Polio and measles: reasons of missed vaccination in Italy, 2015-2017

V. Gianfredi¹,², F. D’Ancona², F. Maraglino³, C. Cenci³, S. Iannazzo³

Key words: Missed vaccination, Measles, Polio, Vaccination coverage
Parole chiave: Mancata vaccinazione, Morbillo, Polio, Copertura vaccinale

Abstract

Background. Also in Italy, a flourishing evidence confirms the recent spread of vaccine hesitancy movements resulting in approximately 4-7% of the paediatric population not immunised every year against polio and approximately 9-15% against measles in the last few years. The aim of this paper is to describe the reasons of polio and measles missed vaccination in Italy, in the period 2015-2017, and to analyse any potential effect of the 2017 mandatory vaccination law.

Methods. Number of missed vaccinations in children younger than 24 months, stratified by reason, were collected separately for measles and polio with a regional level of detail. Data were collected using an electronic form developed using Microsoft Excel®.

Results. The most frequent reason for missed polio vaccination was “definitive informed dissent” with a mean value 1.5%, followed by “found/contacted, but did not attend the appointment” with a mean value 1.3%. Inversely, “acquired immunity subsequent to previous disease or vaccination performed elsewhere” and “excused in a permanent way for health conditions” were the less frequent with a mean value 0.03% for both. For measles vaccination the reason “found/contacted, but did not attend the appointment” was the most frequent (mean value 3.2%), followed by “definitive informed dissent” (mean value 2.9%).

Conclusions. Percentage of missed vaccination showed a remarkable reduction in 2017. This decrease is likely due to the introduction of mandatory vaccination law. In point of fact, “Dissent” decreased for both polio and measles during the study period. While, “Delay” increased during the 3-years. It seems that hesitant parents prefer to postpone vaccinations instead of refusing them. Counselling, parents’ empowerment and vaccine education are central to contrast vaccination postponing. Thus, for parents who refuse vaccines (“Dissent”), monitoring the trend is important as well as trying to understand their reasons.

Introduction

In Italy, the immunisation programme is responsibility of the National Health Service (NHS) and the vaccinations included in the National Immunisation Plan (NIP) are provided free-of-charge by the public vaccination centres, in some areas also through paediatricians and general practitioners. Since 2001, the nineteen Regions and the two Autonomous Provinces (R&AP), are in charge to design their own vaccination strategy and health policy under the guidance of the NIP that is elaborated by

¹ Postgraduate School of Hygiene and Preventive Medicine, Department of Experimental Medicine. University of Perugia, Italy
² National Institutes of Health. Rome, Italy
³ Ministry of Health, Rome, Italy
the Ministry of Health (MoH), in accordance with the R&AP, in order to harmonize the vaccination strategies across the country. The NIP 2017-2019 was published in February 2017, expanding the number of vaccines offered free-of-charge to the target population (1). Moreover, in order to reduce the socio-demographic inequalities, by March 2017, all vaccines scheduled in the NIP were also included in the Essential Levels of Care (LEA in Italian, acronym of “Livelli Essenziali di Assistenza”) – that is the list of health provisions to be guaranteed to all citizens, regardless of which Region they live (2). Lastly, in July 2017, the Italian Parliament approved the law n. 119/2017 that increased the number of mandatory vaccinations from 4 (tetanus, diphtheria, polio and hepatitis B) to 10 (adding pertussis, H. influenzae type B, measles, rubella, mumps and varicella) (3). The law also required that children until 6 years could be admitted to educational services only if they have received all the vaccines required for their age. This important change came-out in Italy after 15 years during which a shift from mandatory to voluntary vaccinations was encouraged and even implemented, in different ways, in many Italian R&AP. However, in the last 4 years, an alarming decline in vaccination coverage (VC) was observed across the country (4). This was particularly true for measles-mumps-rubella (from 90.4% in 2013 to 87.3% in 2016); measles was responsible of a severe outbreak with more than 7,000 cases and eight fatalities during 2017-2018.

