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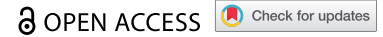


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SHORT REPORT



Parental trust and beliefs after the discovery of a six-year-long failure to vaccinate

Laura Brunelli ^{a*}, Francesca Valent ^{b***}, Federico Romanese ^{a***}, Pierfrancesco Tricarico ^{a†}, Alice Pellizzaro ^{a†}, Matteo d'Angelo ^a, Pier Paolo Benetollo ^{c§}, Andrea Iob ^{c¶}, Mariarita Forgiarini ^{c¶}, and Silvio Brusaferrò ^a

^aDipartimento di Area Medica, Università Degli Studi di Udine, Udine, Italy; ^bIstituto di Igiene Ed Epidemiologia Clinica, Azienda Sanitaria Universitaria Integrata di Udine, Udine, Italy; ^cAzienda per l'Assistenza Sanitaria No.3 Del Friuli Venezia Giulia, Gemona, Italy

ABSTRACT

Background: In Italy vaccine hesitancy worsened after a failure to vaccinate episode that took place in Friuli Venezia-Giulia Region until early 2017 which undermined herd immunity by leaving unprotected more than 5,444 children.

Methods: Between May and June 2017, 2,557 parents were surveyed at the local vaccination clinic where they were invited within the subsequent extraordinary vaccination campaign. The aim of the survey was to evaluate whether the multi-channel extraordinary vaccination campaign had reached the target population and to know parental beliefs and trusted sources of information after the failure to vaccinate event.

Results: While 279 parents were non-hesitant (10.9%) and 1,491 hesitant acceptors (58.3%), just 38 (1.5%) refused to have their children revaccinated. Overall, the most consulted sources of information were print media (18.8%), physicians (16.0%), relatives and friends (12.1%). The majority of parents considered vaccination as a fundamental practice (73.9%), but many were worried about potential side effects (38.8%) or doubtful about the effectiveness of some vaccines (11.0%). According to parents, 19.7% of them (57) changed their opinion about vaccines after the Codroipo case.

Conclusions: After the Codroipo case, most parents chose to have their children re-vaccinated and just a little proportion refused the re-administration of vaccines. More studies are needed to confirm the importance of a coherent multi-channel communication strategy using both traditional and new media in order to counteract vaccine hesitancy.

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Introduction

Vaccine hesitancy is the attitude of delaying acceptance or refusing vaccines despite their availability;¹ it is a complex problem influenced by many factors including context, time, place and specific vaccine.¹⁻³ A debate around vaccines has emerged as a major public health problem in Europe⁴ and in Italy⁵ as well. Since infant vaccination is a milestone for reducing morbidity and mortality of vaccine-preventable diseases (VPDs) all over the world, both the achievement and the maintenance of herd immunity are fundamental for succeeding in primary prevention.

Vaccination is thought to be a victim of its own success: because vaccines have been so effective in preventing diseases, contemporary parents have no first-hand knowledge about VPDs' sequelae and therefore their complacency has grown.^{6,7} When deciding about immunization, their attention is focused on potential risks, thus outweighing efficacy.^{8,9} A lack of confidence in vaccines and in healthcare institutions delivering them are the most common concerns reported by parents,^{1,7,9} and vaccine safety, effectiveness and usefulness are being more and

more questioned.¹⁰ Moreover, a lack of information and healthcare professionals recommendation has been reported.¹¹ Parents are influenced over their decision by families and friends, media, previous negative personal experiences and society.^{6,12-14} In spite of that, healthcare professionals,^{15,16} family members and the internet appeared to be trusted sources of information.¹⁵

In Italy, immunization programs are managed by the National Health Service, but each region is responsible for planning, financing and implementing healthcare services. Before 2017, regional immunization programs and schedules were heterogeneous. In the case of Meningococcal C conjugate vaccine for example, coverage rates differed up to 29.7% among Regions.¹⁷ Between 2009–2015 years, failure to vaccinate episodes happened in a specific FVG (Friuli Venezia Giulia) local health district,¹⁸ hereafter called AAS3 – Azienda per l'Assistenza Sanitaria no.3. The definition of a failure to vaccinate, according to Heininger et al.¹⁹ includes improper vaccine administration, incomplete vaccination series or administration errors. As previously reported,¹⁸ this six-year-long

