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Short communication

Management of reduced vaccine coverage due to 6 years of failure to vaccinate: The Codroipo case, Italy

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ABSTRACT

During 2017 an alert was raised in relation to a possible vaccination failure occurred in Friuli Venezia Giulia Region (Italy) between 2009 and 2015, exposing multiple cohorts of children and the entire community to vaccine preventable diseases outbreak risk. The Codroipo case resulted in 20,441 vaccine doses being in doubt, thus prompting the healthcare system to react in order to revaccinate 5444 children through planning and implementing network actions and multiple channels of communication.

1. Introduction

Since the development of vaccines, actions and policies toward vaccine preventable diseases (VPDs) have faced three main obstacles: general public acceptance and compliance (vaccine hesitancy) [1,2], lack of effective immune response (primary or secondary vaccine failure) and errors in vaccine usage or inadequate immunization programs (failure to vaccinate) [3]. Related to the latter, usage issues can occur after administration errors [4], poor compliance with recommended schedules, storage-related issues [5] or usage beyond expiry date. The aim of this report is to describe an example of failure to vaccinate due to misconduct and measures used to address this unexpected and potentially dangerous public health threat.

Abbreviations: AAS3, Azienda per l'Assistenza Sanitaria n.3, Local Health Trust n.3; FVG, Friuli Venezia Giulia; PHN, public health nurse; VPDs, vaccine preventable diseases.

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1.1. The Codroipo case

On April 20th, 2017 a warning about an employee was issued by a neighboring Region to the Local Health Trust n.3 of Friuli Venezia Giulia (FVG), hereafter called AAS3: one public health nurse (PHN) was suspected by colleagues of not having properly administered vaccine doses on duty. Considering that this particular PHN was in charge of vaccine administration from 2009 to 2015 at the AAS3's District of Codroipo, further controls were put in place to investigate the issue fully. The suspected PHN misconduct had potentially exposed multiple cohorts of children to improper vaccinations, prompting for further investigations and eventually becoming public knowledge and getting wide coverage by media.

2. Material and methods

2.1. The FVG healthcare system reaction

On April 21st, the FVG Preventive Services Task Force including experts in pediatrics, public health, immunology and infectious diseases was created, involving also academic representatives as well as non-profit citizen organizations and AAS3 area Majors' delegates to pursue transparency. All actions taken by the FVG healthcare system starting from the day following the warning are described below and summarized in Fig. 1.

a. Risk assessment and identification of cases

To gather some data on the actual risk, urgent serum antibody titers were randomly requested among 316 children who were documented to have received a complete vaccination for hepatitis B virus (3 doses) and the first and up to that time unique dose of measles vaccine from that PHN. Assuming all vaccine doses had been properly administered, the expected immune response would have been 99 ± 1% for hepatitis B vaccine and 95 ± 2% for measles vaccine; consequently, we estimated that a sample size of 173 and 187 children respectively was sufficient to estimate immune response with 95% power and an alpha-level of 0.05. Thus, we decided to invite 200 of the 316 children for blood sample collection, to allow for refusals and unsuccessful contacts. When results arrived on April 30th, just 24% of children were protected against hepatitis B and 47% against measles, far lower than expected based on prior studies [6,7], thus suggesting the risk for all children assisted by that PHN. Since no detectable differences emerged by comparing purchased vaccine inventory with doses administered, and no improper storage or handling of vaccines were identified, AAS3 health authorities concluded that the cause of low immune response in the tested children ought to be related to improper administration. Cases of positive immunity response for hepatitis B and measles could be explained either by the actual administration of some vaccine doses, both by that PHN or others working in the same clinic, or by natural disease exposure. In order to prevent the occurrence of VPDs, the Task Force decided to pursue the principle of maximum safety by repeating all vaccine doses administered by that PHN. All subjects having received at least one vaccine dose from that particular PHN between 2009 and 15 in the Codroipo District were defined as cases.

Analyzing electronic outpatient records, total working hours and clinic sessions held by that PHN were identified. It resulted that 5444 children were potentially unprotected from several VPDs, for a total amount of 20,441 vaccine doses (Table 1). Children at risk were sorted in two groups according to different priorities: priority 1 was assigned to those who received all doses or the unique dose of any vaccine by that particular PHN; those who received at least one dose of any vaccine by that PHN were assigned priority 2.

b. Plan of action

To deal with this public health problem, the Task Force implemented a set of coordinated actions including an extraordinary vaccination campaign called "Vaccinare-sì", reallocation of resources, management of information release (press conferences, public notice, collaboration with Mayors of the municipalities involved and arrangement of public meetings) and possible legal aspects. An ad-hoc toll-free phone number, an email address and a Whatsapp® channel all dedicated to the extraordinary vaccination plan were made available from the beginning to parents.

Table 1
Distribution of uncertain vaccine doses involved in the 2017 Codroipo case per single vaccine.

Uncertain vaccine doses – 2017 Codroipo case		
Vaccine	N. of doses	%
Hexavalent vaccine (diphtheria, tetanus, pertussis, polio, Haemophilus influenza type B and hepatitis B virus)	7566	37
HPV vaccine	1838	9
Meningococcal C conjugate vaccine	2028	10
MMRV vaccine (measles, mumps, rubella and varicella-zoster viruses)	3937	19
Pneumococcal conjugate vaccine	4695	23
TBE vaccine	377	2
Total	20,441	100

HPV: Human papillomavirus; TBE: Tick-Borne Encephalitis.

