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COMMENTARY

Evaluating the effectiveness of the 4CMenB vaccine against invasive meningococcal disease and gonorrhoea in an infant, child and adolescent program: protocol

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ABSTRACT

Invasive meningococcal disease causes significant morbidity and mortality worldwide, with serogroup B being one of the predominant serogroups in Australia for many years. The South Australian (SA) State Government recently funded the introduction of a 4CMenB vaccination program for infants, children and adolescents. In addition to protecting against invasive meningococcal disease, emerging evidence suggests the 4CMenB vaccine may also be effective against gonorrhoea due to genetic similarities between *Neisseria meningitidis and Neisseria gonorrhoeae*. The proposed project aims to evaluate the effectiveness of the SA 4CMenB vaccination program against invasive meningococcal disease and gonorrhoea through a combination of observational studies using routine surveillance and research data. The main methodological approaches involve an interrupted time series regression model, screening, and case-control analyses with different sets of controls to estimate vaccine impact and effectiveness. These analyses are designed to minimize potential biases inherent in all observational studies and to provide critical data on the effectiveness of the 4CMenB vaccine against two diseases of major global public health concern.

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Introduction

Neisseria meningitidis infection causes significant morbidity and mortality worldwide with approximately 500,000–1,200,000 cases and 50,000–135,000 deaths reported annually.[1,2] Twelve different meningococcal capsular groups have been recognized, of which six serogroups (A, B, C, W, X and Y) are responsible for most cases of invasive meningococcal disease (IMD). Although IMD is uncommon, it is still one of the commonest infectious causes of death in childhood in many developed countries.[3] Meningococcal disease usually presents as meningitis or septicemia, potentially resulting in septic shock and meningitis with sequelae of neurological deficits. A recent systematic review and meta-analysis representing 163,759 patients with IMD demonstrated a case fatality rate between 4.1% and 20.0%.[4] Regional variations in disease epidemiology have been reported with group B (MenB) accounting for a large majority of cases in Europe, the Americas and the Western Pacific and groups A (MenA), C (MenC), W (MenW) and X (MenX) accounting for a substantial proportion of cases in Africa and Latin America.[5] The four most common meningococcal serogroups causing disease in Australia are B, C, W and Y with MenB predominating in South Australia (SA) over the last decade In 2018 in SA, a total of 34 cases of IMD were notified and of these 27 (79%) were due to group B.[6] Similar to many countries, the incidence of IMD in Australia is highest in children under the age of 5 years (4.6 per 100,000), followed by adolescents aged between 15 and 19 years (2.6 per 100,000).[7]

A meningococcal B vaccine, (4CMenB,Bexsero ®) was first licensed for use in Europe in January 2013, and is now licensed in Australia, Canada and the United States of America. In Australia, the vaccine is recommended for use in persons ≥ 6 weeks of age for the prevention of invasive disease caused by group B meningococci. Another meningococcal B vaccine (Trumenba®) is also approved in Australia for individuals ≥ 10 years of age.[8] Commencing from July 2020, the 4CMenB vaccine is funded on the National Immunization Program (NIP) in Australia for Aboriginal and Torres Strait Islander children up to two years of age due to their increased risk of meningococcal disease but not for other age groups. The SA Government introduced the 4CMenB vaccine to the SA State Immunization schedule in October 2018.[9] As part of the SA program, 4CMenB vaccine is provided free to children and adolescents who are residents of SA. The United Kingdom (UK) was the first country to introduce the 4CMenB vaccine into a publicly funded NIP in 2015.[10] As part of the UK program, a three-dose schedule was offered to infants at 2 months, 4 months and 12 months of age. This schedule was shown to be highly effective in preventing MenB disease in infants, with cases in vaccine eligible infants being halved in the first 10 months of the program and recent data showing persistence of protection.[10,11] Emerging evidence suggests the 4CMenB vaccine may offer some protection against gonorrhoea.[12]

