for comparisons. Comparative analyses of pre- and post-intervention questionnaires were performed using McNemar's test for categorical variables and the Wilcoxon signed-rank test for continuous variables. Sensitivity analyses were performed to demonstrate the impact of selected socioeconomic factors on the pre-/post-impact, on the post-/pre-difference of the intervention on VI as well as on VH scores. All statistics were two-tailed. P values of 0.05 or less were considered significant. SAS Institute software version 9.4 (Cary, North Carolina, United States) was used for statistical analyses.

Results

The PromoVaQ RCT was initially proposed to 4,185 parents between March 2014 and February 2015. Of these, we randomised 2,695 consenting participants from the hospital maternity wards at the four following university hospital centres: the CIUSSS de l'Estrie - CHUS (n = 819), the McGill University Health Centre (n = 627), the CHU Ste-Justine (n = 624) and the CHU de Quebec (n = 625). Participants were equally randomised to the intervention (n = 1,347) or to the control arm (n = 1,348).

In the nested study, we only included the 1,347 participants who had been randomised to the intervention arm; of these, 1,289 received the study intervention. The most frequent reasons not receiving the intervention at this stage (n = 58) were refusal to participate, earlier than expected hospital discharge, or a health condition in the mother or her newborn. Of 1,289 participants who received the intervention, 1,246 completed the pre- and post-intervention questionnaires. Of the latter, 1,223 completed the question on VI pre- and post-intervention (CIUSSS de l'Estrie – CHUS: n = 373; McGill University Health Centre: n = 290; CHU Ste-Justine: n = 265; CHU de Québec: n = 295) and their results are thus the focus of this report; 43 participants completed the pre-intervention questionnaire, received the intervention, but did not complete the post-intervention questionnaire. Compared with the 1,246 participants included in the analyses, these 43 participants were not significantly more vaccine hesitant at the pre-intervention stage (mean Opel scores 27.1 vs 30.3; p = 0.38). However, they were significantly less likely to vaccinate their infant ('certainly' category: 78.1% vs 66.7; p = 0.043). Figure 1 depicts the study flowchart.

Table 1 delineates the distribution of participant mothers' sociodemographic variables by maternity ward. The majority of participants gave birth at term

Table 2

Intention of participants to vaccinate their infant at age 2 months before and after the intervention, Quebec, March 2014–February 2015 (n = 1,223)

Intention to vaccinate	Maternity hospital								Total (n = 1,223)	
	CIUSSS de l'Estrie-CHUS (n = 373)		McGill University Health Centre (n = 290)		CHUS Ste-Justine (n = 265)		CHU de Quebec (n = 295)			
	n	%	n	%	n	%	n	%	n	%
Pre-intervention										
Certainly not	4	1.1	3	1.0	1	0.4	0	0.0	8	0.7
Probably not	4	1.1	8	2.8	4	1.5	2	0.7	18	1.5
Probably	89	23.9	55	19.0	37	14.0	61	20.7	242	19.8
Certainly[a]	276	74.0	224	77.2	223	84.2	232	78.6	955	78.1
Post-intervention										
Certainly not	1	0.3	1	0.3	1	0.4	0	0.0	3	0.2
Probably not	1	0.3	2	0.7	0	0.0	0	0.0	3	0.2
Probably	37	9.9	40	13.8	13	4.9	21	7.1	111	9.1
Certainly[a]	334	89.5	247	85.2	251	94.7	274	92.9	1,106	90.4

[a] p value: Vaccination intention post- vs pre-intervention (< 0.0001).

(94.8% at ≥ 37 weeks of pregnancy), nearly half were primigravidas (46.9%), most pregnancies were followed by a gynaecologist-obstetrician (70.4%), and nearly all newborns were healthy, presenting with no condition requiring medical follow-up or assistance (97%). Three quarters of mothers were French speaking (75%) and born in Canada (74.7%). At delivery, a little over half of the mothers were in their 30s (56.7%), held a university degree (54.9%) and were living with a common-law partner (56.4%). Nearly half of participants (48.7%) had an annual family income of at least CAD 80,000 (EUR 54,000). Population characteristics, such as language, age at delivery, educational level, civil status, type of healthcare professional involved in their pregnancy management and annual family income differed significantly between participating maternity wards (all $p < 0.05$).

Figure 2 shows the intention of participants to 'certainly' vaccinate their infant at 2 months of age. Prior to the intervention, total intention to 'certainly' vaccinate was 78.1% among all participants combined and was significantly different between participating maternity wards ($p = 0.02$). Following the intervention, the total intention to 'certainly' vaccinate rose to 90.4%, a total 12% increase between pre- and post-intervention ($p < 0.0001$). We found no significant proportion differences (post- vs pre-intervention) between the four study sites ($p = 0.24$), suggesting that the effect of the intervention was comparable at each site. A significant rise in intention to 'certainly' vaccinate was observed at each site post-intervention ($p < 0.0001$ each site). The very small number of participants in the 'certainly not' category of vaccination intention makes it difficult to accurately measure the effect of the study intervention; we observed a shift from 0.7 to 0.2% in the 'certainly not' category (Table 2).

Participant VH significantly decreased post-intervention. Overall, the combined data from the four study sites showed that the relative proportion of participants with lowest VH (score 0–29) rose from 55.9% to 78.8% (41% increase), while those with intermediate and highest levels of VH (score 30–49 and > 50) decreased from 44.1% to 21.1% (Table 3). Prior to the intervention, 15.6% of our overall population displayed high VH (> 50%). This fraction decreased to only 5.2% post-intervention ($p < 0.0001$). The mean Opel score significantly decreased at each site between pre- and post-intervention evaluations ($p < 0.0001$): -12.1% (IC95: -13.6%; -10.6% - CIUSSS de l'Estrie - CHUS), -8.0% (-9.4%; -6.5% - McGill University Health Centre), -10.8% (-12.9%; -9.1% - CHU Ste-Justine) and -11.5% (-13.1%; -9.9% - CHU de Québec). Overall, the mean Opel score went from 27.1% to 16.4%, for a 40% reduction in VH ($p < 0.0001$) (Table 3).

Table 4 shows the results from a sensitivity analysis conducted to determine if there were any differences in VI and VH, when socioeconomic or cultural characteristics that were found to be different between the sites in Table 1 were analysed. The results supported the finding that the pre-/post-impact of the intervention on both VI and VH scores was effective,

Table 3

Hesitation of participants to vaccinate their infant at age 2 months before and after the intervention, Quebec, March 2014–February 2015 (n = 1,223)

Hesitation to vaccinate[a]	CIUSSS de l'Estrie-CHUS (n = 373)		McGill University Health Centre (n = 290)		CHUS Ste-Justine (n = 265)		CHU de Quebec (n = 295)		Total (n = 1,223)	
	n	%	n	%	n	%	n	%	n	%
Pre-intervention										
0–29	201	53.9	159	55.2	138	52.5	184	62.4	682	55.9
30–49	105	28.2	72	25.0	92	35.0	78	26.4	347	28.5
≥ 50	67	18.0	57	19.8	33	12.5	33	11.2	190	15.6
Mean Opel Score	28.2		28.7		27.3		24.0		27.1	
Post-intervention										
0–29	296	79.4	207	71.4	202	76.2	259	87.8	964	78.8
30–49	59	15.8	60	20.7	51	19.2	25	8.5	195	15.9
≥ 50	18	4.8	23	7.9	12	4.5	11	3.7	64	5.2
Mean Opel Score	16.1[b]		20.7[b]		16.5[b]		12.5[b]		16.4[b]	

VH: vaccine hesitant.

[a] Categories were defined as follows: Opel score: 0–29 = low level VH; 30–49 = moderate level VH; 50 and higher = high level VH.
[b] p value: mean Opel score post- vs pre-intervention (< 0.0001).

irrespective of the differing characteristics (Table 4). An exception was that the pre-/post-impact of the intervention was not effective when a midwife was in charge of pregnancy management. This result should, however, be interpreted with caution as only 16 participants were in that category.

With regard to the intention to vaccinate their infant at 2 months of age, results from sensitivity analyses demonstrated that the mother's age at delivery, i.e. being under or 30 years old, less educated, i.e. only completed high school, or being a primipara, all significantly increased the difference in pre-/post-impact of the intervention between categories. We also found that the VH scores were significantly lower in mothers who were French speakers, of Canadian origin, aged 30 years or younger, had completed at least high school, were in the middle-class income category (CAD 40,000–79,000/EUR 27,000–54,000) and primipara.

Discussion and conclusions

This study assessed the impact of an MI-based intervention conducted with parents post-partum regarding VH and VI for their newborn. We found that the pre-/post-impact of the intervention was effective, irrespective of the potential confounding sociodemographic and cultural factors. These results highlight the generalisability of this novel approach to help parental decision-making regarding immunisation and reduce VH.

A systematic review of literature on currently available interventions aimed at reducing parental vaccine refusal and hesitancy, concluded that reports on such interventions were scarce and given the lack of data to adequately inform policy and decision makers well-designed trials were needed [25]; the results of our study contribute to partially fill this knowledge gap. Our results, showing that a tailored MI-based intervention can raise parental VI, are supported by the conclusions of a 2018 Cochrane database systematic review and meta-analysis [9]. They included seven RCTs and three cluster-RCTs, covering a total of 4,527 participants. Although the studies were at risk of bias and therefore had a low-certainty of evidence, the overall conclusion was that face-to-face interventions can slightly improve VI compared with standard care (standardised mean difference 0.55; 95% CI: 0.24–0.85) [9]. Our PromoVac strategy is a patient-centred approach aimed at increasing parental motivation through exploring and solving personal inherent ambivalences towards immunisation of their infant. While some face-to-face interventions have proven more effective in populations for whom immunisation knowledge was a barrier rather than VI per se [9], our strategy was effective in participants with a high degree of VH pre-intervention. Indeed, parents who fell into the 'probably' category for VI, i.e. those who were most likely to be vaccine-hesitant, were those whose VI shifted the most post-intervention. Overall, 46% of participants in the 'probably' category for VI transitioned to a more favourable position, i.e. in the ‘certainly’ category (data not shown).

Our results indicate that an MI-based intervention is effective in parents presenting high levels of VH – the population that has been identified as crucial for effective intervention; Leask et al. emphasised that these parents’ needs must be met in order for them to be able to modify their perception of childhood vaccination [26]. We found that the MI-based intervention matched participant’s expectations and needs and we believe this was attributable to the MI approach and techniques used in our intervention. For example, we facilitated a highly respectful and empathetic discussion of participants’ concerns about childhood vaccination, which in turn, contributed to help build a trusting relationship between parents and research assistants. In addition, we ensured parents were given an opportunity to freely voice their concerns and questions about immunisation in the absence of any judgmental attitude from the healthcare professional. We believe that this is the distinctive feature of our intervention and may, in part, explain the positive results. A Cochrane review led by Kaufman et al. concluded that a face-to-face intervention may not impact positively vaccine coverage when strictly based on providing practical and logistical information regarding vaccination without any consideration for the parents’ beliefs on the matter [9]. Results from an RCT that enrolled adolescents to assess the impact of MI on human papillomavirus vaccination [27] support the approach we choose among available options. Furthermore, our approach is in line with a 2017 Cochrane review suggesting that parents expect to be provided balanced information, as to the risks and advantages of immunisation, in a simple manner by a professional they trust. When these conditions are not met, uptake of vaccination may decrease [28]. Our study intervention was adapted to each parent’s individual needs, which avoided the backfire that providing unnecessary or unsolicited advice can exert [29]. Also in support for our MI-based intervention is its efficacy in spite of sociodemographic factors. Indeed, it seemed to be more effective, i.e. it exerted a greater difference post-intervention with regard to intention to treat, whether mothers were aged 30 years or younger, had completed no more than high school education, or were primipara. In fact, despite their even lower pre-intervention scores, these mothers had post-intervention scores that were comparable to those of the older, more educated and experienced mothers.

Our results demonstrated the MI-based intervention consolidated decision making of participants who were immunisation favourable at baseline. Post-intervention, an additional 41% fell into the 0–30 Opel score category (lowest VH) and an additional 12% into the ‘certainly’ category of VI. Interestingly, as reported in a meta-analysis, VI may be predictive of behaviour [30], suggesting that parents’ intention may be translated into action to vaccinate their child. Several studies have shown that VI is correlated with the decision and behaviour to vaccinate [31,32]. One study on vaccination against influenza in Dutch healthcare personnel demonstrated that VI was a significant predictor of vaccination behaviour with an odds ratio of 15.50 (95% CI: 9.24–25.99) [33].

Strengths and limitations

This study builds on a variety of strengths increasing external validity including, (i) a unique parent-centred MI-based intervention, (ii) a parent-tailored approach, (iii) the use of validated reliable questionnaires and tools to secure internal validity and outcome assessment (e.g. use of validated questionnaires, standardised research assistant training between sites, use of a standard operating procedures manual, a trial period (refer to the study protocol [17])), and (iv) a considerably large number of participants enrolled at four university hospital centres across the Province of Quebec. The study intervention was standardised and thus reproducible in other maternity wards as indicated by the consistent results across all maternity wards and there being no significant differences for the main outcome. The results are also generalisable to the province, as the study was built upon a large and representative sample from four university hospital maternity wards (accounting for over 20% of all births) in the Province of Quebec and included both English and French speakers. The study population was diverse and suited to our intention to increase the validity of our results. In addition, Quebec’s Provincial Health Insurance Plan covers the hospitalisation of mothers for childbirth, so financial considerations do not affect the decision whether to deliver at a hospital maternity ward or at home. Our results also demonstrate that although the different study-site populations were heterogeneous, as shown by their baseline characteristics, the study intervention had the same impact on participants despite regional population disparities.

This study has some limitations. For instance, the initial reason for the refusal to participate was not collated despite the fact that it might have enriched our understanding of the enrolled population and potential biases. Also, mothers who gave birth at home or in birthing centres were not included in the study and they may have had different opinions regarding childhood vaccination, such as a higher tendency not have their children immunised as midwife-assisted birth (performed at home or in birth centres in Quebec) was associated with an incomplete immunisation status in Quebec and Canada [4,34-36]. However, these women only represent less than 3% of all births in the Province of Quebec [37], thus even if these women would have been approached to participate, we believe study results would not have changed in a predominant way. An additional concern is that this is an RCT-nested study, so participants in the RCT who were randomised to the standard-of-care arm did not complete the VH question or the questionnaire on VH at hospital discharge. Only baseline VI and VH were recorded for these participants. Our study

Table 4A

Intention and hesitation of participants to vaccinate their infant at 2 months before and after the intervention, by mothers' characteristics, Quebec, March 2014–February 2015 (n = 1,223)

Participant characteristics	VI at age 2 months					VH at age 2 months									
	Total	Pre intervention	Post intervention	Pre-post	Diff- in-diff (interaction)	Pre-intervention				Post-intervention				Pre-post	Diff- in-diff (interaction)
	n	%	%	p value	p value	0–29%	30–49%	≥50%	Mean Opel Score	0–29%	30–49%	≥50%	Mean Opel Score	p value[a]	p value[a]
Language															
French	917	77.8	91.2	< 0.0001	0.0621	58.45	27.59	13.96	26.0	82.55	13.20	4.25	14.7	< 0.0001	0.0136
English or other	298	78.9	87.9	< 0.0001		47.65	31.21	20.13	30.4	67.45	24.16	8.39	21.8	< 0.0001	
Country of birth															
Canada	914	77.8	91	< 0.0001	0.0914	60.50	25.93	13.57	25.3	84.25	11.60	4.16	13.9	< 0.0001	0.0032
Other	283	79.1	88.3	< 0.0001		41.70	36.40	20.85	32.6	61.84	29.68	8.48	24.4	< 0.0001	
Age at delivery (years)															
< 30	488	74.4	90.8	< 0.0001	0.0029	52.87	31.56	15.57	28.4	78.48	17.01	4.51	16.4	< 0.0001	0.0124
≥ 30	734	80.5	90.2	< 0.0001		57.77	26.29	15.53	26.3	79.02	15.26	5.72	16.5	< 0.0001	
Educational level															
High school: incomplete / completed	279	71.3	92.8	< 0.0001	0.0003	42.29	37.63	19.35	32.2	72.76	19.71	7.53	19.2	< 0.0001	< 0.0001
College	253	77.9	88.5	< 0.0001		54.15	27.27	18.58	29.1	79.84	17.00	3.16	15.2	< 0.0001	
University	672	80.8	90	< 0.0001		62.65	24.40	12.80	24.1	81.55	13.39	5.06	15.5	< 0.0001	
Living with a partner															
Yes	1,141	78.1	90.1	0.0017	0.2148	56.70	28.31	14.81	26.7	79.49	15.43	5.08	16.1	< 0.0001	0.2302
No	66	74.2	93.9	< 0.0001		39.39	31.82	27.27	34.7	66.67	24.24	9.09	22.4	< 0.0001	

Diff-in-Diff: Difference-in-Difference; VH: vaccine hesitant; VI: vaccination intention.

[a] For Mean Opel Score.

Table 4B

Intention and hesitation of participants to vaccinate their infant at 2 months before and after the intervention, by mothers' characteristics, Quebec, March 2014–February 2015 (n = 1,223)

Participant characteristics	VI at age 2 months					VH at age 2 months									
	Total	Pre intervention	Post intervention	Pre-post	Diff- in-diff (interaction)	Pre-intervention				Post-intervention				Pre-post	Diff- in-diff (interaction)
	n	%	%	p value	p value	0–29%	30–49%	≥50%	Mean Opel Score	0–29%	30–49%	≥50%	Mean Opel Score	p value[a]	p value[a]
Healthcare professional involved in pregnancy management															
Family physician	1,186	78.4	90.9	<0.0001	0.5935	55.99	28.75	15.01	26.9	79.34	15.68	4.97	16.2	<0.0001	0.3430
Midwife	16	56.3	56.3	1.0000		43.75	18.75	37.50	33.5	56.25	25.00	18.75	26.1	0.0039	
Annual family income															
< CAD 40,000 (EUR 27,000)	239	77.4	89.1	<0.0001	0.8711	44.35	35.15	19.67	32.2	66.53	25.10	8.37	22.2	<0.0001	0.0003
CAD 40,000–79,999 (EUR 27,000–54,000)	347	74.9	87.9	<0.0001		47.84	33.43	18.73	30.4	76.66	17.58	5.76	17.1	<0.0001	
≥ CAD 80,000 (EUR 54,000)	595	80.5	92.9	<0.0001		65.71	22.52	11.76	22.9	85.71	11.09	3.19	13.4	<0.0001	
Child's rank in the family															
First	573	67.2	86.7	<0.0001	<0.0001	50.6	31.24	18	29.5	78.4	17.1	4.5	16.8	<0.0001	<0.0001
Second	439	88.8	94.5	<0.0001		65.71	22.52	11.76	22.9	85.71	11.09	3.19	13.4	<0.0001	
Third or more	207	85.5	91.8	0.0029		65.71	22.52	11.76	22.9	85.71	11.09	3.19	13.4	<0.0001	
Number of parents															
Both[b]	866	76.9	89.5	<0.0001	0.3391	57.8	27.4	14.6	26.5	82	13.2	4.8	15.2	<0.0001	0.051
Mother only	331	81.9	92.7	<0.0001		51.4	20.2	17.8	28.3	71.6	22.7	5.7	18.9	<0.0001	

Diff-in-Diff: Difference-in-Difference; VH: vaccine hesitant; VI: vaccination intention.

[a] For Mean Opel Score.

[b] Includes heterosexual and same sex couples.

results are thus mitigated by this limitation. In addition, our conclusions lack some degree of validity, as we were unable to assess whether the Hawthorne effect may have contributed to the participants' VI and VH. The Hawthorne effect is described as being a bias related to a change in behaviour of participants/staff following their recognition of being observed or through desirability concerns, which can alter results [38]. As this was a parallel, rather than a cluster RCT, staff and patients were well aware that of the study intervention, which may have influenced practice or beliefs in the study setting. Another limitation is that external generalisability may be compromised by the fact that this study was conducted in tertiary care centres. Patients giving birth in primary care centres, which represent 75% of all births in the Province of Quebec [39], may have other opinions or may have received the study intervention differently. However, vaccine coverage of children born in areas with and without tertiary care centres are similar throughout Quebec [4], which reduces the effect of this bias. Moreover, the fact that the post-intervention questionnaire was administered to participants immediately following the study intervention may have positively influenced their answers and VI, as per social desirability bias. However, this methodological approach was adopted in order to measure the direct effect of the study intervention and not be mitigated by other external factors on a more long-term basis.

Conclusion

To our knowledge, this is the first study of its kind comparing the efficacy of an MI-based intervention on VI and VH in a large number of participants pre- and post-intervention. Although non-controlled (as per the study's design), our results show the efficacy of our MI-based post-partum intervention in providing parents of newborns with individually-tailored immunisation decision-making and educational support. This intervention reduced parental VH while enhancing VI for their infant at 2 months of age. Going forward, we aim to assess the impact of such an intervention on child vaccine coverage at later ages and to correlate these with VI and VH scores.

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Conflict of interest

None declared.

Authors' contributions

AG created the PromoVac strategy and conceived, designed and coordinated the study. He was the principal investigator of the RCT and responsible of the recruitment and data collection at the CIUSSS de l'Estrie - CHUS maternity ward. He also participated in data interpretation, wrote and reviewed/edited the manuscript. MCB was involved in data interpretation and analyses and drafted the first version of the manuscript. TL participated in the recruitment and data collection at the CIUSSS de l'Estrie - CHUS maternity ward. He also participated in the study design conception and data interpretation and reviewed/edited the manuscript. FDB, BT and CQ were site lead investigators at the Quebec and Montreal maternity wards. They were involved in study design conception, responsible of recruitment, data collection and also reviewed/edited the manuscript. NB, CS, PDW and GP participated in the study design conception and reviewed/edited the manuscript. AF participated in the training of the research assistants and the recruitment and data collection at the CIUSSS de l'Estrie - CHUS maternity ward, reviewed/edited the manuscript. MO performed data analyses and participated in data interpretation and reviewed/edited the manuscript. VG participated in data interpretation and reviewed/edited the manuscript. MCJ participated in the training of the research assistants. She also participated in the study design conception and reviewed/edited the manuscript. ED participated in study design conception and data interpretation. She reviewed/edited the manuscript. All authors made substantial contributions to the conception and design of the work, were involved in drafting and revising the manuscript, and approved its final version as submitted.

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Population perception of mandatory childhood vaccination programme before its implementation, France, 2017

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Background: Vaccination policy in France was previously characterised by the coexistence of eight recommended and three mandatory vaccinations for children younger than 2 years old. These 11 vaccines are now mandatory for all children born after 1 January 2018. **Aim:** To study the French population's opinion about this new policy and to assess factors associated with a positive opinion during this changing phase. **Methods:** A cross-sectional survey about vaccination was conducted from 16 November–19 December 2017 among the GrippeNet.fr cohort. Data were weighted for age, sex and education according to the French population. Univariate and multivariate analyses were performed to identify factors associated with a favourable opinion on mandatory vaccines' extension and defined in the '3Cs' model by the World Health Organization Strategic Advisory Group of Experts working group on vaccine hesitancy. **Results:** Of the 3,222 participants (response rate 50.5%) and after adjustment, 64.5% agreed with the extension of mandatory vaccines. It was considered a necessary step by 68.7% of the study population, while 33.8% considered it unsafe for children and 56.9% saw it as authoritarian. Factors associated with a positive opinion about the extension of mandatory vaccines were components of the confidence, complacency and convenience dimensions of the '3Cs' model. **Conclusions:** In our sample, two thirds of the French population was in favour of the extension of mandatory vaccines for children. Perception of vaccine safety and benefits were major predictors for positive and negative opinions about this new policy.

Introduction

Vaccination suffers in several countries from growing scepticism [1,2]. This complex phenomenon, also known as 'vaccine hesitancy', is defined by the World Health Organization (WHO) as a 'delay in acceptance or refusal of vaccines despite availability of vaccination services' [3]. According to the Strategic Advisory Group of Experts (SAGE) working group on vaccine hesitancy, vaccination determinants belong to the '3Cs' model, composed of confidence, convenience and complacency factors [4]. The confidence dimension refers to the trust in the effectiveness and safety of vaccines, in the system that delivers them and in the motivations of vaccination policymakers. The complacency dimension refers to the perception that vaccination is still a necessary preventive action and the convenience dimension refers to availability and accessibility of vaccines [4]. In France, the confidence dimension has been weakened by several controversies; for example, by claims that the hepatitis B virus (HBV) vaccine might be linked to multiple sclerosis or by safety concerns about human papillomavirus (HPV) vaccine, even though no scientific data support these theories [5,6]. The mass vaccination campaign to protect the French population against the pandemic influenza A(H1N1) in 2009 also appears to have affected population confidence in vaccine safety. The accelerated authorisation procedure to market pandemic vaccines called their efficacy and safety into question, as well as the actual motivations of pharmaceutical firms. Moreover, the public health authorities lost credibility because of the contrast between the large size of the vaccination campaign and the small proportion of the population that was actually vaccinated during the pandemic [7]. Information sources used by the general population

Table 1

Socio-demographic characteristics of survey respondents, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

Socio-demographic characteristics	Data from GrippeNet survey			French population data (%)
	Raw number	Raw percentage (%)	Weighted percentage[a] (%)	
Sex				
Female	2,027	62.9	52.4	52.4
Male	1,195	37.1	47.6	47.6
Age (years)				
18–34	256	7.9	20.9	20.9
35–64	1,807	56.1	54.0	54.0
65–90	1,159	36.0	25.1	25.1
Level of education				
High school diploma	605	18.8	16.7	16.7
›High school diploma	2,135	66.3	27.8	27.8
‹High school diploma	482	14.7	55.6	55.6
Occupation				
Working	1,551	48.8	51.4	53
Student	26	0.8	2.3	4
Unemployed	67	2.1	2.7	5
Stay at home/sick leave	128	4.0	4.7	38[b]
Retired	1,409	44.3	38.9	
Household composition				
Living with children	2,436	75.8	76.2	NA
Living without children	778	24.2	23.8	NA
Place of residence				
Rural	609	18.9	23.2	25
Urban	2,613	81.1	76.8	75
Geographic division (according to French phone area codes)				
1 – Île-de-France (including Paris)	933	28.9	15.7	19
2 – North West	656	20.4	19.5	20
3 – North East	317	19.1	21.1	22
4 – South West	564	17.5	30.3	25
5 – South East	452	14.0	13.4	14

NA: data not available.

[a] Weighted on age, sex and level of education of the French population data.

