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The Impact of COVID-19 Epidemic on Immunization Activities in Italy

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COVID-19 has led to disruption in routine immunization programs around the globe. In Italy, we assessed the impact of COVID-19 epidemic on immunization activities using a questionnaire to explore reasons for decrease in vaccination and measures implemented. Sixteen Regional Health Services over 21 answered (76.1%). A decrease in immunization activities was mostly recorded after the notification of the first local cases in Italy and during the peak of the epidemic. About one-fourth (28%) of immunization centres suspended their activities and more than 33% of health workers in immunization centres were shifted to the COVID-19 response. Specific training on COVID-19 was generally reported. Children above 1 year of age until adolescence were the most affected by disruption of immunization services followed by adults indicating that primary series vaccination were prioritized. Several measures were implemented, such as immunization only under appointment, give priority to some immunization/ subjects and extend the hours of work to avoid overcrowding; telephone call to families; developing a list of children who have missed their vaccine doses; preparing a targeted action plan to ensure rapid catch up of children who are not up to date with their vaccination. Information and awareness raising activities were also indicated, even if in a lesser extent. The results of the survey were used to collect and disseminate best practices in order to minimizing the effect of the pandemic on vaccine preventable diseases.

Keywords: *COVID-19, routine immunization, immunization catch-up activities, vaccination services, Italy*

Introduction

Epidemiology of COVID-19 in Italy

Since the first reported cases in China in December 2019 and until 29 January 2020, in Italy the infection with SARS-CoV-2 was not detected. On 30 January, the same day in which the World Health Organization declared the new coronavirus epidemic a public health emergency of international concern, two imported cases were confirmed in Latium Region. The day after, the Italian Government declared the national emergency in response to COVID-19 epidemic. On 21 February, the first local case was registered in Lombardy Region. In the following weeks, the infection spread all over Italy despite the timely implementation of public health measures. The peak of new cases was reached on 21 March, followed by a slow and irregular decrease until the current transition

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phase characterized by a more stable number of daily reported cases and no overburden of health services.

Some regions, in particular Lombardy, Veneto, Emilia-Romagna and Piedmont were affected earlier and more severely by the epidemic especially during the early phases. Shortage of health workers was a common key problem.

COVID-19 emergency had a strong impact on people and the national health system. Public health measures focused on stay at home policies, social distancing, closure on non-essential services, including schools, until complete lock down, to reduce the spread of SARS-CoV-2. Limiting movement outside the home to essential activities could have influenced the decision to postpone immunization. In few weeks, the number of hospital beds, both in intensive care unit and in medicine wards sharply increased, with *ad hoc* facilities dedicated to the care of COVID-19 patients. Part of the healthcare resources have been shifted to the COVID-19 response, with a presumable impact on the routine immunization activities.

The immunization services are an essential part of the national health system and the Ministry of Health issued guidance to maintain their operation as far as possible. Nevertheless, disruption of immunization activities during COVID-19 pandemic was reported in literature and we decided to evaluate the situation in Italy.

Immunization Activities in Italy

Immunization activities are a core component of the public healthcare assistance: the Italian immunization policy applies across the life-course, with ten mandatory routine immunization for children aged 0–16 years and unaccompanied foreign children: polio, diphtheria, tetanus, hepatitis B, pertussis, *Haemophilus influenzae* type b, measles, rubella; mumps, varicella, chickenpox. In teenagers, further recommended vaccinations include anti HPV and *meningococus*, while in the elderly over 65 years, influenza, herpes zoster and pneumococcus immunization are recommended. Generally, vaccination is offered free of charge by the public immunization services, including general physicians and paediatricians. Seasonal influenza vaccine can also be administered in pharmacies.

Italy is endemic both for measles and for rubella, with large outbreaks occurring in the last years.