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Gonorrhoea, caused by the bacterium *N. gonorrhoeae*, is a sexually transmissible infection (STI) which can infect the urethra, cervix, rectum, conjunctiva, and throat. Untreated infection can lead to pelvic inflammatory disease, tubal scarring and infertility in females, and swelling and scarring in the epididymis or testicles in males. Infection is largely asymptomatic in women (80%) and in men (50%) and increases the chances of acquiring and transmitting HIV.[13] Notifications of gonococcal infection in Australia have more than tripled in the past 10 years from 36 to 134 per 100,000 population (2008 versus 2019) with re-infection occurring commonly.[14]

Evidence for a protective effect of a meningococcal vaccine against gonorrhoea was first reported in Cuba, with a rapid decline in the incidence of gonorrhoea following a vaccination campaign with VA-MENGOC-BC from December 1988 to December 1990.[15,16] Subsequently, it was shown that the MeNZB OMV vaccine introduced in New Zealand in 2004 was also associated with reduced risk of gonorrhoea in adolescents and adults aged 15–30 years over a 10 year follow-up period.[12] Further evidence comes from a recent study conducted in Quebec, Canada that analyzed the cases of gonorrhoea notifications during pre and post vaccination periods of a targeted 4CMenB immunization program for those aged 6 months to 20 years.[17] A decline in gonorrhoea notifications of 59% among individuals aged 14–20 years was observed during the post vaccination period whereas the notifications increased in those 21 years and older but confidence intervals were wide (95% CI: −22% to 84%; $p = .1$) due to the small case numbers (average 22 per year).[17] The authors hypothesized that cross-protection occurred despite the difference in disease manifestation, because *N. meningitidis* and *N. gonorrhoeae* share 80–90% genetic homology in primary sequences.[18] Also, recently presented data show high levels of anti-gonococcal antibodies generated in adults vaccinated with 4CMenB, which may explain the suggested cross-protection against gonorrhoea.[19]

In the absence of randomized controlled trials evaluating the effectiveness of the 4CMenB vaccine against IMD and gonorrhoea, the goal of this evaluation protocol is to undertake well designed observational studies to estimate the effectiveness of the 4CMenB vaccine against both IMD and gonorrhoea.

Methods and analyses

The South Australian 4CMenB vaccine strategy

The 4CMenB childhood program in SA commenced on 01 October 2018. Infants aged 6 weeks to 12 months receive three doses of the vaccine, administered at 6 weeks, 4 and 12 months of age which aligns with the usual schedule points for NIP vaccines. A time limited childhood catch-up program, for children aged 12 months to less than 4 years at the commencement of the program, offers two doses of the vaccine in total, administered with a minimum dose interval of two months.

The adolescent 4CMenB program is offered through a School Immunization Program and commenced on 01 February 2019. Students in year 10 receive two doses of the vaccine administered with a minimum dose interval of two months. A catch-up program is available for those in year 11 (aged approximately 15–16 years) in 2019, and for those who were aged 17 to less than 21 years of age at the commencement of the program. The time limited catch-up program offers two doses of the vaccine administered with a minimum dose interval of two months. In addition to the adolescent program, 34,486 students in years 10, 11 and 12 in SA received the 4CMenB vaccine as part of the Meningococcal B Vaccine Herd Immunity Study (B Part of It Study) in 2017 and 2018.[20,21]

Objectives of the evaluation

The primary objective of the planned evaluation is to estimate the effect of the 4CMenB program (vaccine impact and effectiveness) for infants and adolescents against IMD over a -three year period. The secondary objectives are to: a) estimate the number of potential 4CMenB vaccine failures in the infant and adolescent programs; b) estimate the effect of the adolescent 4CMenB program (vaccine impact and effectiveness) against gonorrhoea; and c) evaluate the cost effectiveness of the 4CMenB vaccination program. We hypothesize that vaccinated cases will have reduced rates of serious complications/sequelae compared to unvaccinated cases. Hence, the severity of IMD and sequelae of IMD among cases pre and post implementation of the SA 4CMenB vaccination program (based on vaccination status of the case)will also be evaluated.