[b] Percentage of 'Stay at home/sick leave' and 'Retired' in the overall French population

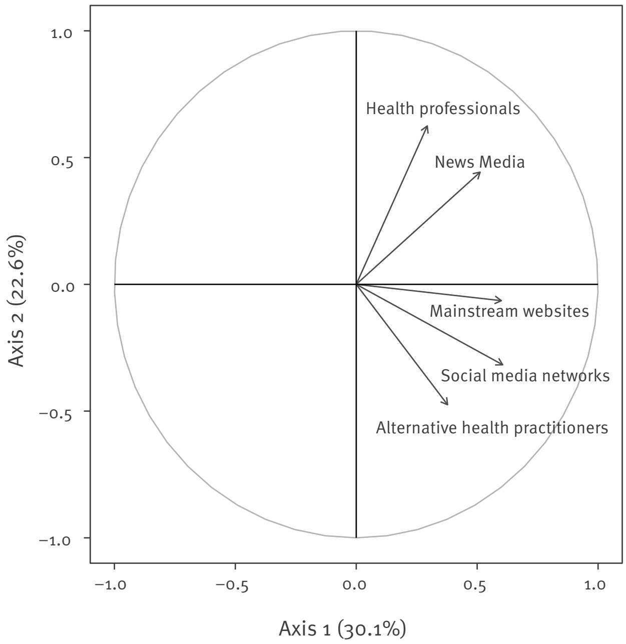
may also influence beliefs about vaccine safety and efficacy, attitude towards vaccination and the level of knowledge about vaccines [8-10]. Several studies have shown that health professionals' recommendations have a positive influence on vaccination behaviour, whereas the Internet has played a large role in disseminating anti-vaccination information [8,9,11]. Negative content related to vaccination tends to proliferate on the Internet, where anti-vaccination arguments are more present, have greater visibility and are rarely countered [10].

In order to address vaccine hesitancy and thus improve vaccination coverage, several new measures were set up in France. For example, in 2016 the national public health agency (Santé publique France) launched the website *Vaccination Info Service* to provide reliable information about vaccination [12]. Concerning the influenza vaccine, since 2017 French government have allowed pharmacists to administer vaccines to adults who have already had a vaccination in the past in order to increase convenience and expand access to vaccination. A new vaccination policy for children was also set up in France in 2018.

Until 2018, French vaccination policy was characterised by the coexistence of recommended and mandatory vaccinations. For newborns, measles-mumps-rubella (MMR), pertussis, pneumococcus, HBV, meningitis C and *Haemophilus influenzae* vaccinations were recommended, whereas diphtheria, tetanus and poliomyelitis (DT-polio) vaccinations were mandatory.

Figure 1

Results of the principal component analysis on the level of trust in different sources of vaccination information, perception of mandatory childhood vaccination programme study, France, 2017



In 2004, the French public health law set a vaccination coverage goal of 95% for children vaccine-preventable diseases. In 2015, only one childhood vaccine reached and surpassed that goal: the mandatory DT-polio vaccine, with 99% coverage. Coverage for three doses of HBV vaccine was estimated at 88%, for two doses of MMR vaccine at 80% and for at least one dose of meningococcal vaccine at 78% by the age of 24 months [13]. A French study revealed that non-mandatory vaccinations were perceived as optional and not as safe and effective as mandatory ones [14]. In order to raise vaccination coverage and restore trust in vaccines, the French government decided to make all eight recommended vaccines mandatory for all children born after 1 January, 2018 [13,15,16]. Public opinion was central to this decision. Indeed, this measure resulted from a citizen consultation on vaccination that took place in 2016, in which the point of view of various groups was analysed: the general population, health professionals, researchers in the humanities and social sciences, and experts on vaccines [16]. However, some studies showed that policies with mandatory vaccination have been controversial, especially in a context of mistrust towards vaccination [17], and could generate opposition from anti-vaccine activists [16,18].

Vaccination policies vary widely between European countries, from no recommended vaccines at all, to entirely mandatory childhood vaccination programmes [19]. In Italy, the low immunisation levels and negative trends also led to the introduction of mandatory vaccination in July 2017 for 10 infectious diseases [11,19]. A few months before this new obligation, an Italian study found that the majority of 1,820 interviewed pregnant women (81.6%) were in favour of compulsory vaccination and that information sources and confidence towards health professionals were the main determinants of acceptance of mandatory vaccines [11].

The main objective of this study is to assess the French population's acceptance of this new mandatory vaccine policy in France and to identify factors associated with its favourable regard during this transitional phase in the end of 2017, in order to guide future public health policies.

Methods

We conducted a cross-sectional survey on GrippeNet.fr participants from November–December 2017, just before implementation of the new vaccination policy in France.

Population

The study was conducted using data collected in the cohort GrippeNet.fr, a web-based participative study conducted in France since 2012 [20]. This project is part of a European multicentric project, Influenzanet (http://www.influenzanet.eu), which allows monitoring of influenza-like illness diffusion directly in the general population. The inclusion criteria to participate in the GrippeNet.fr study include: residence in France and access to the Internet. Upon registration, participants are asked to complete a baseline questionnaire covering demographic factors (age, sex), geographical factors (location of home and work/school, expressed at the municipality level), socio-economic factors (household size and composition, occupation, educational level, number of daily contacts with children or elderly people, daily transportation means) and several health-related factors. Subsequently, they are invited to describe weekly clinical symptoms during the influenza season. According to a previous study, the GrippeNet.fr population was not representative of the general population in terms of age and sex; however, all age groups were represented, including older age groups (≥ 65 years old). Once adjusted for age and sex, the GrippeNet.fr population was found to be more frequently employed, with a higher education level and vaccination rate than the general population (data from 2012 [20]).

For this study, participants in GrippeNet.fr were encouraged from 16 November–19 December 2017 to complete a questionnaire on the theme of vaccination, in addition to the weekly symptom survey. At that time, the new mandatory vaccination policy was approved by the government and was planned to start for all children born after 1 January 2018. An email and a reminder were sent to invite GrippeNet.fr participants to take part in this study. Participation was voluntary.

Table 2

Survey respondents' behaviour towards vaccination, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

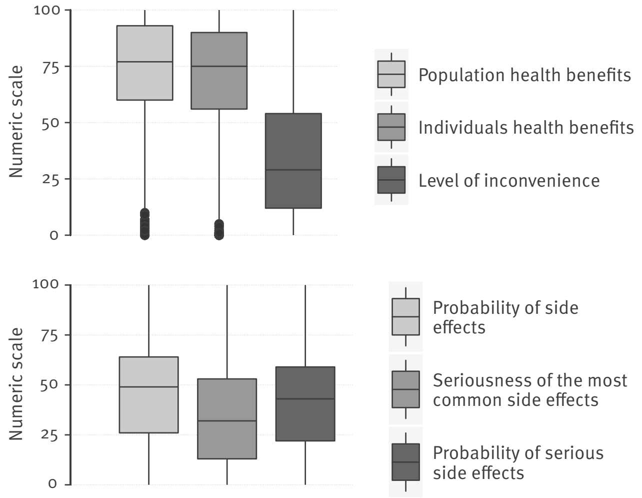
Survey responses	Raw number	Raw percentage (%)	Weighted percentage[a] (%)
Influenza vaccination in the current season			
Yes	1,494	46.4	38.9
No	1,728	53.6	61.1
Has a vaccination record			
Paper format	2,403	74.6	76.1
Electronic format	40	1.4	0.7
Both	60	1.9	2.0
None	647	20.1	19.1
Don't know	72	2.2	2.1
Declares to be up to date with immunisation schedule			
Yes	2,603	80.9	80.4
No	486	15.1	13.7
Don't know	133	4.1	5.9
Aware of Santé publique France's website about vaccination[b]			
Yes	377	11.7	11.6
No	2,845	86.4	86.3
Feels well informed about vaccination			
Yes	2,495	77.4	73.7
No	727	22.6	26.3
Consults as a vaccination information source (multiple-answers question)			
News media	1,547	48.0	49.2
Health professionals	2,181	67.7	68.1
Institutional sources	1,559	48.4	45.0
Scientific publications	672	20.9	16.7
Mainstream websites	443	13.7	14.9
Alternative health practitioners	261	8.1	9.4
Social media networks	130	4.0	6.2
None/Don't know	151	4.7	5.0
Trusts as an information source (multiple-answers question)			
News media	1,540	47.8	47.9
Health professionals	2,762	85.7	85.4
Mainstream websites	1,067	33.1	36.9
Alternative medicine professionals	1,255	39.0	45.5
Social media networks	138	4.3	7.7
Trusts as an information source (grouping by principal component analysis)			
Practitioners and/or news media (missing values: 235)	2,784	93.2	92.0
Social media network and/or mainstream websites and/or alternative practitioners (missing values: 303)	1,110	38.0	42.1
Personal reasons for getting vaccinated (multiple-answers question)			
Obligation only	184	5.7	9.0
Individual protection	2,726	84.6	80.2
Family protection	2,167	67.3	61.1
Population protection	2,262	70.2	59.6
None/Don't know	94	2.9	4.3
Thinks vaccines are thoroughly tested			
Yes	2,434	75.5	70.4
No	788	24,5	29,6
In favour of vaccination by pharmacists			
Yes	2,356	73.1	67.5
No/Don't know	866	26.9	32.5
In favour of vaccination by occupational physician (missing values: 50)			
Yes	2,108	66.4	62.7
No	297	9.4	14.4
Not concerned	817	24.2	22.8

[a] Weighted on age, sex and level of education of the French population.

[b] In 2016, the national public health agency (Santé publique France) launched the website Vaccination Info Service to provide reliable information about vaccination to the general population in France.

Figure 2

Benefits and risks of vaccination, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)



Perceptions were scored on a scale of 0 to 100, with 0 meaning the lowest benefit, level of inconvenience, probability or seriousness and 100 meaning the highest benefit, level of inconvenience, probability or seriousness, respectively.

Inclusion criteria

From the GrippeNet.fr participant pool, we included only participants who: were between 18–90 years old, completed at least one baseline questionnaire, were living in mainland France, had participated in 2016/17 or 2017/18 GrippeNet.fr seasons by filling in at least one questionnaire on weekly clinical symptoms.

Sample size calculation

A previous study showed that around 56% of the French population was in favour of the extension of the mandatory vaccination in 2008 [21]. Considering this proportion, we set a confidence level at 95% and 5% margin of error. The final sample size was expected to be at least 1,208 completed questionnaires.

Questionnaire

The questionnaire was built according to the literature [22,23]. It was then discussed and validated by a panel of experts in the vaccination field: members of the national public health agency (Santé publique France), immunologists, epidemiologists, a general practitioner and a sociologist, with support from biostatisticians. The survey included 36 questions, either optional or mandatory, about vaccination. Five of them were multiple-answers questions, 19 were single-choice questions, seven were numerical scale from 0 to 100 questions and five were free text questions (not analysed here).

Questions were divided into three main categories: (i) behaviour, awareness and opinion towards vaccination (influenza vaccination in the current season, feeling well-informed about vaccines, sources of information towards vaccination, trust in different sources), (ii) perceived risks and benefits of vaccination (population health benefits, individual health benefits, inconveniences, side effects, vaccine testing) and (iii) opinion on the extension to 11 mandatory vaccines.

Socio-demographic characteristics came from baseline questionnaires: age, sex, level of education, occupation, presence of children in the household, place of residence and geographic division (according to French phone area codes).

Questions on vaccine benefits and risk perception were evaluated with a numeric scale ranging from 0 to 100, where 0 meant least benefits, inconvenience, probability and seriousness and 100 meant most benefits, inconvenience, probability and seriousness. Inconvenience of vaccination meant both logistical and physical inconvenience of vaccination (time, money, puncture pain, etc.).

Data analyses

A description of the study population was performed and outliers were verified, corrected or excluded as needed. Duplicate questionnaires were removed (the last questionnaire completed was kept for analyses).

The French National Institute of Statistics and Economic Studies (INSEE) provided the demographic and socio-economic data of the French population.

Some variables were recoded in order to facilitate the analyses and the presentation of the results. The place of residence was defined in two categories (urban or rural), based on the geographical location and according to the INSEE definition. The opinion about new mandatory vaccines and several others variables, were split into two levels, ‘in favour’ (grouping ‘strongly agree’ and ‘agree’ together) and ‘not in favour’ (grouping ‘neither agree nor disagree’, ‘disagree’ and ‘strongly disagree’ together). We classified the neutral answer (‘neither agree nor disagree’) within the negative opinion for analyses, as neutrality may reveal either a lack of perceived benefits or doubts over the successful implementation of mandatory vaccinations. Several authors of studies on vaccine hesitancy have adopted a similar approach [1,7]. The quantitative variable concerning level of trust in institutional sources was split in two levels, ‘in favour’ for a score > 50 of 100 and ‘not in favour’ for a score ≤ 50 of 100. Other quantitative variables were stratified into quartiles, except for age, for which age groups were created: 18–34 years old, 35–64 years old, 65–90 years old.

Survey respondents were weighted to reflect the French population’s proportions on age, sex and level of education, based on the most recent INSEE data available [20]. For descriptive analysis, we expressed the raw number, the raw and weighted proportions of

Table 3

Survey respondents' opinion of new mandatory vaccines in France, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

Survey responses	Raw number	Raw percentage (%)	Weighted percentage[a] (%)
In favour of vaccination in general (missing values 10)			
Strongly agree	1,746	54.2	46.8
Agree	1,098	34.1	34.9
Disagree	288	8.9	13.8
Strongly disagree	80	2.5	4.3
Not in favour of some specific vaccines (missing values: 44)			
Yes	896	28.2	27.8
No	2,287	71.8	71.0
In favour of extension to 11 mandatory vaccines			
Strongly agree	1,123	34.9	29.6
Agree	1,011	31.4	32.8
Disagree	474	14.7	14.3
Strongly disagree	446	13.8	16.7
Neither agree nor disagree	168	5.2	6.5
New mandatory vaccines are as important as those already mandatory			
Strongly agree	977	30.3	26.4
Agree	1,133	35.2	37.6
Disagree	561	17.4	17.5
Strongly disagree	286	8.9	10.4
Neither agree nor disagree	265	8.2	8.2
This is a necessary step (missing values:249)			
Strongly agree	1,276	42.9	36.6
Agree	974	32.8	32.1
Disagree	406	13.7	10.5
Strongly disagree	215	7.2	9.7
Neither agree nor disagree	102	3.4	3.3
This measure is putting children who will be vaccinated at risk (missing values: 307)			
Strongly agree	332	11.4	11.7
Agree	555	19.0	22.1
Disagree	1,185	40.7	31.8
Strongly disagree	594	20.4	15.0
Neither agree nor disagree	249	8.5	10.2
This is an authoritarian measure (missing values 322)			
Strongly agree	931	32.1	28.6
Agree	930	32.1	28.3
Disagree	563	19.4	18.6
Strongly disagree	338	11.7	9.9
Neither agree nor disagree	138	4.8	5.0

[a] Weighted on age, sex and level of education of the French population.

the qualitative variables, and the weighted median and quartiles of the quantitative variables.

To assess the factors associated with positive opinions about the new mandatory vaccines, weighted populations were used in regression models. The effect of each explanatory variable was studied using univariate analysis first, then multivariate analysis. All collected variables were assessed by univariate analysis, and those achieving a p value < 0.20 (using the Wald test for logistic regression) and considered relevant by the authors were included in multivariate analysis. We used a principal component analysis (PCA) to identify independent dimensions of patient trust in sources of information to limit factors included in the multivariate analysis. Sources of information that contributed to the same dimension in PCA were grouped in a unique variable. A backward stepwise variable selection procedure was then used to remove factors with a p value > 0.05. Adjusted odds ratios (aORs) and 95% CIs were calculated for the determinants that remained in the final model. Missing values were indicated and were excluded from the models. All statistical analyses were performed using the R software version 3.5.0 (R Foundation, Vienna, Austria).

Ethical statement

This study was conducted in agreement with French regulations on privacy and data collection and treatment and was approved by the Comité Consultatif sur le Traitement de l'Information en matière de Recherche (CCTIRS, Advisory committee on information processing for research, authorisation 11.565) and by the Commission Nationale de l'Informatique et des Libertés (CNIL, French Data Protection Authority, authorisation DR-2012–024).

Results

Among the 6,383 GrippeNet.fr participants who fulfilled inclusion criteria, 3,222 individuals participated. The response rate was 50.5% (3,222/6,383). Duplicate questionnaires were removed (n = 63).

Socio-demographic characteristics

Before adjustment, the study population was composed of 62.9% women and 37.1% men, with a mean age of 52.7 years; 66.3% of respondents had a level of education higher than high school diploma.

After adjustment for age, sex and level of education, data showed that a majority of the population was working (51.4%) and 38.9% was retired. Most of the population was living in urban areas (76.8%) and with children (76.2%). Influenza vaccination coverage for people ≥ 65 years old was 60.9%. All the following results are adjusted (Table 1).

Behaviour, awareness and opinion towards vaccination

A large majority of respondents had only a paper vaccination record (76.1%) and thought of themselves as being up to date with the immunisation schedule (80.4%). Santé publique France's website about vaccination was little known by the study population (11.6%), whereas individuals gathered information about vaccination mostly from health professionals (68.1%), news media (49.2%) and institutional sources (45.0%). Trust in health professionals was very high (85.4%), whereas less than half of the study population trusted information delivered by the news media (47.9%) and very few trusted information found on social media networks (7.7%). Principal component analysis resulted in identifying two independent dimensions of trust in sources of information: on the one hand, a dimension of respondents who trusted health professionals or news media and on the other hand, a dimension of respondents who trusted social networks, mainstream websites or alternative health practitioners (Figure 1).

Concerning the administration of vaccination, 67.5% and 62.7% of the population approved vaccination by pharmacists and occupational physicians, respectively (Table 2 , Figure 1).

Perception of vaccination benefits and risks

Evaluation of the benefits of vaccination on individual and population health on a scale of 0 to 100, had a median score of 75.0 (interquartile range (IQR): 56.0–89.7) and 77.0 (IQR: 60.0–93.0), respectively. The median level of inconvenience was estimated at 29.0 (IQR: 12.0–54.0). The probability of side effects of any type and of serious side effects had a median of 49.0 (IQR: 26.0–64.0) and 32.0 (IQR: 13.0–53.0), respectively. Evaluation of the seriousness of the most common side effects (without specifying these side effects) had a median of 43.0 (IQR: 22.0–59.0) (Figure 2).

Opinions on vaccination and the extension to 11 mandatory vaccines

A large majority of the respondents supported vaccination in general (81.7%); however, 28.2% were not in favour of some specific vaccines. Concerning the new mandatory vaccination policy, 62.4% were in favour and 31.0% were not in favour (including 6.5% with no opinion). The new programme was considered to be a necessary step for 68.7% of the population, whereas 33.8% of participants regarded it to be a risk for children who will be vaccinated. The policy change was perceived as authoritarian by 56.9% of respondents (Table 3).

Factors associated with a favourable opinion of the extension to 11 mandatory vaccines

In univariate analysis, factors associated with a favourable attitude towards the extension to 11 mandatory vaccines were both socio-demographic and concerning behaviour and opinions towards vaccination (Table 4).

Concerning socio-demographic factors, the respondents were more favourable to the new mandatory vaccination policy if they were men (odds ratio (OR): 1.40; 95% confidence interval (CI): 1.03–1.91), had a higher educational level (OR: 1.77; 95% CI: 1.25–2.51) and lived in an urban area (OR: 1.69; 95% CI: 1.19–2.42). Regarding sources of information on vaccination, the respondents were more favourable to the new mandatory vaccination policy if they trusted news media (OR: 2.46; 95% CI: 1.81–3.33), health professionals (OR: 18.99; 95% CI: 10.10–35.70) or institutional sources (OR: 10.63; 95% CI: 7.77–14.56). They were less in favour of the new mandatory vaccination policy if they trusted alternative health practitioners (OR: 0.51; 95% CI: 0.36–0.71) and social media networks (OR: 0.49; 95% CI: 0.24–0.98).

The numeric scale questions on vaccination's benefits and risks were all significantly associated with an opinion on the new mandatory vaccination policy: the highest quartiles for variables concerning benefits of vaccination and the lowest quartiles concerning the

Table 4a

Univariate analysis for predicting favourable attitudes towards new mandatory vaccines, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

Survey responses	OR (95% CI)	p value[a]
Sex		
Female	Ref.	0.03
Male	1.40 (1.03–1.91)	
Age (years)		
35–64	Ref.	0.33
18–34	1.16 (0.66–2.02)	
65–90	0.84 (0.65–1.09)	
Level of education		
High school diploma	Ref.	<10−4
>High school diploma	1.77 (1.25–2.51)	
<High school diploma	1.02 (0.68–1.52)	
Occupation		
Working	Ref.	0.20
Student	2.22 (0.74–6.68)	
Unemployed	0.53 (0.24–1.18)	
Stay at home/sick leave	0.72 (0.40–1.28)	
Retired	0.88 (0.65–1.19)	
Household composition		
Living without children	Ref.	0.94
Living with children	0.99 (0.67–1.45)	
Influenza vaccination in the current season		
No/Don't know	Ref.	
Yes	2.75 (1.98–3.80)	<10−4
Place of residence		
Rural	Ref.	0.004
Urban	1.69 (1.19–2.42)	
Feels well informed about vaccines		
No	Ref.	<10−4
Yes	2.24 (1.63–3.06)	
Trusts as a vaccination information source		
News media	2.46 (1.81–3.33)	<10−4
Health professionals	18.99 (10.10–35.70)	<10−4
Institutional sources	10.63 (7.77–14.56)	<10−4
Mainstream websites	1.19 (0.85–1.68)	0.31
Alternative health practitioners	0.51 (0.36–0.71)	<10−4
Social media networks	0.49 (0.24–0.98)	0.04
Trusts as a vaccination information source (grouped by principal component analysis)		
Health professionals and/or news media (missing values: 235)	18.52 (10.01–34.25)	<10−4
Social media networks and/or mainstream websites and/or alternative health practitioners (missing values: 303)	1.16 (0.83–1.61)	0.37
Perceived population health benefits		
Q1 (least benefits)	Ref.	<10−4
Q2	4.07 (2.73–6.07)	
Q3	12.71 (8.46–19.10)	
Q4 (most benefits)	36.60 (22.27–60.15)	

OR: odds ratio; Q1: first quartile; Q2: second quartile; Q3: third quartile; Q4: fourth quartile; Ref.: reference.

[a] p value was estimated using Wald's test.

[b] Principal component analysis (PCA) was used to identify independent dimensions of patient trust in sources of information to limit factors included in the multivariate analysis.

Analysis was performed on data weighted on age, sex and level of education of the French population.

TABLE 4B

Univariate analysis for predicting favourable attitudes towards new mandatory vaccines, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

Survey responses	OR (95% CI)	p value[a]
Perceived individual health benefits		
Q1 (least benefits)	Ref.	<10 – 4
Q2	5.08 (3.58–7.22)	
Q3	10.61 (6.92–16.27)	
Q4 (most benefits)	19.90 (12.76–31.03)	
Perceived level of inconvenience		
Q4 (most inconvenient)	Ref.	<10 – 4
Q3	1.21 (0.81–1.82)	
Q2	2.67 (1.72–4.15)	
Q1 (least inconvenient)	4.60 (3.00–7.06)	
Perceived probability of side effects		
Q4 (most probable)	Ref.	<10 – 4
Q3	3.40 (2.27–5.09)	
Q2	5.38 (3.42–8.46)	
Q1 (least probable)	16.70 (10.11–27.60)	
Perceived seriousness of the most common side effects		
Q4 (most serious)	Ref.	<10 – 4
Q3	2.52 (1.66–3.82)	
Q2	6.40 (4.35–9.43)	
Q1 (least serious)	17.67 (11.53–27.09)	
Perceived probability of serious side effect		
Q4 (most probable)	Ref.	$<10^{-4}$
Q3	1.68 (1.15–2.46)	
Q2	4.36 (2.64–7.21)	
Q1 (least probable)	13.09 (8.14–21.03)	
Personal reasons for getting vaccinated		
Protection (personal, family, population)	Ref.	$<10^{-4}$
Obligation only	0.13 (0.05–0.33)	
None/Don't know	0.14 (0.06–0.31)	
Thinks vaccines are thoroughly tested		
No	Ref.	$<10^{-4}$
Yes	15.49 (10.77–22.28)	

OR: odds ratio; Q1: first quartile; Q2: second quartile; Q3: third quartile; Q4: fourth quartile; Ref.: reference.

[a] p value was estimated using Wald's test.

[b] Principal component analysis (PCA) was used to identify independent dimensions of patient trust in sources of information to limit factors included in the multivariate analysis.

Analysis was performed on data weighted on age, sex and level of education of the French population.

probability and seriousness of side effects and the level of inconvenience were associated with a favourable opinion (Table 4).

In multivariate analysis, factors significantly associated with a favourable opinion on the new mandatory vaccination policy were: believing that vaccination brings a very important health benefit to the population (aOR: 8.17; 95% CI: 4.40–15.16), thinking that vaccines are thoroughly tested (aOR: 5.27; 95% CI: 3.54–7.85), trusting health professionals or news media regarding vaccine topics (aOR: 4.34; 95% CI: 2.26–8.32) and expecting that the most common vaccination side effects are not severe (aOR: 3.30; 95% CI: 1.91–5.72) (Table 5).

Discussion

This work uses data from the GrippeNet.fr study to provide an overview of opinions about the new mandatory vaccination law in France, which has been in place since 1 January 2018, in the general population. In our sample, the French population was rather in favour of the extension of mandatory vaccines for children. Perception of vaccine safety and benefits were major predictors for positive opinions towards this new policy.

In our sample of the French population, the proportion in favour of vaccination was 81.7%. This global result is consistent with a random phone survey conducted in France, the French health barometer, which found that 75.1% of respondents were in favour of vaccination in general in 2016 [24]. An Italian survey, also from 2016, found that 83.7% of parents were pro-vaccination [25]. However, these positive results need to be qualified. First, not all vaccines receive a favourable opinion from the population: in 2015, another study among Grippenet.fr participants showed that only 39% of the French population have a positive opinion about influenza vaccination in France [7]. Moreover, doubts about vaccine safety remain, as demonstrated in our study, wherein a third (33.8%) of the population regarded the new vaccination policy to be a risk for children who will be vaccinated. In 2016, an international study pointed out that vaccine safety sentiment is particularly negative in France and Italy, with 41.0% and 18.7% of the population finding vaccines unsafe, respectively [1]. In addition, half of the French parents (46%) were considered vaccine hesitant, following the WHO SAGE definition in 2016 [22].

