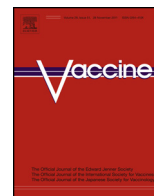




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## Review

Approved but non-funded vaccines: Accessing individual protection<sup>☆</sup>David W. Scheifele<sup>a,\*</sup>, Brian J. Ward<sup>b</sup>, Scott A. Halperin<sup>c</sup>, Shelly A. McNeil<sup>c</sup>,  
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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.

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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

remained insistent on this best practice, which has gradually become easier for physicians to meet as other stakeholders have joined the initiative (outlined below).

## 2.2. Role of pharmacists

As demand increased for private vaccine sales, community pharmacies were more willing to stock and dispense RUVs. In a growing number of provinces, pharmacists can qualify to administer as well as dispense certain vaccines, including RUVs [22]. We believe this to be an important trend in Canada and elsewhere [23] as it will help to increase the uptake of both funded and unfunded vaccines, particularly for adults, given the ease of visiting the local pharmacy even in small communities. Pharmacies are the main source of self-pay zoster vaccine presently across the country. Having this “third source” of vaccines and vaccinators will assist public health to rapidly deliver vaccines in the event of an epidemic. The same infrastructure will be very helpful for expanding RUV use as pharmacists and physicians are natural partners. Physicians find it easier to mention RUVs to appropriate patients knowing the local pharmacist will then help patients make informed decisions, and will deal with vaccine administration, inventory and, payment.

## 2.3. Role of public health

The role played by public health in Canada in delivering immunizations varies among the provinces, some having mainly physician-delivered and others mainly public health-delivered programs. Until recently, public health authorities overseeing both kinds of programs did not consider that they had an obligation to promote or provide RUVs. While consistent with a narrow interpretation of public health’s mandate to provide evidence-based interventions of proven public health benefit, this may be short-sighted given that most nationally recommended vaccines have eventually been funded for public programs. Furthermore, the public will not be aware of nuances of individual versus population benefits and governments will not be able to fund every new vaccine that offers proven health benefits to some citizens. The precautionary principle, taken to its extremes in other public health issues, might also be applied to RUVs since their contribution to risk reduction may well outweigh other costly activities of health departments, such as contact tracing after large exposure events. The final public health concern is about equity and the opportunity cost of promoting a self-pay intervention that only some can afford, usually those at lowest risk, and thereby forgoing other activities directed at the most vulnerable. This latter argument is countered by the need to be transparent in dealing with the public, the opportunity to use RUVs to promote the benefits of vaccines more generally, and the benefits of learning more about new vaccines through their use in the field.

Presently public health agencies in several provinces recognize that an obligation exists to support the use of all NITAG-recommended vaccines, not just the ones their province has chosen to supply for free [24,25]. These health departments provide similar promotional materials for funded and unfunded vaccines, directed at physicians and the public. They also accept the same obligation physicians have to mention the availability and potential benefits of RUVs to appropriate individuals, as best practice. Local clinics sometimes supply RUVs if other sources are limited, akin to travel vaccines. Such a holistic attitude about new vaccines encourages greater use of these vaccines before they move from RUV limbo to the funded category and facilitates extension of vaccine use beyond narrow, funded categories. With RUVs likely here to stay, we hope that this enlightened approach will become the norm for all public health departments across the country.

## 2.4. Role of professional organizations

Professional organizations can play key roles in advocating for the use of RUVs as the public generally values expert advice that is independent of governments and industry. The Canadian Paediatric Society [26] is a prominent advocate for use of new pediatric vaccines (funded and unfunded) and provides helpful educational materials [27] to physicians and parents, sometimes as the only non-industry source. Immunize Canada [28], a consortium of professional organizations led by the Canadian Public Health Association, is increasingly active in providing online and other education materials for consumers and providers of RUVs [29]. With more RUVs directed at special populations such as the elderly or pregnant women, additional professional organizations should become involved to support their members in advocating for vaccinations in these unfamiliar settings. Involvement of Canadian gynecologists was helpful in promoting use of human papillomavirus vaccines [30], within and beyond the populations eligible for free vaccination, and their obstetrician counterparts will be helpful in advocating for immunizations during pregnancy.

## 2.5. Role of vaccine manufacturers

Commercial promotion of vaccines in Canada is limited because the purchasers are usually the provincial authorities rather than individual physicians or patients. Promotional activities are mainly directed at health professionals through print advertisements, with office “detailing” visits being rare. Print ads have to follow strict federal content regulations with emphasis on the NITAG recommendations and approved prescribing information. Educational materials are often developed by manufacturers for use by health professionals in counseling patients or parents about vaccines but the messages are understandably not as readily trusted by consumers as those from public health, when available [31]. The response of industry to RUVs has been slow, for lack of any tradition of direct-to-consumer advertising and federal restrictions on this activity. However, recent television and print ads for zoster and HPV vaccines have been artful and presumably effective.

Other important but less obvious measures to support private vaccine sales included ensuring the availability of approved product within Canada, providing single dose vials, facilitating small shipments of vaccine to local distributors and pharmacies, and accepting return of outdated product. Setting a fair price is also conducive to private sales.

## 2.6. Better approaches to RUV use

Recent history suggests that the RUV phenomenon will continue, with delayed funding of some new vaccines, limited funding of others, and non-funding of still other vaccines. Canadians will either have to forgo the individual protection offered by these vaccines or new means will need to be found to encourage greater use.