CONTACT Laura Brunelli  laura.brunelli@uniud.it  Udine 33100, Italy

*Present address: SOC Accreditamento e Qualità, Azienda Sanitaria Universitaria Friuli Centrale, via Colugna 50, Udine, Italy

**Present address: Istituto di Igiene ed Epidemiologia Clinica, Azienda Sanitaria Universitaria Friuli Centrale; via Colugna 50, Udine, Italy

***Present address: Dipartimento di Prevenzione, Azienda Sanitaria Universitaria Giuliano Isontina; Via Costantino Costantinides, 2, Trieste, Italy

†Direzione Medica, ULSS7 Pedemontana, Via dei Lotti 40, Bassano del Grappa, Vicenza, Italy

§Università degli Studi di Padova, Via 8 Febbraio 2, Padova, Italy

¶Azienda Provinciale per i Servizi Sanitari, Via Alcide Degasperis 79, Trento, Italy

¶Dipartimento di Prevenzione, Azienda Sanitaria Universitaria Friuli Centrale, Udine, Italy

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undesired event was due to a professional misconduct consisting in improper vaccine administrations by a public health nurse and is known as “The Codroipo case”.¹⁸ This misconduct was discovered during early 2017 by FVG public health authorities. In particular, the specific Codroipo case can be classed as a usage error, being half-way between a pure administration error and an incomplete vaccination series.¹⁹ It raised the epidemic risk for the local population, as it left 5,444 children potentially unprotected from VPDs, thus undermining herd immunity. The event prompted for the “Vaccinare-sì” extraordinary vaccination campaign, planned by a multi-stakeholder working group. The aim of this campaign was to recover herd immunity by administering 20,441 missing doses for hexavalent, HPV, meningococcal C, MMRV, pneumococcal and TBE vaccines.¹⁸ The vaccination campaign also included:

- information release management, such as press conferences, public meetings, public notices, collaborations with mayors;
- the creation of a dedicated toll-free number, an institutional e-mail address and a WhatsApp® channel;
- active re-enrollment of families through phone calls and mail letters.

The aims of the present study were to evaluate whether the multi-channel extraordinary vaccination campaign had reached the target population by estimating parental adherence to recommendations to get their children revaccinated and to investigate parental vaccine confidence levels and trusted sources of information after the failure to vaccinate event.

Materials and methods

Vaccination adherence

Parental decisions on having their children revaccinated, were recorded by health professionals of the Codroipo vaccination clinic from May 8th to June 23rd, 2017 for organizational purposes. Following the discovery of the aforementioned failure to vaccinate, parents and families of all children involved were repeatedly contacted by phone and mail, in addition to information being released through press conferences, public meetings and public notices. Characteristics of the population involved, and the revaccination campaign have been detailed in a previous paper.¹⁸ Parental behaviors were categorized into four main groups: a) *non-hesitant acceptors*, those who agreed to revaccinate their children without questioning; b) *hesitant acceptors*, those who agreed to revaccinate their children after counseling or only according to a modified vaccination schedule; c) *delayers*, those who preferred to postpone their decision due to uncertainly or skeptical opinions received from other health professionals (different from surveyor); d) *refusers*, those who refused to have their children revaccinated.

Trust and beliefs

During 14 random days between May 25th and June 27rd, 2017, a short survey to assess parental opinions was conducted

through a paper-based questionnaire. A total of 303 parents accessing the Codroipo vaccination clinic for revaccination were enrolled in the aforementioned observation period. The questionnaire was composed by eight multiple-choice questions asking: where they did get the information about the “Vaccinare-sì” extraordinary vaccination plan; which were their most trusted sources of information; which were their opinions about vaccines; whether both parents agreed about the revaccination choice; whether they changed their opinion about vaccines. Variables regarding age and educational level (middle school or lower level/secondary school/higher education) of both parents were collected. Participation was voluntary, anonymous and without compensation. No personal identifiers were recorded, making tracing the responses back to participants impossible and thus not requiring formal ethical approval according to European regulation (EU-GDPR). No exclusion criteria were set. All participants were informed about the study aims and confidentiality of data. We obtained verbal consent from parents who voluntarily completed the questionnaire.

