



CORE

Public Health Functions for BC

Evidence Review:
Communicable Disease
(Immunization)

Population and Public Health
BC Ministry of Healthy Living and Sport

This paper is a review of the scientific evidence for this core program. Core program evidence reviews may draw from a number of sources, including scientific studies circulated in the academic literature, and observational or anecdotal reports recorded in community-based publications. By bringing together multiple forms of evidence, these reviews aim to provide a proven context through which public health workers can focus their local and provincial objectives. This document should be seen as a guide to understanding the scientific and community-based research, rather than as a formula for achieving success. The evidence presented for a core program will inform the health authorities in developing their priorities, but these priorities will be tailored by local context.

This Evidence Review should be read in conjunction with the accompanying Model Core Program Paper.

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TABLE OF CONTENTS

Executive Summary	i
1.0 Overview/Setting the Context.....	1
1.1 An Introduction to This Paper.....	1
2.0 Methods.....	3
3.0 Barriers to Immunization	4
3.1 Client Factors	4
3.2 Provider Factors	4
3.3 System Factors	5
4.0 Strategies to Increase Coverage	7
4.1 Client Oriented Interventions.....	7
4.2 Provider Oriented Interventions.....	11
4.3 System Oriented Interventions.....	14
5.0 Strategies to Improve Targeted Vaccine Uptake by At-Risk Adults	17
5.1 Provider Reminder Systems.....	17
6.0 Immunization Infrastructure	19
6.1 Immunization Registries	19
6.2 Vaccine Cold-Chain.....	22
7.0 Vaccines in Relation to Other Disease.....	24
7.1 Food- and Water-borne Disease.....	24
7.2 Emerging Communicable and Zoonotic Disease.....	24
7.3 Vector-borne Disease.....	24
7.4 Blood-borne Diseases	25
7.5 Reproductive and Sexual Health.....	25
7.6 Tuberculosis.....	25
7.7 Infection Control.....	25
8.0 Conclusions.....	26
References	27

List of Tables

Table 1: Effectiveness of Client Reminder/Recall Systems	8
Table 2: Effectiveness of Different Types of Client Reminder/Recall Systems.....	8
Table 3: Effectiveness of Multi-Component Interventions that Include Client or Community Education	9
Table 4: Multicomponent Interventions that Include Mass Media Campaigns	10
Table 5: Effectiveness of Vaccination Requirements	11
Table 6: Effectiveness of Provider Reminder or Recall Systems	11
Table 7: Effectiveness of Assessment Plus Feedback for Providers.....	12
Table 8: Effectiveness of Standing Orders.....	14
Table 9: Effectiveness of Reducing Out-of Pocket Costs	15
Table 10: Effectiveness of Expanding Access in Health Care Settings.....	15
Table 11: Effectiveness of Home Visitation	16
Table 12: Effectiveness of Vaccination Programs in Schools	16
Table 13: Effectiveness of Provider Reminder Systems.....	17
Table 14: Effectiveness of Combination of Interventions	18

Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

Appendices

Appendix 1: Immunization Procedure	38
Appendix 2: Methodology of Systematic Reviews	40
Appendix 3: Interventions to Improve Coverage of Universally Recommended Vaccines	44
Appendix 4: Grading Evidence for Public Health Interventions	45
Appendix 5: Interventions to Improve Coverage of Targeted Vaccines	46

EXECUTIVE SUMMARY

Introduction

The efficacy of vaccines is well proven and immunization remains one of the most cost effective measures available in public health. In addition to the direct protection of individuals who are vaccinated, a high level of immunization in a community may disrupt the transmission of disease, thus protecting those who have not been immunized. This indirect protection is called herd immunity.

Despite the incontrovertible evidence that many vaccines are an efficient and cost-effective means of reducing morbidity and mortality, achievement and maintenance of high coverage rates have remained a challenge. Ensuring high coverage rates requires an understanding of the barriers to immunization and effective strategies to overcome them.

The report is divided into four parts. The first addresses client, provider and system barriers to immunization. The second reviews interventions which can improve vaccination coverage. The third discusses infrastructure issues like vaccine registries and vaccine storage and handling. The fourth reviews the role of vaccines in relation to other diseases (e.g., tuberculosis, blood-borne diseases, infection control etc).