According to the SAGE working group on vaccine hesitancy, vaccination determinants belong to the '3Cs' model, composed of confidence, convenience and complacency factors [4]. In our study, several variables concerning the confidence in vaccines (i.e. a perception of low severity of the most common side effects of vaccines, a belief that vaccines are thoroughly tested and confidence in health professionals and news media concerning vaccine topics) and the complacency toward vaccines (i.e. a perception that vaccination brings a very important health benefit to the population) were associated with a positive opinion of the new mandatory vaccination policy in multivariate analysis. The question regarding the convenience dimension found an association between a low level of perceived inconvenience and a favourable opinion in univariate analysis. All of these results confirmed the relevance of the '3Cs' model in the field of vaccination acceptance [23]. Likewise, according to the health belief model, vaccination resulted from the balance between perceived risks and benefits [26]. Beliefs about vaccine safety and efficacy are also frequently associated with opinions on vaccination in other studies [2,27-29]. Controversies about vaccine safety are widespread on the Internet and some news media, causing doubts about vaccine safety, as demonstrated by an Italian study exploring the relationship between MMR vaccination coverage and online search trends asocial network activity on the topic 'autism and MMR vaccine' [5,9]. Therefore, when it comes to vaccines, reliable sources of information are crucial and delivering clear information on vaccine safety should be a priority to overcome vaccine hesitancy [3,11]. In France, Santé publique France's *Vaccination Info Service* website was created for this purpose, but our study reveals that it remained little known by the population [12]. Further efforts are necessary to increase its diffusion and potential impact.

Health professionals play a key role in delivering information on vaccination to the population [3]; they were the most used (by 68.1% of the population) and trusted (85.4%) source of information in our study, confirming what was found previously by the 2016 health barometer in France (81.3% of parents seeking information from a physician about immunisations [24]) and by an American study (90% of parents receiving vaccine information from their child's healthcare provider between 2002 and 2005 [30]). However, several studies conducted in France revealed a considerable level of vaccine hesitancy among general practitioners, possibly reinforcing patients' vaccine hesitancy [31,32].

In our sample of the French population, two thirds were in favour of the new mandatory vaccines. We found a clear difference between being in favour of vaccination and being in favour of mandatory vaccination (81.7% and 64.5%, respectively), pointing to the reluctance of the population when public health interventions are of mandatory nature. More than half of the population deemed this measure authoritarian (56.9%), as opposed to allowing for individual freedom, as is frequently claimed by anti-vaccination groups. Ten years before our study, in 2008, a French opinion survey assessed that only 56.5% of the general population was in favour of mandatory vaccination. The authors suggested that this low percentage may have been the result of a fear of reduced dialogue and a lack of information shared with parents about immunisation, or perhaps that mandatory vaccination was perceived as a violation of individual rights. However, it is interesting to note that in this study another possible response to this question was to be in favour of certain specific mandatory vaccinations, but not all (35% of the study population), which is consistent with our study (28.2%). Some respondents had a negative opinion of certain vaccinations, preventing them from being in favour of the full extension of the mandatory vaccination programme [21]. In particular, HBV immunisation is frequently considered unjustified in children, because of past unfounded controversies and as the disease primarily occurs in adults [21,22]. The feeling of loss of individual choice was also described in an American study that analysed the effects and difficulties of mandatory vaccination programmes implemented in the United States (US). The authors of this study also observed a decrease in perceived necessity and an increase in safety concerns, which led to a steady increase in exemption rates in the US [17].

No socio-demographic factors were associated with a favourable opinion on mandatory vaccines' extension in multivariate analysis. In univariate analysis we assessed that being male, having a high level of education and living in an urban area were positively

Table 5

Multivariate analysis for predicting favourable attitudes towards new mandatory vaccines, perception of mandatory childhood vaccination programme study, France, 2017 (n = 3,222)

Survey responses	aOR (95% CI)	p value[a]
Sex		
Female	NS	NS
Male		
Level of education		
High school diploma	NS	NS
>High school diploma		
<High school diploma		
Place of residence		
Rural	NS	NS
Urban		
Feels well informed about vaccines		
Yes	NS	NS
No		
Trusts (grouped by principal component analysis[b])		
Health professionals and/or news media (Missing values: 235)	4.34 (2.26–8.32)	$<10^{-4}$
Perceived population health benefits		
Q1 (least benefits)	Ref.	$<10^{-4}$
Q2	1.53 (0.96–2.45)	
Q3	3.49 (2.18–5.59)	
Q4 (most benefits)	8.17 (4.40–15.16)	
Perceived individual health benefit		
Q1 (least benefits)	NS	NS
Q2		
Q3		
Q4 (most benefits)		
Perceived level of inconvenience		
Q1 (least inconvenient)	NS	NS
Q2		
Q3		
Q4 (most inconvenient)		
Perceived probability of side effects		
Q1 (least probable)	NS	NS
Q2		
Q3		
Q4 (most probable)		
Perceived seriousness of the most common side effects		
Q1 (least serious)	3.30 (1.91–5.72)	$<10^{-4}$
Q2	2.46 (1.49–4.06)	
Q3	1.70 (1.04–2.80)	
Q4 (most serious)	Ref.	
Perceived probability of serious side effect		
Q1 (least probable)	NS	NS
Q2		
Q3		
Q4 (most probable)		
Personal reasons for getting vaccinated		
Obligation only	NS	NS
Protection (personal, family, population)	NS	NS
None/Don't know	NS	NS
Thinks vaccines are thoroughly tested		
Yes	5.27 (3.54–7.85)	$<10^{-4}$
No	Ref.	

NS: non-significant result ($p > 0.05$); OR: odds ratio; aOR: adjusted odds ratio, Q1: first quartile; Q2: second quartile; Q3: third quartile; Q4: fourth quartile; Ref.: reference.

[a] p values were estimated using Wald's test.

[b] Principal component analysis (PCA) was used to identify independent dimensions of patient trust in sources of information to limit factors included in the multivariate analysis.

Analysis performed on data weighted on age, sex and level of education of the French population.

associated with acceptance of mandatory vaccines' extension. Several studies reported higher levels of confidence in vaccine safety among people with higher educational levels or income [33]. On the contrary, a recent review on determinants of parental decision-making about vaccination revealed an association between parents' higher socio-economic status and anti-vaccination attitudes in high-income countries, such as the US, France or Italy [3]. In France, the association between high economic status and a positive opinion of vaccination was observed in 2016, and of mandatory immunisation in 2008 [21,24]. Thus, interpretation of individual determinants for predicting an opinion on vaccination remains complex and challenging [34].

In the context of political changes in vaccination policies in European countries and efforts to overcome vaccine hesitancy, this study may help to improve understandings of the dimensions that impact populations' opinions on mandatory vaccination programmes [19]. Furthermore, this study may assist countries in deciding whether or not to implement mandatory vaccination programmes and associated measures to increase vaccination coverage.

It is important to note that we deployed our questionnaire a few months after the initial communication by the French Ministry of Health about the mandatory vaccination policy change that occurred in July 2017. This timing allowed us to gather opinions and perceptions while the change was being implemented, and was possible thanks to the use of online participatory technologies. However, the topic's high level of coverage in the news media, concerning both the government's commitment in favour of vaccination and the anti-vaccination movement's claims, may have affected the population's opinions at that time. Thus, the early timing of this study may allow it to become a reference for further studies evaluating trends in public opinion on vaccination policy.

This work is a cross-sectional, self-administered study and the global response rate of 50.5% may have induced a selection bias between respondents and non-respondents; in particular, participants might be more sensitive to health issues or more interested in the vaccination topic than non-respondents. Despite weighting our data to match the French population on age, sex and level of education, our population was still not fully representative of the French population. Influenza vaccination coverage for people ≥ 65 years was higher than in the French general population of the same age group (60.9% vs 49.7% [35]). The over-representation of vaccinated individuals in the sample is a critical point in the evaluation of the population's opinion on vaccination policy. Adjusting for age, sex, education and vaccination status would require an age/sex/education classification of vaccinated individuals in the general population that is not yet available in France.

A bigger difference was expected between the probability of serious side effects and the probability of side effects of any type (median of 32 and 49, respectively), which suggested that respondents may have misread/misunderstood the question or that they may have found difficulty in providing an evaluation on numeric scales.

In conclusion, the French population in our sample was rather in favour of the policy to extend mandatory childhood vaccination. Perceptions seem to depend on the degree of trust in the safety and benefits of vaccination. By evaluating the general population's opinion on mandatory vaccination, this study may contribute to guide action in order to reduce vaccine hesitancy. Long-term benefits of this measure and population acceptance should be evaluated in the near future.

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Conflict of interest

None declared.

Authors' contributions

PM, AG, JR, TG, TL, MD, CG, CT, TH, CJ, VC, TB and LR conceived and designed the experiments. PM, TL AG, JR, TG, CJ, CG and LR performed the experiments. PM, TL and LR analysed the data. PM, AG, JR, TG, TL, MD, CG, CT, TH, CJ, VC, TB and LR wrote the paper.

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Childhood vaccinations: knowledge, attitudes and practices of paediatricians and factors associated with their confidence in addressing parental concerns, Italy, 2016

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Background: Paediatrician recommendations are known to influence parental vaccine decisions. **Aim:** Our aim was to examine vaccination knowledge, attitudes and practices among paediatricians in Italy and identify factors associated with their confidence in addressing parental questions. **Methods:** An electronic questionnaire survey was conducted from February to March 2016, among a sample of Italian paediatricians. **Results:** The survey was completed by 903 paediatricians (mean age: 56 years). Of 885 who responded to the specific question, 843 (95.3%) were completely favourable to vaccinations. Sixty-six per cent (570/862) felt sufficiently knowledgeable about vaccinations and vaccine-preventable diseases to confidently discuss them with parents. Paediatricians who were male, who were 55 years or older, who had participated in training courses in the last 5 years, who reported that taking courses and reading the scientific literature had contributed to their knowledge, or who had implemented vaccination promotion activities, felt more knowledgeable than other paediatricians. When asked to rate their level of agreement with statements about vaccine safety and effectiveness, only 8.9% (80/903) responded fully as expected. One third (294/878) did not systematically verify that their patients are up to date with the immunisation schedule. Only 5.4% (48/892) correctly identified all true and false contraindications. **Conclusions:** The majority of paediatricians in Italy are favourable to vaccination but gaps were identified between their overall positive attitudes and their knowledge, beliefs and practices. Targeted interventions are needed aimed at increasing paediatricians' confidence in addressing parents' concerns, strengthening trust towards health authorities and improving systems barriers.

Background

Vaccination is one of the most important public health measures developed in the history of medicine, allowing for the primary prevention of serious infectious diseases. Currently, many countries in Europe and worldwide, including Italy, are facing declining childhood vaccination rates. This poses a threat to herd immunity and increases the risk for outbreaks of vaccine-preventable diseases (VPD). Vaccine hesitancy, defined by the Strategic Advisory Group of Experts on Immunization (SAGE) as a "delay in acceptance or refusal of vaccines despite availability of vaccination services" is believed to be one of the reasons for the decreasing coverage [1]. According to SAGE, "vaccine hesitancy is complex and context specific varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence" [1]. Vaccine-hesitant individuals may accept some vaccines and refuse or delay others, although some remain unsure about their decision. Some studies have identified vaccine safety concerns as the main reason for not vaccinating or delaying vaccinations [2-4].

Healthcare workers (HCW) are considered the most trusted source of information on vaccines by parents, and their recommendations are known to influence parental vaccine decisions [5,6]. Paediatricians in particular are in a good position to explain to parents the risks of VPD and the benefits and risks of vaccination, and to understand and respond to worries and concerns that parents may have about vaccinating their children. However, HCW, including paediatricians, may themselves have concerns regarding the usefulness of vaccines and vaccine side effects and be vaccine-hesitant

Table 1

Main demographic and professional characteristics of participating paediatricians, survey on vaccine knowledge, Italy, 2016 (n = 903)

Characteristic (with number who responded to the specific question)		n	%
Age in years (n=885)	<35	39	4.4
	35–44	96	10.8
	45–54	169	19.1
	55–64	487	55.0
	>64	94	10.6
Sex (n=882)	Male	308	34.9
	Female	574	65.1
Country where medical degree was obtained (n=875)	Italy	864	98.7
	Foreign	11	1.3
Years since medical degree (n=883)	0–5	3	0.3
	6–10	45	5.1
	11–20	94	10.6
	>20	741	83.9
Years since specialty certification (n=872)	0–5	63	7.2
	6–10	46	5.3
	11–20	77	8.8
	>20	686	78.7
Type of practice (n=880)	Primary care paediatrician	629	71.5
	Community paediatrician	17	1.9
	Hospital paediatrician	161	18.3
	Private practice	57	6.5
	Retired	16	1.8
Practice location (n=883)	Large city (>250,000 population)	182	20.6
	Medium-sized city (50,000–250,000 population)	276	31.3
	Small city/town (<50,000 population)	425	48.1
Years of activity as a paediatrician (n=882)	<1	16	1.8
	1–5	61	6.9
	6–10	47	5.3
	>10	758	85.9
Vaccine courses or conferences in previous 5 years (n=870)	No	165	19.0
	Yes	705	81.0
Vaccinology training (n=882)	No	594	67.3
	Yes	288	32.7
Degree of influence of formal university training (n=717)	Low	252	35.1
	High	465	64.9
Degree of influence of the scientific literature (n=780)	Low	40	5.1
	High	740	94.9
Degree of influence of conference participation (n=803)	Low	29	3.6
	High	774	96.4
Degree of influence of institutional websites (n=652)	Low	133	20.4
	High	519	79.6
Degree of influence of non-institutional websites (n=596)	Low	470	78.9
	High	126	21.1
Degree of influence of discussions with other colleagues (n=679)	Low	107	15.8
	High	572	84.2
Implemented vaccination initiatives (n=901)	No	250	27.7
	Yes	651	72.3
Administers vaccines (n=896)	No	479	53.5
	Occasionally	302	33.7
	Regularly	115	12.8

Denominators differ for each characteristic as not all paediatricians responded to all questions.

Figure 1

Number of participating paediatricians per 100,000 paediatric population aged 0–14 years, by region, Italy, 2016

regarding vaccinations for themselves, their children or their patients [5-7]. Their beliefs and attitudes may lead them to recommend vaccines to their patients less frequently and may have a negative influence on parents' vaccination acceptance [8]. Few published studies from the European Union (EU) have evaluated paediatricians' knowledge, attitudes and practice regarding VPD and vaccines [9,10].

In Italy, everyone must be registered with a primary care provider in order to access healthcare services of the national healthcare system. Primary care paediatricians (PCP) provide general and preventive (well-child) healthcare to children up to 14 years of age but most usually do not provide vaccinations directly to the children registered in their practices. Childhood vaccinations are publicly funded, provided free of charge mainly at vaccination centres managed by local health authorities, and administered mainly by public health physicians or nurses. In some areas, PCP may support vaccination services according to local agreements. Community paediatricians work in outpatient services provided by local health authorities and perform various activities, often in collaboration with PCP and other health professionals, including immunisations, health education, parental counselling as well as management of chronic illnesses and of behavioural and developmental problems. Paediatricians in private practice may deliver vaccinations in their offices.

Overall vaccination rates for most VPD (tetanus, diphtheria, pertussis, poliomyelitis, hepatitis B and *Haemophilus influenzae* type b), but not for measles, have historically been very high in Italy and this has resulted in either elimination or a decreased incidence of these diseases. However, since 2013, uptake has been steadily decreasing and pockets of vaccination opponents exist in some Regions [2]. In 2017, more than 5,000 measles cases including four deaths were reported in Italy, 93% of which occurred in persons that were either not vaccinated or vaccinated with only one dose of measles-containing vaccine. About 25% of measles cases occurred in children up to 14 years of age [11,12].

Given the critical role that paediatricians play in providing information to parents about childhood vaccinations, we performed a study to examine vaccination knowledge, attitudes and practices among paediatricians in Italy, and to identify factors associated with their feeling sufficiently knowledgeable about vaccinations and VPD to be able to confidently address parental questions. The survey was part of a wider project funded by the Ministry of Health, aiming to describe vaccine refusal in Italy and to prepare ad hoc communication tools. It was conducted before the introduction in Italy of a law extending the number of mandatory vaccinations from four (poliomyelitis, tetanus, diphtheria and hepatitis B) to 10 (pertussis, *Haemophilus influenza* type b vaccine, measles-mumps-rubella and varicella, in addition to the four already mandatory) in children up to 16 years of age. Since September 2017, proof of vaccination has been required to attend kindergarten and nurseries; lack of compliance in older children does not limit their access to school, but financial sanctions are applied to parents refusing vaccination.

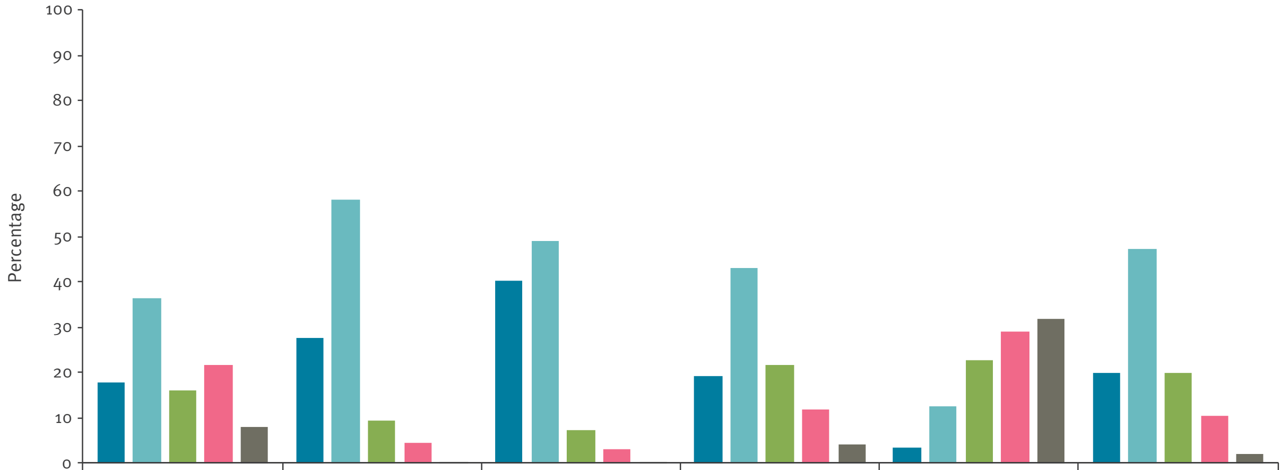
Methods

A self-completed electronic survey, developed with the SurveyMonkey internet platform (San Mateo, California, United States (US)), was conducted from February to March 2016 among Italian paediatric specialists registered with any of the five main scientific paediatric societies in Italy. About 10,000 of the ca 13,000 paediatricians in Italy are members of the largest of the five paediatric societies and ca 90% of the ca 7,700 PCP are members of the second largest society. A third society has 1,400 members, and we are not aware of the total number of members of the two remaining societies. Paediatricians may be members of more than one scientific society.

A two-step procedure was used to enrol paediatricians in the study. Firstly, we contacted the five paediatric societies and asked them to send an email to all their registered members to explain the aims of the survey and ask them whether they were willing to participate.

Figure 2

Paediatricians' responses to the question 'How much do/have the following six training tools influence/influenced your knowledge on vaccine-preventable diseases?', Italy, 2016 (n = 903)



	Formal university training (n=854)	Published scientific literature (n=860)	Training courses/ conferences (n=866)	Institutional websites (n=834)	Non-institutional websites (n=773)	Exchanges with colleagues (n=849)
Very strongly	17.9	27.8	40.2	19.2	3.6	19.9
Strongly	36.5	58.3	49.2	43.1	12.7	47.5
No opinion	16.0	9.3	7.3	21.8	22.9	20.0
Very little	21.6	4.5	3.0	11.9	29.0	10.5
Not at all	8.0	0.1	0.4	4.1	31.8	2.1

We then sent a link to the electronic questionnaire to those paediatricians who expressed an interest in participating. The survey was completely anonymous and did not collect personal identifiers nor sensitive data; it therefore did not require approval by an Ethics Committee.

Questionnaire

We developed the questionnaire after reviewing the literature and also used or adapted some questions used in previous studies on this topic [13-15]. The questionnaire consisted of two sections (Supplement). The first section contained 20, mostly closed-ended questions, to collect information about paediatricians' (i) knowledge regarding vaccine effectiveness and true and false contraindications (questions 15–16), (ii) perceptions regarding frequency and severity of VPD, vaccine safety, parents' level of concern about vaccination and their reasons for refusing vaccinations for their child (questions 7–8, 13–14, 17), (iii) beliefs and attitudes towards vaccinations (questions 18–19) and (iv) professional experience and practice regarding vaccinations (questions 1–6, 9–12, 20). To assess paediatricians' beliefs and attitudes towards vaccinations, they were asked to rate their level of agreement with each of 19 statements according to a five-point Likert scale (completely disagree, partially disagree, no opinion, partially agree, completely agree). To evaluate their knowledge regarding vaccine contraindications, they were asked to classify 11 clinical conditions or situations as false contraindications, temporary contraindications or permanent contraindications to administering hexavalent vaccine (containing diphtheria, tetanus, acellular pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B components).

In the second section, made up of 16 questions (questions 21–36), paediatricians were asked to provide demographic information, information regarding their training, and type and years of practice. We also asked participants whether they considered themselves sufficiently knowledgeable about vaccines and VPD (including incidence, complications, contraindications and vaccine benefits and risks) to be able to confidently address parental questions, and if not, for which of eight topics (listed in the questionnaire) they would like to receive further training and in which order of priority (1 lowest priority to 8 highest priority). We then calculated an average score for each topic. The questionnaire was pilot-tested for clarity, length and ease of administration among 15 paediatricians in two Italian Regions (Piemonte and Emilia-Romagna).

Statistical analysis

We show questionnaire responses as absolute frequencies and percentages (categorical variables) and as means with standard deviation (continuous variables). Paediatricians' demographic and professional characteristics are described.

The association between the outcome 'feeling knowledgeable about vaccinations' and other variables was evaluated using the chi-squared test or Fisher's exact test when appropriate. All variables describing the

Table 2

Paediatricians' responses to the question 'Your patient is scheduled to receive the second dose of hexavalent vaccine[a]; which of the following conditions do you consider to be a contraindication?', Italy, 2016 (n = 892)

Condition	False contraindication		Temporary contraindication		Permanent contraindication		Don't know		Total
	n	%	n	%	n	%	n	%	
Severe allergic reaction to a previous dose, including anaphylaxis	26	3.0	133	15.2	**693**	**79.1**	24	2.7	876
Fever following a previous dose	**831**	**94.6**	38	4.3	7	0.8	2	0.2	878
Acute severe gastroenteritis	431	49.2	437	49.9	6	0.7	2	0.2	876
Otitis media, without fever	**553**	**63.2**	319	36.5	1	0.1	2	0.2	875
Family history of adverse reaction following a pertussis vaccine dose	**717**	**82.2**	62	7.1	40	4.6	53	6.1	872
Acute upper airway infection, without fever	**629**	**72.0**	236	27.0	8	0.9	1	0.1	874
History of pertussis	**636**	**73.1**	192	22.1	21	2.4	21	2.4	870
Diagnosis of epilepsy, well controlled	**790**	**90.4**	52	5.9	13	1.5	19	2.2	874
Fever 38–40 °C and moderate illness	67	7.7	**796**	**91.0**	10	1.1	2	0.2	875
Fever > 40 °C and severe illness	30	3.4	**811**	**92.0**	37	4.2	4	0.5	882
Congenital immunodeficiency	**251**	**28.7**	64	7.3	460	52.6	99	11.3	874

Correct responses are indicated in bold. Denominators differ for each contraindication as not all paediatricians responded to all contraindications.

[a] Diphtheria, tetanus, acellular pertussis, poliomyelitis, *Haemophilus influenzae* type b, hepatitis B.

demographic and professional characteristics of paediatricians and potentially associated with the outcome ($p < 0.20$ in bivariate analysis) were considered for possible inclusion into the multivariable model. These included: sex, age, practice location, type of paediatric practice, vaccine courses or conferences attended in the previous 5 years, vaccinology training, country where medical degree was obtained, years since medical degree, years since specialty certification, years of activity as a paediatrician, whether the paediatrician directly administers vaccines, degree of influence of each of various sources of information or training opportunities on their knowledge of VPD and whether the responding paediatrician implemented any vaccination initiatives in the previous year to promote vaccine uptake among their patients. Adjusted odds ratios (OR) and their corresponding 95% confidence intervals (CI) were calculated for each variable.

We then determined the final model using a backward selection process according to the likelihood ratio test for goodness-of-fit. All statistical analysis were performed using STATA software version 11.2 (Stata Corporation, College Station, Texas, US).

Results

Characteristics of participating paediatricians

The questionnaire was sent to 1,256 paediatricians, of whom 903 (71.9%) returned it with responses and were included in the study. Table 1 summarises their main demographic and professional characteristics: 65.6% (581/885) were 55 years or older (mean age: 56 years), 65.1% (574/882) were women, 78.7% (686/872) had completed postgraduate medical training more than 20 years ago and 71.5% (629/880) were PCP. Practice locations of the responding paediatricians were distributed throughout all 21 Regions of Italy; inside each Region, 91% of the provinces were represented (median: five paediatricians per province; range: 1–73) (Figure 1).

Training and knowledge

Two thirds of paediatricians (570/862) felt sufficiently knowledgeable about vaccinations and VPD to be able to confidently discuss them with parents. When asked to indicate how much each of six possible training tools/settings influenced their knowledge of vaccines and VPD, 30% (252/854) reported that they had received either very little or no formal training in vaccinology during their university studies. Participation in immunisation conferences and courses played an important role for most paediatricians (Figure 2).