Statistical analyses

For the vaccination adherence assessment there was no sample size calculation as all parents accessing the clinic during the observation period were included. Sample size calculation for trust and beliefs assessment, expecting that 80% of the subjects \pm 5% still trusted vaccinations, at least 240 surveyed people were needed to reach a 95% confidence level. In addition to comparing specific sources of information, we also compared macro-categories defined as follows: institutional sources (institutional websites, free toll number, AAS3 website, AAS3 e-mail address, WhatsAAS3 channel); internet and social (social media, other websites); mass media (print media, television, radio); health professionals (physicians, pediatricians, public health professionals, others).

All the answers were collected in an electronic spreadsheet and analyzed using SAS v9.2 (SAS Institute Inc, Cary, NC, USA). The frequency distribution of answers was analyzed.

Results

Vaccination adherence

Among the 2,557 parents accessing the clinic during the selected time frame, 279 resulted to be *non-hesitant acceptors* (10.9%) and 1,491 *hesitant acceptors* (58.3%). On the other hand, there were 639 *delayers* (25.0%) and 38 *refusers* (1.5%). Detailed parental behaviors are reported in Table 1.

Trust and beliefs

Median maternal age was 41 years (min 21, max 57), median paternal age was 44 years (min 25; max 66). Most parents (65.3%) attended secondary school (mothers 64.4%, fathers 66.0%), lower level of education was obtained by 17.5% of parents (mothers 15.0%, fathers 20.1%); overall, parents with a degree were 17.2% (mothers 20.5%, fathers 13.8%).

Respondent parents obtained information about the “Vaccinare-sì” vaccination campaign most frequently from:

Table 1. Parental adherence to recommended revaccination for children living in the AAS3 health district related to vaccine hesitancy spectrum, data collected from parents who accessed the Codroipo vaccination clinic during the selected time window.

Parental adherence to recommended revaccination of children living in the Codroipo health district.			
Parental behavior	No.	%	Category
Agrees to re-vaccination without questioning	279	10.9	Non-hesitant acceptors
Agrees to re-vaccination after counseling	1,383	54.1	Hesitant acceptors
Agrees to modified vaccination schedule after counseling	108	4.2	
Defers the decision	Because he/she is uncertain	50	2.0
	Because he/she wants a second opinion	82	3.2
	Without giving any reason	31	1.2
	Because he/she has received skeptical opinion from	28	1.1
	Other health professional	2	0.1
	GP	17	0.7
	Pediatrician	6	0.2
	Others		
	Other reasons	236	9.2
	Because he/she wants to know serology	203	7.9
Refuses to have their children administered the vaccines again	38	1.5	Refusers
Other	94	3.7	Other
Total	2,557	100.0	

print media (n.135, 18.8%), physicians (n.115, 16.0%), relatives and friends (n.87, 12.1%), television (n.82, 11.4%). Other information providers were: AAS3 website (n.68, 9.5%), Whatsapp® channel (n.28, 3.9%) and e-mail address (n.24, 3.3%) along with free toll number (n.67, 9.3%), other health professionals (n.34, 4.7%), other websites (n.21, 2.9%), social media (n.20, 2.8%), radio (n.13, 1.8%), active phone call (n.8, 1.1%) and other non-specified providers (n.16, 2.2%).

As reported in Table 2, most trusted sources of information by parents were: physicians, AAS3 website, AAS3 e-mail address and the dedicated free toll number.

The majority of parents believed that vaccines are a fundamental practice to ensure their child's health. In spite of that, many of them were worried about potential side effects, and others were doubtful about the effectiveness of some vaccines. Parental opinion about vaccines are reported in Table 3. According to parents, 19.7% of them (n.57) changed their opinion about vaccines after the Codroipo case.

Table 2. Trusted sources of information according to parents.

Most trusted sources of information ^a	n. (%)
AAS3 e-mail address	72 (11.9)
AAS3 website	94 (15.7)
Family/friends	11 (1.8)
Free toll number	63 (10.5)
Health professionals	54 (9.0)
Other websites	6 (1.0)
Physician	229 (38.3)
Print media	17 (2.8)
Television	17 (2.8)
WhatsAAS3 channel	18 (3.0)
Other	18 (3.0)
Total answers	598

^aup to three answers allowed

Table 3. Parental opinion on vaccines after the event (Codroipo case + extraordinary vaccination campaign).

