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Review

Approved but non-funded vaccines: Accessing individual protection☆

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ABSTRACT

Funded immunization programs are best able to achieve high participation rates, optimal protection of the target population, and indirect protection of others. However, in many countries public funding of approved vaccines can be substantially delayed, limited to a portion of the at-risk population or denied altogether. In these situations, unfunded vaccines are often inaccessible to individuals at risk, allowing potentially avoidable morbidity and mortality to continue to occur. We contend that private access to approved but unfunded vaccines should be reconsidered and encouraged, with recognition that individuals have a prerogative to take advantage of a vaccine of potential benefit to them whether it is publicly funded or not. Moreover, numbers of "approved but unfunded" vaccines are likely to grow because governments will not be able to fund all future vaccines of potential benefit to some citizens. New strategies are needed to better use unfunded vaccines even though the net benefits will fall short of those of funded programs.

Canada, after recent delays funding several new vaccine programs, has developed means to encourage private vaccine use. Physicians are required to inform relevant patients about risks and benefits of all recommended vaccines, publicly funded or not. Likewise, some provincial public health departments now recommend and promote both funded and unfunded vaccines. Pharmacists are key players in making unfunded vaccines locally available. Professional organizations are contributing to public and provider education about unfunded vaccines (e.g. herpes zoster, not funded in any province). Vaccine companies are gaining expertise with direct-to-consumer advertising. However, major challenges remain, such as making unfunded vaccines more available to low-income families and overcoming public expectations that all vaccines will be provided cost-free, when many other recommended personal preventive measures are user-pay. The greatest need is to change the widespread perception that approved vaccines should be publicly funded or ignored.

During the past decade an unprecedented number of important new vaccines were approved for use in economically advantaged countries but subsequent population access was seldom speedily achieved. The process by which new vaccines gain approval and ultimately reach consumers is increasingly complex as vaccine technology advances and costs increase. The approval process begins with in-depth review of vaccine properties and performance by the national biologics regulator, the successful conclusion of which is marketing authorization (or licensure in some countries). In theory, vaccine consumption can begin at this point. However, vaccines are best provided to populations through funded public programs, consideration of which requires additional review, usually by the national immunization technical advisory group (NITAG) [1]. These experts consider the broader public health implications of vaccine use including local disease epidemiology, program feasibility, cost-effectiveness, potential herd immunity, equity of access, and other issues, sometimes using a formal analytical framework [1,2] to reach a recommendation for population use. The final step towards a public program is funding approval, often involving other government departments with competing funding requests impinging on the process. Whereas requests to fund vaccines are increasingly framed in economic terms, equally stringent criteria are seldom applied to other major healthcare expenditures, such as new therapeutic agents.

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An unfortunately common consequence of this multi-step process is delayed population access to an approved vaccine. A recent study of European countries [3] showed that the median interval between marketing authorization and population access to three newer vaccines (if granted) was 6.5 years, with wide variation among countries. Prolonged NITAG deliberations were the major source of delay.

A number of other circumstances can limit population access to a new vaccine. Countries may reach different conclusions about vaccine use, with some supplying it to their population and others not. For example, varicella vaccination programs receive public funding in the USA, Canada, and Australia but not in the United Kingdom; however, the UK funds zoster vaccine for seniors [4] while the other countries mentioned do not. The UK's NITAG [5] recently decided not to recommend funding a new vaccine against group B meningococcal infection (MenB), citing mainly inadequate cost-effectiveness, a decision decried by some as flawed [6,7]. Countries with multiple independent health jurisdictions can have discordant internal programs that depart from the national recommendation. Australia provides an example, where one of seven states provides influenza vaccine to healthy young children [8]. Population access to a new vaccine is also influenced by program scope and whether a catch-up component is included. Provision of influenza vaccine to healthy children in the UK is illustrative: currently 2 and 3 year olds are eligible and ultimately all children 2–16 years of age will be eligible [9]. Meanwhile, a few areas of the country are already extending vaccinations to older children. Such discrepancies in population access may be of concern for parents whose children are at risk but not presently eligible for particular vaccines.