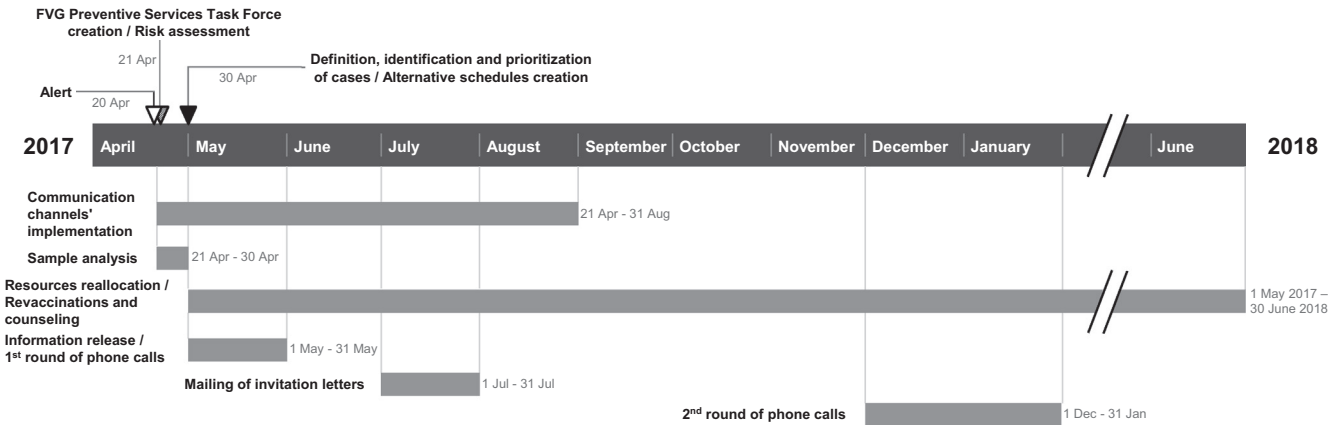

Fig. 1. Timeline of the Codroipo case events and FVG healthcare system reaction.

Table 2
Strengths of the Public Health reaction to the 2017 Codroipo case.

Strong points – 2017 Codroipo case	
Risk assessment and identification of cases	• Timely FVG healthcare system reaction • Multi-disciplinary team of experts • Electronic tracking of healthcare workers on duty
Plan of action	• Collaboration with different regional Institutions • Public accountability of the Task Force • Transparency and direct involvement of Mayors and citizens • System capability to deliver tailored vaccination schedules • Networking and reallocation of Regional healthcare resources

Families were contacted and invited to have their children vaccinated in three rounds: through phone calls (May-June), by mail letters (July) and then by phone again (December-January).

3. Results

In all, 2406 children (44%) were priority 1, while the remaining 3038 were priority 2 (56%). Of 3497 with available numbers, 2249 families were contacted (64%), while 4402 letters were delivered to 4444 available addresses (99%).

To fit different needs related to vaccines effectively received by children, a core set of 26 alternative vaccination schedules (supplementary material) was created. Until the end of January 2018, trained healthcare workers held 8054 outpatient consultations; a total of 11,303 vaccines doses have been administered (55%) and 1410 counseling encounters with parents were delivered. Re-vaccinations started on May 2nd, 2017 and their end is scheduled for June 2018.

The amount of additional working hours needed has been significant: doctors were required for 629 extra hours and nurses worked 6724 hours more in total, around a quarter of those were dedicated to e-mails and phone calls answering. To deal with the unexpected need of healthcare services, most resources were provided by AAS3; important contributions were given also by the Udine University and Healthcare Integrated Trust and the neighboring Health Authorities of FVG Region. Since the beginning, the Task Force organized meetings with local press, Local medical council, general practitioners and pediatricians working in the District, local authorities and Majors, public meetings with the population, press conferences, scientific/medical reports in collaboration with the Italian Public Health Society and with the Ministry of Health.

4. Discussion

The effort required to AAS3 to manage and solve the issue has been tremendous. A gap in vaccine coverage due to malpractice is a public health emergency and no specific strategies were readily available or already implemented to deal with that, so it was mandatory to build a multi-disciplinary network as suggested in prior research [8]. To achieve this goal, a team of experts from different fields had to be created and different institutions from the same Region needed to work in concert.

Actions implemented by the Task Force allowed an effective public health response, enabling AAS3 to recover more than half of missing vaccines in 9 months while continuing to perform routine activities. Although no VPD outbreaks in the area were identified, evaluation of long-term effects on herd immunity will require further investigations. Nevertheless, the FVG healthcare system preparedness allowed narrowing the gap between expected and actual vaccine coverage; strong points are summarized in Table 2.

5. Conclusions

To our knowledge, the occurrence of a gap in vaccine coverage due to a healthcare worker misconduct going on for several years was the first event of its kind. We believe that, due to its unicity as far as resource rearrangement and tailored vaccination scheduling are concerned, this experience could be usefully disseminated among scientific audiences and in particular public health professionals. The event is currently under legal investigation, and at the time of writing it is not possible to attribute final liabilities. Despite the presence of a regional accreditation system for quality assurance of vaccination clinics, this critical problem remained undetected. No data are available about possible motivations for the suspected behavior and only speculations can be made: this could have been due to gross carelessness, negligence or willful misconduct based on personal beliefs against vaccination. An active involvement of parents during the vaccination session, surprise site inspections, random serum antibody titers and the raised awareness of health authorities toward professional misconduct could be helpful in reducing the specific risk of failure to vaccinate. Furthermore, the active involvement of the community in preventive care programs could help in facing vulnerabilities of healthcare systems.

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Declaration of interests

The authors declare that there is no conflict of interest regarding the publication of this article.

Appendix A. Supplementary material

The supplementary material presents all the tailored vaccine schedules created by experts of the FVG Preventive Services Task Force to fit different needs related to vaccines effectively received by children. Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2019.01.082.

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