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The impact of immunization programs on 10 vaccine preventable diseases in Italy: 1900–2015

Patrizio Pezzotti [a,*], Stefania Bellino [a], Francesca Prestinaci [a], Simone Iacchini [a], Francesca Lucaroni [b], Laura Camoni [c], Maria Maddalena Barbieri [d], Walter Ricciardi [e,f], Paola Stefanelli [a], Giovanni Rezza [a]

[a] Department of Infectious Diseases, Istituto Superiore di Sanità (Italian National Institute of Health), Rome, Italy
[b] Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy
[c] National Center of Health Technology Assessment, Istituto Superiore di Sanità, Rome, Italy
[d] Department of Economics, Roma Tre University, Rome, Italy
[e] Istituto Superiore di Sanità, Rome, Italy
[f] Institute of Hygiene and Public Health, Catholic University of the Sacred Heart, Rome, Italy

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ABSTRACT

Background: Vaccination has determined a dramatic decline in morbidity and mortality from infectious diseases over the last century. However, low perceived risk of the infectious threat and increased concern about vaccines' safety led to a reduction in vaccine coverage, with increased risk of disease outbreaks.
Methods: Annual surveillance data of nationally communicable infectious diseases in Italy between 1900 and 2015 were used to derive trends in morbidity and mortality rates before and after vaccine introduction, focusing particularly on the effect of vaccination programs. Autoregressive integrated moving average models were applied to ten vaccine-preventable diseases: diphtheria, tetanus, poliomyelitis, hepatitis B, pertussis, measles, mumps, rubella, chickenpox, and invasive meningococcal disease. Results of these models referring to data before the immunization programs were projected on the vaccination period to estimate expected cases. The difference between observed and projected cases provided estimates of cases avoided by vaccination.
Results: The temporal trend for each disease started with high incidence rates, followed by a period of persisting reduction. After vaccine introduction, and particularly after the recommendation for universal use among children, the current rates were much lower than those forecasted without vaccination, both in the whole population and among the 0-to-4 year olds, which is, generally, the most susceptible age class. Assuming that the difference between incidence rates before and after vaccination programs was attributable only to vaccine, more than 4 million cases were prevented, and nearly 35% of them among children in the early years of life. Diphtheria was the disease with the highest number of prevented cases, followed by mumps, chickenpox and measles.
Conclusions: Universal vaccination programs represent the most effective prevention tool against infectious diseases, having a major impact on human health. Health authorities should make any effort to strengthen public confidence in vaccines, highlighting scientific evidence of vaccination benefits.
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1. Introduction

Vaccination programs, along with sanitation measures, are considered the most important public health tools, having a considerable impact on morbidity and mortality at the global level [1,2]. However, vaccines are often victims of their own success, and low risk perception due to the dramatic decline of vaccine preventable diseases (VPDs) may lead to complacency, which is an important component of vaccine hesitance or even refusal [3]. As a consequence, a decline in vaccination coverage may occur, even in contexts where access to high quality vaccination services is ensured. In order to increase confidence on the positive effects of vaccines, it is extremely important to provide information on their impact on the health of both individuals and communities. Up to now, only a few long term series of cases of vaccine preventable diseases were available in a limited number of countries [4–7].

In Italy, a country with universal access to care and treatment, an increasing number of vaccines has been actively offered

* Corresponding author at: Department of Infectious Disease, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy.
E-mail address: patrizio.pezzotti@iss.it (P. Pezzotti).

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free-of-charge to all the individuals belonging to age groups or risk categories included in the vaccination schedules approved at the national level, even though the implementation may have varied across the country (administratively divided in 19 Regions and two autonomous Provinces), causing a certain degree of heterogeneity for some vaccines through the national territory. Up to the end of 2016, four vaccines were mandatory by law for all newborns (anti-polio, tetanus, diphtheria, and hepatitis B), whereas other vaccines (against measles-mumps-rubella, pertussis, *Haemophilus influenzae* type b, pneumococcus, and meningococcus C) were only recommended [8].

In order to quantify the impact of vaccination programs on morbidity and mortality in Italy, we reconstructed and evaluated the temporal trends of 10 VPDs. We estimated also the number of cases and deaths prevented by vaccination in the last 115 years. The present study is focused on early childhood vaccines.

2. Methods

2.1. Data sources

Yearly surveillance data on morbidity and mortality of vaccine preventable infectious diseases occurred between 1900 (or the first year of reporting) and 2015 (2012 for mortality) in Italy were obtained from the National Institute of Statistics (ISTAT) and the Ministry of Health (MoH). Specifically, mortality data by gender and class of age were retrieved from the annuaries and, since 1980, from the mortality database of ISTAT; morbidity data were retrieved from the annuaries of ISTAT for the period 1900–1997, and from the Infectious disease information system of MoH for the period 1998–2015. Population data were obtained from the Human Mortality Database (http://www.mortality.org/cgi-bin/hmd/country.php?cntr-ITA&level=1) for the period 1900–1951, and from ISTAT database for the period 1952–2015 (www.demo.istat.it).