Literature Review

The World Health Organization (WHO 2020, WHO EURO 2020, WHO and UNICEF 2020) issued guidance on routine immunization services during COVID-19 pandemic, warning about the risk of vaccine preventable disease outbreaks due to the disruption of immunization services, even for limited period of time, which could cause further pressure on health services. During COVID-19 pandemic, it is critical to ensure trust of the population in the health system guaranteeing that activities are performed under safe conditions, implementing optimal infection

prevention measures during immunization sessions and adequate observation of adverse events following immunization (AEFIs). Primary series vaccination and other vaccination for vulnerable groups should be prioritized. Communication plays an important role and should clearly explain the benefit of vaccination even during a health emergency to address community reluctance. WHO recommends resuming and restoring immunization services as soon as possible when SARS-CoV-2 transmission decreases to close immunity gaps created during the epidemic.

In the Americas, the Pan American Health Organization (PAHO) (2020) conducted a survey in 38 countries and territories of the region to monitor the functioning of immunization services and the main challenges during COVID-19 pandemic. After lessening the lockdown measures, immunization activities resumed, but the demand remained low due to people's concern about the risk of exposure in healthcare settings, restrain in public transport and other public health measures. Several innovative strategies were implemented by countries such as drive-through vaccination, mobile vaccination centres, vaccination in homes, vaccination with prior appointment, vaccination in strategic locations, and communication strategies. Difficulties were recorded in several countries in delivery of vaccines and other supplies and in maintaining epidemiological surveillance due to laboratory services shifted to COVID-19 testing.

Hungerford and Cunliffe (2020) welcomed the launch of the European Vaccination Information Portal in conjunction with the European Immunization Week 2020, as it is important to ensure sufficient resources and priority to delivery of routine immunization especially in COVID-19 time. In fact, preventive measures, such as lock down, quarantine and social distancing represent a big challenge for delivering immunization. To mitigate COVID-19 effects, it is important to monitor immunisation rates at all levels.

Santoli et al. (2020) examined two data sources to assess the impact of the pandemic on paediatric immunization in the United States. The first is the cumulative doses of vaccines ordered by healthcare providers. The second is the aggregate counts of measles-containing vaccine doses administered between two paediatric age groups: children aged ≤ 24 months and children aged >24 months through 18 years. Both data sources compared the same period of 2019 and 2020. The authors found a considerable decline both in orders and in administered doses, starting the week after the national emergency declaration. Children ≤ 24 months were less affected by the decrease in immunization. According to their study, parental concern about possible exposure during vaccine session might contribute to the drop registered.

Another study conducted in Michigan (Bramer et al. 2020) found that vaccination coverage decreased in all age cohorts except for birth-dose hepatitis B coverage, which is generally administered in the hospital setting. Compared to 2019, the 16-months age cohort suffered a decline of 5.2% in 2020, while children aged 5 months experienced a decrease of about 17% of all recommended vaccines. They called for concrete efforts to ensure a quick catch-up for children that missed their scheduled vaccination.

In Canada, a life-course vaccination policy applies, in line with WHO recommendations (WHO 2019). In this country, Mac Donald (Mac Donald et al. 2020) reported a disruption in routine immunization programs due to COVID-19 and identified three components to improve catch-up: find who has been missed; detect delivery gaps and develop tailored strategies for catch-up; and communicate, evaluate and adjust programs taking into account the evolving situation.

According to Adamu et al. (2020), COVID-19 disrupted routine immunization services for children and this is of particular concern because coverages in many African countries are suboptimal. The authors reported that it was demonstrated by scientists that the benefit of routine immunization in Africa is greater than the risk of COVID-19 death that could result from attending a vaccine session. They suggest affording the immunization system as a whole because all components are interdependent. In addition, they warn against the effect of preventive measures adopted for combating COVID-19 on poverty, because these actions can wider socioeconomic inequalities with implication on immunization coverage. Also in this context, information plays a key role to combat misinformation and contrast vaccine hesitancy.

Despite concerns have been raised on the effects of COVID-19 on routine children immunization, also older adult immunization is at risk, as described in the study of Privor-Dumm et al. (2020). In particular, they support the need to build a global system for both routine and pandemic/epidemic older adult immunization. Several vaccines against other pathogens, such as influenza, pneumococcus and herpes zoster, can keep adults in good health conditions and prevent co-infection with COVID-19. They call for a wide communication initiative focused on the importance of older adult immunization, as recommended in the Immunization Agenda 2030. In addition, they recommend integrating older adult immunization with other country priorities, including emergency preparedness plans for infectious threats. The authors underline the opportunity that the new COVID-19 vaccines will represent for exploring innovative strategies in delivery immunization to older adults to avoid potential risks such as the need to travel to reach the vaccination centre or spend time in waiting rooms.