Conclusions

1. Client reminder and recall systems as well as provider reminder and recall systems have been found to be effective in improving immunization coverage in children and adults in a range of primary care settings.
2. Multi-component interventions which include client or community or provider education as a component have been found to be effective in improving vaccination coverage. There is inadequate evidence to show the effectiveness of client or provider education when used alone.
3. System-oriented interventions such as standing orders, reducing out-of-pocket costs of immunization, expanding access to health care settings have been found to be effective in improving vaccination coverage.
4. Existing home visitation programs should consider including vaccination assessment and delivery as a component of its service because this would increase vaccine coverage.
5. Multi-component interventions that enhance access combined with provider interventions and/or client interventions have been found to be effective in improving vaccine uptake by at-risk groups (e.g., health care workers).
6. Provincial governments should commit to developing and supporting immunization registries, and be prepared to provide adequate ongoing operating funds.
7. Great strides have been made to improve vaccine thermostability but many vaccines remain sensitive to temperature and environmental conditions. In order for vaccines to induce optimal immunity, vaccine potency needs to be maintained by careful attention to the cold-chain.

Summary of the Evidence to Improve Coverage

Effective Interventions to Improve Coverage of Universally Recommended Vaccines

Effective Interventions	Type of Evidence*
Client reminder and recall systems	1+
Multi-component interventions that include client or community or provider education	2++
Vaccination requirements for child care, school, and college attendance	2++
Standing orders for adults	2++
Reducing out-of-pocket costs of vaccination	2++
Expanding access in health care settings as part of a multi-component intervention	2++
Vaccination programs in schools	2++
Home visits	2++
Provider/reminder and recall systems	2++
Assessment plus feedback for vaccination providers	2++

Effective Interventions to Improve Coverage of Targeted Vaccines

Interventions When Used Alone

Effective Interventions	Type of Evidence*
Provider reminder system	2++

Interventions When Implemented in Combination

Intervention	Type of Evidence
Enhanced access <i>plus</i> Provider/system intervention	2++

Intervention	Type of Evidence
Enhanced access <i>plus</i> Provider/system intervention <i>plus</i> Client intervention	2++

1.0 OVERVIEW/SETTING THE CONTEXT

In 2005, the British Columbia Ministry of Health released a policy framework to support the delivery of effective public health services. The *Framework for Core Functions in Public Health* identifies communicable disease as one of the 21 core programs that a health authority provides in a renewed and comprehensive public health system.

The process for developing performance improvement plans for each core program involves completion of an evidence review used to inform the development of a model core program paper. These resources are then utilized by the health authority in their performance improvement planning processes.

This evidence review was developed to identify the current state of the evidence-based on the research literature and accepted standards that have proven to be effective, especially at the health authority level. In addition, the evidence review identifies best practices and benchmarks where this information is available.

1.1 An Introduction to This Paper

Prior to the institution of routine immunization, vaccine-preventable diseases were a major cause of morbidity and mortality. With the introduction of vaccines, diseases like diphtheria, measles and polio have dramatically declined. One recent example of the effectiveness of vaccines was the rapid decline in acute hepatitis B rate in British Columbia from 6.2 per 100,000 in 1995 to 1.1 per 100,000 in 2004. This occurred after introduction of grade 6 hepatitis B immunization in 1992, and universal infant and expanded high risk program in 2001.

The efficacy of vaccines is well proven and immunization remains one of the most cost effective measures available in public health (Tengs 1995). In addition to the direct protection of individuals who are vaccinated, a high level of immunization in a community may disrupt the transmission of disease, thus protecting those who have not been immunized. This indirect protection is called herd immunity.

Under the *Health Act* (1981), health authorities are required to ensure the provision of immunization programs designed to reduce vaccine-preventable diseases. Currently, it is recommended that children receive immunization against 12 diseases: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, *H. influenza*, meningococcus, *S. pneumonia*, hepatitis B, varicella. Most of the immunizations are given as combined vaccines in the first 2 years of life (BCCDC Immunization manual). All adults who were previously immunized need to receive reinforcing doses for two diseases (diphtheria and tetanus). Additional vaccines may be needed because of occupation, travel, lifestyle, health status or age.