Data collection

IMD and gonorrhoea are both notifiable diseases under the *South Australian Public Health Act 2011*. Consequently, all cases of suspected and confirmed IMD and gonorrhoea in SA are reported to the Communicable Disease Control Branch (CDCB), South Australian Government Department of Health and Wellbeing (SA Health), by medical practitioners and diagnostic laboratories.

SA Pathology provides laboratory results on culture and/or PCR positivity, genogroup and serogrouping for IMD. Any available meningococcal isolates undergo whole genome sequencing (WGS) with multi-locus sequence type (MLST) and fine typing.

The Australian Immunization Register (AIR) is the population-based register of residents enrolled in the national publicly funded health care system, Medicare, regardless of vaccination status (99% enrollment of all Australian children by 12 months of age). Vaccine providers report administered vaccines to the AIR. In addition, from the commencement of the 2019 school year, contracted school immunization providers in SA enter all school immunizations on the Immunization Records and Inventory System (IRIS). Data from IRIS are routinely transferred to the AIR. Vaccine uptake data will be obtained through AIR. It is not mandatory to enter 4CMenB immunization data in the AIR. Therefore, there will be some under reporting but it is likely to be minimal.

Vaccine safety is routinely monitored through SA Health's Vaccine Safety Surveillance (SAVSS) system, an enhanced passive surveillance system of adverse events following immunization (AEFI). Data on any AEFI will be available through SAVSS.

Disease severity during pre and post 4CMenB vaccination program introduction will be assessed using data from the Integrated South Australian Activity Collection (ISAAC), the PAEDS (Pediatric Active Enhanced Disease Surveillance) and the AMEND (Adolescent MENingococcal Disease) study. Hospital separation data on length of hospital stay, requirement for intensive care unit (ICU) admission and length of stay in ICU will be obtained from ISAAC. Data on IMD cases among children will be obtained from PAEDS. The PAEDS network is a hospital-based active surveillance system employing prospective case ascertainment for selected serious childhood conditions, particularly vaccine preventable diseases including IMD, and potential AEFI.[22] Data on IMD cases among 15–24 year olds will be obtained from the AMEND study.[23] The AMEND study is a multi-center case control study currently conducted in Australia with the aim of identifying long term clinical, physical, neurocognitive, economic and societal impact of IMD on adolescents and young adults.

Statistical analyses

Evaluation of 4CMenB vaccine impact against IMD

Vaccine impact on IMD will be estimated using state surveillance data from CDCB for laboratory confirmed MenB cases, comparing six pre-vaccine surveillance years to the post vaccination period, annually for three years for the childhood and the adolescent programs after introduction of 4CMenB vaccine. Interrupted time series analysis will be used to compare the number of cases observed to the number of cases predicted if the pre-vaccine trends continued in the post vaccination period.[24] To estimate impact in each vaccine eligible group, incidence rate ratios will be estimated by comparing case numbers in each post vaccination surveillance year with cases in the equivalent cohort during the six pre-vaccination years. To take into account any changes over time unrelated to MenB vaccination, the incidence rate ratios will be adjusted using in the relevant annual MenB incidence in all children/adolescents who were not in the vaccine-eligible cohorts.

Evaluation of 4CMenB vaccine effectiveness (VE) against IMD

Screening method. VE will be estimated for vaccine-eligible infants/adolescents under the program with onset of laboratory confirmed IMD within the first post vaccine implementation year and for each calendar year afterward. For cases, vaccine doses (≥ 2 doses for infants and 2 doses for adolescents and for children 12 months to less than 4 years who are eligible to receive the vaccine as part of the catch up program) will be counted if disease onset occurred ≥ 14 days after the dose. This 14-day period allows for an immune response post vaccination. The comparator group will include all children and adolescents who are eligible for the MenB vaccine program in SA. VE will be estimated as where PCV is the proportion of vaccinated MenB cases and PPV is the age-specific vaccine coverage.[25] In order to use this age and period matched coverage for each case, a logistic regression model will be fit with vaccination status of each case as the exposure. VE will be calculated as 1 minus the odds ratio estimated from the model. VE will be estimated in this way for each age group in the vaccine program.

