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Original Article

Meningococcal B vaccine acceptability: Results of a longitudinal study in Quebec (Canada)

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ABSTRACT

A mass vaccination campaign with the 4CMenB vaccine (Bexsero®) was launched in a serogroup B endemic area in Quebec. A study was conducted to assess parents' and adolescents' opinions about the acceptability of the vaccine before and after the campaign (two telephone surveys). This paper reports the results of the second survey and describes the factors associated with complete and incomplete 4CMenB vaccine status. Overall, 82.5% of children and 58.7% of adolescents were completely vaccinated. A positive association between intention reported prior to the campaign and vaccine receipt reported after the campaign was observed for both children and adolescents. Protection against meningococcal diseases was the main reason reported for those who completed the 4CMenB dose series, while lack of time, interest or information remained one of the main reasons for having refused the vaccine or not having completed the series. About half of the vaccinees reported an adverse event after having received a dose of 4CMenB and pain at the injection site and fever were the most often cited. Neither negative perceptions regarding the safety of the vaccine nor report of adverse events after having received a dose of the vaccine were associated with the vaccine refusal.

1. Introduction

Invasive meningococcal disease (IMD), caused by *Neisseria meningitidis*, is one of the most frequent causes of meningitis and septicemia worldwide and continues to be a health concern in high-income countries because of its severe morbidity, especially in young children [1]. In Canada, where serogroup C meningococcal vaccines are used, most cases of invasive meningococcal diseases are now caused by serogroup B [2].

Important changes in the epidemiology of IMD have been observed in the province of Quebec during the last two decades. In Quebec, 945 IMD cases were identified by laboratory surveillance between 1997 and 2011, of which 642 were caused by serogroup B (68%), followed by serogroup C (20%), Y (8%), and W135 (3%) [3]. Serogroup C meningococci have virtually disappeared in the province since the implementation of a serogroup C childhood immunization program in 2002. This program was implemented following the 2001 mass vaccination campaign to control a serogroup C meningococcal disease outbreak targeting all Quebecers between 2 months and 20 years of age using the newly licensed serogroup C meningococcal conjugate vaccine (C-MCV). Serogroup B has now emerged as the dominant group. In Quebec, most cases of serogroup B IMD are caused by an hyperinvasive *Neisseria meningitidis* serogroup B (MenB) clonal complex, namely ST-269cc, which is less common in other Canadian provinces [3,4]. This MenB clonal complex was first seen in adolescents and young adults prior to its general distribution across the population [3,5]. The number and proportion of ST-269cc has been steadily increasing among the identified clonal complexes of serogroup B IMD since its first identification in 2003, representing 65% of serogroup B IMD in 2011 [3]. ST-269cc and the incidence of meningococcal disease cause by this clonal complex is five to seven times higher in the region of Saguenay–Lac-St-Jean compared to the rest of the province [6].

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Health Canada approved Bexsero®, a multicomponent meningococcal B vaccine (4CMenB), manufactured by Novartis [7], in December 2013. In May 2014, the Quebec Immunization Committee (CIQ) recommended the implementation of a targeted vaccination campaign to control the serogroup B meningococcal disease outbreak in the Saguenay–Lac-St-Jean region, targeting all individuals born between May 6, 1993, and December 31, 2014 (between 2 months and 20 years of age) residing or studying in the region [6]. The vaccine was administered as a 2-dose series in adolescents and children over 1 year of age. A 3-dose series was used if the child received his/her first dose of the vaccine between 6 and 11 months, while a 4-dose series was used if the child received it between 2 and 5 months.

In clinical trials, the 4CMenB vaccine had a reactogenicity profile that was comparable to vaccines administered routinely [8,9]. However, when coadministered with routine vaccines, the 4CMenB vaccine was associated with more solicited systemic adverse events, especially fever [8]. During the 4CMenB vaccine campaign, prophylactic administration of antipyretics was recommended by the CIQ for children aged less than 2 years to prevent fever and, potentially convulsion.