Eighty-one per cent of paediatricians (705/870) reported having attended conferences or courses in the previous five years, of whom 42.7% (301/705) completed four or more training courses. The five main topics for which paediatricians who do not feel knowledgeable about vaccinations would like to obtain additional training in were, in order of priority, safety of vaccines (priority score: 5.25), how to respond to parental concerns (4.97), VPD epidemiology and complications (4.84), vaccine contraindications (4.74) and vaccine efficacy (4.70). Only 5.4% of paediatricians (48/892) correctly identified all 11 true and false contraindications to hexavalent vaccine (diphtheria, tetanus, acellular pertussis, poliomyelitis, *Haemophilus*

Table 3
Paediatricians' attitudes towards vaccination, Italy, 2016 (n = 903)

Questionnaire statements	Completely disagree		Partially disagree		Unsure		Partially agree		Completely agree		Total
	n	%	n	%	n	%	n	%	n	%	
Vaccines weaken or overload the immune system	808	91.5	35	4.0	8	0.9	21	2.4	11	1.2	883
It is better for children to develop natural immunity by getting sick rather than to get a vaccine	707	80.2	102	11.6	11	1.2	49	5.6	13	1.5	882
Healthy children do not need to be vaccinated	835	94.7	22	2.5	2	0.2	7	0.8	16	1.8	882
Conditions such as autism and multiple sclerosis may be caused by vaccines	804	91.0	39	4.4	15	1.7	8	0.9	18	2.0	884
Allergies are on the rise because of vaccinations	743	84.3	47	5.3	36	4.1	30	3.4	25	2.8	881
I am afraid that one of my patients may develop a severe adverse reaction following vaccination	550	62.6	162	18.4	39	4.4	99	11.3	29	3.3	879
Children receive too many vaccines	696	79.1	64	7.3	14	1.6	73	8.3	33	3.8	880
Vaccine policy is influenced by financial profits of pharmaceutical companies	394	44.8	190	21.6	88	10.0	174	19.8	33	3.8	879
Childhood vaccines are given too early	739	84.3	42	4.8	21	2.4	40	4.6	35	4.0	877
The frequency of adverse reactions to vaccines is underestimated	446	51.2	185	21.2	78	9.0	116	13.3	46	5.3	871
In the US, paediatricians are increasingly rejecting patients whose parents refuse vaccinations. I agree with this attitude.	236	26.8	154	17.5	54	6.1	199	22.6	236	26.8	879
Vaccination is cost-effective	128	14.8	46	5.3	73	8.4	122	14.1	496	57.3	865
I am favourable to reintroducing mandatory school immunisation requirements	91	10.3	77	8.7	42	4.8	161	18.2	512	58.0	883
Vaccine information provided by health authorities and scientific societies is reliable	51	5.8	48	5.4	20	2.3	185	20.9	580	65.6	884
Vaccines are among the safest and most tested medicinal products	109	2.5	45	5.1	25	2.9	120	13.7	576	65.8	875
The second dose of MMR is useful	56	6.4	15	1.7	16	1.8	63	7.2	727	82.9	877
When children get vaccinated, the whole community benefits	35	4.0	2	0.2	2	0.2	14	1.6	829	94.0	882
If we stop vaccinating. many diseases that have become rare may re-emerge	2	0.2	11	1.3	4	0.5	22	2.5	838	95.6	877
Vaccines are important for my patients' health	5	0.6	3	0.3	1	0.1	9	1.0	867	98.0	885

MMR: measles-mumps-rubella vaccine; US: United States.
Denominators differ for each characteristic as not all paediatricians responded to all questions.

influenzae type b, hepatitis B) listed in Table 2; 44.2% (394/892) correctly classified at least nine of 11 contraindications, 91.5% (816/892) at least six, and 8.5% (76/892) less than six.

Most paediatricians considered vaccines to be effective or very effective, with a range from 83.5% (738/884) for the human papillomavirus (HPV) vaccine to 99.6% (887/891) for the diphtheria-tetanus-acellular pertussis vaccine.

Beliefs, attitudes and perceptions

In general, 95.3% (843/885) of paediatricians reported being completely favourable to vaccinations, 3.8% (34/885) were moderately favourable, 0.8% (7/885) had a neutral attitude and one paediatrician (0.1%) was completely against vaccinations. Fifty-eight per cent (512/883) reported being favourable to schools requiring pupils to be vaccinated.

When asked to rate their level of agreement with 19 statements about vaccine safety and effectiveness (Table 3), we would have expected the paediatricians to be in complete disagreement with vaccine-critical statements and in complete agreement with positive statements. However, only 8.9% (80/903) fully responded in that way. For example, a proportion of paediatricians either agreed (completely or partially) or only partially disagreed with the negative statements that "Children receive too many vaccines", "It is better for children to develop natural immunity rather than to get a vaccine", "Healthy children do not need to be vaccinated" and "Conditions such as autism and multiple sclerosis may be caused by vaccines" (Table 3). On the other hand, only about two thirds completely agreed with either of the positive statements "Vaccines are among the safest and most tested medicinal products" and "Vaccine information provided by health authorities and scientific societies is reliable".

TABLE 4A

Factors associated with feeling knowledgeable about vaccinations, multivariable logistic regression model, Italy, 2016 (n = 903)

Variables	Crude OR	95% CI	Adjusted OR	95% CI
Sex				
Female	1	Ref	1	Ref
Male	2.23	1.63–3.07	1.62	1.10–2.38
Age (years)				
35–54	1	Ref	1	Ref
> 54	3.02	2.25–4.06	2.15	1.49–3.12
Country where medical degree was obtained				
Foreign	1	Ref	NI	
Italy	0.82	0.21–3.20		
Practice location				
Medium-sized city	1	Ref	NI	
Large city	1.39	0.93–2.09		
Small city/town	1.14	0.83–1.57		
Type of paediatric practice				
Other	1	Ref	1	Ref
Primary care	1.44	1.06–1.97	0.61	0.40–0.95
Vaccine courses or conferences in previous 5 years				
No	1	Ref	1	Ref
Yes	3.00	2.12–4.25	2.16	1.34–3.49
Vaccinology training				
No	1	Ref	NI	
Yes	1.31	0.96–1.77		
Years since specialty certification				
0–5	1	Ref	NI	
6–15	1.62	0.81–3.24		
16–23	3.10	1.63–5.89		
> 23	5.29	3.03–9.22		
Years since medical degree				
0–5	1	Ref	NI	
6–10	0.18	0.02–2.19		
11–20	0.36	0.03–4.10		
>20	1.25	0.11–1.38		
Years of activity as a paediatrician				
<1	1	Ref	NI	
1–5	1.61	0.46–5.64		
6–10	2.31	0.65–8.24		
>10	7.23	2.30–22.67		

CI: confidence interval; NI: not included in the final model; OR: odds ratio; Ref: reference value.

Most paediatricians (837/899; 93.1%) perceived that, in the previous 2 years, parents had become increasingly worried about vaccinations. Vaccine safety concerns were perceived by most paediatricians (595/899; 66.2%) as the single most important reason for which parents refuse to vaccinate their child.

Practice

Ninety-nine per cent of paediatricians (891/900) recommend that parents follow the national immunisation schedule, 0.3% (3/900) recommend only compulsory vaccinations and 0.2% (2/900) recommend parents not to vaccinate against any VPD. Four paediatricians (0.5%) responded that they have a neutral attitude and do not express their opinion regarding vaccinations to parents.

Overall, 89.9% (808/899) reported frequently discussing with parents about the importance of vaccination, 7.8% (70/899) did so occasionally, 1.9% (17/899) only if parents brought up the topic and 0.4% (4/899) never. Older paediatricians seemed to be more willing to discuss vaccinations with parents than their younger colleagues: 94.5% (549/581) of those 55 years and older

Table 4b

Factors associated with feeling knowledgeable about vaccinations, multivariable logistic regression model, Italy, 2016 (n = 903)

Variables	Crude OR	95% CI	Adjusted OR	95% CI
Degree of influence of formal university training				
Low	1	Ref	NI	
High	0.81	0.59–1.13		
Degree of influence of the scientific literature				
Low	1	Ref	1	Ref
High	2.11	1.12–4.01	1.97	0.96–4.04
Degree of influence of conference participation				
Low	1	Ref	1	Ref
High	3.82	1.74–8.40	3.07	1.21–7.79
Degree of influence of institutional websites				
Low	1	Ref	NI	
High	1.04	0.70–1.56		
Degree of influence of non-institutional websites				
Low	1	Ref	NI	
High	1.33	0.87–2.04		
Degree of influence of discussions with other colleagues				
Low	1	Ref	NI	
High	1.58	1.03–2.41		
Administers vaccines				
No	1	Ref	NI	
Occasionally	3.60	2.10–6.17		
Regularly	1.57	1.14–2.14		
Implemented vaccination initiatives				
No	1	Ref	1	Ref
Yes	2.34	1.72–3.18	2.27	1.54–3.33

CI: confidence interval; NI: not included in the final model; OR: odds ratio; Ref: reference value.

reported using every available opportunity to discuss vaccinations, vs 81.3% (247/304) of younger paediatricians ($p < 0.001$).

When faced with parents who refuse to vaccinate their child against one or more diseases, 97.8% (861/880) of paediatricians stated that they try to change parents' minds by providing information about vaccines and risks of diseases. The remaining respondents either do not interfere or support parents' decisions. Instead, when faced with parents who want to delay vaccinations, only 90.1% (790/877) of paediatricians stated that they try to change their minds; no significant differences were found by age, sex, location or type of practice (data not shown).

Only 66.5% (584/878) of paediatricians verify systematically that their patients are up to date with the national immunisation schedule, 28.6% (251/878) verify frequently, 4.7% (41/878) occasionally and 0.2% (2/878) never. No differences by sex were identified. Paediatricians 55 years and older verify their patients' vaccination status more frequently than their younger colleagues aged 35–54 years (71.9% vs 56.3%; $p < 0.001$). A higher proportion of PCP systematically verify that their patients are up to date with immunisations, compared with other paediatricians (72.4% and 50.4% respectively; $p < 0.001$). Also, a higher proportion of those who have participated in training courses or conferences within the previous five years verify immunisation status of their patients systematically or frequently, compared with those who have not (96.6% vs 88.5%; $p < 0.001$).

Most paediatricians (651/901; 72.3%) reported having implemented vaccination promotion activities in the previous year, including putting posters and information materials in their waiting rooms (491/901; 54.5%), sending reminders by post or phone (50/901; 5.6%), organising meetings with parents or groups of parents (110/901; 12.2%), sending or giving written information materials to parents (39/901; 4.3%), and recommending websites with reliable vaccine information.

Factors associated with feeling knowledgeable about vaccinations and vaccine-preventable diseases

The percentage of paediatricians who reported feeling knowledgeable about vaccinations and VPD was significantly greater among paediatricians 55 years and older compared with younger paediatricians (74.7% vs 49.5%; p<0.001), increasing proportionally with the number of years since specialty certification, from 33.9% (21/62) among those who completed their training a maximum of 5 years previously to 73.0% (436/597) among those who completed their training at least 24 years ago (p<0.001). No differences were found with respect to practice location (large city vs medium-sized city vs small town, defined in Table 1). Most paediatricians (494/567; 87.1%) who felt knowledgeable about vaccinations had attended training courses in the previous 5 years, compared with only 69.3% (203/293) of those who did not feel knowledgeable (p<0.001).

Table 4 shows the results of the univariate and multivariable logistic regression model of the factors associated with feeling more or less knowledgeable about vaccinations and VPD. In multivariable analysis, male paediatricians, paediatricians 55 years or older, those who had participated in training courses in the previous 5 years, those who reported that taking courses and reading the scientific literature had contributed moderately or a great deal to their vaccinology knowledge and those who had implemented vaccination promotion activities, felt more knowledgeable about vaccinations compared with other paediatricians. Contrary to what was initially observed in the univariate analysis, PCP felt less knowledgeable than hospital and community paediatricians.

Discussion

A large number of paediatricians participated in our study and their demographic and professional characteristics (mean age, male to female ratio, years in practice) closely matched those reported in the latest Statistical report of the Italian National Health Service which describes the characteristics of healthcare providers practicing in Italy by specialty [16]. In addition, the number of participating paediatricians per 100,000 paediatric population was evenly distributed throughout Italy's 21 Regions. The study sample was therefore representative of the paediatric specialist population in Italy. The PCP who participated in the study represented 8.2% of all PCP in Italy (n=7,705).

The most important finding of this study is that the vast majority of Italian paediatricians are favourable to vaccination and believe that children should receive all vaccines in the childhood immunisation schedule. This is in agreement with the findings of another European study that examined in 2015 the attitudes of Swiss physicians and pharmacists (including 431 paediatricians) towards immunisation and found that most paediatricians were in agreement with the Swiss universal immunisation schedule [10]. As recommended by some authors, the finding that the paediatric medical community is vastly favourable to vaccinations should be communicated to parents whenever possible as this can be an important pro-vaccine message that may increase public support for vaccination [17,18]. Interestingly, more than half of the paediatricians in our study, which we conducted before the introduction of the new Italian mandatory vaccination law, also reported being favourable to schools requiring pupils to be vaccinated.

Although most paediatricians were favourable to vaccinations in general, our study identified some gaps between their overall positive attitudes towards vaccination and their knowledge, beliefs and practices. A considerable proportion (one third) of our sample did not feel sufficiently informed about vaccines and VPD and about how to address parental concerns. Some paediatricians were found to have a falsely low perception of disease risk. In addition, we found that a relevant number held false beliefs about vaccines and expressed concerns about the safety or usefulness of vaccines. About one third reported that they did not completely trust vaccine information given by health authorities and scientific societies. These results add to similar studies conducted among healthcare workers in Europe indicating that vaccine hesitancy exists not only in the general population but also, to some extent, in HCW [7,19,20]. In particular, a qualitative study in four European countries published in 2016 reported an overall positive attitude towards vaccination among HCW but also vaccine safety concerns, questions about the need for vaccines and/or mistrust especially of pharmaceutical companies [7]. Two studies examined vaccination-related behaviours and perceptions of French general practitioners (GPs) and found a moderate prevalence of vaccine hesitancy [19,20]. Some doubts about vaccine risks were found to exist also among physicians (in this case GPs) with no or slight vaccine hesitancy, most of whom are very favourable toward vaccination in general [20].

In terms of knowledge, our study identified some knowledge gaps regarding true and false contraindications to vaccinations. False contraindications are conditions or circumstances that do not preclude vaccination but are mistakenly considered to be contraindications. It is essential that paediatricians are aware of what constitutes true and false contraindications, to be able to confidently reply to parents' questions, avoid adverse reactions following vaccinations and avoid missing opportunities to administer recommended vaccines in a timely manner. In a recent survey conducted in 2014 among French GPs, 94% of 1,582 respondents reported that they would recommend postponing hexavalent vaccination (diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus Influenzae* type b and hepatitis B) in a child with a minor febrile illness (false contraindication); the authors called for clearer and more consistent guidelines on contraindications to vaccination [21]. In our study, age of at least 55 years was an important determinant of feeling knowledgeable about vaccinations. It is expected that older physicians feel more knowledgeable than younger paediatricians since they have acquired experience during their many years in practice. Younger paediatricians must rely almost exclusively on what they have learned during medical and residency training, while formal training in vaccinology is lacking in many paediatric residency programmes in Italy. In fact, two thirds of paediatricians who had completed their residencies 5 years or less before the survey did not feel sufficiently knowledgeable about vaccinations. Major gaps in the initial training and continuous medical education of physicians regarding vaccination have also been identified in other countries in Europe [21]. Vaccinology courses, including courses in communication, should be part of the university core curriculum for all future health professionals and of compulsory continuing medical education requirements for health professionals involved in vaccinations [22].

In agreement with data from the literature, having participated in training courses in the previous 5 years was another determinant of feeling knowledgeable about vaccinations [6,9,19]. In a recent review of studies on vaccine hesitancy among healthcare providers, knowledge about vaccines and vaccine efficacy and safety was found to contribute to providers' confidence and increase their willingness to recommend vaccination [6]. Another study conducted in December 2013 to January 2014 among 218 paediatric providers in Israel (92% nurses, 8% paediatricians) found that increasing their knowledge and addressing their concerns about vaccination improved their adherence to the routine immunisation programme regarding their own children [9]. Finally, a study conducted in 2014 among general practitioners in France showed that physicians recommended vaccines frequently when they felt comfortable explaining their benefits and risks to patients or trusted official sources of information highly [19].

It is interesting to note that in our study, ca 70% of paediatricians who did not feel knowledgeable had in fact attended training courses. These results suggest that although vaccination training courses are widespread, their contents may need to be more focused on vaccine safety, false contraindications and how to respond to parents' concerns.

The interaction between paediatricians and parents is important in building and maintaining confidence in the vaccination programme and maintaining high levels of vaccination uptake, and paediatricians should be more proactive in initiating the conversation about vaccines with parents rather than waiting for them to raise specific questions or concerns. A recent study (2016) evaluating Italian parents' attitudes towards vaccination, found that only 84% of parents had received a recommendation from their paediatrician to have their children vaccinated with all vaccines included in the national vaccination schedule. In the same study, not having received a recommendation was found to be a determinant of vaccine hesitancy, confirming the crucial role of PCP in influencing parental choice about vaccination [2,19,23-25]. According to more than half of the interviewed parents, information provided by HCW should highlight not only vaccination benefits but also risks.

Our study showed that about one third of paediatricians do not systematically verify their patients' vaccination status. In Italy, PCP but not hospital paediatricians are expected to verify their patients' vaccination status during the periodic health evaluations; however, 28% of PCP in our survey did not systematically do this. This is an important system barrier to achieving and maintaining vaccination uptake: vaccination checks should become common practice for both primary care and hospital paediatricians, and children whose vaccinations are not up to date should be referred to the local vaccination clinic.

Most Italian paediatricians reported having encountered some type of vaccine refusal in their practices and the vast majority said they would try to change the minds of parents' who refuse vaccinations; however, they do not seem to consider it equally important to change parents' minds about delaying vaccinations. Delaying vaccinations leaves children susceptible to preventable diseases for an unjustifiable longer period of time and should be discouraged. This issue should be highlighted in vaccination courses.

This survey was self-completed and we cannot exclude that paediatricians who are sceptical about vaccinations may have decided not to participate in the study. On the other hand, it is also possible that because the questionnaire was anonymous, they may have decided to participate in order to have a chance to express their opinions. In addition, with behaviours being self-reported, desirability biases cannot be excluded. Finally, our results are context-specific and may not be generalisable to paediatricians in other countries.

Conclusions

The vast majority of Italian paediatricians are favourable to vaccination. However, gaps were identified between their overall positive attitudes and their knowledge, beliefs and practices. A significant proportion, particularly of younger paediatricians, does not feel sufficiently knowledgeable about vaccine safety and how to address parent's questions. To maintain high levels of vaccination uptake, paediatricians must be familiar with risks of VPD, vaccine safety, and false contraindications, dispel any doubts they themselves may have regarding false myths and be able to effectively communicate information about vaccines to parents. Our results will be useful when developing targeted interventions to increase paediatricians' knowledge about vaccinations and their confidence in addressing parents' concerns. There is also a need to strengthen paediatricians' trust in the health authorities; this can be achieved through transparent, complete and accurate information and recommendations about vaccines and VPD and through increased involvement of paediatricians in the decision-making process regarding vaccination strategies. Finally, it is necessary to reduce system barriers to achieving and maintaining vaccination uptake, through a uniform approach or guidance on regularly checking vaccination status and evidence-based interventions such as reminder/recall systems.

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Conflict of interest

None declared.

Authors' contributions

AF conceived and designed the study, drafted the questionnaire, contacted the scientific societies, coordinated and monitored study activities, interpreted study results and wrote the manuscript. MCR contributed to designing the study, writing the questionnaire, interpreting results and to writing the manuscript. AB contributed to study design, managed the electronic survey, analysed the data and contributed to writing and revising the manuscript. LF and MGP pretested the questionnaires and contributed to revising the questionnaires. MF contributed to designing the study and the questionnaire and critically revised the manuscript. FDA, CG and CR contributed to designing the study and the questionnaire and to reviewing the original manuscript. All authors read and approved the final manuscript.

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Knowledge, attitudes and beliefs about vaccination in primary healthcare workers involved in the administration of systematic childhood vaccines, Barcelona, 2016/17

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Background: Healthcare professionals are a reliable and impactful source of information on vaccination for parents and children. **Objectives:** We aimed to describe the knowledge, attitudes and beliefs primary care professionals involved in administration of childhood vaccines in Barcelona have about vaccines and vaccination. **Methods:** In 2016/17, surveys were administered in person to every public primary care centre (PCC) with a paediatrics department (n = 41). Paediatricians and paediatric nurses responded to questions about disease susceptibility, severity, vaccine effectiveness, vaccine safety, confidence in organisations, key immunisation beliefs, and how they vaccinate or would vaccinate their own children. We used standard descriptive analysis to examine the distribution of key outcome and predictor variables and performed bivariate and multivariate analysis. **Results:** Completed surveys were returned by 277 (81%) of 342 eligible participants. A quarter of the respondents reported doubts about at least one vaccine in the recommended childhood vaccination calendar. Those with vaccine doubts chose the response option 'vaccine-hesitant' for every single key vaccine belief, knowledge and social norm. Specific vaccine knowledge was lacking in up to 40% of respondents and responses regarding the human papilloma virus vaccine were associated with the highest degree of doubt. Being a nurse a risk factor for having vaccine doubts (adjusted odds ratio (ORa) = 2.0; 95% confidence interval (95% CI): 1.1–3.7) and having children was a predictor of lower risk (ORa = 0.5; 95% CI: 0.2–0.9). **Conclusions:** Despite high reported childhood immunisation rates in Barcelona, paediatricians and paediatric nurses in PCC had vaccine doubts, especially regarding the HPV vaccine.

Introduction

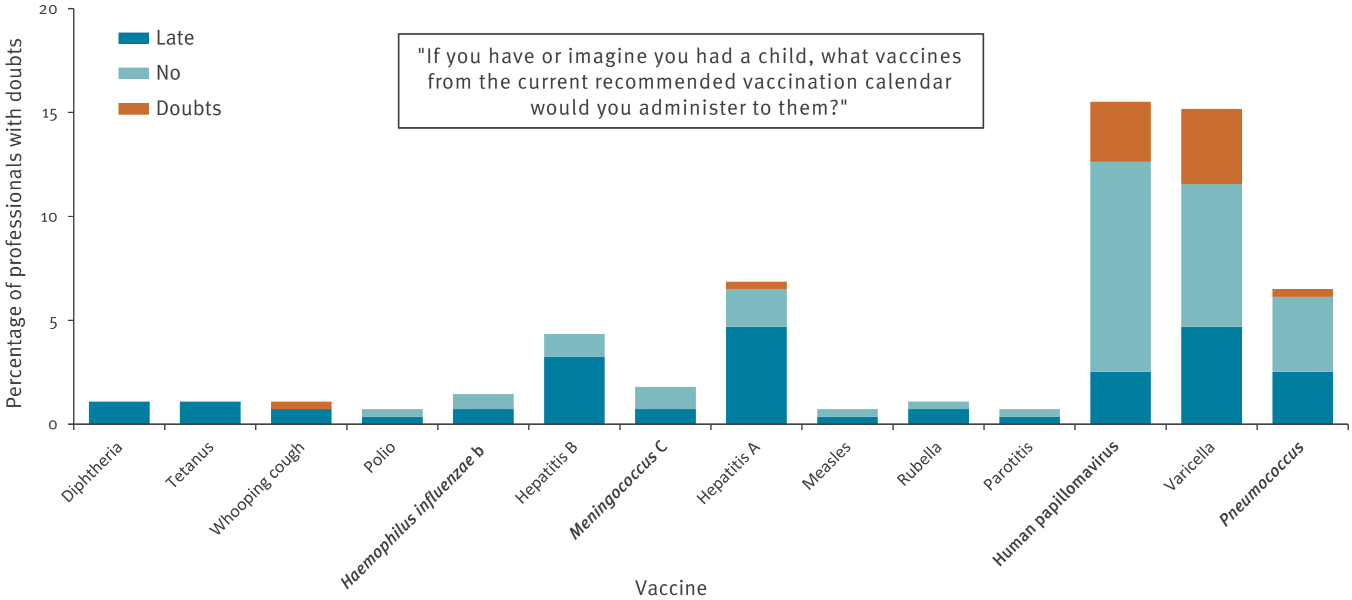
The term vaccine hesitancy (VH) was defined in 2012 by the World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) on Immunization as 'delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence' [1].

During the last decade, groups or subpopulations where vaccination coverage is below the required threshold because of VH have been associated with outbreaks and the reappearance of vaccine-preventable diseases, like measles [2]. In 2017, the WHO reported a total of 21,315 cases of measles and 35 deaths in the European Region of the WHO alone, representing an increase of 400% compared with the previous year [3]. In Barcelona, however, the situation was more stable despite 46 confirmed measles cases that originated from imported cases in the same year [4,5].

Notwithstanding the impact of the media and the easy access to the Internet, which can contribute positively or negatively [6] to the acceptance of childhood immunisation, healthcare professionals (HCPs) have repeatedly been identified as the most reliable and impactful source of information on vaccination for parents and their children [2,7-9]. Sixty-nine per cent of Spanish families identified their paediatrician as the most

Figure 1

Paediatric health professionals who responded 'late', 'doubts', or 'no' to vaccinating their own children, survey about vaccine knowledge, attitudes and beliefs, Barcelona, 2016/17 (n = 277)



important source regarding vaccines [10]. Nonetheless, although it is internationally recommended [8] to work with this population to counter VH, HCPs in the region of Catalonia in Spain have not been studied.

Given that VH has been described among European vaccine providers [11], it is of the utmost importance to address the loss of confidence in vaccines in this population. Entire vaccination programmes could be jeopardised if healthcare professionals' recommendations to immunise children are deficient as a result of VH [7]. Faced with this situation at the European level, and in spite of adequate vaccine coverage, the Public Health Agency of Barcelona (ASPB) launched in 2016 a line of research to monitor VH in HCPs and study its determinants in Barcelona. The main objective of this study was to describe the knowledge, attitudes and beliefs about vaccines among professionals who are directly involved in the administration of systematic childhood vaccines in the public health system of the city.

Methods

This investigation is an observational cross-sectional study consisting of data collected through a structured survey.

Population surveyed

In Barcelona, systematic childhood vaccination is recommended and administered by paediatric health professionals (paediatricians and paediatric nurses). The public health system covers more than 90% of all childhood vaccinations in the city. The study population enrolled were HCPs who were directly involved in the administration of systematic childhood vaccines in public primary care centres (PCC) in Barcelona. Family doctors or practitioners who specialise in fields not related to paediatrics and nurses who were not directly involved in the administration of childhood vaccines were excluded. Students, residents and temporary substitutes of any kind were also excluded.

Of the 54 PCC serving the city of Barcelona, 41 have a paediatrics department with overall 342 professionals.

Questionnaire

A questionnaire was developed following available literature [12-14]. The questionnaire was translated into Spanish and Catalan and culturally adapted using the cognitive debriefing method [15]. Cognitive debriefing is a process where representatives of the target population actively test the translated questionnaires to determine whether respondents would understand the questionnaire as easily as the English version would be understood [16].