Case control method. Confirmed cases of IMD in each age cohort will be obtained from CDCB. For the purpose of assessing vaccine effectiveness, we will include only cases eligible for vaccination under the state MenB vaccine program.

At least 20 controls will be randomly sampled for each case from a de-identified dataset of individual records extracted from the AIR, following restriction of the database to SA. As the analysis relies on discordance in vaccination status between cases and matched controls, ≥ 20 controls for each case will be selected from AIR, this database provides a readily available source of controls. In addition, a previous similar study that assessed the effectiveness of the varicella vaccine in Australia demonstrated maximum precision using 20 controls per case.[26] Controls will be matched to cases by date of birth (± 28 days).Vaccination status of controls will be ascertained from the AIR after selection and vaccination considered valid if received ≥ 14 days before the date of disease onset in the matched case. This method of control ascertainment has been used previously to assess VE of *Haemophilus influenzae* serotype B, pertussis, varicella and measles vaccines in Australia.[26] Conditional logistic regression models, explicitly recognizing each stratum of cases and controls will be generated to estimate VE.

Estimation of potential vaccine failures

All cases of IMD in children, adolescents and young adults < 25 years of age reported to CDCB will be investigated for prior vaccination with 4CMenB and timing since vaccination. Clinical history will be obtained to determine any underlying risk factors. Causative genogroups will be identified from blood culture and/or cerebrospinal fluid, in accordance with usual clinical practice. Where an isolate is not available (PCR only), informed consent will be sought and a throat swab taken to aid in identification of the causative organism. Determination of whether a case should have been prevented by vaccination (i.e. vaccine antigens identified in the isolate) is important in determining true vaccine failures as distinct to those cases where disease arose from isolates that do not carry the vaccine antigens.

Isolates will undergo whole genome sequencing to identify vaccine antigens using the Bexsero® Antigen Sequence Type (BAST) scheme to assess likelihood of coverage by 4CMenB vaccine using the PubMLST database. In addition, isolates will be transferred to the Public Health England Vaccine Evaluation Unit, Manchester, United Kingdom to undergo MATS testing to identify the likelihood of coverage of the isolate by 4CMenB vaccine.[27] The Meningococcal Antigen Typing System (MATS) was developed to identify MenB strains with a high likelihood of being covered by 4CMenB.[28] Results of MATS testing of isolates during the period January 2007-June 2011 suggest that 4CMenB vaccine will cover 90% of MenB strains causing disease in SA.[29] This provides a more nuanced interpretation of vaccine coverage, providing estimates of the presence of vaccine antigen and expression.

Evaluation of 4CMenB vaccine impact and effectiveness against gonorrhoea

Laboratory confirmed cases of gonorrhoea will be obtained from CDCB. Similar methods as described for assessment of 4CMenB impact and effectiveness against IMD will be undertaken to assess the impact and effectiveness of the vaccine against gonorrhoea in adolescents. Two separate analyses will be conducted in the evaluation of vaccine effectiveness, with (1) controls randomly selected from AIR and (2) from the SA notifiable disease database for chlamydia. Planned statistical analyses are similar to those described for IMD.

Evaluation of the cost effectiveness of the 4CMenB vaccination program in SA

A decision analytic model will be used to assess the cost-effectiveness of the 4CMenB vaccine against IMD and gonorrhoea. A systematic review has already been conducted to evaluate the clinical and financial burden of IMD.[4,30] In addition, a comprehensive systematic review of the extant literature will be performed to assess the burden of gonorrhoea. This review will be used to identify the best model for cost effectiveness analysis. Costs associated with the management of these infections will be estimated using Australian hospital costing data. These estimates will be combined with literature-based estimates of the broader costs associated with these infections, as well as quality of life and mortality effects to estimate Quality Adjusted Life Year gains.[31]