Despite the incontrovertible evidence that many vaccines are an efficient and cost-effective means of reducing morbidity and mortality, achievement and maintenance of high coverage rates have remained a challenge (Freeman, 2003). Ensuring high coverage rates requires an understanding of the barriers to immunization and effective strategies to overcome them. A great deal of research has been conducted in this area and these will be reviewed in this report. As

Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

well, infrastructure support such as vaccine registries and cold chain management will be discussed.

Issues of clinical practice such as immunization technique, informed consent and adverse reaction reporting will not be addressed. Instead, readers can refer to the Canadian Immunization Guide 2002 and relevant clinical guidelines (see Appendix 1).

The report is divided into four parts. The first addresses client, provider and system barriers to immunization. The second reviews interventions which can improve vaccination coverage. The third discusses infrastructure issues like vaccine registries and vaccine storage and handling. The fourth reviews the role of vaccines in relation to other diseases (e.g., tuberculosis, blood-borne diseases, infection control, etc.).

2.0 METHODS

The literature search included the following databases: MEDLINE, OLDMEDLINE, EMBASE, CINAHL, Cochrane and the Task Force on Community Preventive Services. To be considered relevant, research had to be conducted in a developed country. Searches were limited to human studies in English-language publications using the following search terms:

Vaccine or Immunization plus one of the following: coverage, registries, health promotion, provider education, community education, cold chain, storage, access, barriers, health care worker, at risk groups, mass media, reminder systems.

Titles and abstracts of citations were reviewed and potentially relevant articles were retrieved. Reference lists in all retrieved articles were scanned and additional citations were obtained. Websites of Canadian and US government agencies as well as the World Health Organization were also searched. In addition, standard texts on immunization such as the Canadian Immunization Guide (2002) and Plotkin and Orenstein's Vaccine (2004) were reviewed.

This paper was developed by a working group consisting of:

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3.0 BARRIERS TO IMMUNIZATION

3.1 Client Factors

Various client factors are associated with under-immunization. Many of these factors are underscored by lower socio-economic status (Santoli 1998; Gust 2004) such as lower parental education level, single-parent families, larger families, minority families and mothers without prenatal care (Kreuter, 1996; Lutwick, 2000; Gust, 2003; Bardenheier, 2004).

Many clients cannot remember the recommended immunization schedule and parents are often unaware of their children's immunization status (Szilagy, 2000). In a survey conducted in public clinics in Idaho, nearly 90% of parents reported that their children were up-to-date with immunization when in fact only 19-32% of children were fully immunized according to medical records (Grabowsky, 1996). One study of 219 children admitted to BC Children's Hospital in Vancouver found that 84% of parents believed their children's immunizations were up-to-date. In fact, a significant proportion had not received the recommended immunizations (Provincial Health Officer, 1999).

Parental beliefs have often been thought to have an impact on immunization rates but studies suggest that the effect is actually small (Lutwick, 2000; Orenstein, 1999). In a nationwide US study, over 13,000 parents were surveyed about immunization barriers such as confusing vaccination schedules, expense of vaccines, religious objections etc. Their children's immunization data were abstracted from the practice medical record, and specific survey responses for each parent were compared with the immunization status of his or her child. Researchers found that each barrier was only identified by a small group of parents. Collectively, it was estimated that such barriers accounted for <10% of under-immunization among children seen in pediatrician offices (Taylor, 2002).

Vaccine side effects have frequently (22-50%) been expressed by parents as a concern. However, it is unclear how much this affects under-immunization. Some studies have found no difference between immunization rates (Taylor, 2002; Bardenheier, 2004) while others have found small differences (Gust, 2004) in immunization rates between children whose parents expressed concerns about vaccine safety and those who did not.

3.2 Provider Factors

Missed opportunities have been found to occur in virtually all primary care settings, including private offices and public health department clinics (Hueston, 1994, Kimmel, 2003). A missed opportunity is a health care encounter in which a client is eligible to receive a vaccine but is not vaccinated. In a study of adolescent immunization practices, 95% of providers said they checked immunization status during well-child visits but only 43% checked immunization status during sick-child visits (Schaffer, 2001). Ninety-five percent of Illinois physicians surveyed reported that they were likely to vaccinate children during well-child visits, but only 27% would vaccinate during acute-care visits (Smith, 1999). Missed opportunities are believed to have a substantial effect on vaccination rates (Lutwick 2000; Santoli, 1998).