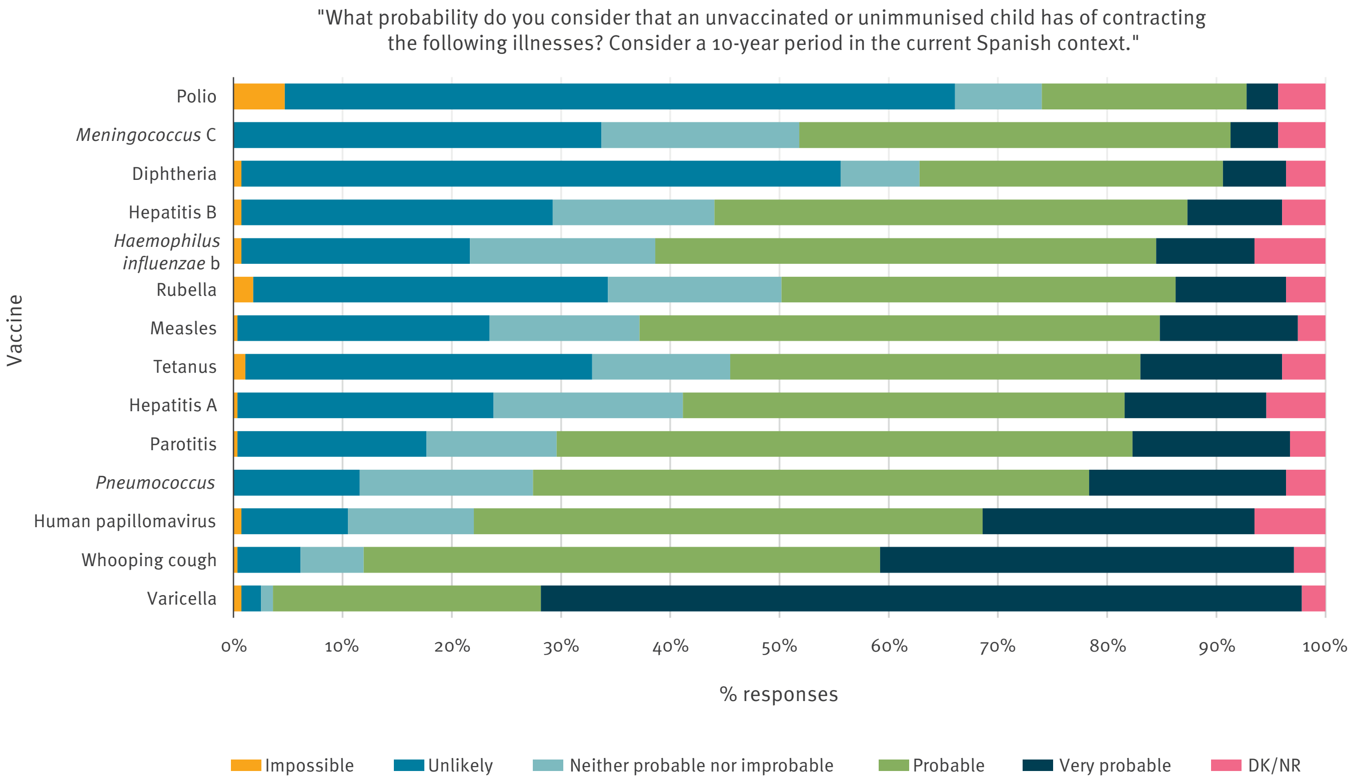
Respondents answered questions about disease susceptibility, disease severity, vaccine effectiveness, vaccine safety, who benefits from childhood immunisations, key immunisation beliefs, whether or not they had children, how they vaccinated or would vaccinate their own children, and whether they felt they had enough information and tools in order to adequately respond to vaccine-hesitant parents.

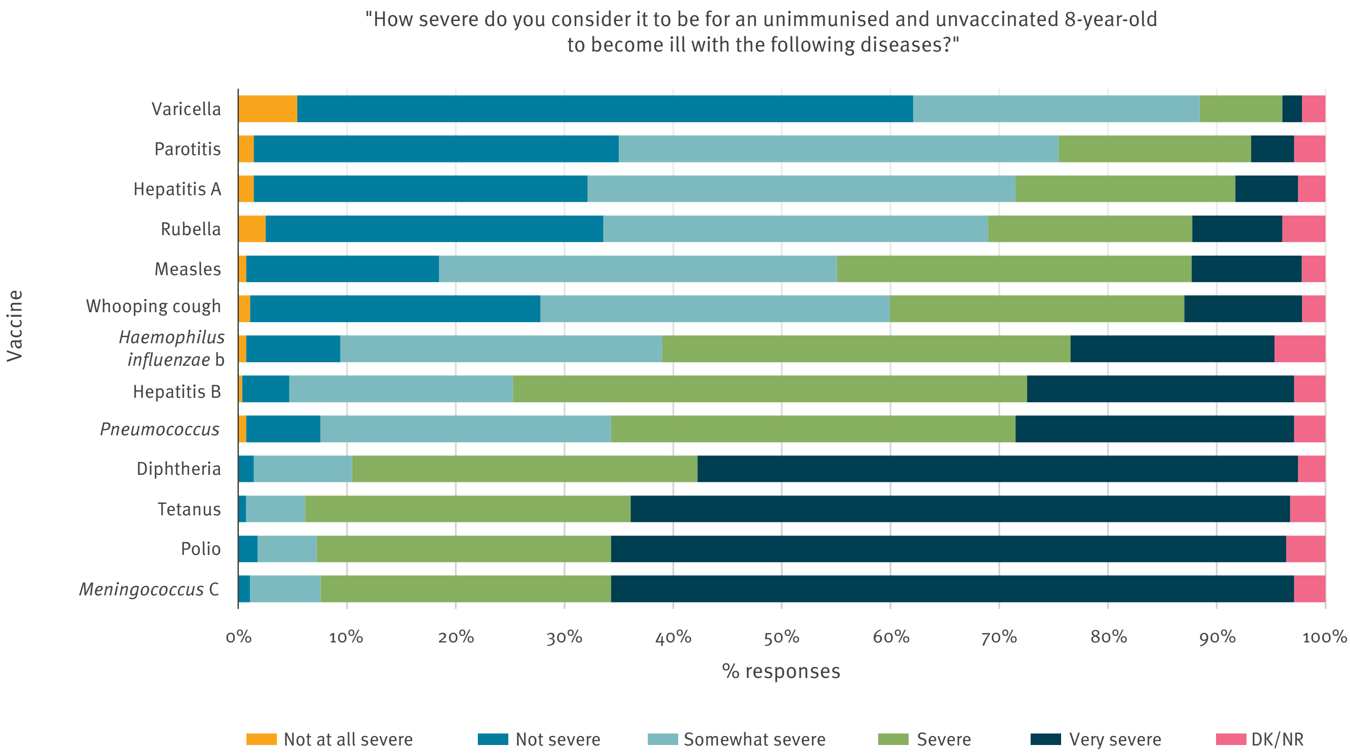
Administration

Questionnaires were self-administered by the HCPs at the PCC during a date and time that was previously agreed between the investigators and contact person from each centre. Contact with centres began in March

Figure 2

Disease susceptibility and severity perceived by paediatric health professionals, survey about vaccine knowledge, attitudes and beliefs, Barcelona, 2016/17 (n = 277)

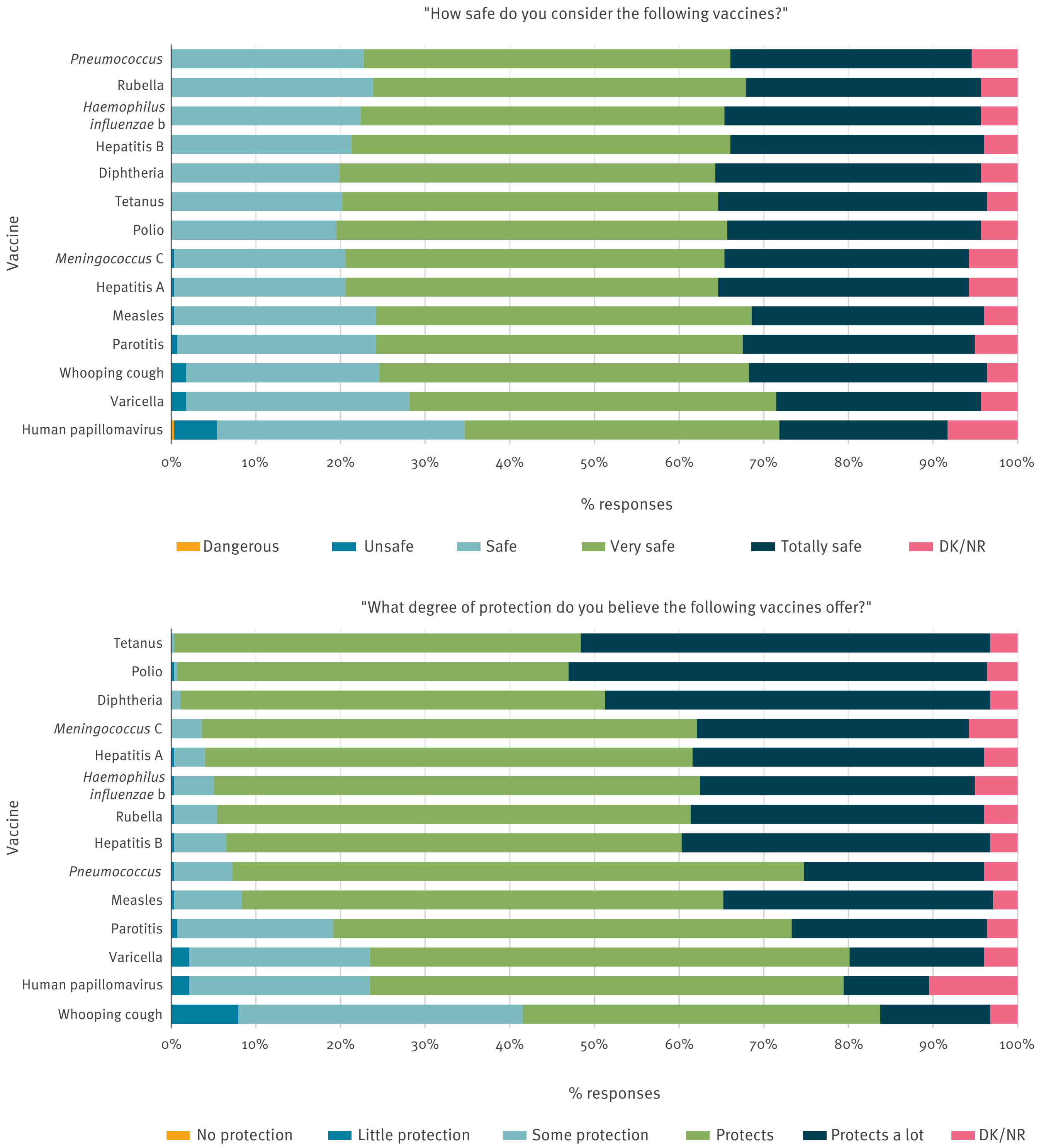




DK/NR: don't know/no response.

Figure 3

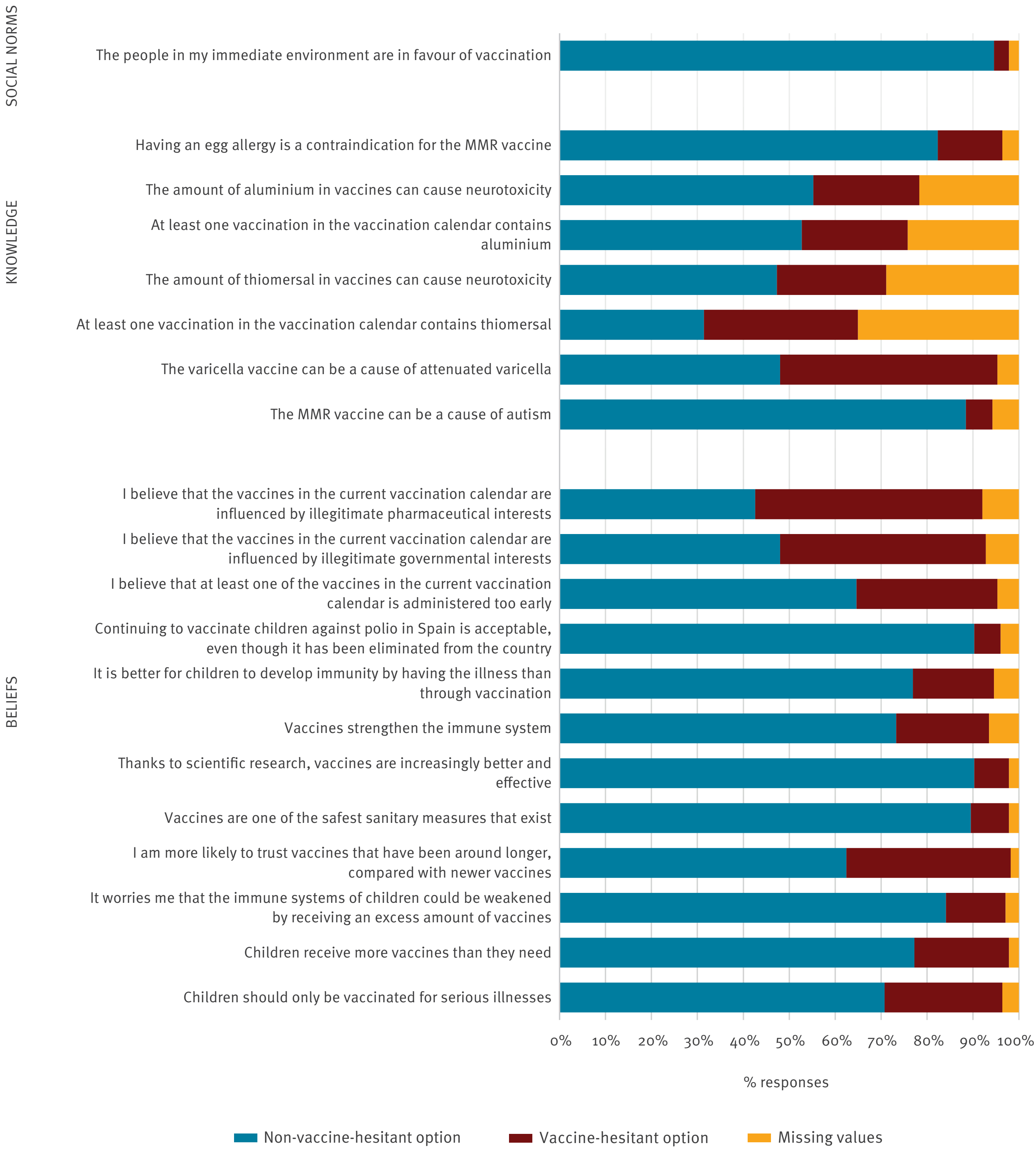
Vaccine safety and effectiveness perceived by paediatric health professionals, survey about vaccine knowledge, attitudes and beliefs, Barcelona, 2016/17 (n = 277)



DK/NR: don't know/no response.

Figure 4

Key beliefs, knowledge and social norms about vaccines, by affirmation, survey among paediatric health professionals, Barcelona, 2016/17 (n = 277)



MMR: measles-mumps-rubella vaccine.

Responses to key vaccine knowledge, beliefs and social norms were categorised as either vaccine-hesitant or non-vaccine hesitant.

2016 and ended in February 2017. Some centres were contacted up to six times.

Variables

Demographical variables were collected. All other variable responses were categorised on a 5-point Likert scale that was later dichotomised. Responses to whether or not they would vaccinate their children against the listed vaccines included in the calendar were dichotomised into 'yes' and the outcome variable 'vaccine doubts' which was a combination of all other options (late/doubts/no). Disease susceptibility and severity variables were dichotomised into 'likely/very likely' vs all other responses and 'severe/very severe' vs all other responses. Vaccine safety was dichotomised into 'safe/very safe/completely safe' vs all other responses and vaccine efficacy was dichotomised into 'protects/protects a lot' vs all other responses. Benefit of vaccination was dichotomised into benefits 'considerably/a lot' vs all other responses. Key vaccine beliefs, knowledge and social norms were also dichotomised into the 'vaccine-hesitant' option vs no VH. Because the key affirmations were positive and negative, agreeing with the affirmation was the vaccine-hesitant option in some cases, while in others, disagreeing corresponded to VH. Missing values and don't know/no response (DK/NR) were all treated the same in the analysis.

Data analysis

Standard descriptive statistics was performed using STATA version 11.0. Mean, standard deviation and Student's t-test were used for quantitative variables and frequency, chi-squared test, and Fisher's exact test were used for qualitative variables. To study sociodemographic correlates with VH, a multiple logistic regression was performed where odds ratios (OR) were obtained with their 95% confidence intervals (95% CI), adjusting for all sociodemographic variables. Missing values and DK/NR were included only in the descriptive analysis. All analyses were based on two-sided p values with statistical significance defined by $p \leq 0.05$.

Ethical considerations

This study was approved by the ethics committee of the Consorci Parc de Salut Mar de Barcelona. The researchers declare no conflicts of interest.

Results

Of the 342 paediatric health professionals in the Barcelona public primary care centres, 277 (81%) participated in the study; 136 were paediatricians, 138 were paediatric nurses and three were not defined. The rate of participation of paediatricians and paediatric nurses was 76.8% and 83.6%, respectively. Only one PCC chose not to participate. The mean age was 48 years (SD = 10.5 years) and 244 (88.4%) were female. The mean number of years of experience was 23 years (SD = 10.5 years). Of those who responded to the survey, 75 (27.1%) reported not having children.

Of those that were surveyed, 71 (25.6%; 95% CI: 20.8–31.1) had doubts about at least one of the vaccines in the current vaccination calendar. Respondents reported the most doubt regarding the HPV and varicella vaccines (Figure 1, Supplementary Table S1). Excluding the HPV and varicella vaccines, 34 (12.3%; 95% CI: 8.8–16.7) of health professionals reported having a doubt about at least one vaccine in the current calendar.

Statistically significant differences existed between professions for the pneumococcus (3.8% vs 9.9%; $p = 0.049$), Hepatitis B (1.5% vs 7.6%; $p = 0.034$) and HPV (9.9% vs 22.9%; $p = 0.005$) vaccines where nurses reported more doubts. Statistically significant differences existed between those with and without children for the varicella vaccine (12.5% vs 25.4%; $p = 0.012$) where those without children reported more doubts.

Perception of probability and severity of illness and of vaccine safety and protection

Thirteen (4.7%) respondents felt that it would be impossible for an unvaccinated and unimmunised child to contract polio and 198 (71.5%) responded that it is probable or very probable for an unvaccinated child to contract HPV. Respondents reported that polio, illness from meningococcus C and tetanus were the most serious illnesses, with varicella being the least serious (Figure 2, Supplementary Tables S2 and S3). All vaccines were reported to be safe, with the exception of the HPV vaccine, which was described as dangerous by one participant and unsafe by 14 (5%). Five respondents also reported the varicella and whooping cough vaccines as being unsafe (Figure 3, Supplementary Tables S4 and S5). We saw the largest number of missing values for questions surrounding HPV. Eighteen missing values (6.5%) were received for HPV susceptibility, 23 (8.3%) for HPV vaccine safety and 29 (10.5%) for the level of protection the vaccine provides. In general, there were no statistically significant differences in sex, age or years of profession in relation to the variables on probability and severity of illness and on the protection offered by vaccines. Statistically significant differences were seen among those without children who reported more doubts regarding the safety of the HPV vaccine (11.5% vs 3%; $p = 0.019$). Statistically significant differences between professions were seen in almost every category.

Key vaccine beliefs, knowledge and social norms

Of the 277 who participated, 269 (97.1%) believed that the child receiving the vaccine benefits considerably/benefits a lot from vaccination, 267 (96.4%) believed that the community benefits considerably/benefits a lot, 256 (92.4%) believed that health personnel benefit considerably/benefit a lot, 253 (91.3%) believed that the government benefits considerably/benefits a lot, and 244 (88.1%) believed that the pharmaceutical industry benefits considerably/benefits a lot. There were no significant differences regarding the responses to beliefs about the benefits of vaccination.

Table

Respondents with or without doubts about vaccines who selected the vaccine-hesitant option, survey among paediatric health professionals, Barcelona, 2016/17 (n = 277)

	Respondents with doubts (n = 71) [a]		Respondents without doubts (n = 206)[a]		p value
	n	%	n	%	
Children should only be vaccinated for serious illnesses	36	53.7	35	17.50	<0.001
Children receive more vaccines than they need	33	47.1	24	11.94	<0.001
It worries me that the immune systems of children could be weakened by receiving an excess amount of vaccines	19	27.9	17	8.46	<0.001
I am more likely to trust vaccines that have been around longer, compared with newer vaccines	33	47.1	66	32.67	0.030
Vaccines are one of the safest sanitary measures that exist	10	14.5	13	6.44	0.038
Thanks to scientific research, vaccines are increasingly better and effective	10	14.5	11	5.45	0.015
Vaccines strengthen the immune system	23	34.3	33	17.19	0.003
It is better for children to develop immunity by having the illness than through vaccination	24	36.3	25	12.76	<0.001
Continuing to vaccinate children against polio in Spain is acceptable, even though it has been eliminated from the country	7	10.0	9	4.59	0.102
I believe that at least one of the vaccines in the current vaccination calendar is administered too early	36	54.5	49	24.75	<0.001
I believe that the vaccines in the current vaccination calendar are influenced by illegitimate governmental interests	40	59.7	84	44.21	0.029
I believe that the vaccines in the current vaccination calendar are influenced by illegitimate pharmaceutical interests	46	68.6	91	48.40	0.004
The MMR vaccine can be a cause of autism	7	10.9	9	4.57	0.065
The varicella vaccine can be a cause of attenuated varicella	35	52.2	96	48.73	0.620
At least one vaccine in the vaccination calendar contains thiomersal	28	70.0	65	46.43	0.009
The amount of thiomersal in vaccines can cause neurotoxicity	17	37.7	49	32.24	0.489
At least one vaccine in the vaccination calendar contains aluminium	40	74.0	106	67.95	0.399
The amount of aluminium in vaccines can cause neurotoxicity	18	31.5	46	28.75	0.688
Having an egg allergy is a contraindication for the MMR vaccine	12	17.6	27	13.57	0.411
The people in my immediate environment are in favour of vaccination	6	8.4	3	1.50	0.011

MMR: measles-mumps-rubella.
[a] Missing values were excluded.

Of the 229 participants who believed that pharmaceutical companies benefit considerably/benefit a lot from vaccination and responded to the question about illegitimate interests influencing the vaccination calendar, 129 (56.3%) believed that the vaccines currently recommended are influenced by illegitimate pharmaceutical interests compared with 100 (43.7%) who did not believe this (p = 0.012).

Twenty-five (12.8%) participants who reported having children felt worried that children's immune systems could be weakened from receiving too many vaccines, and 65 (33%) of these same respondents believed that at least one vaccine in the current calendar is administered too early. A total of 262 (94.6%) participants reported that the people in their immediate environment were in favour of vaccination and 10 (3.6%) participants did not believe that thanks to scientific research, vaccines are increasingly better and more effective (Figure 4).

Key vaccine knowledge affirmations showed the highest number of missing values, and a higher percentage of respondents chose the VH option. A total of 133 (48.0%) respondents correctly responded that the varicella vaccine can cause attenuated varicella. With respect to the components that make up our vaccines today, 93 participants (33.5%) responded that at least one vaccine in the current vaccination calendar contains thiomersal and 97 (35%) did not know the answer or chose not to respond. Further, 80 respondents (28.9%) did not know or chose not to answer the question which stated that the amount of thiomersal in vaccines can cause neurotoxicity. In addition, 67 (24.2%) did not respond or did not know whether or not vaccines contain traces of aluminium, and 60 (21.7%) did not know whether or not the amount of aluminium in vaccines causes neurotoxicity (Figure 4).

Those with vaccine doubts chose the VH response option for every single key vaccine belief, knowledge and social norm (Table). Of those who had doubts about at least one vaccine in the current vaccination calendar, 60% responded that they believed that the current vaccines in the calendar were influenced by illegitimate governmental interests (p = 0.029). Similarly, of those who had vaccine doubts, 69% reported believing that the current vaccination calendar was influenced by illegitimate pharmaceutical interests (p = 0.004).

Multivariate analysis adjusted for sociodemographic characteristics revealed the profession of nursing to be a risk factor for VH (ORa = 2.0; 95% CI: 1.1–3.7) and having children as a factor of less risk for VH (ORa = 0.5; 95% CI: 0.2–0.9).

Professional practice and vaccine doubts

Overall, 81 (29.2%) of the 277 HCPs responded that they felt they did not have sufficient information and training to adequately answer questions vaccine-hesitant parents may have. The majority of respondents wished to receive more information about vaccines online 145 (52.3%) and through training sessions 139 (50.2%).

Discussion

Our study showed that, in general, public paediatric professionals in Barcelona supported vaccination. However, one in four respondents reported having doubts about at least one vaccine in the current recommended childhood vaccination schedule. Half of the doubts expressed were described in association with the HPV and varicella vaccines. Moreover, we identified a lack of trust in the government and the pharmaceutical industry, a lack of knowledge about vaccine components and the belief in certain myths held by vaccine-hesitant parents.

Despite recent attempts in Spain to unify childhood vaccination schedules, different ones coexist: one for each autonomous region. The Catalan recommended vaccination calendar has been changed four times in the past 10 years [17]. The two vaccines which generated the most doubt in our study population were only recently added to the recommended systematic childhood vaccination calendar (HPV in 2008 and varicella in 2016), and their introduction was accompanied by social and scientific criticism. The doubts surrounding these vaccines described in our population can in part be explained by the frequent changes in the vaccination calendar and differing calendars within the country [18]. This lack of confidence in certain vaccines could be highlighting the need to improve communication between those who dictate public health policies and health professionals who directly care for families. Karafillakis et al. described similar scenarios in France and Greece where a lack of trust in the government and pharmaceutical industry could potentially stain the credibility of vaccine information [19].

While the vaccine effectiveness responses we received were in line with available literature [20-22], it is alarming that some health professionals considered vaccines that are being administered to children as unsafe or even dangerous. The large number of missing responses associated with the HPV vaccine indicates a sense of doubt or unawareness about this vaccine's proven safety and efficacy. Karafillakis et al. also described that the HPV vaccine was singled out in their recent study and explain the hesitancy by the fact that it is a new vaccine [19].

Doubts surrounding the vaccine which protects young girls from HPV is in line with the opinions of certain groups [23], but indicating that the varicella, whooping cough and mumps vaccines are also unsafe, potentially indicates an inability to differentiate between vaccine safety and effectiveness, a crucial determinant when educating vaccine-hesitant parents.