Methodology

We conducted a survey from 28 May to 9 July 2020 using a questionnaire to understand the impact of COVID-19 on immunization activities and measures implemented at local level, in order to identify best practices to share at national level. The tool was organized in five sections respectively on general data; effects of COVID-19 emergency on vaccinations; organization measures; reactive activities and vaccine supply. We mostly used pre-defined multiple or single choice answers, with the possibility to add comments, in order to catch up further information. The specific aims of the survey were to explore:

- immunization decrease due to the suspension of activities and to staff reduction or reallocation due to COVID-19 emergency;

- specific training of staff on COVID-19;
- the period of highest disruption of immunization services;
- the most affected age and type of vaccination;
- the organization and contrast measures implemented at local level;
- the impact of COVID-19 on vaccine supply and use of doses.

Due to the semi-federal Health System in Italy, the Ministry of Health transmitted the questionnaire to the Regional Health Services, which collected information from the Local Health Agencies (LHAs) belonging to their territory. Then, the Regional Health Services sent the compiled questionnaires back to the Ministry of Health. As the number of LHAs for each Region varies according to the organization model, this factor can have partially biased the results.

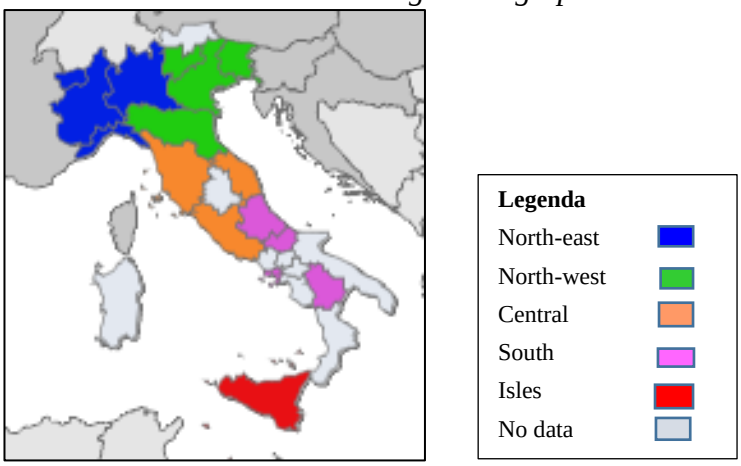
We analysed data, using MS Excel tools. All the variables included in the survey were described using the appropriate statistics: categorical variables were described with proportion and percentages, while ordinal variables using the mean value. In addition, we made a semi-quantitative analysis of comments, to complement the information.

Data were investigated at national level, and for geographic area according to the National Institute of Statistic classification: North-west (Piedmont, Aosta Valley, Liguria, Lombardy); North-east (Trento, Bolzano, Veneto, Friuli Venezia Giulia, Emilia Romagna), Central (Marches, Tuscany, Umbria, Latium), South (Campania, Abruzzo, Molise, Apulia, Basilicata, Calabria) and Isles (Sardinia, Sicily).

Results

Overall, 16 Regions over 21 answered (76.1%) (Figure 1): in total we collected 97 questionnaires from LHAs.

Figure 1. *Italian Regions Participating in the Survey on Impact of COVID-19 on Immunization Activities according to Geographic Area*