In this context, VC is an essential performance measure of the immunisation system. In Italy, the R&AP estimate their own VC using different computerised Information Immunisation Systems (IIS). According to the last national survey (2016), eleven R&AP were fully computerised using the same software, and seven were fully computerised but with different software at sub-regional level (so called Local Health Units – LHU), while the remaining were partially or non-computerised at all (5). Usually, vaccinations are administered by public vaccination centres in the LHU, and vaccination data are stored in local or regional IIS in real-time. In Italy, the national VC is estimated using aggregated data provided by each R&AP. Annually – within the first half of the year – the Ministry of Health collects and publishes data referred to the previous year. Immunisation data are reported in a standard electronic form aimed to collect, for every vaccine type, the number of subjects vaccinated among their target population (numerator) and the target population (denominator). The standard electronic form requires data for all vaccines scheduled in the NIP, i.e. vaccine against poliomyelitis, diphtheria, tetanus, whooping cough, hepatitis B, Haemophilus influenzae type b, meningococcus ACYW135, meningococcus B, meningococcus C, pneumococcus, chickenpox, measles, mumps, rubella administered within 24 months of age. In the same form are also routinely required data on reasons for missing measles and polio vaccinations (scheduled before 24 months) separately. In particular, polio missed vaccination are collected since 2003; while, the section for measles was added in 2015. Previous data on polio missed vaccination in Italy were already published in 2014 (6).

These two vaccinations are used as proxy of the other vaccinations due within the 24 months, being polio mainly administered with the hexavalent vaccine (poliomyelitis, diphtheria, tetanus, whooping cough, hepatitis B, Haemophilus influenzae type b) and measles with trivalent MMR (measles, mumps, rubella) vaccine or tetravalent MMRV (measles, mumps, rubella, varicella) vaccine. Even though both polio and measles are object of global elimination and eradication plans, respectively, only polio was eliminated in Italy since 2002. However, in October 2018, polio is still endemic in
three countries (Afghanistan, Nigeria and Pakistan), moreover, there are 19 additional countries in which polio VC is too low, with occasional outbreaks or risk of outbreaks (7). Furthermore, considering the high migration pressure from these countries, it is extremely important to continue in global monitoring, in achieving and maintaining a high VC, and to collect and describe reasons for no-vaccination, especially because a growing anti-vaccination sentiment is being experienced worldwide (8). Vaccine hesitancy is defined by the World Health Organisation’s (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) as a “delay in acceptance or refusal of vaccines despite availability of vaccine 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” (3C model) (9). Complacency is determined by the reduction of perceived disease risk, and “vaccination is not deemed a necessary preventive action”; Confidence is the trust in vaccine safety and effectiveness; lastly, Convenience includes economic, geographic, social factors and the ability to understand them (9, 10). Also in Italy, a flourishing evidence confirms the spread of vaccine hesitancy movements resulting in approximately 4-7% of the paediatric population not immunised every year for polio and approximately 9-15% for measles in the last years (11). Considering these aspects, the National Ethics Committee has highlighted the increasing Italian parents’ dangerous behaviour to delay or refuse vaccines. Therefore, the Committee recommended to monitor strictly the reasons for non-vaccination, both at local and national level, in order to identify non-compliant parents and to carefully inform and persuade them (12). The availability of data on explanations for missed vaccinations is an useful information for interventions aimed to improve vaccination coverage and for a better description of the collected data.

The aim of this paper is to describe the reasons of polio and measles missed vaccination in Italy, in the period 2015-2017, and to analyse any potential effect of the mandatory vaccination law. Furthermore, we also compared R&AP’s capacity to collect and analyse data.