In the base case, future costs will be discounted to their present value at 5% annually and the healthcare system perspective will be employed as recommended by Australian guidelines.[32] Discount rates of 0% and 3.5% will be considered in sensitivity analyses. The healthcare system perspective captures direct medical costs associated with IMD and gonorrhoea. The cost-effectiveness analysis will also be performed from the societal perspective, including direct healthcare costs, direct non-healthcare costs/government subsidies (e.g. home modification and special education) and indirect costs associated with productivity loss. To estimate indirect costs, two approaches will be used: human capital[33] and friction cost methods.[34] The human capital method estimates the reduction in gross earnings due to morbidity and/or premature mortality.[31] The friction cost method only considers the time span employers need to restore the initial production level.[35]

Comparison of the severity of IMD and sequelae of IMD among cases pre and post implementation of the SA 4CMenB vaccination program

Data on severity and sequelae of IMD cases during the three post- vaccination surveillance years will be compared with those of the six years preceding the implementation of the program. Data for these descriptive analyses will be obtained from ISAAC, PAEDS and the AMEND Study.

Discussion

A State funded MenB immunization program is now available for infants, children, adolescents and young people, in the most extensive funded MenB vaccine program globally. It is expected that the majority of disease-causing MenB strains in SA express at least one of the vaccine antigens, which would make them susceptible to effective killing by vaccine-induced antibodies. In the absence of a randomized controlled trial, to evaluate the effectiveness of the 4CMenB vaccine against IMD, the proposed suite of observational studies will provide a comprehensive evaluation of the newly introduced MenB vaccination program in SA. Emerging evidence additionally suggests a protective effect of the 4CMenB vaccine against gonorrhoea. Therefore, the proposed evaluation presents a unique opportunity to confirm the findings from studies conducted in New Zealand and Canada, in the Australian population. Overall, the results will be important in providing vital information to guide future policy decisions and inform the cost effectiveness of the SA program. These results will also have international significance for other countries considering implementation of a MenB vaccine program.

Disclosure of potential conflicts of interest

HM is an investigator on clinical trials of investigational vaccines sponsored by Industry. HM's, PA's BW's and MM's institution receives funding from Industry (GSK, Pfizer, Sanofi-Pasteur, Novavax) for Investigator led research and for sponsored studies. HM, PA, BW and MM receive no personal payments from Industry. Other authors report no conflict.

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References

1. Chang Q, Tzeng Y, Stephens D. Meningococcal disease: changes in epidemiology and prevention. Clin Epidemiol. 2012;4:237–45.
2. Jafri RZ, Ali A, Messonnier NE, Tevi-Benissan C, Durrheim D, Eskola J, Fermon F, Klugman KP, Ramsay M, Sow S, et al. Global epidemiology of invasive meningococcal disease. Popul Health Metr. 2013;11(1):17. doi:10.1186/1478-7954-11-17.
3. Hart CA, Thomson AP. Meningococcal disease and its management in children. BMJ (Clinical Research Ed). 2006;333 (7570):685–90. doi:10.1136/bmj.38968.683958.AE.
4. Wang B, Santoreneos R, Giles L, Haji Ali Afzali H, Marshall H. Case fatality rates of invasive meningococcal disease by serogroup and age: A systematic review and meta-analysis. Vaccine. 2019;37:2768–82. doi:10.1016/j.vaccine.2019.04.020.
5. Abad R, Bailey F, Garcia IF, Decheva A, Krizova P, Melillo T, Skoczynska A, Vladimirova N. Meningococcal serogroups and surveillance: a systematic review and survey. J Glob Health. 2019;9:010409. doi:10.7189/jogh.09.010409. PMID: 30603079; PMCID: PMC6304171.