Opinions on vaccines: "Vaccines are ..."	n. (%)
... a fundamental practice to ensure my child's health	215 (73.9)
... useful, but I am very worried about side effects	113 (38.8)
... some are useful, while I don't understand why others are offered	32 (11.0)
... an obsolete practice, given the improvements in healthcare	6 (2.1)
... dangerous for my child's health	4 (1.4)

Discussion

In Italy, vaccine coverage for mandatory immunizations in 2016 was lower than the 95% coverage target for any of the mandatory vaccines and almost two thirds of the 21 Italian regions did not reach target coverage levels.¹⁷ The overall vaccine coverage for children under 24 months for polio, diphtheria, tetanus, pertussis, hepatitis B, *Haemophilus influenzae* type B (Hib), varicella, measles, mumps, rubella, meningococcus and pneumococcus in Italy and in the North-Eastern Italian Region Friuli Venezia-Giulia are reported in Table 4.²⁰

One of the major consequences of the growing distrust toward vaccination is that immunization rates are decreasing below critical thresholds required for herd immunity to the extent that outbreaks of measles have been recently reported in some countries^{21,22} including Italy.²³ The effect of this failure to vaccinate episode overlaps with the existing situation, that already prompted the Italian Ministry of Health to issue the 2017–2019 National Immunization Prevention Plan and later enforcing it with the 119/17 Law, in response to decreasing vaccination rates. This law increased the number of mandatory child vaccines from four to ten. In particular, vaccination against pertussis, *Haemophilus influenzae* type b, measles, mumps, rubella and varicella became compulsory, as well as immunization against diphtheria, tetanus, poliomyelitis and hepatitis B virus already were. The same policy also imposed fines on families of unvaccinated children attending primary school. Nevertheless, the public debate is still ongoing in Italy and some politicians' approach to the problem is to soften the compulsory rule.

According to our results, only a small proportion of parents (1.5%) refused to revaccinate their children. Our findings are consistent with the "no-vax" quotas reported in a recently published Italian study (0.7%).²⁴ The proportion of parents looking for more information was considerable, as our data showed that 54% of them agreed to revaccination only after counseling. The strangeness of the Codroipo case¹⁸ could have generated some peculiar effects compared to usual vaccine hesitancy causes and underlying mechanisms, as mistrust toward health professionals or institutions could have risen. The high parental request of being informed can be seen as a consequence of the failure to vaccinate episode occurred in this particular FVG district. Nevertheless, most parents finally agreed to have their children revaccinated: the active re-enrollment of children and the availability of private counseling session with health professionals may have played a fundamental role, but the multi-channel communication put in place can contributed as well.

Table 4. Vaccine coverage of children at 24 months of age (June 2017), comparison among national, regional and local data (Gallo et al. 2015).

Vaccine coverage within Codroipo Health District compared to regional and national level.										
Geographical area	Polio	Diphtheria	Tetanus	Pertussis	Hepatitis		Measles –		Meningococcal	Pneumococcal
					B	Hib	MMR	Varicella	C (conjugated)	(conjugated)
Italy*	94.6	94.6	94.7	94.5	94.5	94.2	86.6	35.9	74.9	87.2
Friuli Venezia Giulia Region*	92.2	92.5	92.5	92.0	91.7	91.6	83.5	60.2	82.6	82.3
Codroipo health district**	91.8	91.8	92.0	91.8	91.8	91.8	85.0	80.0	87.5	81.5

*as of 2014, national population at baseline 60,795,612; regional population at baseline 1,227,122

** as of 2015, baseline population 51,626

Data emerging from this study confirmed parental sources of information preferences,^{13,15} but the role of print media emerged to be predominant after the Codroipo case. On the other hand, sources of information reported as the most reliable were the institutional ones: healthcare professionals and ad-hoc services such as AAS3 e-mail address, website and free toll number. As a result, in our study the most used and the most trusted sources of information differed, similarly to the case of 2014–15 measles outbreak in California²⁵ and the Canadian H1N1 and SARS outbreaks.²⁶ This may suggest that the population is aware that information given by media can be uneven in quality and that a careful evaluation is needed, as recently proven in an Italian survey on parental vaccine hesitancy.²⁴ When considering trusted sources of information after the Codroipo case, the level of trust toward health professionals again should be seen in light of the fact that a professional misconduct emerged as the main cause of the failure to vaccinate.