Our respondents' perceptions of disease severity and probability were almost identical to those reported by Salmon et al. [12]. In our study, however, the perception of probability of infection varied. Some professionals considered polio virus infection virtually impossible, an opinion that may have consequences. For example, overconfidence in the safety and effectiveness of a vaccine such as the one against polio, a disease assumed to be eliminated in our environment, could prevent an HCP from recommending the vaccine to families who have doubts about it.

We interpret the high rate of missing values and DK/NR in our study as a gap in specific key vaccine knowledge. Hence, the conclusion can be drawn that HCPs administering vaccines to children in the public health system in Barcelona are lacking crucial information about vaccine components, contraindications and critical general vaccine knowledge. Paterson et al. described that overall, knowledge about particular vaccines, their efficacy and their safety helped build healthcare professionals' own confidence in vaccines and their willingness to recommend them to others [9]. Improving vaccine knowledge among these professionals is crucial for guiding vaccine-hesitant parents and recommending vaccination.

The frequency of vaccine misconceptions in our study was similar to the study by Salmon et al. [12]. A large number of participants chose the VH response and did not answer questions related to myths that vaccine-hesitant parents might ask. Myths could become part of the belief structure of a society and our results suggest that the environment has already influenced the surveyed professionals in the same way as it does vaccine-hesitant families. Addressing this aspect would require working within the socio-cultural context as suggested by Yaqub et al. [2]. These investigators warned of the risks of focusing only on vaccine uptake rates and overlooking the underlying attitudes and beliefs associated with VH.

One third of those surveyed felt that they do not have sufficient information and training to adequately address questions from vaccine-hesitant parents. We must ensure that health professionals who are in contact with families are adequately informed and are capable of delivering clear and accurate messages to their patients [18,24]. To this effect, new and improved training workshops and information material need to be made available as continued education to these healthcare professionals as soon as possible.

Our results must be interpreted in the context of several methodological limitations. While the high response rate is a strength of this study, it can also be seen as a drawback. The response rate, which surpasses those described in other similar studies [12,14,25], was achieved because the surveys were administered in person. This means that the self-reported evaluations may be subject to expectancy bias and complacency bias. In addition, there could have been a sample selection bias because the study examined only those in the public health sector who willingly participated. We are therefore unaware if those who did not wish to participate held more vaccine doubts or not. Nevertheless, we would like to emphasise that this is the first study that addresses this issue in our environment and that it was aimed at the entire population of paediatric primary care professionals in public centres in the city, which account for the majority of vaccinations in Barcelona.

Conclusions

The data collected has proven useful for understanding VH in Barcelona and serves as a starting point for continued monitoring of VH in this large European city. Because differences among paediatricians and paediatric nurses were seen for almost every variable, and profession was the factor most associated with VH, a more detailed analysis by profession is currently underway.

In a time where other sources of information could potentially outweigh the importance of primary healthcare workers, it is crucial that those involved in the systematic administration of childhood vaccines are equipped with the skills and resources needed to manage the growing issue of VH.

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Conflict of interest

None declared.

Authors' contributions

MSV, MGC and CR created the questionnaire that was administered. MGC contacted each centre to set up a time and date and MGC, MSV, CR and CAP travelled to each centre to administer the questionnaires. Data analysis was performed by CAP using STATA. CAP, MGC and CR actively participated in discussion of results and key ideas for the article, and wrote and edited the article.

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Timeliness and completeness of routine childhood vaccinations in young children residing in a district with recurrent vaccine-preventable disease outbreaks, Jerusalem, Israel

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Background: Childhood vaccination schedules recommend vaccine doses at predefined ages. **Aim:** We evaluated vaccination completeness and timeliness in Jerusalem, a district with recurrent vaccine-preventable disease outbreaks. **Methods:** Vaccination coverage was monitored by the up-to-date method (vaccination completeness at age 2 years). Timeliness of vaccination was assessed in children (n=3,098, born in 2009, followed to age 48 months, re-evaluated at age 7 years) by the age-appropriate method (vaccine dose timeliness according to recommended schedule). Vaccines included: hepatitis B (HBV: birth, 1 month and 6 months); diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b (DTaP-IPV-Hib: 2, 4, 6 and 12 months); pneumococcal conjugate (PCV: 2, 4 and 12 months); measles-mumps-rubella/measles-mumps-rubella-varicella (MMR/MMRV: 12 months) and hepatitis A (HAV: 18 and 24 months). **Results:** Overall vaccination coverage (2014 cohort evaluated at age 2 years) was 95% and 86% for MMR/MMRV and DTaP-IPV-Hib4, respectively. Most children (94%, 91%, 79%, 95%, 92% and 82%) were up-to-date for HBV3, DTaP-IPV-Hib4, PCV3, MMR/MMRV1, HAV1 and HAV2 vaccines at 48 months, but only 32%, 28%, 38%, 58%, 49% and 20% were vaccinated timely (age-appropriate). At age 7 years, the median increase in vaccination coverage was 2.4%. Vaccination delay was associated with: high birth order, ethnicity (higher among Jews vs Arabs), birth in winter, delayed acceptance of first dose of DTaP-IPV-Hib and multiple-dose vaccines (vs MMR/MMRV). Jewish ultra-Orthodox communities had low vaccination coverage. **Conclusions:** Considerable vaccination delay should be addressed within the vaccine hesitancy spectrum. Delays may induce susceptibility to vaccine-preventable disease outbreaks; tailored programmes to improve timeliness are required.

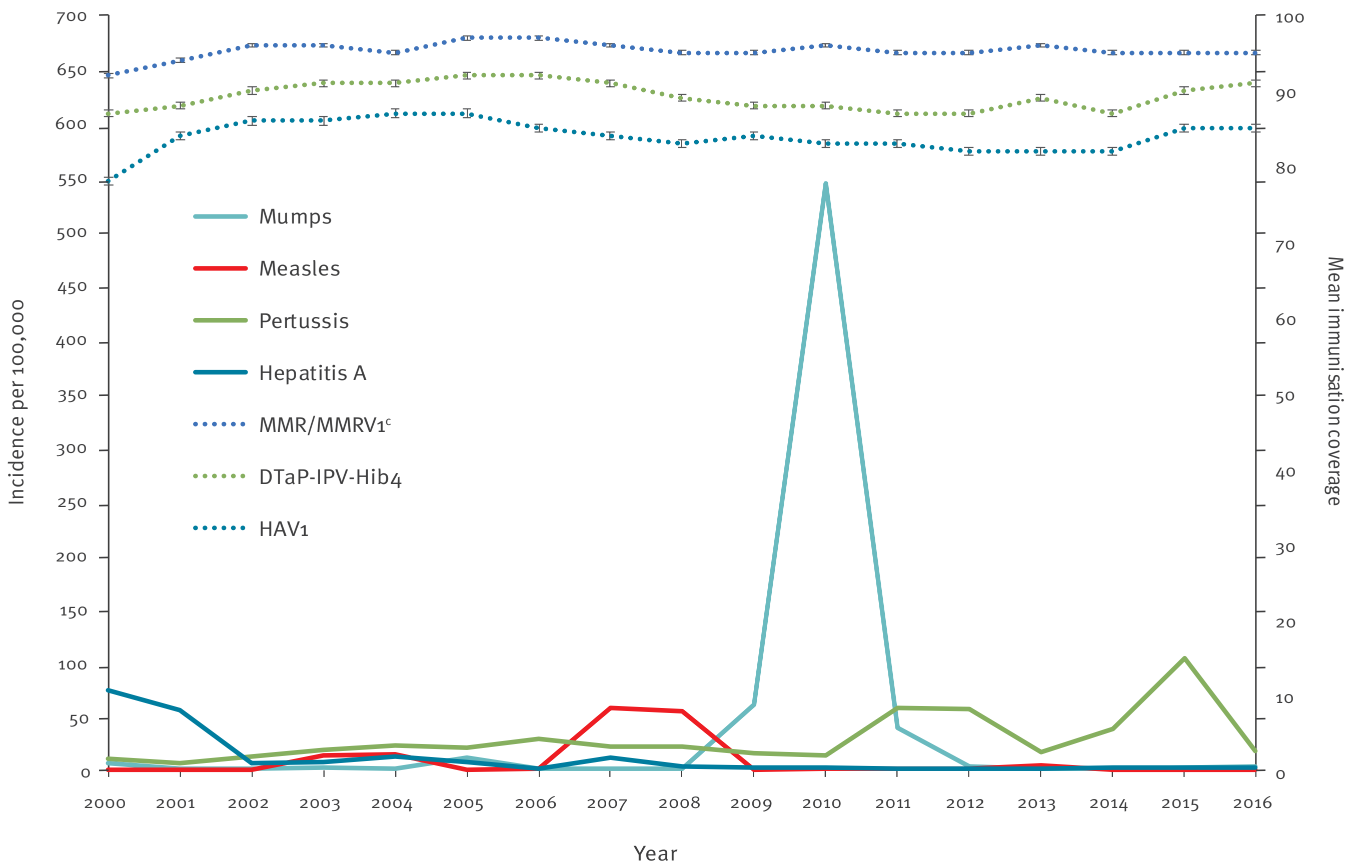
Background

Vaccines have contributed to substantial reductions of morbidity and mortality from vaccine-preventable diseases (VPD), mainly in children. Vaccinations avert 2–3 million deaths annually; if global vaccination coverage improves, another 1.5 million deaths are preventable [1]. The estimated global coverage for the first dose of measles-containing vaccine (MCV1) and for diphtheria-tetanus-pertussis (DTP3) was 82% for both in 2009 and 85% and 86%, respectively, in 2014; this is below the Global Vaccine Action Plan (GVAP) targets of 90% nationally and 80% in all districts [2]. For measles, the recommended coverage is higher, at 95% or more across all districts and age groups [3].

Routine vaccinations in Israel are included in the National Health Insurance Law. Community-based maternal and child health (MCH) clinics provide free vaccination to children regardless of civil status, with high rates (96%) of service utilisation [4,5]. Vaccine doses are documented in digital health files. The overall vaccination coverage rates reported in Israel are adequate (at age 2 years in 2016: DTaP-IPV-Hib4 at 94%, HBV3 at 97% and MMR/MMRV1 at 96%) with all districts well in line with World Health Organization (WHO) goals [6,7]. Yet, VPD outbreaks observed in specific communities (Arab Bedouin in southern Israel and Jewish ultra-Orthodox in Jerusalem) revealed under-immunised population groups [8-10].

Figure 1

Incidence of selected notifiable vaccine-preventable diseases[a] and reported overall mean coverage of selected routine childhood vaccinations[b], Jerusalem district, Israel, 2000–2016



DTaP-IPV-Hib4: diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b vaccine, fourth dose; HAV1: hepatitis A vaccine, first dose; MMR/MMRV1: measles-mumps-rubella/measles-mumps-rubella-varicella vaccine, first dose.

[a] Incidence per 100,000 population of measles, mumps, pertussis and hepatitis A.

[b] MMR/MMRV1, DTaP-IPV-Hib4 and HAV1, as up-to-date at age 2 years (vaccination completeness).

[c] MMRV vaccine replaced MMR in 2008.

In the last two decades, several VPD outbreaks emerged in the Jerusalem district (Figure 1). Measles and mumps outbreaks emerged mainly in Jewish ultra-Orthodox communities, with epidemiological links to similar communities in Europe and the United States (US) [10-13]. The district health office's teams perform surveillance, epidemiological investigations and outbreak control activities; community-wide vaccination campaigns led to outbreaks' containment, with remarkable population compliance during the campaigns.
Recurrent VPD outbreaks indicated the need for a detailed assessment of vaccination coverage in the affected district. Our study evaluated timeliness and completeness of routine childhood vaccinations in order to identify factors associated with vaccination receipt patterns and to gather information for planning public health intervention programmes.

Methods

Setting and study population

The Jerusalem district's population increased from 1 to 1.2 million between 2009 and 2016 (30% Arabs and 70% Jews; about 40% of the Jews are ultra-Orthodox). Neighbourhoods in the area are homogenous, with Arab, Jewish ultra-Orthodox and Jewish traditional-secular residents. The socioeconomic status of the district's population is medium to low. The district's total fertility rate is four (Jewish ultra-Orthodox: 6.2–6.5), compared with three nationally. Children under 6 years comprise 15% of the district's population [14,15].

The study group for detailed vaccine acceptance evaluation included children born in 2009 in the Jerusalem district. The sample size was calculated taking the

Table

General characteristics of the study group, children born in 2009 and followed up to 7 years of age, Jerusalem district, Israel, 2016 (n = 3,098)

Variables	n[a] = 3,098	%
Male	1,571	50.7
Birth weight (g), mean ± SD	3,245 ± 528	NA
Birth weight < 2,500 g	257	8.3
Birth order, mean ± SD	3.4 ± 2.4	NA
Birth order, median (range)	3 (1–14)	NA
Birth order ≥ 4	1,151	37.2
Mother's age (years), mean ± SD	29.1 ± 6	NA
Mother's age (years), median (range)	28 (15–55)	NA
Mother's birth country is Israel	2,506	80.9
Mother's status is married	3,009	97.1
Maternal education (years), mean ± SD	13.7 ± 2.4	NA
Maternal education, median (range)	14 (4–23)	NA
Ethnicity: Jewish/Arab	2,163/935	70/30
Month of birth		
January–March	722	23.3
April–June	762	24.6
July–September	818	26.4
October–December	796	25.7

g: grams; NA: not applicable; SD: standard deviation.
[a] Unless otherwise specified.

following into account: unvaccinated fraction (5–25%), 1.5% precision and a 95% confidence interval (CI). Post adjustment, the study group was selected from the district's newborns file using the Statistical Package for Social Sciences (SPSS) software v23.0 (IBM, New York, US) random sampling of data procedure (n = 3,180 children, 10.7% of the 29,700 live births registered in the district in 2009). The inclusion criteria were: born in Israel, has a unique identifier (identification (ID) number allowing data matching) and survived 48 months. The exclusion criteria were: born abroad (different schedules), lacks a unique identifier and did not survive 48 months.

Variables collected

The general variables collected included the child's date of birth, sex, ethnicity, address, birth order and birthweight, as well as the mother's age, country of birth and marital status.

Vaccination variables

The Jerusalem district routine vaccination coverage is monitored by data aggregation in the up-to-date method (vaccination completeness, Figure 1). The up-to-date method does not reflect vaccination timeliness, which is better assessed by the age-appropriate method (indicating the child's age at specific vaccine doses). The launch of a national immunisation registry in 2009 enabled appraisal of both completeness and timeliness.

The scheduled immunisations included: hepatitis B vaccine (HBV: at birth, 1 month and 6 months); diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b vaccine (DTaP-IPV-Hib: at 2, 4, 6 and 12 months); pneumococcal conjugate vaccine (PCV: at 2, 4 and 12 months); measles-mumps-rubella/measles-mumps-rubella-varicella vaccine (MMR/MMRV: at 12 months) and hepatitis A vaccine (HAV: at 18 and 24 months). MMRV vaccine replaced MMR in 2008 and PCV vaccine was introduced in 2009.

Vaccine doses were defined as valid according to the Israel Ministry of Health (MoH) guidelines for minimum ages and time intervals between doses. Vaccine doses received up to 1 month after the recommended age were considered timely (no delay). The children's ID numbers and dates of birth were cross-checked against the vaccination registry and vaccination data were extracted. After data assembly, records were available for 3,098/3,180 (97%) of the children. The groups of children with available records and those with missing records had similar birthweight, sex, birth order and maternal variables.

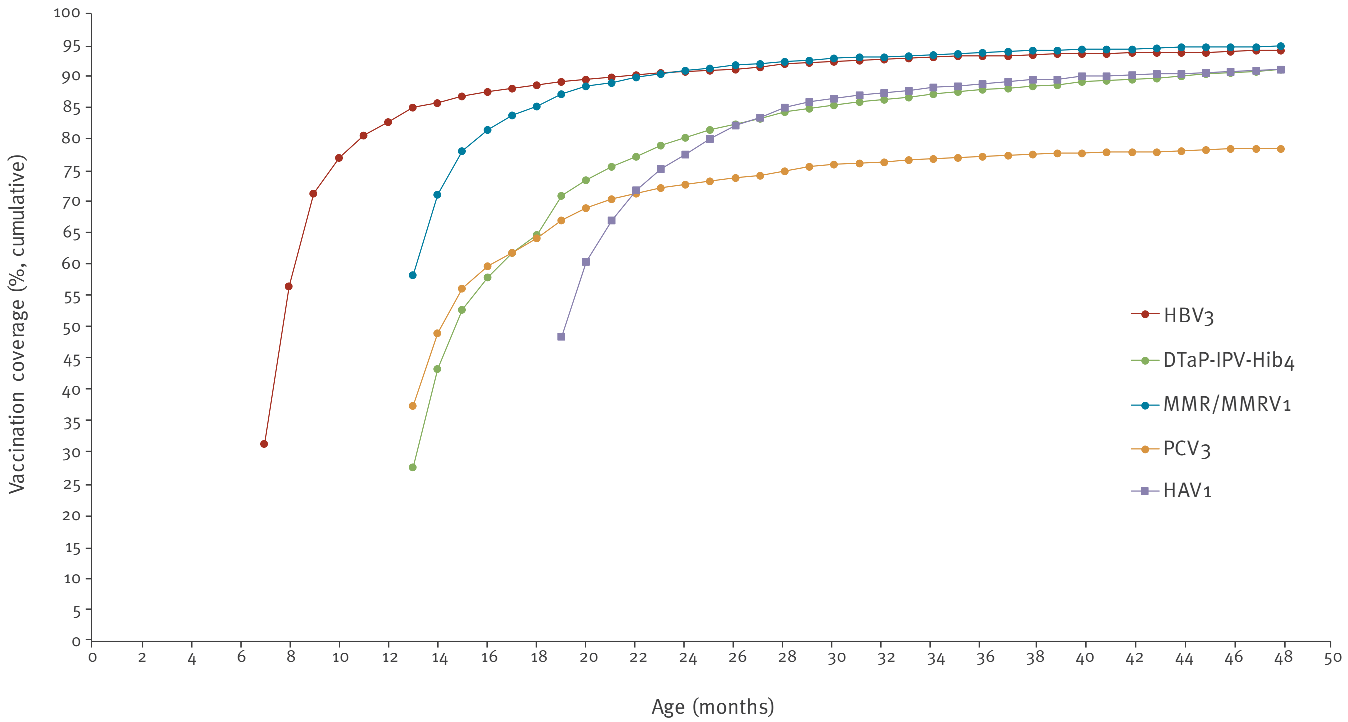
The vaccination data were evaluated at age 24 months (2011) and age 48 months (2013), then re-evaluated at age 7 years (2016). For the present study's purposes, the following categories were defined according to the child's vaccination status: (i) age-appropriate (vaccinated at the recommended age or ≤ 1 month later), (ii) mild-moderate delay (delayed ≤ 6 months; mild: > 1 month and ≤ 3 months, moderate: > 3 months and ≤ 6 months) (iii) severe delay (delayed > 6 months) and (iv) unvaccinated (at 48 months).

Data analysis

Data analysis was performed with SPSS software v23.0. The age-specific immunisation coverage was retrieved from a cumulative fraction of vaccinated children by age and plotted in inverse Kaplan-Meier curves (survival analysis curves). Days of vaccination delay were converted into months as 30.5 days/month. A univariate analysis was performed for each vaccine (HBV3, DTaP-IPV-Hib4, PCV3, MMR/MMRV1, HAV1 and HAV2) exploring child and maternal characteristics for association with vaccination timeliness. Variables with statistical significance at p value < 0.05 were included in the multivariate analysis. A multiple regression analysis model was performed for general variables associated with a child's vaccination status being up-to-date. Associations between the variables and vaccination status are presented as odds ratio (OR) and 95% CI. A p value of < 0.05 was considered significant for all comparisons.

Figure 2

The cumulative proportion of vaccine uptake by child's age in months using the inverse Kaplan-Meier curves for selected vaccine doses[a], in children born in 2009 and followed up to 7 years of age, Jerusalem district, Israel, 2016 (n = 3,098)



DTaP-IPV-Hib4: diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b vaccine, fourth dose; HAV1: hepatitis A vaccine, first dose; HBV3: hepatitis B vaccine, third dose; MMR/MMRV1: measles-mumps-rubella/measles-mumps-rubella-varicella vaccine, first dose; PCV3: pneumococcal conjugate vaccine, third dose.

[a] DTaP-IPV-Hib4 is scheduled at 12 months, HAV1 at 18 months, HBV3 at 6 months, MMR/MMRV1 at 12 months (MMRV vaccine replaced MMR in 2008) and PCV3 at 12 months.

Ethical approval

This study was approved by the Israel MoH Institutional Review Board and was conducted according to the relevant MoH instructions. All collected data were treated as confidential, in strict compliance of legislation on observational studies.

Results

The general characteristics of the 3,098 children born in the Jerusalem district in 2009 and their mothers are presented in Table 1. Half of them (50.7%) were male.

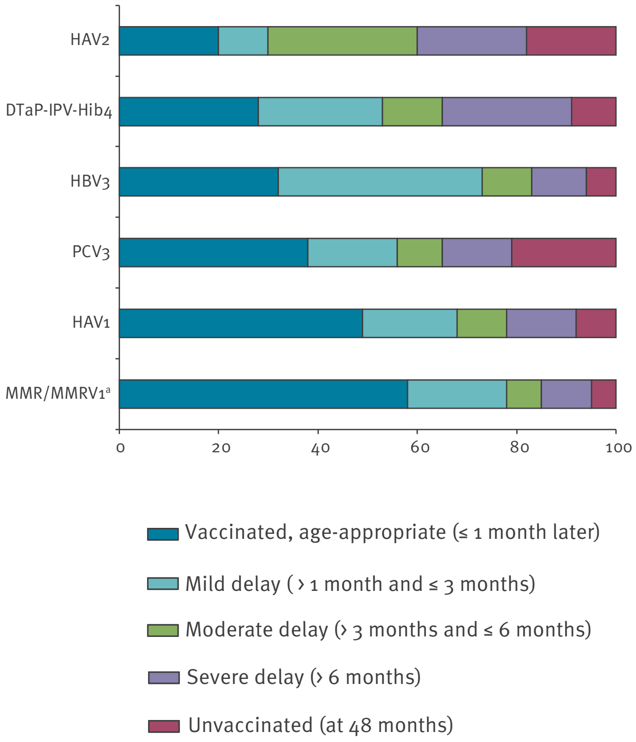
The cumulative fraction of vaccine uptake by inverse Kaplan-Meier curves for HBV3, DTaP-IPV-Hib4, MMR/MMRV1, PCV3 and HAV1 are presented in Figure 2. The age-specific rates at three points in time were as follows: for HBV3, 31.5%, 82.8% and 90.8% were vaccinated at 7, 12 and 24 months, respectively. For DTaP-IPV-Hib4, 27.7%, 64.8% and 80.2% at 13, 18 and 24 months. For PCV3, 37.6%, 64.1% and 72.6% at age 13, 18 and 24 months. For MMR/MMRV1, 58.3%, 85.2% and 90.8% at 13, 18 and 24 months. For HAV1, at 19 and 24 months, 48.6% and 78%.

The distribution by vaccination categories at age 48 months (Figure 3) showed that, depending on the vaccine, between 82–95% of the children were defined as vaccinated up-to-date. The up-to-date rates for the HBV3, DTaP-IPV-Hib4, PCV3, MMR/MMRV1, HAV1 and HAV2 vaccine doses were 94%, 91%, 79%, 95%, 92% and 82%, respectively. The age-specific vaccination rates showed that only 32%, 28%, 38%, 58%, 49% and 20% of children were defined as age-appropriate for these vaccine doses. The fraction of severe delay was higher in the multiple-dose vaccines (26% for DTaP-IPV-Hib4, 22% for HAV2) compared with 10% for MMR/MMRV1. The fraction of children defined as unvaccinated at 48 months also ranged between 18% for HAV2, 21% for PCV3 (in the cohort year of introduction into the schedule) and 5–9% for the other vaccine doses.

The cumulative fraction of vaccine uptake among children in the three main population groups—Arab, Jewish ultra-Orthodox and Jewish traditional-secular—for DTaP-IPV-Hib4 and MMR/MMRV1 are presented in Figure 4. Vaccination completeness and timeliness were higher in Arab children compared to Jewish

Figure 3

Distribution of vaccination coverage by defined categories (status at the age of 48 months) for selected vaccine doses, in children born in 2009, Jerusalem district, Israel, 2016 (n = 3,098)



DTaP-IPV-Hib4: diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b vaccine, fourth dose; HAV1: hepatitis A vaccine, first dose; HAV2: hepatitis A vaccine, second dose; HBV3: hepatitis B vaccine, third dose; MMR/MMRV1: measles-mumps-rubella/measles-mumps-rubella-varicella vaccine, first dose; PCV3: pneumococcal conjugate vaccine, third dose.

[a] MMRV vaccine replaced MMR in 2008.

children, with the lowest rates among children in Jewish ultra-Orthodox communities.

Multiple logistic regression analysis with the dependent variable 'vaccinated up-to-date' at age 24 months and the study group general variables was performed (Supplement S1). The up-to-date vaccination status defined for age 24 months included the vaccine doses HBV3, DTaP-IPV-Hib4, PCV3 and MMR/MMRV1. The variables that were significantly associated with vaccination delay were: high birth order, ethnicity (higher among Jews vs Arabs), birth in winter (January–March) and delayed receipt of the first dose of DTaP-IPV-Hib vaccine scheduled at age two months (OR: 4.67; 95% CI: 3.72–5.87).

A re-evaluation of vaccination status was carried out for the study group children at the age of 7 years. The vaccination coverage rates showed some increase for all the evaluated vaccine doses: HBV3 (1.7%), DTaP-IPV4 (3.1%), PCV3 (1%), MMR/MMRV1 (1.2%) and HAV2 (8%). The median increase observed in vaccination coverage rates was 2.4%.