A longitudinal study begun two weeks after the official announcement of the vaccination campaign. The objective of the study was to assess the knowledge, attitudes and behaviour of both parents of eligible children (between 2 months and less than 16 years of age) and adolescents (between 16 and 20 years of age) before and after the vaccination campaign. The results of the first phase of this study indicated that most parents (93%) and adolescents (75%) intended to vaccinate their child or to be vaccinated or had already vaccinated their child or received a first dose of the vaccine. Meningitis was perceived as being a dangerous disease by the majority of them and most considered the 4CMenB vaccine to be safe and effective. The main reason for positive vaccination intention or behaviour was self-protection while a negative attitude toward vaccination in general was the main reason mentioned by parents who did not intend to have their child vaccinated. Adolescents mainly reported lack of interest, time or information and low perceived susceptibility and disease severity as the main reasons for not intending to be vaccinated or not being vaccinated [10].

This paper reports the results of the second phase of this study, which was conducted in February 2015 among the same respondents. The factors associated with complete and incomplete 4CMenB vaccine status are described. The impact of adverse events after having received a dose of the vaccine on the acceptability of the subsequent doses is also reported.

2. Methods

2.1. Study design

The survey population included all individuals aged between 2 months and 20 years of age living in Saguenay–Lac-St-Jean. A representative sample was selected among this population, using a two-stage random sampling design, with the household and the respondent as the primary and secondary sampling units. To be eligible to participate, respondents had to be the main caregiver of at least one child between 2 months and less than 16 years of age or to be between 16 and 20 years of age; and to live or to study in Saguenay–Lac-St-Jean at the time of the first survey. The original sample (first survey in May 2014; phase I) was constituted using random-digit dialing methodology [11], and the second phase of this longitudinal study was conducted in February 2015 among respondents who consented to be re-contacted after having responded to the first survey (phase I). When the selected person was <16 years of age, the person in charge of health decisions for the selected person responded to the survey questionnaire, while participants ⩾16 years of age answered for themselves. Four age groups were targeted for sampling: 2 months to <5 years of age; 5 to <12 years of age; 12 to <16 years of age and 16–20 years of age (adolescents). For phase I, 877 interviews were completed in May 2014 (72% response rate; 703 interviews completed with parents of children between 2 months and <16 years of age). Among respondents in phase I, 759 of them (86.5%) agreed to be re-contacted for phase II.

For phase II, computer-assisted telephone interviews were carried out from February 3rd to February 21, 2015, by the same professional research and polling firm chosen for phase I (SOM Recherches et Sondages).

The study was evaluated positively in regards to its methodology by the Ethics Review Board (ERB) of the CHU de Quebec – Université Laval and was exempted from complete evaluation by the ERB due to the article 2.5 of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans in Canada.

2.2. Survey instrument

The survey instrument was developed in French and included questions to measure the respondents' decision to have their child vaccinated (or to be vaccinated themselves for adolescents) and the main reasons for having received one, all or none of the recommended doses of the 4CMenB vaccine. Among vaccinees, adverse events (real or perceived) after having received a dose of the vaccine were collected and the questionnaire investigated their impact on the acceptability of the subsequent doses of 4CMenB vaccine. The survey also included questions on attitudes toward vaccination in general (based on a validated questionnaire to measure vaccine hesitancy [12,13]), perceptions of having been well-informed during the campaign and the overall satisfaction toward the vaccination campaign. A question documenting if the respondents had hesitated while making the decision to vaccinate his/her child or be vaccinated with 4CMenB vaccine was also included in the questionnaire (Have you hesitated prior to making your decision to vaccinate <*NAME*> against meningococcal B disease?).

Most of the questions used a 4-point Likert scale ranging from "totally agree" to "totally disagree". Open-ended questions were used to collect reasons for having received one, all or none of the recommended doses of the 4CMenB vaccine, reasons for having hesitated while making a decision in regard to 4CMenB vaccine and adverse events reported. Standard socio-demographic variables were collected at the phase I (for parents: age, level of education as well as age and sex of the child; for adolescents: main occupation, level of education) and were linked with respondents for phase II. All vaccine uptake information was reported by the respondents and was not validated in registries.

The survey questionnaire was pre-tested with 10 respondents and additional clarifications were made in the wording of some questions. The survey instrument is available upon request.

2.3. Data analysis

Expansion weights were assigned to ensure that the results were representative of the target population by adjusting for disproportionate sampling and non-response bias at each phase. Weighting included a calibration that was applied to each respondent in the sample, based on socio-demographic characteristics drawn from the data contained in the Quebec immunization registry developed specifically for the campaign and from census data. Descriptive statistics were generated for all variables. 95% confidence intervals (CI) were calculated and comparisons among respondent groups by demographic characteristics were done using chi-square test.