Methods

Aggregated VC data were required by Ministry of Health to all R&AP for the different birth cohorts in accordance with the national vaccination schedule. The sources used were the regional or local IISs. Reasons of missed vaccination were gathered for children 24 months old, belonging to the same birth cohort for which VC for the primary series were calculated. Data stratified by reason, were collected separately for measles and polio with a regional level of detail. Number of individuals as target population was considered the same for both vaccinations. These data were collected using the same electronic form developed in Microsoft Excel® for VC collection that contains a specific section named “Reasons for no or incomplete vaccination against polio and measles". This section includes a list of pre-defined reasons, updated in 2014, which consists of:

- emigrated to a different Local Health Unit or abroad;
- excused permanently for health conditions;
- excused temporarily for health conditions or other cause;
- not found because nomadic or homeless;
- not found although known address;
- temporary informed dissent;
- definitive informed dissent;
- immigrants who are waiting for their vaccination certificate from their own
country or immigrants who re-start but did not complete the vaccination schedules;
• acquired immunity subsequent to previous disease or vaccination performed elsewhere;
• found/contacted, but did not attend the appointment;
• others reasons without further details.

The electronic form was sent to the Representatives of each Italian R&AP.

We evaluated the completeness of data, the annual and regional differences regarding the possible reasons of missed vaccination for both measles and polio. Rates of missed vaccination in total and for each reason for both national and regional level were also calculated. Furthermore, an evaluation of missed vaccinations according to geographical distribution was performed. Geographical classification was done according to the National Institute of Statistics ISTAT (13) as follows: a) north: Piedmont, Valle d’Aosta, Liguria, Lombardy, Autonomous Province of Trento, Autonomous Province of Bolzano, Veneto, Friuli-Venezia Giulia, Emilia–Romagna; b) centre: Tuscany, Umbria, Marche, Latium; c) South: Abruzzo, Molise, Campania, Apulia, Basilicata, Calabria, Sicily, Sardinia). Lastly, type of IIS was also taken into account. We performed a frequency analysis using Microsoft Excel®.

**Results**

For the entire period, Lombardy and the Autonomous Province of Bolzano reported vaccination coverages, but they did not report the reasons of missed polio and measles vaccinations, and consequently they were excluded from the analysis; in addition, Umbria did not report data for 2015.

In the analysed period, the missed vaccination for polio was 5.5% as mean value, while for measles the mean was 10.9%. Data stratified per year and per reasons are reported in Table 1. The completeness of the data was particularly high: 90.6% of non-vaccination for polio was recorded with a specific reason different from “Others reasons without further details” (ranging from 91.8% in 2015 to 90.6% in 2017, along the period 2015-2017) (Data not shown). A similar result was obtained also for measles with 91.3% of reported reasons different from “Others reasons without further details” (ranging from 94.9% in 2015 to 90.9% in 2017) (Data not shown). An important decrement in missed vaccination was recorded after the introduction of mandatory law for both polio and measles with the consequent increase of VC. The reduction was evident especially for measles (-4.1%) (Table 1).

At national level, the most frequent reasons for missed polio vaccination were “definitive informed dissent”, with a mean value 1.5% (1.9% in 2015, 1.5% in 2016 and 1.2% in 2017), followed by “found/contacted, but did not attend the appointment” with a mean value 1.3% (1.2% in 2015, 1.4% in 2016 and 1.3% in 2017). Inversely, “acquired immunity subsequent to previous disease or vaccination performed elsewhere” and “excused in a permanent way for health conditions” were the less frequent, with a mean value 0.03% for both. For measles vaccination the reason “found/contacted, but did not attend the appointment” was the most frequent (mean value 3.2%; 3.7% in 2015, 3.7% in 2016, and 2.3% in 2017), followed by “definitive informed dissent” (mean value 2.9%; 4.0% in 2015, 3.0% in 2016 and 1.8% in 2017). Uncommon were “acquired immunity subsequent to previous disease or vaccination performed elsewhere” and “excused in a permanent way for health conditions”, approximately 0.1% for both (Table 1).