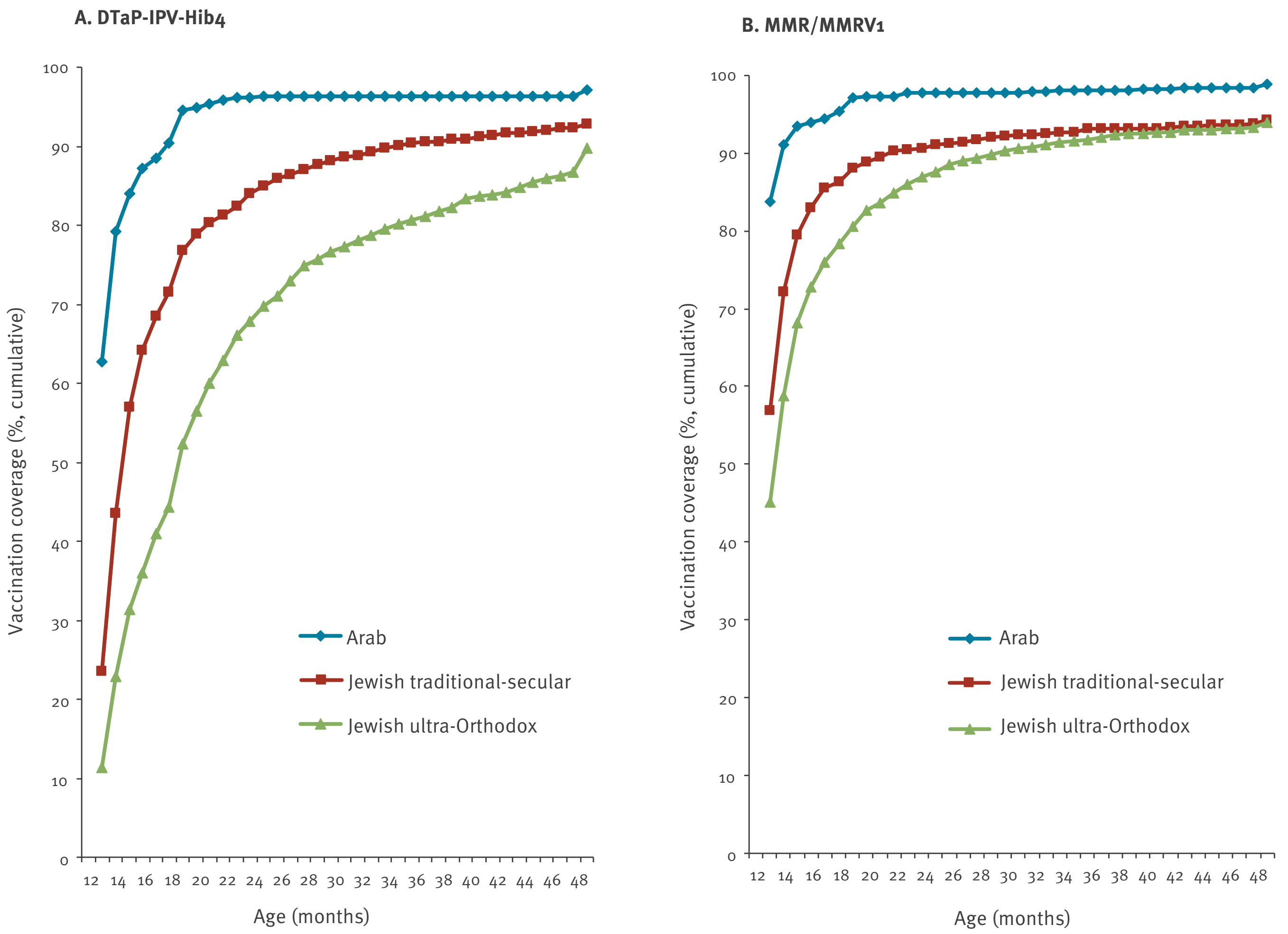
Discussion

The overall childhood vaccination coverage reported in Israel is consistently high [6,7]. While aggregated vaccination rates are high, disaggregated data reveal gaps amid population groups [4,8,16]. Vaccinations gaps and delays, despite appropriate up-to-date coverage, have been reported from developed and developing countries [17-25]. Hence, accurate monitoring of vaccination coverage and timeliness is essential [9,21,26]. The up-to-date vaccination coverage rates were all over 90% for the vaccines evaluated in our study; age-appropriate rates were lower. A similar percentage of children were in the categories 'mild-moderate delay' and 'age-appropriate' for multiple-dose vaccines. The MMR/MMRV1 vaccine was less delayed, perhaps because its application does not depend on the timing of a previous dose and because efforts are made to ensure timeliness to prevent outbreaks. The 7-valent pneumococcal conjugate vaccine (PCV7) was included into the routine schedule in 2009 and PCV13 replaced PCV7 in 2010 [27]. The coverage rate for the third dose of PCV in our group was lower than the 91% national rate [4]. Mothers in the Jerusalem district reported declining 'new' vaccines (e.g. PCV) more often [28]. The reasons for this are unclear and may be attributed to the provision and promotion of new vaccines.

The association between social determinants and health outcomes has been well established [29]. A medium to low socioeconomic status and a high proportion of children in the Jerusalem district have been linked to the spread of communicable disease [10,13]. Delayed vaccinations were associated with a child's birth order, ethnicity, season of birth and delayed receipt of the first dose of the DTaP-IPV-Hib vaccine. The median child's birth order was third in Jerusalem, compared with second nationally, with 37% of children born fourth and above. A high birth order has been associated with vaccination delay [18,21-25]. Vaccination completeness and timeliness were higher in Arab children compared to Jewish children in Jerusalem, which is similar to data for the country overall [4,16]. In a polio vaccine campaign in Israel (2013), the compliance was higher in the Arab than in the Jewish population [30]. Birth in the winter months was also associated with childhood vaccination delay. Delays, most of which are unnecessary, are often related to acute respiratory infections during winter [28]. Parents may perceive delaying vaccination as a safer alternative to the routine childhood vaccination schedules [31]. In our group, delayed receipt of the first dose of the DTaP-IPV-Hib vaccine was highly associated with not being up-to-date at 24 and 48 months. In a US survey, children with delayed vaccines at 3 months had significantly lower up-to-date coverage (at 19–35 months) compared to children without early delay [32]. In a study among Jewish ultra-Orthodox mothers in Israel, infant vaccination receipt at age 2 months was highly predictive for later adherence to

Figure 4

The cumulative proportion of vaccination uptake by age for (A) DTaP-IPV-Hib4 and (B) MMR/MMRV1[a], in children born in 2009 and followed up to 7 years of age, by main population groups, Jerusalem district, Israel 2016 (n = 3,098)



DTaP-IPV-Hib4: diphtheria, tetanus, acellular pertussis, polio, *Haemophilus influenzae* b vaccine, fourth dose; MMR/MMRV1: measles-mumps-rubella/measles-mumps-rubella-varicella vaccine, first dose.

[a] MMRV vaccine replaced MMR in 2008.

the schedule [33]. Children in Jewish ultra-Orthodox communities were found at risk for delayed and missing vaccinations [10,13], as in these communities delay was not perceived as affecting a child's health [28].

The results of this study are subject to limitations. Only children with full data were included and this may have led to an underestimate of vaccine delay. However, counting documented vaccine doses was the only way to obtain accurate vaccination dates. Yet, even the digital records may have been incomplete, with some dates not registered, resulting in an overestimate of vaccine delay. Children who left the area or died were also excluded; therefore, there may be a bias in estimates of the cumulative proportion of vaccination. As for factors affecting vaccination receipt, we included mainly sociodemographic factors. We were unable to include health-related parameters or factors related to the performance of the preventive health services supplier, which should be further evaluated.

After the completion of our study, from March to December 2018, measles importation to Israel resulted in spread to unvaccinated persons, with some 3,150 notified cases (https://www.health.gov.il/English/Topics/Pregnancy/Vaccination_of_infants/Pages/measles.aspx). The outbreak reached Jerusalem in late August 2018 and at present some 1,800 cases have been notified in Jerusalem; 82% (1,470) are children under 15 years of age who almost exclusively reside in ultra-Orthodox Jewish neighbourhoods. An 18-month-old toddler died in Jerusalem in November 2018 and in December 2018 an 82-year-old woman in Jerusalem became the second fatality from the outbreak. The child's death was the first recorded death from measles in Israel in 15 years

The recent outbreak and our findings denote the importance of accurate vaccination data for detecting risk groups, reducing missed opportunities and planning tailored immunisation programmes. Vaccination delay is a common phenomenon that may induce pockets of susceptible populations to VPD outbreaks; therefore, it should be adequately addressed within the vaccine hesitancy spectrum. Vaccine hesitancy refers to the delay in acceptance or refusal of vaccines despite availability of vaccination services. It includes factors such as complacency, convenience and confidence [34]. It has been estimated that 7.5–9% of Israeli parents deviate from the routine vaccination schedule mostly as a consequence of parental decision [35,36]. While most Israeli parents (90%) reported that they had fully immunised their children, the confidence in official recommendations declined from 87% in 2008 to 72% in 2016 [37]. Addressing various forms of vaccine hesitancy is an increasingly complex challenge for health professionals [34,38]. The preventive framework should combine vaccination plans with health promotion measures, the most effective of which are multi-component [34,39]. Particularly in areas and communities with suboptimal vaccine uptake (as found in our study), efforts and budget allocations should prioritise investments that support availability, accessibility and appropriateness of preventive services for children [40]. Implementation of systematic supplementary immunization activities (SIAs) such as mass vaccination campaigns is still essential while the current preventive services are being strengthened [41]. The integration of multiple vaccination-related activities will hopefully further reduce the burden of vaccine-preventable diseases in children.

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Conflict of interest

None declared.

Authors' contributions

The conception and design of the study were formed by Chen Stein-Zamir and Avi Israeli. The study was approved by the Israel Ministry of Health Institutional Review Board and conducted according to the relevant Ministry of Health instructions. Data assembly, analysis, interpretation and final approval of the manuscript were performed by Chen Stein-Zamir and Avi Israeli.

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Increasing childhood vaccination coverage of the refugee and migrant population in Greece through the European programme PHILOS, April 2017 to April 2018

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After the 2016 Balkan route border closures, vaccination of refugee children in Greece was mainly performed by non-governmental organisations. Activities varied between camps, resulting in heterogeneity of vaccination coverage (VC). In April 2017, the European programme 'PHILOS - Emergency health response to refugee crisis' took over vaccination coordination. Interventions were planned for the first time for refugee children in the community and unaccompanied minors at safe zones. From April 2017–April 2018, 57,615 vaccinations were performed against measles-mumps-rubella (MMR) (21,031), diphtheria-tetanus-pertussis (7,341), poliomyelitis (7,652), pneumococcal disease (5,938), *Haemophilus influenzae* type b (7,179) and hepatitis B (8,474). In April 2018, the vaccination status of children at camps (reception and identification centres and community facilities such as hostels/hotels were excluded) was recorded and VC for each disease, stratified by dose, nationality and camp size, was calculated. More than 80% of the children received the first MMR dose, with VC dropping to 45% for the second dose. For all other vaccines, VC was < 50% for the first dose in children aged 0–4 years and < 25% for the second dose. Despite challenges, PHILOS improved planning and monitoring of vaccination activities; however, further efforts towards improving VC in refugee children are needed.

Background

In 2015, during the refugee crisis, over one million refugees and migrants journeyed across the Mediterranean Sea to Europe; in 2016 and 2017, a further 535,054 people arrived in Europe through the same route [1].

Greece is one of the major entry points of Europe. After the Balkan route border closures in 2016, thousands of refugees who entered Greece were not able to proceed towards their intended country of refuge and had to remain in Greece [2]. In 2016, 2017 and 2018 (January to April), 173,450, 29,718 and 8,362 people, respectively, arrived at Greece's north-eastern Aegean Islands, with children < 15 years of age accounting for 38% of the total population [1]. In 2016, the Hellenic Immunisation Advisory Committee recommended vaccination against the following priority diseases for these newly arrived children: measles, mumps and rubella for children 1–14 years old and diphtheria, tetanus, pertussis, poliomyelitis, pneumococcal disease, *Haemophilus influenzae* type b and hepatitis B for children 2 months–4 years old [3].

Until March 2017, vaccination of refugee children was mainly performed by non-governmental organisations (NGOs) under the coordination of the Greek Ministry of Health (MoH). Vaccination activities varied by camp and not all camps were consistently covered by an NGO [4]. Moreover, the vaccination needs of the population living in the community (hostels, hotels, apartments, etc.) or 'safe zones' for unaccompanied minors, were not addressed in this phase. This lack of harmonisation of vaccination practices and the resulting heterogeneity of vaccination coverage (VC) was a public health concern.

Therefore, in April 2017 it was decided that the programme 'PHILOS – Emergency health response to refugee crisis' would take over the coordination of vaccination of refugee children in Greece. PHILOS was a programme of the Greek MoH, implemented by the Hellenic Centre for Disease Control and Prevention (HCDCP) and funded by the Asylum, Migration and Integration Fund (AMIF) of the European Union's Directorate-General for Migration and Home Affairs. All activities were implemented under the supervision of the General Directorate of Public Health of the MoH.

Here we present the activities of the PHILOS programme from April 2017–April 2018 and the results of

Table 1

Demographic characteristics of refugee children at 25 mainland camps, Greece, April 2018 (n = 3,786)

Characteristics		Children n	Children %
Sex	Male	2,002	52.9
	Female	1,720	45.4
	Unknown	64	1.7
Age group (years)	<1	285	7.5
	1–4	1,224	32.3
	5–14	2,277	60.2
Nationality	Syria	1,591	42.0
	Iraq	1,066	28.2
	Afghanistan	749	19.8
	Other[a]	375	9.9
	Unknown	5	0.1

[a] There were 19 different nationalities recorded for the 375 children in the category of 'Other'.

the concluding assessment of VC in April 2018 of refugee children in Greece, by disease, as well as the challenges faced in the programme's implementation.

In this manuscript, we refer to refugees, asylum seekers and newly arrived migrants as refugees.

Setting

In recent years, refugees have entered Greece mainly through the north-eastern Aegean Islands. They are then placed at RICs (each island has one RIC) and are offered medical assessment and medical care, if needed. Depending on their asylum or vulnerability status, most people are then transferred to accommodation camps on the mainland, where they stay for a more extended period until they are finally hosted at hostels, hotels, apartments or other community facilities under the initiatives of the United Nations High Commissioner for Refugees (UNHCR) and other European Civil Protection and Humanitarian Aid Operations (ECHO) partners.

Unaccompanied children are initially placed at specially designed areas inside camps and RICs called 'safe zones', where they stay for a short period of time before they are transferred to community facilities.

Vaccination activities at camps and reception and identification centres

The PHILOS programme set up standard operating procedures (SOPs) regarding vaccination practices at camps and RICs. Each NGO had to inform the PHILOS team about planned vaccination activities and had to request permission from the MoH to proceed with vaccinations. From April 2017 to April 2018, Red Cross, Praksis, Doctors Without Borders (MSF) and Doctors of the World (MdM) supported vaccination at camps, alongside the 'Health for All' programme of the University of Athens [5]. Camps not covered by an NGO were assigned to PHILOS mobile unit teams and all interventions were organised with the cooperation of the Ministry of Migration Policy.

Before each vaccination intervention, assessment of vaccination needs was required. To overcome the challenges posed by the mobility of the population and the heterogeneity of previously implemented interventions, PHILOS personnel visited families door-to-door and actively recorded the vaccination status of all children 0–14 years of age using a standardised form, within 2 weeks of each vaccination intervention. The resulting data were deposited in a specially designed database and sent to the HCDCP, in accordance with Greece's legal framework for sensitive data protection.

All refugees were informed that they could opt-out of sharing their vaccination history or having their children vaccinated; however, written informed consent was not required given the practical limitations in the field.

The recorded information included: (i) a list of all the children 0–14 years of age hosted at each camp and their demographic characteristics (age, sex, nationality), (ii) each child's exact place of residence (container/isobox) inside the camp or other information needed to locate them in future for vaccination, (iii) whether a child already had the World Health Organization (WHO) booklet or other type of vaccine documentation, (iv) any vaccines that a child had already received and (v) if a child had never been vaccinated or whose vaccination status was unknown. Collected data were used to establish the needs of refugee children at each individual camp, as well as at all of the camps as a whole, for better coordination of interventions.

While conducting the door-to-door household survey, personnel also informed the refugees of the planned vaccinations, their importance and how they would benefit the children. Whenever possible, the surveys were conducted with the support of cultural mediators to address possible queries from the population. Personnel also advised parents/guardians to keep their children's vaccine records for future reference and informed them of the importance of these documents for the children's registration at schools. Written information was also provided in English, Farsi, Urdu and Arabic.

A medical and a managerial coordinator were appointed for each intervention, in accordance with Greek law, which states that vaccination can only be performed in the presence of a medical doctor, preferably a paediatrician.

After the end of each intervention, vaccination teams reported the number of vaccinations performed to the HCDCP. Challenges encountered during interventions were also reported. All data were recorded in a common database.

Table 2

Vaccination coverage[a] of refugee children at 25 mainland camps, Greece, April 2018

Disease	Vaccine doses	Number of vaccinated children/total number of children recorded	%
MMR	First	2,843/3,501	81.2
	Second	1,575/3,501	45.0
DTP	First	699/1,509	46.3
	Second	369/1,509	24.5
Poliomyelitis	First	704/1,509	46.7
	Second	370/1,509	24.5
Pneumococcal disease	First	750/1,509	49.7
	Second	267/1,509	17.7
Haemophilus influenzae type b	First	697/1,509	46.2
	Second	370/1,509	24.5
Hepatitis B	First	733/1,509	48.6
	Second	372/1,509	24.7

DTP: Diphtheria-tetanus-pertussis; MMR: measles-mumps-rubella.

[a] The National Immunisation Advisory Committee in Greece recommends vaccination against MMR for children 1–14 years of age (n=3,501) and against diphtheria-tetanus-pertussis, poliomyelitis, pneumococcal disease, *Haemophilus influenzae* type b and hepatitis B for children 0–4 years of age (n=1,509). Vaccination campaigns followed the aforementioned recommendations; thus, vaccination coverage for each disease is presented for the respective age group.

Interventions were also organised at safe zones to accommodate unaccompanied minors, after permission was granted by the Ministry of Migration Policy to organise such an intervention and to contact unaccompanied minors. The Ministry of Migration Policy informed the district attorneys that act as the legal guardians of unaccompanied minors in Greece about the interventions and their scope.

Planning vaccination activities for refugee children living in the community

As refugees were increasingly housed in hostels, hotels and apartments under the UNHCR initiatives, it was difficult to capture VC and needs. Therefore, a meeting with the UNHCR and their associated partner NGOs was organised to assess the VC of the refugee children living in the community and identify opportunities for better vaccination coordination. The NGO representatives at the meeting indicated that the children's VC was low and that the majority of children in their premises were unvaccinated for most of the diseases included in the Greek National Childhood Immunisation Programme (NCIP). It was agreed that the HCDCP and the NGOs' representatives would collaborate closely to address this.

For this reason, each of Greece's seven health regions designated at least two community healthcare centres as vaccination centres that would cover the needs of the refugee child population living in the community. Vaccines and vaccination booklets were sent to the vaccination centres, and NGOs booked the appointments and trained the refugees on how to access the healthcare system.

Vaccination campaigns

Vaccinations at camps and RICs were delivered through mass vaccination campaigns. The number of campaigns held at each camp depended on the size of the hosted population, the amount of new arrivals and the site's resources. At minimum, camps were to perform a vaccination campaign at least once every 2 months.

Overall, from April 2017–April 2018, a total of 57,615 vaccinations were performed by NGOs and PHILOS in 15 and 10 camps, respectively: 21,031 against measles-mumps-rubella (MMR), 7,341 against diphtheria-tetanus-pertussis (DTP), 7,652 against poliomyelitis, 5,938 against pneumococcal disease, 7,179 against *Haemophilus influenzae* type b and 8,474 against hepatitis B.

Of the conducted vaccinations, 24,241 (42.1%) were performed at camps on the mainland, 17,649 (30.6%) at RICs, 14,941 (25.9%) in the community and 784 (1.4%) in safe zones.

Assessment of vaccination coverage at mainland camps, April 2018

An assessment to estimate the VC of refugee children living in camps on the mainland took place in April 2018. PHILOS personnel visited the mainland camps over 2 weeks and went door-to-door to identify children aged 0–14 years and their vaccination status, based on WHO booklets or other documents they had been provided after their arrival to Greece. Parents' statements regarding prior vaccinations were not taken into account.

The proportion of children 1–14 years of age that had been vaccinated against MMR and the proportion of

Table 3

Number of vaccinated[a] refugee children at 25 mainland camps, by sex and nationality, Greece, April 2018 (n=3,786)

Disease	Vaccine doses[b]	Sex[c]					Nationality[d]						
		Male		Female		p value[e]	Syria		Iraq		Afghanistan		p value[e]
		n	%	n	%		n	%	n	%	n	%	
MMR	First	1,528	82.0	1,299	82.1	0.975	1,166	80.1	811	79.8	608	88.0	0.001
	Second	828	44.4	746	47.1	0.115	586	40.2	418	41.1	445	64.4	<0.001
DTP	First	363	46.8	334	47.8	0.698	296	40.7	144	40.0	192	69.1	<0.001
	Second	192	24.8	177	25.4	0.796	142	19.5	66	18.3	128	46.0	<0.001
Poliomyelitis	First	366	47.2	336	48.1	0.726	300	41.3	145	40.3	192	69.1	<0.001
	Second	193	24.9	177	25.4	0.841	143	19.7	66	18.3	128	46.0	<0.001
Pneumococcal disease	First	394	50.8	355	50.9	0.994	336	46.2	153	42.5	194	69.8	<0.001
	Second	146	18.8	121	17.3	0.455	98	13.5	39	10.8	111	39.9	<0.001
Haemophilus influenzae type b	First	363	46.8	332	47.6	0.781	294	40.4	144	40.0	192	69.1	<0.001
	Second	193	24.9	177	25.4	0.841	143	19.7	66	18.3	128	46.0	<0.001
Hepatitis B	First	381	49.2	350	50.1	0.707	316	43.5	151	41.9	194	69.8	<0.001
	Second	193	24.9	179	25.6	0.744	145	19.9	66	18.3	128	46.0	<0.001

DTP: Diphtheria-tetanus-pertussis; MMR: measles-mumps-rubella.

[a] For the calculation of the vaccination coverage for MMR that refers to children 1–14 years of age (n = 3,501) the respective denominators were used: 1,863 of the children were male, 1,583 female, 1,456 were from Syria, 1,016 from Iraq and 691 from Afghanistan. Similarly, for the calculation of vaccination coverage for diphtheria-tetanus-pertussis, poliomyelitis, pneumococcal disease, Haemophilus influenzae type b and hepatitis B that refers to children 0–4 years of age (n = 1,509), the following denominators were used: 775 children were male, 698 females 727 were from Syria, 360 from Iraq and 278 from Afghanistan.

[b] Coverage for more doses of the aforementioned vaccines (when applicable) was also recorded; however, the data was not presented here due to the low numbers of vaccinated children.

[c] Information regarding sex was missing for 64 records.

[d] Information regarding nationality was missing for five records. The other 375 children of 19 different nationalities are not included in the table.

[e] Pearson's chi-squared test p value.

children 0–4 years of age that had been vaccinated against diphtheria-tetanus-pertussis, poliomyelitis, pneumococcal disease, *Haemophilus influenzae* type b and hepatitis B—by dose, sex and nationality—were calculated. The association between the VC for at least one dose of each vaccine and the size of the camp (1–99 hosted children, ≥ 100 hosted children) was assessed.

In total, 3,786 children were recorded at the 25 camps on the mainland; 3,501 were 1–14 years of age and 1,509 were 0–4 years of age. Of these, 78.9% had the WHO booklet (2,572/3,261 for whom this information was available). Of the 3,722 children for whom the information was available, 2,002 were male (53.8%) and the mean age was 6 years (standard deviation (SD) ± 4.16). Overall, 22 different nationalities were recorded. Demographic data of children at the time of the survey are summarised in Table 1.

VC by disease is presented in Table 2. More than 80% of the children 1–14 years of age (2,843/3,501) had been vaccinated with the first dose of the MMR vaccine; however, for the second dose the coverage dropped to 45% (1,575/3,501). Coverage among children 0–4 years of age was < 50% for the first dose of all the other vaccines and below 25% for the second dose.

The number of vaccinated children by sex and nationality is presented in Table 3. Sex did not have a statistically significant association with VC. The proportion of children vaccinated at each camp had a statistically significant association with nationality. Children from Afghanistan had higher VC compared with Syrian and Iraqi children. Larger camps had higher VC for at least one dose of MMR vaccine (p = 0.016) (Table 4). This difference appeared consistently for all other vaccines when looking at the point values, albeit without statistical significance.

Lessons learnt and challenges

Despite the positive outcome of PHILOS, a number of challenges were encountered while the programme was active.

Availability of cultural mediators

PHILOS and NGO personnel had to deal with an insufficient number of cultural mediators on site, a well-documented challenge in such settings [6,7]. Additionally, the camps' populations were constantly changing, with people moving from one camp to another or to community shelters. Eight camps closed in 2017 and two new ones opened, making vaccination status follow-up and planning of vaccination campaigns difficult.

To address this, vaccination campaigns were designed to be flexible and in several cases campaigns were postponed to assure the presence of cultural mediators. In other cases, campaigns had to be prolonged

Table 4

Vaccination coverage[a] of refugee children at 25 mainland camps, Greece, April 2018 (n=3,786)

Disease	Vaccine doses	Camp size (1–99 children) Mean (±SD)	Camp size (≥100 children) Mean (±SD)	p value[b]
MMR	No dose	39.9 (±32.28)	16.9 (±11.43)	0.016
	At least one dose	60.1 (±32.28)	83.06 (±11.43)	
DTPc	No dose	69.2 (±13.15)	56.2 (±19.85)	0.094
	At least one dose	30.8 (±13.15)	43.8 (±19.85)	
Poliomyelitis	No dose	69.2 (±13.15)	56.0 (±20.04)	0.090
	At least one dose	30.8 (±13.15)	44.0 (±20.04)	
Pneumococcal disease	No dose	56.1 (±29.40)	56.4 (±19.67)	0.977
	At least one dose	43.9 (±29.40)	43.6 (±19.67)	
Haemophilus influenzae type b	No dose	69.7 (±13.00)	56.2 (±19.84)	0.081
	At least one dose	30.3 (±13.00)	43.8 (±19.84)	
Hepatitis B	No dose	68.5 (±13.66)	52.8 (±22.75)	0.073
	At least one dose	31.5 (±13.66)	47.2 (±22.75)	

DTP: Diphtheria-tetanus-pertussis; MMR: measles-mumps-rubella; SD: standard deviation.

[a] Vaccination coverage against MMR for children 1–14 years of age (n=3,501) and vaccination coverage against diphtheria-tetanus-pertussis, poliomyelitis, pneumococcal disease, Haemophilus influenzae type b and hepatitis B for children 0–4 years of age (n=1,509), by camp size (1–99 children and ≥100).

[b] Student's t-test p-value.

in order to cover newcomers or unexpected needs. All available human resources that could support mediation were utilised. In addition to NGO and PHILOS personnel, volunteers from the community and in some cases members of the camps' populations also supported vaccination efforts.