Providers have difficulty staying current with immunization schedules because of expanding numbers of vaccines recommended for routine use and newly added high-risk groups (Burns, 2005). In a study of pediatricians and family physicians, substantial knowledge deficits were found about recommended vaccine schedules and contraindications. Almost one third of respondents answered all questions incorrectly (Cohen, 2003). In a study of school personnel (e.g., nurses, health care paraprofessionals) who were involved in the review of immunization records vaccine misconceptions¹ were relatively common. For example, 19% of respondents were concerned that a child's immune system would be weakened by too many vaccines (Salmon, 2004).

A study of over 500 chiropractors in Alberta found that 70% advised patients that they were free to decide if they should be immunized. While the majority indicated that there was strong scientific evidence that immunization prevented infectious diseases, 58% believed that it is better to be naturally infected than to be vaccinated and 30% indicated that the elderly should not receive vaccines (Russell, 2004). These findings are concerning when studies show that the vast majority of parents follow the advice of their child's health care provider with regards to vaccination (Gust, 2003; Gustafson, 2005; Lashuay, 2000; Shrownowski, 2004).

In recent years, the public has increasingly used the internet for medical information even though the content is largely unregulated. Concerns have been raised that misinformation on the Web may influence people to refuse immunization. Of all child-related websites retrieved, the single keyword vaccination yielded 40% provaccination sites and 60% antivaccination sites. By contrast, the single keyword immunization yielded 98% provaccination sites and 2% anti-vaccination sites. Thus, any use of the term vaccination during an Internet search is likely to expose a parent to a significant amount of antivaccination information (Wolfe, 2005). One study which evaluated the quality of web pages about Measles-Mumps-Rubella (MMR) vaccine found that 32.5% of pages were pro-vaccination whereas 42.5% were anti-vaccination and 25% were neutral (Abbott, 2000). Another study showed that an interactive web-based decision aid for parents significantly improved parental attitudes towards MMR vaccination (Wallace, 2006). To date, few studies have been conducted to evaluate the impact of internet information on vaccine uptake.

3.3 System Factors

In our mobile society, many clients do not spend their life with a single health care provider. Record scattering comes about when clients receive vaccines from several sources and no single complete and accurate immunization record exists (Kempe, 2004; Burns, 2005). Fragmentation of client care makes it more likely for over-immunization as well as under-immunization to occur.

Economic factors such as the cost of vaccines are known to be barriers to immunization (Taylor, 2002; Kimmel, 2003; Bardenheier, 2004). In Canada, routine childhood vaccinations are provided free-of-charge to all citizens. However newly licensed vaccines such as varicella are

¹ This refers to information that is sometimes published that is inaccurate or can be misleading when taken out of context. The Centers for Disease Control and Prevention in Atlanta lists six common misconceptions that have appeared in the literature. See <http://www.cdc.gov/nip/publications/6mishome.htm>.

Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

only provided free in some provinces. When parents in BC were asked if they would vaccinate their child against varicella, 59% indicated that they would do so if the vaccine was provided free-of-charge (Gustafson, 2005). Long waiting times or inconvenient clinic hours have also been cited as barriers (Santoli, 1998; Taylor, 2002).

4.0 STRATEGIES TO INCREASE COVERAGE

Interventions designed to improve vaccination coverage are covered in this section. They are separated into those which are client-oriented, provider-oriented and system oriented. When improvement in vaccination coverage is sought, the underlying causes of under-immunization need to be assessed and interventions should be chosen to match local needs.

The US Task Force on Community Preventive Services have conducted systematic reviews of interventions to increase vaccination coverage for universally recommended vaccines i.e., childhood vaccines, hepatitis B for adolescents and annual influenza vaccinations for adults ≥ 65 years. One of the interventions, client reminder and recall systems was also the subject of a systematic review by the Cochrane Group. Their findings are summarized below.