Furthermore, for polio it was possible to identify a progressive increase for
Reasons of missed vaccination

Table 1. Reasons for polio and measles missed vaccination, 2015-2017, Italy

<table>
<thead>
<tr>
<th>Reason</th>
<th>Polio</th>
<th>Measles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emigrated to a different Local Health Unit or abroad</td>
<td>0.6%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Not found because nomadic or homeless</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Not found although known address</td>
<td>0.6%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Total “Not found”</td>
<td>1.4%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Temporary informed dissent</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Definitive informed dissent</td>
<td>1.9%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Found/Contacted, but did not attend the appointment</td>
<td>1.2%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Total “Dissent”</td>
<td>3.3%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Excused temporarily for health conditions or others</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Immigrants who are waiting for their vaccination certificate from their own country or immigrants who re-started but did not complete the vaccination schedules</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Total “Delay”</td>
<td>0.2%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Acquired immunity subsequent to previous disease or vaccination performed elsewhere</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Excused permanently for health conditions</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total “Excused”</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Other reasons without further details</td>
<td>0.4%</td>
<td>0.6%</td>
</tr>
<tr>
<td>National</td>
<td>5.4%</td>
<td>5.8%</td>
</tr>
</tbody>
</table>

“excused in a temporary way for health conditions or others” (0.1% in 2015, 0.1% in 2016 and 0.3% in 2017) and “temporary informed dissent” (0.3% in 2015, 0.3% in 2016 and 0.4% in 2017), while “definitive informed dissent” decreased over the time (1.9% in 2015, 1.5% in 2016 and 1.2% in 2017) (Table 1). For measles, the percentage of “excused in a temporary way for health conditions or others” increased during the three years (0.3% in 2015, 0.4% in 2016 and 0.4% in 2017), while “definitive informed dissent” (4.0% in 2015, 3.0% in 2016 and 1.8% in 2017), “temporary informed dissent” (1.3% in 2015, 0.9% in 2016 and 0.7% in 2017), “excused in a permanent way for health conditions” (0.08% in 2015, 0.07% in 2016 and 0.06% in 2017) and “found/contacted, but did not attend the appointment” (3.7% in 2015, 3.7% in 2016 and 2.3% in 2017) decreased during the study period (Table 1).

Comparable trends were also reported at regional level (data not shown). However, “informed dissent” (both temporary and definitive), “excused for health conditions” (both temporary and permanent) and “found/contacted, but did not attend the appointment” were highly reported by the Northern Regions, while “not found because nomadic or homeless” and “not found although known address” were highly reported by Southern Regions, for both polio and measles (Figure 1 and 2). Missed vaccination rate decrease all over the period approximately in all Regions; however, in
Figure 1 - Geographical distribution of polio missed vaccination, 2017.
“All other reasons” includes: Permanently excused for health conditions, Temporarily excused for health or other conditions, Temporary informed dissent, Definitive informed dissent, Immigrants who are waiting for their vaccination certificate from their own country or immigrants who re-started but did not completed the vaccination schedules, Found/Contacted, but did not attend the appointment, Acquired immunity subsequent to previous disease or vaccination performed elsewhere, Other reasons without further details.
“Not found” includes: Emigrated abroad or to a different Local Health Unit, Not found because nomadic or homeless, Not found although known address.

Figure 2 - Geographical distribution of measles missed vaccination, 2017.
“All other reasons” includes: Permanently excused for health conditions, Temporarily excused for health or other conditions, Temporary informed dissent, Definitive informed dissent, Immigrants who are waiting for their vaccination certificate from their own country or immigrants who re-started but did not completed the vaccination schedules, Found/Contacted, but did not attend the appointment, Acquired immunity subsequent to previous disease or vaccination performed elsewhere, Other reasons without further details.
“Not found” includes: Emigrated abroad or to a different Local Health Unit, Not found because nomadic or homeless, Not found although known address.
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Some of them, the percentage remained high. Particularly, Sicily (8.7%), Friuli-Venezia Giulia (8.5%), Veneto (8.3%), Marche (7.0%), Valle d’Aosta (6.3%), Autonomous Province of Trento (6.1%) maintain a percentage higher than the national value, for polio (Figure 3). The trend was also confirmed for measles (data not shown).