Decrease of Immunization Activities

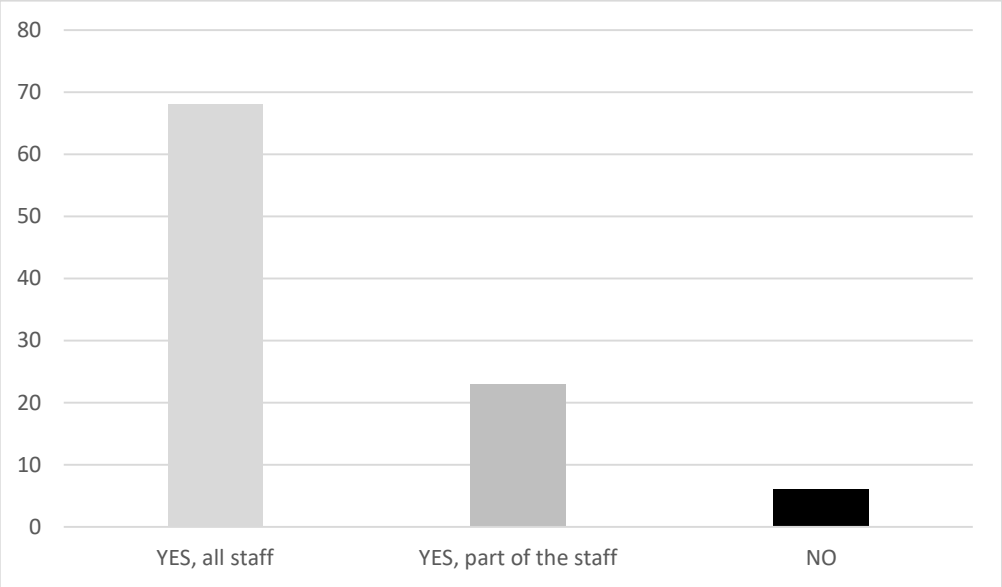
Almost all LHAs (94/97 = 96.9%) affirmed that immunization activities have decreased during COVID-19 emergency, compared to the same period of the previous year.

At national level, about one-fourth (28%) of immunization centres suspended their activities: the closing period, when reported, was limited in time, maximum 17 days. In Lombardy, the number of immunization centres that suspended the activities due to COVID-19 was higher (more than 50%) while it was lower in the Isles (about 11%). The shifting of the health workers to the COVID-19 response from the immunization centres (more than 33% at national level) concerned all professional categories, including physicians, nurses, administrative staff, but mostly the health assistants (more than half of those on duty). About 5.5% of staff working in the immunization centres was infected by SARS-CoV-2.

Specific Training on COVID-19

As shown in Figure 2, the great majority of answers (91/97 = 93.8%) affirms that the staff of the immunization centres received a specific training on COVID-19. This training generally concerned the whole staff (n=68; 70.1%) or only part of the staff (n=23; 23.8%). It must be underlined that about 6% of answers were negative, showing the need to continue and complete training activities.

Figure 2. *Specific Training on COVID-19 at National Level (Total 97 Answers)*

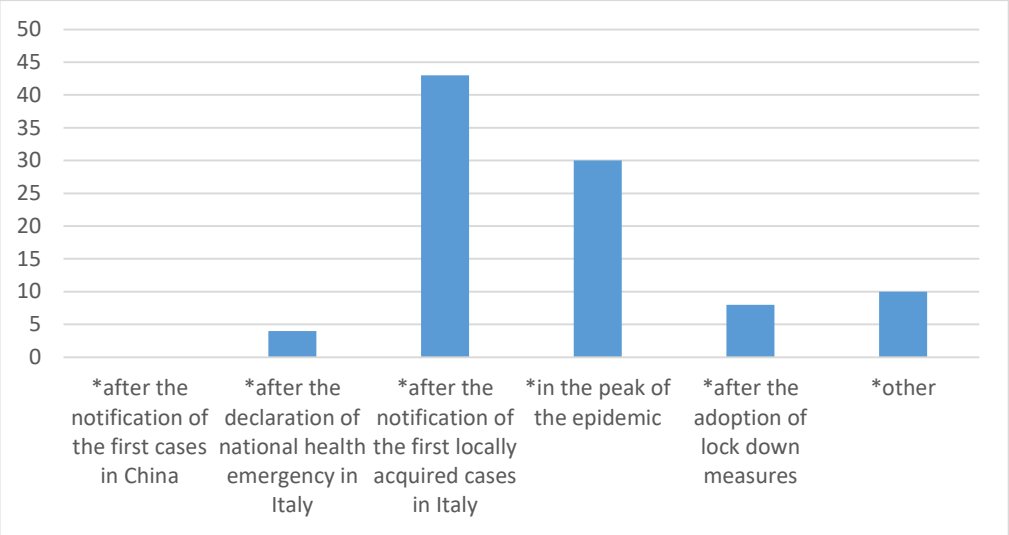


Period of Highest Disruption

A decrease in immunization was mostly recorded after the notification of the first local cases in Italy and during the peak of the epidemic (Figure 3). The lock-down measures implemented at national level, adopted on 22 March 2020, seem to

have had a less relevant impact on routine immunization. In the questionnaires collected in the South, the decrease of immunization activities was noted earlier, especially after the declaration of national health emergency on 31 January 2020.