See Appendix 2 for a description of the methodology used by the Task Force on Community Preventive Services and the Cochrane Collaboration.

See Appendix 3 for a summary of the level of evidence for each intervention.

4.1 Client-Oriented Interventions

4.1.1 Client Reminder and Recall Systems

Reminder messages can improve clients' awareness that vaccinations are due and the importance of keeping appointments, thereby increasing up-to-date rates. Recall messages can decrease vaccination drop-out rates and reduce the time clients remain at risk for vaccine-preventable disease (Centers for Disease Control, 1998). A variety of methods such as postcard, letter, telephone call, autodialer computerized phone message, or a combination of the above have been used in client reminder and recall systems. The use of emails in reminder and recall systems has not been studied.

There are many published studies of client reminder and recall systems in developed countries. Systematic reviews by the Task Force on Community Preventive Services and the Cochrane Collaboration have concluded that this intervention is highly effective in increasing immunization coverage in both children and adults, and in many settings including private practices and public health department clinics. It has also been found to be effective whether used alone or as a part of multi-component interventions (Shefer, 1999; Task Force on Community Preventive Services, 2000; Jacobson, 2005).

The most recent systematic review² of randomized controlled trials and controlled before/after studies was published by the Cochrane group in July 2005; this was an update of an earlier review. Forty-three studies were included in the review, of which 40 were randomized controlled trials and three were before/after studies. Of these, 33 studies were included in the meta-analysis. Thirty-two (74%) of the studies were performed in the US and the rest in developed countries

² A systematic review evaluates the quality of studies while a meta-analysis integrates quantitative findings from high-quality RCTs. In the systematic review by Cochrane, a meta-analysis was conducted of a subset of studies.

including Canada. Studies were conducted in diverse settings ranging from urban to rural and public to university-based to private practice. Findings are summarized in Tables 1 and 2:

Table 1: Effectiveness of Client Reminder/Recall Systems

Type of Immunization Program	Pooled Odds Ratio (95% Confidence Interval) ^a	Number of studies included in analysis ^c
Routine Childhood Immunization	1.45 (1.28-1.66) ^b	14
Childhood Influenza Immunization	2.87 (1.65-4.98)	3
Adult Pneumococcal, Tetanus and Hepatitis B	2.19 (1.21-3.99)	6
Adult Influenza Immunization	1.66 (1.31-2.09)	18

^a Meta-analysis integrates quantitative findings from separate randomized controlled trials and provides a numerical estimate of the overall effect.

^b Interpretation: In routine childhood immunization programs, we can say with 95% confidence that clients who received reminders had 28% to 66% increase in immunization coverage compared with controls.

^c Adds up to more studies than were included in the meta-analysis because some studies examined more than one type of vaccine

Table 2: Effectiveness of Different Types of Client Reminder/Recall Systems

Type of Reminder/Recall	Pooled Odds Ratio (95% Confidence Interval) ^a	Number of studies included in analysis ^c
Telephone	1.92 (1.20-3.07)	8
Letter	1.89 (1.53-2.34)	21
Postcards	1.27 (0.96-1.68)	8
(Postcard or letter) plus telephone	1.54 (1.12-2.14)	4
Autodialer computerized telephone reminder	1.43 (1.30-1.57)	4
Client Reminder plus Provider reminder	2.15 (1.49-3.11)	5

^a Meta-analysis integrates quantitative findings from separate randomized controlled trials and provides a numerical estimate of the overall effect.

^b Interpretation: In routine childhood immunization programs, we can say with 95% confidence that clients who received reminders had 28% to 66% increase in immunization coverage compared with controls.

^c Adds up to more studies than were included in the meta-analysis because some studies examined more than one type of vaccine

In a separate systematic review, The Task Force on Preventive Services found that client reminder and recall systems when used alone increased vaccination coverage by 8% (range -7% to 31%); when used in conjunction with other activities, it increased vaccination coverage by 16% (range -8% to 47%). More intensive or more specific reminders were found to generate greater increases in vaccination coverage e.g., more vs. fewer reminders, specific vs. general reminders, personalized vs. generic, and letters signed by a physician.