Moreover, taking into account the different types of IIS used by Italian R&AP, we identified two patterns of missed vaccination distribution (5). Notably, the Regions with IIS fully computerised and using the same software across the Region (Apulia, Abruzzo, Molise, Basilicata Marche, Umbria, Tuscany, Friuli, Veneto, Autonomous Province of Trento, Valle d’Aosta) and Regions with IIS fully computerised but with different software across the Region (Sicily, Latium, Emilia, Liguria, Autonomous Province of Bolzano, Piedmont, Lombardy) show lower rate of “not found because nomadic or homeless”, “not found although known address” and “emigrated abroad or in a different Local Health Unit” compared to Regions with IIS partially computerised both with same or different software (Figure 4a, 4b).

Discussion and conclusions

Comparing our results to the previous analysis regarding the period 2006-2010, completeness of the data was higher: the percentage of non-vaccinations recorded with a specific reason different from “other reasons without further details” was approximately 80% in 2006-2010 compared to more than 90% in 2015-2017 showing a better monitoring of the reasons for non-vaccination. Comparison was feasible only for polio.

In addition, while in the period 2006-2010 non-vaccination was as a mean 3.4%, it was 5.5% in 2015-2017. Indeed,
vaccination coverage was higher in the previous range of time than in the period covered by our analysis, characterized by VC lower than the target indicated by Ministry of Health (4); in particular the percentage of missed vaccination has increased in 2015 and 2016, whilst a remarkable reduction – especially for measles vaccination – was recorded in 2017. This decrease is likely due to the introduction of the law increasing the number of mandatory vaccinations. In point of fact, “definitive informed dissent” decreased for both polio and measles during the study period. While, “temporary informed dissent” and “excused in a temporary way for health conditions or others” increased during the 3-years. In other words, permanent or final refusal decreased, while deferral or delay increased over the study period. It seems that hesitant parents prefer to postpone vaccinations than to refuse them. In fact, vaccination opinions and communication preferences of parents who postpone vaccines are different if compared to those who refuse (11). Likewise, counselling, parents’ empowerment and vaccine education are central to contrast vaccination postponing. Previous results show an active role played by tailored communication strategies in effectively address vaccine delay (14). Thus, for parents who refuse vaccines (“dissent”), monitoring the trend is important as well as trying to understand their reasons and, if possible, to prevent this choice filling in the potential gaps.

As a consequence, in order to reduce the number of “Not found” it is important to enhance IIS’s functionalities and hopefully to set up a national IIS. With this tool and a well-established organization at local
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level, it is likely to minimize the impact of “not found because moved to another Local Health Units” and “not found although known address” categories.

According to our results, reasons for missed vaccination seem to be associated with type of vaccine and operational aspects. Particularly, the characteristics of IIS appear to play an important role, and results obtained taking into account the different types of IIS used by Italian R&AP are very interesting. Regions fully computerised and using the same software across the region and Regions with IIS fully computerised but using different software across the Region seem to be able to better identify people, therefore reducing the number of subjects classified as “not found”, according to the definition used in our analysis. Probably, the implementation of a national IIS will improve the efficacy for both identifying and inviting people. Furthermore, it will enable Health Authorities at national, regional, and local level, to monitor vaccination programmes in real time (5).

These data need to be interpreted with caution. A plausible explanation is that, mandatory vaccination law might have played a role in contrasting the “complacency” of the 3C model of vaccine hesitancy (10). As stated before, complacency is directly related to the high efficacy and efficiency of immunization program. In fact, vaccination program success, paradoxically, may result in complacency due to the reduction of perceived risk of diseases themselves. In this “safe” context, too many families have become complacent, relying on the false security that infections are diseases of someplace else. Probably, a negative impulse in this direction may have been due to the tolerant behavior assumed by the Government against noncompliant parents. In fact, mandatory vaccinations were firstly introduced in Italy since 1939, and a fine and even temporary suspension of parental authority had established for unvaccinated children. However, during the last two decades, Health Authorities were well-disposed to override the compulsoriness and to reach high VC through a promotion of voluntary vaccination uptake (15). Unfortunately, VC did not arise, and since 2013, it dropped dramatically. In this scenario, mandatory vaccination law was an urgent measure that Parliament was requested to take. The mandatory vaccination law, implemented thanks to a hard work done at each level in order to make it functioning and effective, and supported by the related communication campaign and amplified by the media, might have positively pulsed complacent parents. Furthermore, according to Larson and colleagues (16) Italy, Slovenia, France and Greece are the four European countries reporting the highest percentage of parents who “disagree/strongly disagree” with the three following statements “vaccines are important for children to have”; “overall I think vaccines are safe”; and “overall I think vaccines are effective”. Whilst for the statement “vaccines are compatible with my religious beliefs”, the four countries reporting the higher rates are Slovenia, Greece, Belgium, and the Netherlands, followed by Italy (16). In this regard, the SAGE group stated: “In some instances (a combination of) policy, legal, and communications changes may be needed, once the specific hesitancy problems are identified” (17). Due to Italian organization, the implementation of vaccination strategy and the contrast to vaccine hesitancy must be implemented at local and regional level, and the national government can take special initiatives aimed to manage specific difficulties and to face common risks to ensure the protection of the population in the whole country. This is the case of the mandatory vaccination law.