Figure 3. *Stage of COVID-19 Epidemic Most Affecting Immunization Activities (Total 95 Answers)*



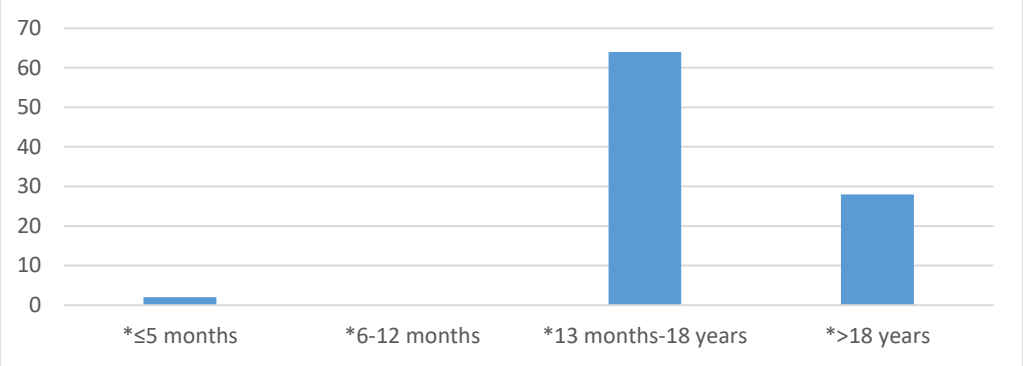
Most Affected Ages and Type of Vaccine

We recorded 94 answers on this topic, whose results are shown in Figure 4. At national level, children above 1 year of age until adolescence are the most affected by disruption of immunization services (n=64/94; 68%) and, less frequently, adults (n=28/94; 29.8%). Only 2 times children < 1 year were mentioned. This result is confirmed by the analysis of open comments, indicating that primary immunization cycles, pregnant women, at risk people, and urgent immunization (for bites, accidents, etc.) were prioritised.

The results show some geographic differences: in the North-east the impact is higher in the adult population, while in the Central, South and Isles areas the impact is almost entirely on children aged 1 year or more.

With respect to vaccines, at national level anti-HPV was mentioned as the most affected, followed by Herpes Zoster, DTPa and meningococcal B. The decrease in other antigens was reported a very limited number of times. In the North-west area, a relevant reduction of polio (IPV) immunization was referred while in the Central area both IPV and measles, rubella, mumps (MPR) immunizations.

Figure 4. *Classes of Age Experiencing the Highest Reduction in Immunization Activities at National Level (Total 94 Answers)*



Organization and Public Health Measures

Almost all answers (n=95/97; 98%) show that some extra organization measures during COVID-19 emergency were implemented, most generally consisting in: immunization only under appointment, give priority to some immunization/subjects and extend the hours of work to avoid overcrowding. A limited number of answers indicated other organization models. Home vaccination and mobile vaccination posts were never mentioned.

To contrast the disruption of immunization, the measures more frequently reported were: telephone call to families; developing a list of children who have missed their vaccine doses; preparing a targeted action plan to ensure rapid catch up of children who are not up to date with their vaccination. Information and awareness raising activities were also indicated, even if in a lesser extent, while the following measures were rarely described: targeted action plan for at risk categories and strengthening vaccine preventable disease (VPD) surveillance. Information and awareness raising activities seem to be particularly implemented in the South area, where they rank first among the countermeasures.