To increase vaccine uptake, the implemented strategy involved the use of new media in addition to traditional ones, as suggested by Odone et al.²⁷ and also outlined in the Declaration of Erice.²⁸ Due to their pervasiveness, instant messaging and e-mail communications have been exploited for this extraordinary vaccination campaign.²⁷ The inclusion of a Web 2.0 strategy may have helped in strengthening the relationship between citizens and healthcare institutions, enabling parents to interact with healthcare professionals in a tailored manner.²⁹ The five most trusted sources of information turned out to be those allowing direct communication with institutional healthcare services. Ultimately, the proportion of parents who refused to have their children re-vaccinated resulted to be small. The effectiveness of the multi-stakeholder coordinated strategy put in place in coping with this challenging public health issue⁹ cannot be ruled out, but further studies are needed to confirm it. Our data show that a good proportion of parents still consider vaccination as a fundamental practice, but many are still worried about side effects. The absence of VPD outbreaks during the years 2009–2015, although probably due to the remaining herd immunity of the local setting, could have had effects on parental complacency, confirming in turn that the absence of first-hand experience related to VPDs can affect public trust in vaccines.^{1,6} In addition, missed reporting of VPD cases by pediatricians could not be ruled out.

Study limitations

Only parents who accessed the vaccination clinic were surveyed and parental opinions about vaccines and information sources

were assessed after the Codroipo case, and no assessments before the vaccination campaign were made. In addition, the questionnaire was not previously used in other studies, leading to difficult comparison and discussion. The effectiveness of the extraordinary vaccination campaign could not be tested as it was not possible to identify a control group of parents not being exposed to the urgent public health campaign.

Conclusions

In conclusion, after the Codroipo case most parents chose to have their children re-vaccinated and just a little proportion refused the re-administration of vaccines. Nevertheless, we cannot ascribe this result to the revaccination campaign for sure and underlying behavior of single persons and community can have played an important role as well. More studies are needed to confirm the importance of a coherent multi-channel communication strategy in order to counteract vaccine hesitancy.

To our knowledge, there is little evidence about evaluating parental attitudes on vaccines and selection of information sources in the context of a failure to vaccinate. Our study suggest the possibility to use traditional and new media to cope with vaccine hesitancy and stresses the importance of an active presence of healthcare institutions on multiple communication channels to restore threatened trust and herd immunity.

Authors' contribution

LB, PT and FV designed the study; AP, Md'A and FR collected data; LB, FR wrote the article; PPB, AI, FM, FV and SB revised intellectual contents; all authors read and approved the final version of the manuscript.

Disclosure of potential conflicts of interests

No potential conflicts of interest were disclosed.

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ORCID

Laura Brunelli  <http://orcid.org/0000-0002-5475-0021>
 Francesca Valent  <http://orcid.org/0000-0002-4071-0897>
 Pierfrancesco Tricarico  <http://orcid.org/0000-0002-1436-2817>
 Pier Paolo Benetollo  <http://orcid.org/0000-0002-2041-8194>
 Silvio Brusaferrò  <http://orcid.org/0000-0003-1018-7094>

Research involving human participants

Procedures performed in this study involving human participants were in accordance with the ethical standards, 1964 Helsinki declaration and its later amendments or comparable ethical standards. Due to the urgent, unexpected and threatening situation that parents were living, being their children potentially unprotected against vaccine preventable diseases, we opted for completely anonymous questionnaires in accordance to European regulation (EU-GDPR), assuring participants that neither any personal identifier would have ever been collected nor any personal choice/vaccine status linked to their questionnaire.

Informed consent

Oral informed consent was obtained from all participants included in the study, as written consent was not required being data completely anonymous. Oral vs written consent was chosen for convenience. Participation was voluntary, questionnaires were not collected in absence of consent.

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