Nevertheless, mandatory vaccination law could not be the only strategic effort aimed to contrast vaccine hesitancy in Italy. Actually, according to our results, there is still a small
but stable group of parents who did not turn up at the vaccination appointment or are trying to delay the vaccination. For instance, good and adequate communication can positively impact vaccine uptake and contribute to contrast the lack of “confidence” and “complacency”. Satisfactory communication is an essential part of high quality vaccination strategy. According to the SAGE group, communication can encourage vaccination acceptance in any setting, especially in well-resourced vaccination programs (10).

In conclusion, a high quality communication campaign combined with a conscientious observation of mandatory vaccination law could better educate parents on the importance of vaccination. Regular monitoring of the VC and ordinary evaluation of reasons for missed vaccination are essential efforts needed to understand as to reduce the burden of infectious diseases, increasing VC, and mobilizing society against vaccine preventable diseases. Only by systematic monitoring, we will be able to document progresses in contrasting vaccine hesitancy.

Acknowledges
We would like to thank all the Regions/Autonomous Provinces which participated in data collection.

Conflict of interest
None to declare

Ethical approval
No ethical approval was required

Metodi. I motivi di mancata vaccinazione, in bambini di età inferiore ai 24 mesi, sono stati raccolti separatamente per morbillo e polio, raggiungendo un livello di dettaglio regionale. I dati sono stati raccolti utilizzando un modulo elettronico sviluppato in Microsoft Excel®.

Risultati. Il motivo più frequente di mancata vaccinazione antipolio è stato il “dissenso informato definitivo” con un valore medio dell’1,5%, seguito da “trovato/contattato, ma non presentatosi all’appuntamento” con un valore medio dell’1,3%. Inversamente, “l’immunità acquisita successiva a precedente malattia o vaccinazione eseguita altrove” e “esonerato in modo permanente per motivi di salute” erano i meno frequenti, con un valore medio dello 0,03% per entrambi. Per la vaccinazione contro il morbillo, il motivo “trovato/contattato, ma non presentato all’appuntamento” era il più frequente (valore medio 3,2), seguito da “dissenso informato definitivo” (valore medio 2,9%).

Conclusioni. La percentuale di mancata vaccinazione ha avuto una notevole riduzione nel 2017. Questa diminuzione è probabilmente dovuta all’introduzione della legge sull’obbligatorietà vaccinale. In effetti, il “dissenso” è diminuito sia per la polio che per il morbillo durante il periodo di studio. Mentre, il “ritardo” è aumentato durante i 3 anni. Dai dati ottenuti, appare che i genitori titubanti preferiscano rinviare le vaccinazioni invece di rifiutarle. Il counselling, l’empowerment dei genitori e l’educazione vaccinale sono fondamentali per contrastare il rinvio della vaccinazione. Mentre, per i genitori che rifiutano i vaccini (“dissenso”), monitorare il trend è importante, così come cercare di capirne le ragioni.

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Corresponding Author: Dr. Stefania Iannazzo, Ministry of Health, Viale Giorgio Ribotta 5, 00144 Rome, Italy e-mail: s.iannazzo@sanita.it