The analysis on comments regarding organization measures indicates that the health staff optimized all available spaces also through active research of new vaccination sites in order to avoid overcrowding, guarantee social distancing, implement safety measures to minimize risk of infection, prolonged opening hours, controlled and limited entry or only upon advanced scheduling, telephone triage. In addition, they focused their efforts in contacting families both before vaccination and in case of missed vaccination to re-programming of scheduled appointments with active call, and in strengthening collaboration with paediatricians.

Impact on Vaccine Supply and Use of Doses

Supply shortage was very rarely mentioned (n=3/97; 3%), while an increase of wasted doses was reported in about one third of respondents (36%), with highest values in Lombardy (60%) and in the North-east area (47.6%) and minimum values in the Isles (0%) and in the North-west area (5.5%).

Discussion

In Italy, we implement a life-course policy of immunization, with most of vaccinations offered for free by public health services. In addition, some vaccinations, especially those for preventing outbreak-prone VPDs, are mandatory for accessing schools.

As recommended by WHO, during the epidemic primary series vaccinations were prioritized in the whole country, reducing the risk of VPD outbreaks, due to an accumulation of susceptible persons, the same finding reported by Santoli (Santoli et al. 2020) in her survey in the United States. According to the surveillance data collected by the European Centre for Disease Prevention and Control (ECDC), the reported cases of measles in the first trimester of 2020 in Italy were 102 compared to 581 in the same period of 2019. This reduction in the number of notified measles cases during COVID-19 seems to suggest a lack of major gaps of immunization in outbreak-prone VPDs coupled with a reduced risk of spread due to social distancing measures, stay at home and lock down policies. In Italy, schools were closed in the early phase of SARS-CoV-2 epidemic, replaced by on-line teaching activities. Schools are recognised as common setting for the spread of outbreak-prone VPDs.

It is important to note that for other antigens, such as HPV, the impact was worse. In this case, catch-up activities could be easier to manage, as the vaccination, both for females and males, can be done from 11 until 14 years and over, depending on the type and schedule of the vaccine. In addition, the Italian vaccination plan recommends its use also in women of 25 years of age, at the moment of the first PAP-test.

Older people are those most seriously affected by COVID-19 in terms of morbidity and mortality, and several VPDs, including influenza, pneumococcal disease and herpes zoster represent a significant concern, and programs to deliver these immunizations are more urgent than before and should be prioritized, as reported by Privor-Dumm et al. (2020). In Italy, anti-herpes zoster vaccination was reported as the second most reduced. This can be due to the fact that older people were strongly recommended by the Government to stay at home since the beginning of the national epidemic. Considering the coming influenza season, special efforts should be put in communication strategies to encourage a wide adhesion to seasonal influenza vaccination in older adults, and to take this opportunity to propose other immunizations.

In our study, we found that the disruption of immunization services was reduced by the prompt adoption of organization and response measures at local and regional level. Almost all respondents reported more than one measure, including pre-scheduled in person appointments for vaccination and extend the hours of work to avoid overcrowding; telephone call to families; developing a list of children who have missed their vaccine doses; preparing a targeted action plan to ensure rapid catch up of children who are not up to date with their vaccination; and in strengthening collaboration with paediatricians. These finding are in line with recommendations from international organizations (WHO 2020, WHO

EURO 2020, WHO and UNICEF 2020) and with reports from other countries (PAHO 2020, Bramer et al. 2020, MacDonald et al. 2020).

Our study suggests that the number of health workers in vaccination centres during COVID-19 pandemic was reduced in many cases: on the other side, they needed to develop and implement new strategies to cope with the new reality, with extra efforts to ensure that safety protocols were respected and to address the concerns of families. Their wellbeing should be monitored to avoid risks of burnout.

To ensure the highest level of safety during immunization activities, the Ministry of Health recommended to:

- prioritize on-line schedule, using the dedicated regional telephone lines (Regional Centre of Reservation), the affiliated pharmacies or the website of the health facilities, with priority given to children for mandatory vaccinations and to people at higher risk;
- permit entry into the waiting rooms only to one accompany person for each child, non-self-sufficient or fragile persons, and for persons with cultural-linguistic difficulties;
- remain in the facility under observation for AEFIs at least for 15 minutes, according to Italian guidelines;
- activate effective logistic measures in order to guarantee social distancing especially in case of free or mixed access to vaccination services;
- take body temperature and check respiratory symptoms before entrance;
- ensure procedures for hand hygiene (alcohol-based hand sanitizer, poster with clear indication of hygienic services, poster displaying how to wash hands);
- use of masks in people above 6 years of age;
- applicate appropriate measure for the safety of health workers;
- define effective protocols for cleaning and disinfection of environment with special attention to ventilation of premises;
- implement specific training on COVID-19 for all staff, irrespective of their role and profession.