Limitations of recording VC

The results of the survey in April 2018 were useful, as constant monitoring of VC in the camps via a specially designed vaccination registry was not possible. However, the estimated coverage only accounts for the 3,786 children recorded as living in the camps in April 2018 and cannot be extrapolated to the population living in RICs or in the community, or to those who occupied the camps in the following months. RICs were not included in the study because the increased workload for the medical staff and the continuous arrival of refugees made door-to-door surveying impossible.

Insufficient vaccination coverage remained for a number of diseases

As at April 2018, VC was high for the first dose of the vaccine against MMR, but was far from optimal for the second dose, as well as for the first and second dose against pneumococcal disease, hepatitis B, poliomyelitis, diphtheria-tetanus-pertussis and *Haemophilus influenzae* type b. Therefore, mass vaccination campaigns were still needed. During the months following the assessment, new campaigns were designed, giving priority to the camps with the lowest VC.

The use of a combination vaccine that protects against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and infection with *Haemophilus influenzae* type B bacteria in most of the vaccination campaigns explains the similar VC for all six diseases.

Differing vaccination coverage by nationalities and camp size

The difference in VC by nationality may be attributed to the quicker turnover of the Syrian population at camps, as they had more straightforward access to the asylum processes. Syrian children represented in the study may have missed prior vaccination campaigns if they had recently entered the camps. However, this is just a hypothesis, as the dates of arrival at the camps were not recorded.

The higher vaccination coverage at larger camps may be explained by the fact that vaccination campaigns might have been more organised, frequent and effective compared with those at smaller ones.

Increased refugee childhood population in the community

Vaccination activities for refugee children living in the community at hotels, hostels or private houses were designed for the first time; however, the estimated number of unvaccinated children in the community was beyond the purposes of this study. By the end of April 2018, the number of refugees living in the community had increased to more than 20,000, 48% of whom were children [8]. As the number of refugee children in the community steadily became greater than the number of children hosted at the mainland camps, priority had to be given to this population. Therefore, vaccination interventions began to be implemented in the community, not only at the camps, as was done previously. During this period, the PHILOS programme focused on covering vaccination gaps, with the support of health regions as previously described, and guiding families living outside camps to acquire national health security numbers that would allow for vaccinations based on the NCIP, free of charge.

Conclusion

Vaccination of refugee children is a priority for host countries; however, several studies have documented that refugees have low immunisation rates and encounter essential barriers in accessing routine healthcare services.

In 2017, the PHILOS programme took over the coordination of refugee children's vaccinations in Greece. PHILOS set standard operating procedures for identifying vaccination needs at camps and RICs, performing information campaigns with the support of cultural mediators and promoting the use of a singular booklet for documenting vaccination history for all children. PHILOS' activities showed that the implementation of a coordinated approach to vaccinations in such a complex situation and setting is feasible and provided a useful experience of cooperation between the HCDCP, MoH, regional public health authorities, international organisations, NGOs and other stakeholders in organising vaccination campaigns. Overall, the programme demonstrated progress in the coordination of vaccinations for refugee children in Greece. Vaccination of all refugee children upon arrival and enhancement of continued access to healthcare should be future public health priorities.

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Conflict of interest

None declared.

Authors' contributions

KM conceived of the study and its design, led the study organization and coordination, contributed to the interpretation of the data, as well as the manuscript's first draft and revisions. CS contributed to the collection of the data, to the analysis of the results and drafting the manuscript. ESP performed the statistical analysis, contributed to the background and methodology and reviewed the manuscript. AS participated in the design of the work and coordination, and reviewed the manuscript. IDP, TG, CB and AT contributed to the critical revision of the manuscript. All authors discussed the results and approved the final manuscript.

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Perspective

The law on compulsory vaccination in Italy: an update 2 years after the introduction

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Italy introduced a national law extending the number of compulsory vaccines from four to 10 in July 2017. The implementation placed a further burden on immunisation centres as they were required to cover the increased demand of vaccination by the parents of unvaccinated children. Vaccine coverage (VC) estimated 6 months and 1 year later, at 24 and 30 months (same birth cohort), had increased for all vaccines. At 24 months of age, measles VC increased from 87.3% in 2016 to 91.8% in 2017 and 94.1% at 30 months of age as at June 2018. In six of 21 regions and autonomous provinces, VC for measles was >95%. Despite the implementation of this law, vaccine hesitancy is still a problem in Italy and the political and social debate on mandatory vaccination is ongoing. Regardless of the policy to be adopted in the future, strategies to maintain high vaccination rates and the related herd immunity should be considered, including adequate communication to the population and the implementation of electronic immunisation registries.

Background

The occurrence of a large measles outbreak in January 2017, triggered the establishment of a new law, adopted in July 2017, which extended the number of mandatory vaccines from four to 10 vaccines for those aged 0–16 years [1]. Vaccinations against pertussis, measles-mumps-rubella (MMR), varicella and *Haemophilus influenzae* type b (Hib) were added to the list of already mandatory vaccines (diphtheria, tetanus, hepatitis B and polio) in the national immunisation plan (NIP). More information on the law was previously published [2].

In Italy, individual vaccinations are recorded in the local or regional immunisation information systems (IISs) at the time of vaccine administration. In each of the 21 regions (R)/autonomous provinces (AP), the population for the estimation of VCs is taken from population registers or from healthcare registers. Every year, R/AP send aggregated data to the Ministry of Health (MoH). These data are used to estimate and publish the national VCs for all vaccines included in the NIP for the target age groups (i.e. VC at the age of 24 months, 36 months, 7 years and 16–18 years) [3]. Here, we describe the impact on VC in Italy 2 years after the implementation of the law and the challenges that needed to be overcome in its implementation.

Vaccination coverage before and after the law

The national VC in Italy from 2013 to 30 June 2018 (1 year after the introduction of the law) can be seen in Table. There was a decline of all VCs since 2014 due to increasing vaccine hesitancy. The impact of the law on the vaccine uptake was positive in the first estimation of all VCs (December 2017) just after 6 months since the implementation of the law [2]. Because evaluating the impact of law was a topic of critical importance to guide a possible revision of the vaccination strategy in Italy, which is currently under discussion in the Italian Parliament, the MoH decided to conduct an extra VC data collection on 30 June 2018 to update the VCs for the birth cohorts already evaluated at the end of 2017.

The data from 2018 show an increase of VCs at the national level (Table) and in almost all the R/AP [4]; at 30 months, VC for MMR vaccine was 94.1% (range 82.2–97.5), with 6 of 21 R/AP having more than 95% children vaccinated (data not shown). For non-mandatory vaccinations (i.e. meningococcal and pneumococcal vaccines) VC were also increasing. However, the data recorded in 2018 showed a wide range in VCs among R/AP, suggesting that there is space for improvement in the implementation of vaccination strategies, especially for vaccinations that were not mandatory before the law.

Table

Vaccination coverages by year and vaccine, Italy, 2013–30 June 2018

Vaccine	Number of doses	Year						Difference	Range of vaccination coverages among the R/AP in 2018[a]
		2013	2014	2015	2016	2017	2018[a]	2017–18[a]	
Vaccination coverage (%) at 24 months[b]									
Polio	3	95.7	94.7	93.4	93.3	94.6	95.5	+0.9	89.4–98.4
Diphtheria	3	95.8	94.7	93.4	93.6	94.6	95.4	+0.8	89.4–98.4
Tetanus	3	95.8	94.8	93.6	93.7	94.7	95.5	+0.8	89.4–98.4
Pertussis	3	95.7	94.6	93.3	93.6	94.6	95.4	+0.8	89.3–98.4
Hepatitis B	3	95.7	94.6	93.2	93.0	94.4	95.2	+0.8	88.9–98.3
Hib	3	94.9	94.3	93.0	93.1	94.3	95.0	+0.7	88.6–98.4
Measles	1	90.4	86.7	85.3	87.3	91.8	94.1	+2.3	82.2–97.5
Mumps	1	90.3	86.7	85.2	87.2	91.8	94.2	+2.4	82.2–97.5
Rubella	1	90.3	86.7	85.2	87.2	91.8	94.1	+2.3	82.2–97.5
Varicella	1	33.2	36.6	30.7	46.1	45.6	46.7	+1.1	4.1–91.7
Meningococcal C	1	77.1	73.9	76.6	80.7	82.6	87.8	+5.2	56.9–95.4
Pneumococcal 13v	3	86.9	87.5	88.7	88.4	90.9	92.0	+1.1	83.1–96.6
Vaccination coverage (%) at 36 months[c]									
Polio	3	96.3	95.7	95.4	94.1	95.1	95.8	+0.7	91.4–99.1
Measles	1	92.3	90.7	89.2	88.0	92.4	94.4	+2.0	84.5–96.5
Vaccination coverage (%) in their seventh year of life (plus 6 months)									
Polio	4	90.9	89.2	87.6	85.7	88.7	92.3	+3.6	85.6–96.6
Measles	2	83.5	82.7	83.0	82.2	85.7	90.1	+4.4	78.7–94.0

R/AP: regions and autonomous provinces.

[a] Partial data as at 30 June 2018. Two of 21 R/AP did not send data.
[b] Vaccination coverage (%) at 30 months for 2018.
[c] Vaccination coverage (%) at 42 months for 2018.
Source: Italian Ministry of Health.

Challenges in implementing the new law

Vaccine offer and delivery

In Italy, vaccination is actively offered to target population groups and administered free of charge by public immunisation services. The Italian health system is decentralised and the NIP is issued by the MoH [5,6], but implemented on a local level by the health authorities in the R/AP according to their regional immunisation plans.

To comply with the requirements of the new law, children aged less than 6 years are required to have complete vaccination cycles to attend educational services and the same applies for students over 6 years of age in order for their parents to avoid being sanctioned with a fine, by the start of the school year in September 2017. After the adoption of the law, the local health units (LHUs), responsible for administering vaccinations to children had a dramatic increase in appointments, both for parent counselling and catch-up vaccinations. The MoH was unable to calculate the exact number of children that would require catch-up vaccinations, but estimated that a total of 4,600,000 doses of the different mandatory vaccines would be needed to cover the full catch-up of the partially vaccinated/not vaccinated from 1 to 16 years of age.

While some R/AP actively provided planned appointments for the catch-up vaccinations through invitation letters, problems arose when parents did not have a vaccination certificate. In these instances, parents had to contact the LHUs to verify the vaccination status and, eventually, to book an appointment for the vaccination. This resulted in excess requests for public immunisation services and in slowing down their regular activities e.g. administration of other non-mandatory vaccinations (pneumococcal, meningococcal B and C infection, rotavirus and HPV); this slowing down lasted several months. To help alleviate this problem, the MoH permitted all partially/unvaccinated children seeking an appointment for catch up vaccinations at the time of school year opening to have access to the educational services.

Parental informed consent for vaccinations was used in many LHUs, even if not required by the law; no child was forced to receive any vaccination. In order to identify unvaccinated individuals, the MoH issued a definition of ‘unvaccinated children’ and proposed a table with the catch-up immunisation schedule for children aged up 16 years [7].

Identification of the unvaccinated children and their catch up

The 2017 measles outbreak was due to low MMR VC among in infants and in adolescents in Italy [4]. In order to identify unvaccinated children aged up to 16 years, in absence of a national IIS, the R/AP used the local or regional IIS [3]. Local immunisation services were supported by educational service managers at schools and preschools, which were required to collect vaccination certificates for all children aged less than 17 years at the moment of school enrolment and transmit the information to LHUs. Difficulties were reported by the educational service managers, due to the different communication strategies to the LHUs in each R/AP. For example, in some schools all the parents had to present the vaccine certificates, while in others the certificates were only requested of children not registered in the local IIS. After the first year following the introduction of the law, all these critical points were gradually solved.

Application of penalties

As part of the law, a fine was introduced for parents/guardians refusing vaccination and partially/unvaccinated children under the age of 6 years were not permitted to attend pre-school education services. However, political and social debate, typically fuelled by groups opposed to the law (e.g. 'free-vax' movement), led to some R/AP authorities delaying the implementation of the financial fines for unvaccinated children until early 2019, creating inequalities among the R/AP. Self-certification of the vaccine status by the parents was accepted by school managers until March 2019 [8,9]. As the attendance of educational services for children under age of 6 years is on voluntary basis, it was not possible to estimate the number of children to whom access was denied.

Increasing the population's knowledge and awareness of the importance of vaccination

In order to raise awareness of the law, the MoH created a website dedicated to vaccinations, with a special section dedicated to the new law [10] and provided a free phone number and two mailboxes dedicated to questions about vaccination that are still active. In addition, five circular letters providing information regarding the new law were sent to public regional and national institutions, health and educational authorities and healthcare professionals all around Italy.

The implementation of the law, resulted in media interest with particular focus on the safety and effectiveness of vaccinations and contributed to increasing the awareness of the importance of vaccination in the population. LHUs, R/AP authorities and scientific societies additionally implemented communication and training activities for public health and healthcare providers. In late 2018, the MoH launched a national TV and internet campaign on the benefits of vaccination using two celebrities as testimonials, a volley ball champion and an astronaut, in order to contrast vaccine hesitancy [11]. The increase of vaccination coverage may be a result of this debate and information campaign raising awareness of the importance of vaccination. A survey conducted by Giambi, and colleagues (Istituto Superiore di Sanità, Rome, Italy) in 2018 (data not shown) compared recent data (following the implementation of the law) with a previous survey conducted in 2016 [12]. They found that the percentage of hesitant parents had decreased in Italy from 15.5% in 2016 to 11.5% ($p < 0.001$) in 2018 and that the number of anti-vaxxers had decreased from 0.7 to 0.5 (not statistically significant).

Conclusions

Vaccines have become a national talking point in Italy as a result of the newly introduced law. While reasons for low VC include a low perceived risk regarding vaccine preventable diseases [13], vaccine hesitancy due to low confidence in vaccines, safety concerns and lack of specific recommendations [12]. Prior to the introduction of the new law, attempts to improve the quality of public immunisation services and communication campaigns were not sufficient to have a positive impact on these factors and therefore VC [4,14]. Some of these points have been addressed during the implementation phase of the new law and there are encouraging signals that the situation may have improved as indicated by the survey conducted by Giambi et al. and by the positive trend in VC coverage for the vaccinations that before law were not mandatory, e.g. for measles.

In Italy, mandatory vaccination is still debated and a source of controversy due to unresolved different opinions and the need to strike balance between individual freedom and the public health perspective. After the elections in March 2018, the new government prepared a proposal to revise the law moving towards a more flexible approach in the definition of the mandatory vaccinations, that is now under discussion in the Parliament [15].

There are some limitations that should be considered when interpreting the VC data. The 2018 VC refers to older children (30 months rather than 24 months), which could affect the comparability with the previous year. The absence of data from two R/AP could also have affected the national average and decreased the comparability with 2017 data. The estimation at the end of the first half of 2018 could be less comparable with data collected at the end of the year, due to possible different methods used to estimate numerator and denominator for VCs being the first interannual data collection. The complete 2018 data as at 31 December 2018, were collected and they are currently under validation. The planned implementation of a national IIS may minimise the bias due to the difficulties of local and regional IISs to estimate the number of vaccinated people, given the high mobility in the country, and provide more accurate VC estimates.

Any future change in the law should be accompanied by a strong communication campaign to the population to explain the rationale of such changes and support them with scientific evidence and adequate investments to avoid losing trust in vaccination. The implementation of electronic immunisation registries should be ensured at national level to enforce the monitoring of the vaccination strategy and to rapidly identify areas or population groups with lower coverage.

Whatever the policy to be adopted in the future, strategies to maintain or even improve high vaccination rates and the related herd immunity should be considered. Moreover, with regard to measles, 95% VC among children aged 2 years has been almost achieved, but there are still geographical variations throughout the country. All these aspects should be taken into account when planning effective vaccination strategies.

Conflict of interest

None declared.

Authors' contributions

Fortunato D'Ancona wrote and draft the manuscript, contributed to the data analysis, prepared the tables. Stefania Iannazzo proposed the manuscript, contributed to the data analysis, critically revised the manuscript. Giovanni Rezza contributed to draft the manuscript and critically revised it. Claudio D'Amario, Francesco Maraglino critically revised the manuscript.

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Perspective

Towards equity in immunisation

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In the World Health Organization (WHO) European Region, differences in uptake rates of routine childhood immunisation persist within and among countries, with rates even falling in some areas. There has been a tendency among national programmes, policymakers and the media in recent years to attribute missed vaccinations to faltering demand or refusal among parents. However, evidence shows that the reasons for suboptimal coverage are multifactorial and include the social determinants of health. At the midpoint in the implementation of the European Vaccine Action Plan 2015–2020 (EVAP), national immunisation programmes should be aware that inequity may be a factor affecting their progress towards the EVAP immunisation targets. Social determinants of health, such as individual and household income and education, impact immunisation uptake as well as general health outcomes – even in high-income countries. One way to ensure optimal coverage is to make inequities in immunisation uptake visible by disaggregating immunisation coverage data and linking them with already available data sources of social determinants. This can serve as a starting point to identify and eliminate underlying structural causes of suboptimal uptake. The WHO Regional Office for Europe encourages countries to make the equitable delivery of vaccination a priority.

Despite the success of routine childhood immunisation programmes in reducing the incidence of vaccine-preventable diseases, immunisation uptake varies among countries, and among groups and districts within countries in the World Health Organization (WHO) European Region. There are also differences in coverage between the different scheduled vaccines. Inequity in uptake of routine vaccines has contributed to an accumulation of susceptible individuals in several countries of the Region [1,2] and hence also to the continued occurrence and spread of some vaccine-preventable diseases [3].

Inequities in health are associated with the social determinants of health, and inequities in immunisation are related to the concepts of social justice, fairness and ethics (Box 1)

Commitment to equitable extension of vaccination services

In 2014, all 53 countries in the Region committed to achieve the six goals and five objectives of the European Vaccine Action Plan 2015–2020 (EVAP) [4]. Unfortunately, progress towards Objective 3, equitably extending the benefits of vaccination to all, and towards Goal 4, meeting regional vaccination coverage targets, has been slow [5]. The tendency among many national programmes, policymakers and the media in recent years has been to attribute decreasing or suboptimal vaccination uptake to parental concerns about vaccines or refusal, but this is only part of the problem. Evidence shows that the reasons for suboptimal coverage are multifactorial, and social determinants and systems-related barriers can play an equally or more important role, depending on the context [6,7]. Targeted studies with the beneficiaries are needed to understand which barriers are most critical to address. EVAP's Objective 3 specifically states that "the benefits of vaccination are [to be] equitably extended to all people" [4], however, this key pathway which will help reach EVAP goals has not yet been sufficiently explored or used.

At the midpoint of EVAP, all national immunisation programmes should investigate the extent to which equity is an issue that affects their progress towards EVAP's goals and targets (Box 2).

Identifying inequities in immunisation

Acknowledging that immunisation coverage may be affected by social determinants is an important step in addressing those differences in uptake that arise from inequity in vaccine delivery and access.

Box 1

Concepts of equity and immunisation

Inequity in immunisation: Avoidable differences in immunisation coverage between population groups that arise because barriers to immunisation among disadvantaged groups are not addressed through policies, structures, governance or programme implementation [4,8].

Equitable access to vaccines: All individuals are offered the same vaccines through delivery services that are tailored to meet their needs.

Social determinants of health: The underlying conditions in which people are born, grow, live, work and age [27]. These determinants include parental income, education, living standards, gender equity, distribution of power, policy frameworks and social values.

Box 2

Critical actions in addressing inequities in immunisation

- Acknowledge that immunisation coverage may be affected by social determinants and that parental concern about vaccination is only one of several potential reasons for suboptimal uptake;
- Reveal and monitor disaggregate data to reveal inequities in uptake (e.g. by income of parent, geographical region, age, ethnicity);
- Conduct research to identify root causes of identified inequities;
- Apply an equity focus in all immunisation-related activities by first considering how population groups may be impacted differently;
- Ensure fair and inclusive structures, policies and decision-making that goes beyond prioritisation based on cost-effectiveness.

National immunisation uptake statistics do not usually provide sufficient detail to identify which local populations are not fully vaccinated. There is a clear need to move beyond measuring the difference between worst- and best-performing geographical areas and to accurately identify who or which groups are not being immunised and where. Most countries that have undertaken to identify inequities in immunisation have found them – most often related to social determinants such as parental socioeconomic status, number of years in education and/or ethnicity [9-11].

Research on different vaccines in various countries has shown that immunisation uptake is related to the same factors associated with other health inequities and social determinants of health, e.g. parental number of years in education and level of income [12-16]. The collection and analysis of disaggregate data at district level has proven useful to identify where inequities exist. For example in Wales, disaggregate data are routinely used to monitor socioeconomic inequalities in vaccination coverage in 4-year-old children and have also revealed that socioeconomic inequities in uptake are largest for vaccinations scheduled for older children [17,18]. In Ireland, disaggregate data analysis led to identifying a large socioeconomic gradient in infant vaccination, a problem previously unknown and not addressed [19]. A range of similar studies exist, bearing witness to the correlation between vaccination coverage and social determinants and demonstrating the need for more countries to use similar methods to identify inequities in uptake [20-23].

From data to action

Treating all people the same will not necessarily reduce inequities in immunisation. There is no single way to 'start' to address inequities in immunisation, in some countries it may be necessary to develop policies, in others to adapt services, in others to develop systems to analyse and disaggregate data and in other countries to maintain and improve these disaggregate data. Addressing inequities is not a one-off action, it is a shift in conceptualising how services are delivered and how the goals and targets are set.

The first step in understanding inequities in immunisation is making inequities visible [20,21]. Understanding *who* is not immunised will help to understand *why* they are not immunised. Good quality, robust disaggregate data should be able to identify, map and track populations affected by inequities [22]. The goal should be for each country to analyse immunisation uptake data to identify presence or absence of inequities. This requires immunisation uptake data to be disaggregated by key determinants of inequalities: (i) socioeconomic status, (ii) geographical location, (iii) educational status of parents and (iv) ethnicity and migration status.

Once pockets of un- or under-vaccination in specific geographic areas or among certain population groups are identified, national programmes can research the barriers that prevent some individuals from getting vaccinated (for example, barriers related to individual beliefs, attitudes and knowledge as well as those related to access, cost and service provision) and identify interventions to address them. Identifying underlying structural causes allows countries to design equitable immunisation services, remove barriers to immunisation and ensure that the benefits of immunisation reach every child [1,17,23-26].

Immunisation services alone cannot address the social determinants of health. However, immunisation programmes should consider these factors and adapt vaccine service delivery to meet the needs of all populations to increase uptake. If not seen and designed through an equity lens, immunisation programme activities can in fact increase inequity [27]. There is a growing body of research, including systematic reviews, showing that multi-component, locally designed interventions are most effective in reducing inequities in immunisation uptake [15,28]. Inequities are not resolved by providing the same immunisation services to all; they are resolved by providing different immunisation services that satisfy the needs of all.

Flexible and opportunistic immunisation programmes and good relationships between healthcare services and parents appear to improve vaccination coverage and reduce inequities [29]. Flexible interventions and services involve considering where immunisations are delivered and who administers vaccines, as well as providing multiple offers of immunisation.

Where immunisations are delivered

Equitable immunisation programmes consider where it is easiest for families and individuals to be vaccinated. Vaccines can be delivered outside of health clinics, for instance in schools, pharmacies, community centres, hospitals or at home. For example, Belgium offered school-based vaccination against human papillomavirus (HPV), which increased rates of vaccination initiation/completion and lowered inequalities based on socioeconomic factors [30].

Who administers vaccines

In some countries in the WHO European Region, only licensed family doctors are able to vaccinate. This may limit the flexibility of a service and add unnecessary costs. Enabling other healthcare workers such as nurses, midwives, school nurses and pharmacists to vaccinate may help increase equity. For example in the UK, school nurses' familiarity with their students and their established relationships with socially excluded communities were key to increasing uptake among girls who did not attend or who missed doses of the HPV vaccine [31].

Multiple offers of immunisation

The WHO Missed Opportunities for Vaccination strategy recommends any child or adult eligible for vaccination coming to a health service (for whatever reason) should be offered needed vaccines during their visit. This means offering vaccinations during visits to health services for curative services (e.g. treatment of fever, cough, injuries) or preventive services (e.g. parental classes), as well as offering them to accompanying family members [32]. For example, Scotland addressed inequities in their immunisation programme by offering vaccines many times and found it was "effective in minimising socioeconomic variation in the uptake of routine HPV immunisation in girls". [33]

In the WHO European Region, some countries have mandatory vaccination policies, however, it is yet to be studied when and how such policies reduce inequities in immunisation uptake. Whether a country chooses to mandate vaccination or not, all 53 Member States of the Region have agreed to a set of immunisation goals in the European Vaccine Action Plan. It is up to the national health authorities to take measures suitable to their national context and ensure equitable and high immunisation coverage hereby protecting their citizens from life-threatening diseases.

The wider benefits of improving equity in immunisation uptake

Equitable immunisation policies, like all equitable health policies, generate wider health, social, political and economic benefits [34]. Immunisation is a powerful method to attract people into healthcare, especially the most vulnerable [35]. Improving equity in immunisation can therefore also improve coverage of other health interventions [6].

EVAP suggests that countries in the Region ensure that every individual is eligible to receive all appropriate vaccines, irrespective of their geographic location, age, gender, educational level, socioeconomic status, ethnicity, nationality or religious or philosophical affiliation [3]. Governments are tasked with creating fair and inclusive structures and policies, in partnership with immunisation teams, health professionals and the recipients of vaccines, all working together to reduce inequities in health and in vaccination uptake. To support this work, organisations such as the WHO Regional Office for Europe works continuously to share evidence and normative guidance and to help countries learn from each other's work through the Tailored Immunization Programmes (TIP) [36]. The TIP helps countries identify the root causes of under-vaccination.

Conflict of interest

None declared.

Authors' contributions

TB drafted the article and AG, CK, MM, RB and KBH all contributed to subsequent drafts.

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http://www.infectieziektebulletin.be

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https://epidemio.wiv-isp.be/ID/Pages/flashs.aspx?lcid=1036

Monthly, online. In Dutch.

https://epidemio.wiv-isp.be/ID/Pages/flashs.aspx?lcid=1043

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Landlknisembtti, Directorate Of Health, Seltjarnarnes

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https://www.landlaeknir.is/english/epi-ice/

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http://europa.eu

European Commission - Public Health

The website of European Commission Directorate General for Health and Consumer Protection (DG SANCO).
http://ec.europa.eu/health/

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http://ec.europa.eu/health-eu/

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http://www.ecdc.europa.eu

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