A question that is too seldom asked is why should individuals who could be protected by a newly approved vaccine not take advantage of it, whether it is publicly-funded or not? MenB vaccine is a case in point since the UK decision against funding [5] inevitably means that some unvaccinated children will die or suffer permanent harm [6,7]. When public funding of nationally recommended or approved vaccines is delayed, limited, or denied, individual protection through vaccination is often inaccessible to persons at risk for lack of alternatives such as private sales or awareness thereof. Potentially avoidable morbidity and mortality will continue to occur. It is timely to consider alternatives to all-or-none public access to new vaccines. Should an individual's prerogative to take advantage of an approved vaccine not be recognized and encouraged, even in the absence of publicly-funded programs? If so, how might this be accomplished?

Canada has had recent experience with a number of "recommended but unfunded vaccines" (RUVs) and is beginning to recognize an obligation to facilitate vaccine use outside of public programs. Placement of a newly licensed product in the RUV category has doomed some previous vaccines to limited uptake [10–12], but improvements may be possible with supportive social changes. This review shares Canadian experiences with RUVs and offers suggestions that might have broad application for increasing public access to unfunded vaccines.

1. Recommended but unfunded vaccines in Canada

Canada has historically been a world leader in quickly adding new vaccines to public programs [13–15], but recently, delays of several years have occurred between marketing authorization and public funding of 6 new vaccines. These included pneumococcal and meningococcal conjugates, varicella, zoster, Tdap, and rotavirus vaccines. Canada resembles Europe in microcosm: while we have a single regulatory authority and central NITAGs [16], each of the 13 provinces and territories that make up the country is individually responsible for immunization program funding and scope. Consequently, vaccines can be supplied to the public in some provinces but not others, for varying periods of time. For example, pneumococcal and meningococcal C conjugate vaccines were approved for sale in 2001 but were not supplied to children in all provinces until 2005–2006. Rotavirus vaccines were first recommended by the NITAG in 2008 [17] but only 5 of 10 provinces currently offer funded programs. Zoster vaccine was recommended by the NITAG in 2010 [18] but no province currently supplies it to seniors without cost. Furthermore, there appears to be no movement towards public funding of zoster vaccine, tied to the broader challenges of prioritizing and delivering immunizations for adults. The RUV category is expected to grow as more vaccines are marketed for adults, including alternative formulations of influenza vaccines for seniors. Variability also exists in the scope of funded provincial programs, which often target only a portion of potential beneficiaries, without a catch-up program for others at risk. Human papillomavirus (HPV) vaccines are currently used in limited-scope programs that differ among provinces, with only a subset providing catch-up programs for older girls/women or targeting boys, as recommended in 2012 [19].

Thus a recommendation from Canada's NITAG to use a new vaccine is no longer synonymous with provision of the vaccine in publicly-funded programs, as it once was. A recommendation from the primary NITAG (National Advisory Committee on Immunization, NACI) endorses the safety and usefulness of a new vaccine to protect individuals at risk from infection [16]. Importantly, this NITAG does not address the additional considerations relevant to public health for population use. Currently, a second NITAG (Canadian Immunization Committee) [20] representing all provinces and territories uses a standard analytical framework [2] to examine the population health benefits that would support public funding of a new vaccine program. However, recommendations from this second-level committee have sometimes been much delayed, similar to the situation in Europe [3]. While the evidence supporting routine vaccine use should be equally compelling for each province, the ability and willingness to pay often differ among them. Even when provincial public health officials favor the introduction of a new vaccine program, funding decisions ultimately rest with ministries of finance, which face many competing priorities.

While health system administrators may contend that delays and limitations in funding public immunization programs reflect "due diligence", the opportunities lost to improve health and avoid morbidity and mortality that result from this approach deserve greater attention. The existence of recommended but unfunded vaccines was a new phenomenon for which the medical community was unprepared and resulted in the unfunded vaccines being largely ignored and inaccessible for a time.

2. Recent experiences with RUVs in Canada

2.1. Role of physicians

In 2002, a different perspective began to emerge about RUVs. The Canadian Medical Protective Association (CMPA, the nation's major medical malpractice insurer) recognized the potential for physician liability if patients in their practice suffered from infections that could have been prevented by RUVs. CMPA advised physicians to inform patients about all recommended vaccines they could benefit from if they choose to pay [21]. There were objections from some physicians about the extra time required to mention RUVs, when many were already finding it difficult to adequately discuss funded vaccines in the busy office setting. There were also practical difficulties with community access to such vaccines given limited demand. The ability to pay was limited for many families and awkward to discuss. Nevertheless, the insurer