Information and awareness raising activities were also reported in Italy, even if in a lesser extent. As mentioned in several studies, correct and widespread information of parents regarding the continued need for vaccination during COVID-19 and its safety, plays a key role in reducing immunization gaps both for routine childhood and adult immunization. Despite its recognised importance, social communication initiatives were jeopardized, therefore the Ministry of Health advised to reinforce these activities with a focus on:

- informing clearly on the need to vaccinate also during COVID-19 emergency to keep people in good health, and describing what organization changes were introduced;
- stressing the safety and preventive measures adopted to avoid SARS-CoV-2 transmission.

Especially during COVID-19 time, it was recommended to use the increased opportunities to contact families to re-schedule missed vaccinations and recall for outreaching. Communication activities at local level can be implemented in collaboration with other public administrations and stakeholders, with targeted initiatives for marginalised groups.

The vaccination schedule can be applied with some flexibility, adopting the more appropriate protocol according to the current scientific evidence, to facilitate catch-up.

Another recommendation concerned the need to have an updated analysis of staff requirements, taking into consideration its reinforcement, whenever possible, and introducing new organization models, aiming at developing the professional autonomy of non-medical staff in the management of immunization sessions.

Collaboration with general practitioners and paediatrician should be strengthened through specific agreements based on the local situations.

To broaden the possibilities of vaccination, it could be useful to find new spaces, guaranteeing the application of safety and preventive measures, also using, whenever possible, mobile immunization services and immunization at home.

Conclusion

COVID-19 had a nationwide impact on immunization services, despite some regions were much more challenged by the epidemic. Italy was the first and one of the most affected countries in the European Union to be affected by COVID-19. In our study, we found that immunization activities decreased during COVID-19 emergency, compared to the same period of the previous year, and this is in line with finding of other studies all over the world.

During the most acute phase of the epidemic, more than one fourth of the centres suspended their activities, also if for a limited period of time, being the maximum reported value 17 days. Disruption of immunization services was worsened by the shifting of healthcare workers to the COVID-19 response, which affected about one third of the staff, irrespective of their profession.

Both national and local lever developed training activities for COVID-19: the possibility to access on-line fostered participation as shown by more than 90% positive response. Nevertheless, further efforts are required to let no staff without appropriate training, as this is a key element to protect the health of patients as well as of healthcare workers.

The decrease of immunization activities was observed at different times in different areas. While in general it was noted mostly after the notification of the first local cases and during the peak of the epidemic when social distancing and stay at home policies were implemented, in the South it was perceived earlier especially after the declaration of national health emergency.

At national level, children above 1 year of age until adolescence were the most affected by disruption of immunization services (n=64/94; 68%) and, less frequently, adults (n=28/94; 29.8%). With respect to vaccines, at national level

anti-HPV was mentioned as the most affected, followed by Herpes Zoster, DTPa and meningococcal B.

In our study, we found that the disruption of immunization services was reduced by the prompt adoption of organization and response measures at local and regional level, most generally consisting in: immunization only under appointment, give priority to some immunization/subjects and extend the hours of work to avoid overcrowding. On the contrary, supply shortage was generally not observed.

Based on the results of the survey, the Ministry of Health disseminated best practices for effective catch-up in Italy, considering the epidemiological situation still diversified at local level and the regional organization of health services. At present lockdown policies have declined and relaxed and the supply of vaccination services can resume in full.

The Italian Government approved adequate legislative measure to strengthening primary health care, allocating more resources and improving coordination and integration with other actors, such as general practitioners and paediatricians in the case of immunization activities. Further opportunities for innovation could be explored when one or more COVID-19 vaccines will be available.

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