2.2. Statistical analysis

Ten vaccine-preventable infectious diseases were selected to calculate annual mortality and morbidity rates: diphtheria, tetanus, poliomyelitis, hepatitis B, pertussis, measles, mumps, rubella, chickenpox, and meningococcus. Currently, the number of deaths due to hepatitis B are partially available and morbidity data before 1987 were recorded in an aggregate way for all types of hepatitis, therefore these data were not considered. In addition, the impact of vaccination against *Haemophilus influenzae* type b and pneumococcus was not included, since data on invasive bacterial diseases caused by these pathogens were reported grouped with other pathogens before vaccine introduction. Finally, data on meningococcal meningitis by serogroup were not available.

Annual mortality rates were calculated by standardizing the reported counts of deaths by gender and age class, considering the 2016 Italian population as reference, to take into account changes over time in the age structure of the population. With regard to morbidity, incidence rates were calculated as crude rate, since the reported counts of cases classified by gender and age class were available only after 1954. Mortality and morbidity rates for children aged 0–4 years were also computed.

Autoregressive integrated moving average (ARIMA) models were applied to log-transformed annual mortality and morbidity rates before vaccination started, both for all ages and for 0–4 years old children. Dickey–Fuller test was used to assess the non-stationarity (trend or difference stationarity) of the time series. Autocorrelation and partial autocorrelation plots were used for identifying the order of the autoregressive model, while the Akaike's and Schwarz's Bayesian information criteria were considered for assessing model fit. Results of these ARIMA models referring to data before the immunization programs were projected on the vaccination period to show the impact of immunization and to estimate the expected number of cases in absence of vaccination. Expected deaths after vaccine introduction were estimated only for diphtheria, tetanus and poliomyelitis, which presented the highest mortality rates before the implementation of universal immunization. The difference between observed and projected cases provided estimates of cases avoided by vaccination.

Statistical analyses were performed using the Stata software, version 13 (Stata Cooperation, College Station, Texas, USA).

3. Results

3.1. Temporal trend of mortality and morbidity rates for ten vaccine-preventable diseases

3.1.1. Diphtheria

Immunization with the inactivated diphtheria toxoid was compulsory introduced in 1939 for children aged 2–10 years; in 1968, it was indicated for children in the second year of life, in combination with the inactivated tetanus toxoid. Until 1939, diphtheria was a common disease, causing thousands of deaths every year (Fig. 1A and Supplementary Fig. S1A). From the beginning of the twentieth century to the forties, between 15,000 and 30,000 cases were annually reported (incidence rate was 30–75 per 100,000) (Fig. 1B and Supplementary Fig. S1B). After World War II, large-scale immunization programs allowed a rapid decrease of morbidity and mortality rates, although the latter had already begun to decline. Until the late thirties, mean mortality rates were 4.20 and 66.30 in the whole population and in the 0-to-4 years old class, respectively, falling to 0.52 and 8.08 after vaccine introduction (Supplementary Table S1). Similarly, morbidity rates sharply declined during the vaccination period (Table 1). The last case of diphtheria in Italy was notified in 1996.

3.1.2. Tetanus

The number of tetanus cases has dramatically dropped since the introduction of tetanus toxoid vaccine for at risk professional categories in 1963, while mortality rates have begun to decrease in the fifties (Fig. 2C–D and Supplementary Fig. S1C–D). This vaccination became mandatory for children in the second year of life in 1968. Over 13,000 cases were annually reported until the mid-sixties, with a morbidity rate of 1.3–1.5 per 100,000; then, the number dropped to less than 1000 at the beginning of the seventies (morbidity rate 0.5–0.7 per 100,000). In the same period, the annual number of deaths decreased from 500-to-1000 to less than 200 (mortality rate 0.4–0.5 per 100,000). The temporal trend of mortality rates for children aged 0–4 years showed an irregular pattern, with peaks at the beginning of the twentieth century, in 1920s and 1950s (Supplementary Fig. S1C). Morbidity rates declined under 0.5 per 100,000 since the early seventies; however, a peak of cases (53) occurred in 1989 (Supplementary Fig. S1D).

3.1.3. Poliomyelitis

Following the epidemic peak in 1958, the inactivated Salk polio vaccine (IPV) was recommended for the population aged 0–20 years in 1959. In 1964 the Sabin live attenuated oral polio (OPV) vaccine was used in the vaccination campaign against poliomyelitis, and became compulsory in 1966 for children within the first year of age. Before the universal vaccination thousands of cases of acute flaccid paralysis were reported every year (morbidity rate 17.2 per 100,000), and mortality rates ranged from 4 to 7 per 100,000 among 0-to-4 years old children (Fig. 2A–B and

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