6. Invasive meningococcal disease national surveillance report. Australian Government Deparment of Health; 2018.
7. Australian government Department of Health. National notifiable disease surveillance reports. Canberra, Australia: Commonwealth of Australia; 2019.
8. Beeslaar J, Absalon J, Balmer P, Srivastava A, Maansson R, York LJ, Perez JL. Clinical data supporting a 2-dose schedule of MenB-FHbp, a bivalent meningococcal serogroup B vaccine, in adolescents and young adults. Vaccine. 2018;36(28):4004–13. doi:10.1016/j.vaccine.2018.05.060.
9. Marshall HLN, Flood L, Phillips P on behalf of the SA meningococcal B expert working group group introduction of the first state-wide meningococcal B vaccine program in infants, children and adolescents: evidence for implementation in South Australia. MJA. 2019 (In Press).
10. Parikh SR, Andrews NJ, Beebeejaun K, Campbell H, Ribeiro S, Ward C, White JM, Borrow R, Ramsay ME, Ladhani SN, et al. Effectiveness and impact of a reduced infant schedule of 4CMenB vaccine against group B meningococcal disease in England: a national observational cohort study. Lancet. 2016;388 (10061):2775–82. doi:10.1016/S0140-6736(16)31921-3.
11. Ladhani SN, Andrews N, Parikh SR, Campbell H, White J, Edelstein M, Bai X, Lucidarme J, Borrow R, Ramsay ME, et al. Vaccination of infants with meningococcal group B vaccine (4CMenB) in England. N Engl J Med. 2020;382(4):309–17. doi:10.1056/NEJMoa1901229.
12. Petousis-Harris H, Paynter J, Morgan J, Saxton P, McArdle B, Goodyear-Smith F, Black S. Effectiveness of a group B outer membrane vesicle meningococcal vaccine against gonorrhoea in New Zealand: a retrospective case-control study. Lancet. 2017;390 (10102):1603–10. doi:10.1016/S0140-6736(17)31449-6.
13. Vincent LR, Jerse AE. Biological feasibility and importance of a gonorrhea vaccine for global public health. Vaccine. 2019 Nov 28;37(50):7419–26.. doi:10.1016/j.vaccine.2018.02.081 Epub 2018 Apr 18. PMID: 29680200; PMCID: PMC6892272.
14. Ageing; DoHa. Notification Rate of Gonococcal infection, received from State and Territory health authorities in the period of 1991 to 2019 and year-to-date notifications for 2020 [Internet].
15. Pérez O, Del Campo J, Cuello M, González E, Nuñez N, Cabrera O, Llanes R, Acevedo R, Zayas C, Balboa J, et al. Mucosal approaches in Neisseria vaccinology. VacciMonitor. 2009;18:53–55.
16. Ochoa-Azze RF. Cross-protection induced by VA-MENGOC-BC(R) vaccine. Hum Vaccin Immunother. 2018;14:1064–68. doi:10.1080/21645515.2018.1438028.
17. Longtin J, Dion R, Simard M, Betala Belinga JF, Longtin Y, Lefebvre B, Labbé AC, Deceuninck G, De Wals P. Possible impacts of wide-scale vaccination against serogroup B Neisseria meningitidis on gonorrhoea incidence rates in one region of Quebec, Canada.Open Forum Infectious Diseases 2017;4(Suppl 1):S734–S735. doi:10.1093/ofid/ofx180.002.
18. Tinsley CR, Nassif X. Analysis of the genetic differences between Neisseria meningitidis and Neisseria gonorrhoeae: two closely related bacteria expressing two different pathogenicities. Proc Natl Acad Sci U S A. 1996;93:11109–14. doi:10.1073/pnas.93.20.11109.
19. Semchenko EA, Tan A, Borrow R, Seib KL. The serogroup B meningococcal vaccine bexsero elicits antibodies to neisseria gonorrhoeae. Clin Infect Dis. 2019;69:1101–11. doi:10.1093/cid/ciy1061.
20. Marshall HS, McMillan M, Koehler A, Lawrence A, MacLennan JM, Maiden MCJ, Ramsay M, Ladhani SN, Trotter C, Borrow R, et al. B Part of It protocol: a cluster randomised controlled trial to assess the impact of 4CMenB vaccine on pharyngeal carriage of Neisseria meningitidis in adolescents. BMJ Open. 2018;8(7):e020988. doi:10.1136/bmjopen-2017-020988.
