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Factors influencing the adoption of meningococcal vaccines in immunization programs

Context

The adoption of new vaccines in publicly funded immunization programs often results in a complex decision making process which can include many different actors. Several theoretical frameworks have been proposed and are used to evaluate the pertinence of the adoption of a new vaccine or immunization program (Erickson et al, 2006; Burchett et al, 2012). Cost-effectiveness analyses and budget impact estimates are usually included in these frameworks and can become the most important factors in a context of budget restriction. The decision making process is relatively simple when the vaccine in question is one that prevents common and serious diseases (for example, poliomyelitis or pertussis) and where the cost-effectiveness is highly favourable. Likewise, an economic analysis from the perspective of a health care provider is often decisive when it is for a vaccine which prevents a disease which is frequent but not severe (for example, varicella or diarrhea caused rotavirus). However, the decision making process is much more complex when it is for a vaccine which targets rare but serious diseases which are not attractive from a strictly economic point of view. There is currently a large diversity in the immunization programs against the meningococcal disease in industrialized countries. This diversity is not entirely explained by the epidemiology of the disease. Other factors related to the perception of the risk of the disease and the vaccine also play a role. The socio-cultural, economic, and political context may also influence the decision makers. The relative importance of these different factors is often hard to establish from the documents issued by scientific committees or public health authorities to justify the adoption or rejection of a new vaccine. It is thus pertinent to carry out a study on the processes used to decide whether to implement an immunization program with conjugate meningococcal vaccines targeting serogroups A, C, W, and Y and protein-based meningococcal vaccines targeting serogroup B. This would help explain the different immunization programs which exist within and between different countries and regions and help optimize the strategies for favouring the adoption of vaccines which are effective at preventing rare but serious diseases dreaded by the population.

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Objectives

The general objective of the study is to identify the relative importance of various factors which influence the adoption of meningococcal vaccines in publicly funded immunization programs.

The specific objectives are:

1. to describe the history of the immunization programs targeting the meningococcus in different countries and different regions of the same country;
2. to characterize the economic analyses done to support the decisions;
3. to identify the factors which led to the adoption or rejection of immunization programs with conjugate and protein-based meningococcal vaccines and to describe the relative importance of these factors;
4. to identify in a specific way the role of economic analyses in the decision making process.

Methodology

The study is a journalistic observational multiple case study with both qualitative and quantitative methodologies (Yin, 2003). It is intended to be exploratory (inductive) so no theoretical framework is proposed at the outset, but it is hoped that, eventually, it will help elaborate an explanatory theory.

The jurisdictions targeted were chosen empirically based on operational considerations in order to include both countries with centralized and decentralized decision making processes. The jurisdictions chosen are Canada (Quebec, Ontario, British Columbia, and Nova Scotia), Belgium (French and Flemish), Italy (Tuscany, Lazio, and Umbria), the United Kingdom (England and Scotland), Holland, France, Australia, New Zealand, and the USA.

Two different approaches will be used. The first consists of a review of writings (reports, position papers, scientific articles) on immunization programs targeting the meningococcus. The second will be made up of interviews with key players (experts) who have played a role in the decision making process or know the context well.

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For the review, general search engines, such as Google, and specialized search engines, such as PubMed, will be used with a series of keywords (to be defined). The exhaustivity of the review will be verified with the interviews with the key actors. From this review, the history of the immunization programs will be reconstructed. Economic analyses will be classified based on their point of view (societal or tax-payer), their methodology (a static or dynamic model), the epidemiological context, the choice of vaccine effectiveness parameters, the cost-effectiveness indicators generated (\$/QALY or \$/DALY, for example), and their timing in the decision making process.

In each of the jurisdictions, a series of key actors (experts) will be met, trying to have at least two people from each of the following sectors: upper level professionals in public health, academic scientists who are members of consultation committees, and the personnel responsible for medical matters in pharmaceutical companies commercializing the relevant vaccines. These people will be identified by the knowledge of the main researcher and through the snowball method.

