



# Changing epidemiology of Infant Meningococcal Disease after the introduction of meningococcal serogroup C vaccine in Italy, 2006–2014



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## ABSTRACT

**Background:** In Italy, the incidence of Invasive Meningococcal Disease (IMD) was around 0.28 per 100,000 over the last years. Since the risk IMD is usually high among infants aged less than 1 year, we decided to evaluate the trend of IMD cases reported between 2006 and 2014 in this age group. In particular, the study aim was to describe the main characteristics of IMD cases in infants following the introduction of MCC vaccine (2005) and to estimate the number of cases which are potentially preventable through early vaccination.

**Methods:** The National Surveillance System of Bacterial Meningitis was established in 1994 and in 2007 was extended to all invasive bacterial diseases. Clinical data and isolates and/or clinical samples are collected from hospitalized patients throughout the country. IMD cases are reported by clinicians to the local health authorities, and samples are sent to the Reference Laboratory at the Istituto Superiore di Sanità for further characterization and storage at  $-80^{\circ}\text{C}$ . In particular, serogroup identification is obtained by agglutination with commercial antisera or by multiplex PCR.

**Results:** The annual incidence for infants <1 year old remained rather stable of 3.6 per 100,000, with several upward and downward oscillations and a peak in 2010. The incidence of IMD among infants was more than 10 times higher than the overall rate of IMD observed in Italy. Finally, serogroup B was more frequently detected among infants aged <1 year, accounting for 65% of the total ( $p < 0.01$ ).

**Conclusions:** During the study period, IMD incidence reported among infants aged less than one year old was 10 times higher than the overall rate, and serogroup B was the most commonly detected over time. The long-term impact of meningococcal C conjugate vaccine and the effect of the introduction of meningococcal B vaccination among infants need to be evaluated.

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## 1. Background

In the era of new vaccines and advanced care management, the invasive meningococcal disease (IMD) is still a leading cause of morbidity and mortality among infants [1]. This severe disease may become rapidly life-threatening, often within hours, especially in absence of early differential diagnosis and treatment. Moreover, fulminant sepsis and meningitis may cause considerable disease burden, and neurological sequelae have been also extensively reported in children [2]. The distribution of the different

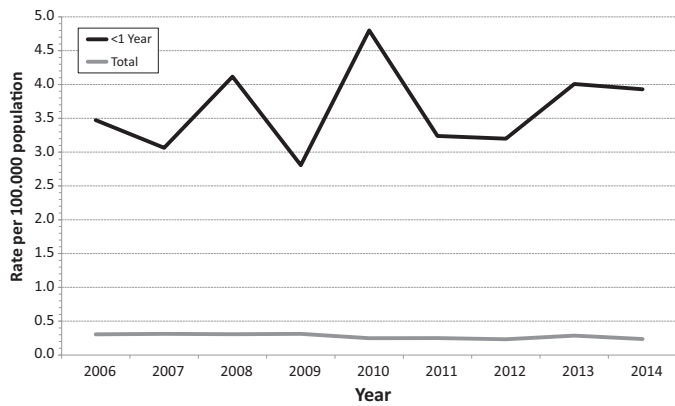
serogroups by geographic area and by age is well known. In the industrialized world, most cases of IMD are caused by serogroup B, C, Y, W whereas serogroups A and X are detected mainly in the African meningitis belt [3]. In Europe, where serogroup B and C are predominant among both infants and older age groups, the detection rate of serogroup Y has shown a recent increase in young adults [4]. In a recent paper, Ladhani et al. [5] reported an increase in endemic *Neisseria meningitidis* W associated with severe IMD in England and Wales.

Different vaccines against the main meningococcal serogroups have been licensed in Europe: conjugate polysaccharide or protein vaccines are recommended, with different immunization schedules in the different countries. The monovalent meningococcal serogroup C (MenC) glycoconjugate (MCC) vaccine has been found to have an overall impact on the number of cases of IMD and on

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**Fig. 1.** Overall IMD incidence in infants less than 1 year of age and in the general population from 2006 through 2014 in Italy.

carriage in the nasopharynx, and increasing immunogenicity among children, contributing to stem IMD cases [6,7].

In Italy, the incidence of IMD is relatively low (about 0.28 per 100,000 inhabitants), also as a result of the immunization programs against serogroup C among children, which started in 2005 in 17 out of 21 Italian regions [8]. In the light of the introduction of meningococcal B vaccination, we performed an analysis of the data of the national surveillance system, in order to describe the trend and the

characteristics of IMD cases among infants aged less than 1 year, in the period 2006–2014, to describe the main traits of the disease in this age group and to identify IMD cases potentially preventable through vaccination.

**2. Methods**

In Italy, the National Surveillance System of Bacterial Meningitis was established in 1994; in 2007, the national surveillance was extended to all invasive bacterial diseases, including those due to *N. meningitidis*. In accordance with the Ministry of Health recommendations, all cases of IMD should be reported to the Istituto Superiore di Sanità. Clinical data and isolates and/or clinical samples are collected from hospitalized patients throughout the country. Specifically, IMD cases are reported to the local health authorities, and samples are sent to the national reference laboratory at the Istituto Superiore di Sanità for further characterization and strains storage at –80 °C. In particular, serogroup identification is obtained by agglutination with commercial antisera (Remel Europe, Ltd, UK) or by multiplex PCR [9]. DNA was extracted from clinical samples with commercial kit (Qiagen, Hilden, Germany). Currently, vaccination strategies are decided at the Regional level, in accordance with the 2012–2014 national immunization plan.