21. Marshall HS, McMillan M, Koehler AP, Lawrence A, Sullivan TR, MacLennan JM, Maiden MCJ, Ladhani SN, Ramsay ME, Trotter C, et al. Meningococcal B vaccine and meningococcal carriage in adolescents in Australia. N Engl J Med. 2020;382(4):318–27. doi:10.1056/NEJMoa1900236.
22. Zurynski Y, McIntyre P, Booy R, Elliott EJ. Paediatric active enhanced disease surveillance: a new surveillance system for Australia. J Paediatr Child Health. 2013;49:588–94. doi:10.1111/jpc.12282.
23. Marshall H, McMillan M, Wang B, Booy R, Afzali H, Buttery J, Blyth CC, Richmond P, Shaw D, Gordon D, et al. AMEND study protocol: a case-control study to assess the long-term impact of invasive meningococcal disease in Australian adolescents and young adults. BMJ Open. 2019;9:e032583. doi:10.1136/bmjopen-2019-032583.
24. Moore MR, Link-Gelles R, Schaffner W, Lynfield R, Lexau C, Bennett NM, Petit S, Zansky SM, Harrison LH, Reingold A, et al. Effect of use of 13-valent pneumococcal conjugate vaccine in children on invasive pneumococcal disease in children and adults in the USA: analysis of multisite, population-based surveillance. Lancet Infect Dis. 2015;15:301–09. doi:10.1016/S1473-3099(14)71081-3. Epub 2015 Feb 3. PMID: 25656600; PMCID: PMC4876855.
25. Farrington CP. Estimation of vaccine effectiveness using the screening method. Int J Epidemiol. 1993;22:742–46. doi:10.1093/ije/22.4.742.
26. Quinn HE, Gidding HF, Marshall HS, Booy R, Elliott EJ, Richmond P, Crawford N, McIntyre PB, Macartney KK. Varicella vaccine effectiveness over 10 years in Australia; moderate protection from 1-dose program. J Infect. 2019;78(3):220–25. doi:10.1016/j.jinf.2018.11.009.
27. Brehony C, Rodrigues CMC, Borrow R, Smith A, Cunney R, Moxon ER, Maiden MCJ. Distribution of Bexsero(R) Antigen Sequence Types (BASTs) in invasive meningococcal disease isolates: implications for immunisation. Vaccine. 2016;34:4690–97. doi:10.1016/j.vaccine.2016.08.015.
28. Medini D, Stella M, Wassil J. MATS: global coverage estimates for 4CMenB, a novel multicomponent meningococcal B vaccine. Vaccine. 2015;33:2629–36. doi:10.1016/j.vaccine.2015.04.015.
29. Nissen M ST, Whiley D, Smith HV, Rockett R, Jennison A, Doyle C, Graham R, Gilchrist S, Frosi G, Orlandi L, et al. Use of the Meningococcal Antigen Typing System (MATS) to assess the australian meningococcal strain coverage with a multicomponent serogroup B vaccine. 20th International Pathogenic Neisseria Conference (IPNC). Würzburg, Germany; 2016 September 4–9; Manchester (UK). p. 257.
30. Wang B, Santoreneos R, Afzali H, Giles L, Marshall H. Costs of invasive meningococcal disease: a global systematic review. PharmacoEconomics; 2018 Oct;36(10):1201–22. doi:10.1007/s40273-018-0679-5. PMID: 29948965.
31. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the economic evaluation of health care programmes. 4th ed. Oxford: Oxford university press; 2015. https://books.google.co.uk/books?id=lvWACgAAQBAJ
32. Pharmaceutical Benefits Advisory Committee. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (version 5.0). Canberra, Australia: Australian Government Department of Health and Ageing; 2016.
33. van den Hout WB. The value of productivity: human-capital versus friction-cost method. Ann Rheum Dis. 2010;69(Suppl 1):i89–91. doi:10.1136/ard.2009.117150.
34. Koopmanschap MA, Rutten FF, van Ineveld BM, van Roijen L. The friction cost method for measuring indirect costs of disease. J Health Econ. 1995;14:171–89. doi:10.1016/0167-6296(94)00044-5.
35. Kigozi J, Jowett S, Lewis M, Barton P, Coast J. Estimating productivity costs using the friction cost approach in practice: a systematic review. Eur J Health Econ. 2016;17:31–44. doi:10.1007/s10198-014-0652-y.