The targeted people will be contacted and invited to participate by email (or by post or telephone if circumstances demand). The objectives of the study and the terms of participation will be presented in a letter of introduction and invitation. A consent form will also be sent and an interview arranged.

During the interview, participants will be invited to sign the consent form (two copies). The interviews will be done in an informal and friendly way in order to avoid doublespeak or non-responses. The participant will first be asked to describe their title and function as well as their responsibility during process deciding to accept or reject an immunization program with a meningococcal vaccine in their jurisdiction. The participant will then be asked to confirm the information collected during the review. They will then be asked to describe the relative importance of the various factors related to the disease or the vaccine (for example, the frequency and severity of the disease, whether it is endemic or epidemic, the efficacy and safety of the vaccine) and those related to the context (for example, the economic, socio-political, cultural, and historic contexts) which influenced the decisions. This information is not always obvious in published documents. We will not ask the participant to give their personal opinion on the decisions and their soundness. Notes of the interview will be taken, but the interviews will not be recorded.

Original documents (consent forms and interview notes) will be kept in a secured locale at the CRIUCPQ for 5 years after the end of the study and will then be destroyed (no later than 31

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December, 2023). The analysis of the interviews will be done qualitatively, using a classification of factors of influence and a categorization of their relative importance. The profiles of the influence of various factors will then be compared between jurisdictions having established or rejected an immunization program and those choosing different vaccines. The validity of the information gathered will be assured by triangulation. Verbatim transcripts of the interview will not be made available and the results will be presented in a way that prevents the identification of the participants. A table showing the number of participants by sector and by region will be made. The names of the participants will not be published.

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References

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Burchett, H. E. D., et al. "National decision-making on adopting new vaccines: a systematic review. *Health policy and planning* 27.suppl 2 (2012): ii62-ii76.

De Wals, P. Optimizing the acceptability, effectiveness and costs of immunization programs: the Quebec experience. *Expert Rev Vaccines*. 2011;10(1):55-62.

Erickson, L. J., P. De Wals, and L. Farand. "An analytical framework for immunization programs in Canada. *Vaccine* 23.19 (2005): 2470-2476.

Yin RK. Case study research. 3rd edition. Sage Publisher, Thousand Oaks (CA), 2003.

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Interview structure (preliminary)

A. Participant

A1 : First and last name

A2 : Institution

A3 : Current position

A4 : Role in the decision making process concerning the immunization programs

A5 : Accept, or not, to be cited in the list of participants

B. Conjugated meningococcal vaccines

B1 : Current program

Deciding organisation

Advising organisation (consulting committee)

Introduction date

Changes since the introduction

Recommended calendar

Vaccine used

Method of financing (vaccine purchase and administration)

The most important factors influencing the adoption or rejection of the vaccine

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B2 : Factors of influence and their importance: very, average, little, not at all

Frequency of the disease

Character epidemic of the disease

Severity of the disease

Efficacy of the vaccine

Safety of the vaccine

Number of follow-up doses

Societal acceptability of the program

Claims of health professionals

Claims of the population

Pressure from the media

Pressure from the vaccine distributors

Pressure from patients rights groups

Pressure from anti-vaccination groups

Economic studies

Cost of the program

Cost-effectiveness of the program

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C. Proteinic meningococcal vaccines

C1 : Current program

Deciding organisation

Advising organisation (consulting committee)

Introduction date

Changes since the introduction

Recommended calendar

Vaccine used

Method of financing (vaccine purchase and administration)

The most important factors influencing the adoption or rejection of the vaccine

C2 : Factors of influence and their importance: very, average, little, not at all

Frequency of the disease

Character epidemic of the disease

Severity of the disease

Efficacy of the vaccine

Safety of the vaccine

Number of follow-up doses

Societal acceptability of the program

Claims of health professionals

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Claims of the population

Pressure from the media

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Pressure from patients rights groups

Pressure from anti-vaccination groups

Economic studies

Cost of the program

Cost-effectiveness of the program

D. For more information

D1 : Sources of information to investigate

D2 : People to contact