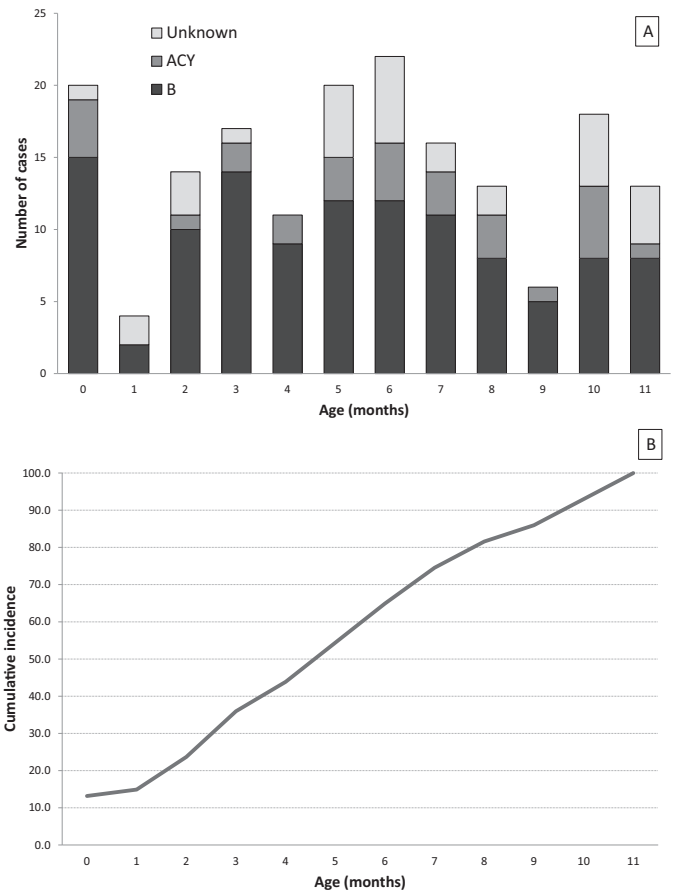
To the purpose of this study, IMD cases reported from 2006 through 2014 were included in the analysis. Anonymized data were analyzed using Epiinfo software vers.3.5. Comparison between two age groups (<1 or >1 years old) which was included for the epidemiological analysis, were done by using Odds Ratios (OR) with 95%

**Table 1**  
Epidemiological and clinical characteristics of IMD cases in infants and in older age groups in Italy, 2006–2014.

Variable	<1 year of age, no. (%) patients	≥1 year of age, no. (%) patients	Total, no. (%) patients
<b>Gender<sup>1</sup></b>			
Male	102 (57.3)	672 (51.5)	774 (52)
Female	76 (42.7)	630 (48.3)	706 (48)
<b>Clinical picture</b>			
Meningitis <sup>2</sup>	78 (43.8)	318 (24.4)	397 (26.6)
Septicaemia	52 (29.2)	673 (51.6)	730 (49)
Meningitis + septicaemia	47 (26.4)	306 (23.5)	355 (23.8)
Other	1 (0.6)	3 (0.2)	3 (0.2)
<b>Geographical area<sup>1</sup></b>			
North	101 (56.7)	765 (58.7)	869 (58.3)
Centre	39 (21.9)	264 (20.2)	303 (20.3)
South and Islands	38 (21.3)	275 (21.1)	318 (21.3)
<b>Outcome<sup>1</sup></b>			
Death	24 (13.5)	133 (10.2)	158 (10.6)
Live	154 (86.5)	1171 (89.8)	1332 (89.4)
<b>Method of diagnosis</b>			
Culture <sup>2</sup>	143 (80.3)	937 (71.9)	1086 (72.9)
PCR	24 (13.5)	144 (11)	168 (11.3)
Agglutination, latex test	8 (4.5)	162 (12.4)	172 (11.5)
Microscopy	2 (1.1)	31 (2.4)	33 (2.2)
<b>Capsular serogroup</b>			
A	1 (0.6)	10 (0.8)	11 (0.7)
B <sup>2</sup>	116 (65.2)	519 (39.8)	637 (42.8)
C	24 (13.5)	297 (22.8)	323 (21.7)
Y	5 (2.8)	95 (7.3)	100 (6.7)
W	0	34 (2.6)	34 (2.6)
X	0	1 (0.1)	1 (0.1)
Other	0	2 (0.15)	2 (0.1)
UNK	32 (18)	346 (26.5)	382 (25.6)

<sup>1</sup> p > 0.05.

<sup>2</sup> p < 0.01, OR = 3.



**Fig. 2.** Distribution of IMD cases due to serogroup B meningococci vs others and unknown serogroups by month of age (A); cumulative incidence of IMD serogroup B cases under 1 year of age (B).

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