The preferred strategy is obviously to minimize RUV situations. Better coordination of decision-making among stakeholders regarding the use of new vaccines could help to narrow the gap between marketing approval and funded use and to avoid glaring discrepancies among provincial programs. The ideal would be a single, fully integrated Canadian NITAG in which all funding stakeholders (provincial, territorial, federal) participate, with a commitment to promptly implement programs with selected products. An offer of substantial initial federal funding to aid concurrent implementation of programs in all jurisdictions might suitably reward such collective decision-making. Federal funds made available for the first time as part of a new national immunization strategy in 2005 [32,33] successfully launched programs in all

provinces with pneumococcal and meningococcal C conjugates, acellular pertussis vaccine for adolescents, and varicella and, in 2009, with HPV vaccines [34]. This approach ought to be continued, as immunization programs should be uniform across the country [26]. The goal for Canada is already the norm in the USA, where a central NITAG (ACIP) determines national recommendations and triggers federal funding to provide access by low income families (Vaccines for Children program), state programs and expectations of matching coverage by health insurance programs.

Realistically, governments will not be able to fund every vaccine that offers potential benefits. Public immunization programs are tailored to benefit those most at risk rather than all who are at risk. However, individuals should have an option to obtain protection or enhance it if they wish to take advantage of an available, unfunded vaccine. This will become increasingly important as personalized vaccinology [35] advances: what works for most may not be optimal for some, who would be better served by a non-standard, possibly unfunded, vaccine.

To create conditions more favorable to using RUVs, a number of changes are needed, as described below.

### 3. Increasing public awareness and education

CMPA [21] was prescient a decade ago in recognizing that individuals should be made aware of their options to prevent infections through vaccination, whether the particular vaccines of potential benefit to them are publicly funded or not. This obligation should apply to all professionals who administer vaccines. However, the burden for informing the public should not fall on vaccine providers alone. Vaccine information pamphlets and web summaries produced by professional organizations are very useful for public education, given that individuals typically have most trust in their physician and related professional organizations [31]. It would be helpful for more professional organizations to assist with the educational challenges of RUVs, with alliances such as Immunize Canada [28] providing a convenient vehicle. Advocacy should also include public health at every level, which should position itself as supporting all recommended vaccines, whether funded or not. Acknowledging limitations in public funding might attract criticism of government decisions but will also foster healthy debate about the scope of vaccine provision. To encourage RUV use, health departments should provide the same types of information (such as website entries) to immunizers and the public as they do for funded vaccines. Consumer organizations such as the Canadian Association of Retired Persons (CARP) could provide valuable advocacy and education among their peer groups for relevant vaccines [36]. With greater mobilization, large organizations like CARP might influence funding decisions for vaccines [36,37] like zoster, the cost-effectiveness of which has been repeatedly demonstrated [38,39].

Clearly, RUVs will always be at a great disadvantage compared with publicly-funded vaccines in terms of public acceptance. They may also be more vulnerable to public complacency and anti-vaccination sentiments. A key countermeasure will be common messaging among the advocates for RUV use, emphasizing the value of these “optional” immunizations for individuals at risk.

### 4. Reducing financial barriers for RUV purchase

Current RUVs are expensive, putting them beyond the means of many who are most vulnerable. In Canada, medication costs for low-income households are covered by provincial drug plans. At present, such plans do not cover vaccines but there is no logical reason to exclude RUVs for eligible individuals. Eligibility should also include individuals who will be better served by unfunded

alternative vaccines (e.g. a non-egg derived influenza vaccine, for someone with hypersensitivity to egg). Drug plans currently pay for preventive medications such as cholesterol-lowering agents, at far greater costs per person (\$313–\$1,428 per year in a recent US survey) [40] than are involved for vaccines and with much less evidence of benefit. For employed persons, a minority of supplemental health insurance plans cover unfunded vaccines and more could do so with sufficient demand from policy holders. Fair pricing will be important for all consumers; rebates for low-income consumers should be offered by companies as they do for some drugs. Some vaccine companies have developed “access programs” offering discounted prices of certain new vaccines [41], a commendable measure worth expanding. Fees charged by pharmacists to administer a RUV pose another barrier to consumers [41] and would be better assigned to healthcare insurance plans given the potential benefits of the intervention. Another solution would be federal funding directed at low-income consumers, analogous to the Vaccines for Children program in the USA that follows the recommendations of the national NITAG (ACIP).

Economic analyses are creating a further barrier to the adoption of some approved vaccines [42,43]. The costs and benefits of new vaccines are rigorously evaluated in a way that many other types of healthcare products and procedures are not [44]. If a bar is to be set for vaccines, it should not be higher than that applied to other parts of healthcare, and decisions to fund or not should be taken in the full context of the breadth of healthcare spending. This requires a more rigorous approach to healthcare spending decisions in other sectors of the industry.

### 5. Changing public perceptions about RUVs

A final barrier to use of RUVs is the widely-held perception among Canadians that if a vaccine will benefit them individually it will be provided to them at no cost. This reluctance to pay for vaccines is rooted in history but stands in sharp contrast to many other recommended personal preventive measures that Canadians must pay for such as statin drugs, infant car seats, sunscreens, and bicycle helmets. Studies to examine attitudes of health professionals and the public about purchasing vaccines and how to modify them are urgently needed. Central to success will be a better understanding of what motivates individuals to accept a vaccine [45,46] and how best to market vaccines to individual consumers. The public is increasingly health conscious and heeds other user-pay prevention advice. Optimal roles of public health, professional organizations/collaborations and the vaccine industry in educating the public need to be clarified, including the role and ethics of direct-to-consumer advertising by any of these stakeholders.

The greatest need is to change the widespread perception that vaccines should be publicly funded or ignored. The long-standing and total dominance of population over individual considerations for vaccines needs to end or the potential benefits of some vaccines will not be realized, to the detriment of those at risk. It is a form of discrimination against vaccines compared with (preventive) drugs that urgently needs to be corrected.

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