Practical issues need to be considered when designing reminder and recall systems such as accuracy of client telephone numbers or addresses and estimated client responsiveness to different types of reminders. In a study of letter and telephone recall in an economically disadvantaged urban population, coverage for pneumococcal conjugate vaccine did not increase because subjects could not be reached by mail and telephone (Daley, 2002). Therefore, it is important to tailor the type of reminder and recall system to specific provider and practice needs.

Cost effectiveness studies of client reminder and recall systems were assessed by the Cochrane Collaboration but were found to be of limited use because of variability in methods of calculating costs, different types of reminders used and different levels of intensity of interventions. In general, the review found that telephone reminders were more costly than letter or postcard reminders (Jacobsen, 2005).

4.1.2 Multi-component Interventions that Include Client or Community Education

The Task Force on Community Preventive Services reviewed 17 studies which evaluated community or client education, along with other activities like client reminders, provider reminders, provider education, improved access to clinics, reducing out-of-pocket costs, client-held vaccination records, and home visits. The reviewed studies were conducted among adults and children of different socioeconomic status and in a variety of settings including public health clinics, private practices and academic clinics. The interventions increased delivery of routine childhood vaccines as well as vaccines for adults like pneumococcal or influenza.

In the reviewed studies, information was provided to clients in many ways, including community outreach activities, media reports, posters in waiting rooms, flyers, brochures, educational sessions by nurses etc.

Fifteen studies with follow-up periods of up to five years found that multi-component approaches were effective in increasing coverage:

Table 3: Effectiveness of Multi-Component Interventions that Include Client or Community Education

	Median Increase in Vaccination Coverage	Range
Clinic setting	16%	-4% to 25%
Community setting	12%	5% to 29%
Overall	16%	-4% to +29%

The reviewers found more solid evidence of the effectiveness of multi-component approaches than of education alone. They hypothesized that combined activities reinforce each other or multi-component interventions are delivered more intensively than single-component interventions or multi-component interventions increases the likelihood that a client is exposed to at least one component.

4.1.3 Multi-Component Interventions that Include Mass Media Campaigns

The Cochrane Collaboration evaluated the effects of mass media interventions on health service utilization (Grilli, 2002). Mass media intervention was defined as radio, television, newspapers, magazines, leaflets, pamphlets and posters, targeted at the population level. Interventions based on individual patient education at health care settings such as booklets, leaflets and videos were excluded. The use of the internet was not evaluated in any of the studies reviewed. Studies were only included in the review if they were randomized controlled trials, controlled clinical trials, controlled before before-and-after studies or interrupted time series analysis.

Of the studies which met the inclusion criteria, two evaluated immunization campaigns. One based in South Australia used TV and radio commercials as well as posters, leaflets, coverage by newspaper, TV and radio programs to promote measles and rubella vaccination (Macdonald, 1985). This was combined with seminars for health care providers as well as articles in professional journals. The study showed an increase in clinic attendance for measles and rubella following the campaign. The second study evaluated a nationwide vaccination program in Finland for measles, mumps and rubella which included a one week mass media campaign, as well as reminders to parents of non-vaccinated children. Regression analysis showed statistically significant increase in vaccine coverage following the mass media campaign as well as following patient reminders (Paunio, 1991).

Table 4: Multicomponent Interventions that Include Mass Media Campaigns

	Increase in Vaccination Coverage	Range
Mass Media Campaign	9%	NA*

* Study by Macdonald was not included in the table because it reported vaccination clinic attendance not vaccine coverage. In this study, attendance for measles and rubella vaccination increased 63% after the mass media campaign.

There is congruence in the conclusions drawn by the Task Force and the Cochrane Collaboration. Both showed that multi-component interventions which include mass media campaigns/community education are effective in improving vaccination coverage.

4.1.4 Client Education or Community-Wide Education When Used Alone

Client-based and/or community-wide education are usually directed at clients to let them know about services and recommended vaccinations. Educational efforts can use one or more approaches, including mail, radio, television, newspapers and posters.

The Task Force found insufficient evidence to determine the effectiveness of client education or community-wide education when used alone. In a randomized trial, provider education plus client education produced no significant increase in receipt of influenza and pneumococcal vaccines compared with provider education alone (Herman, 1994). Two before/after studies showed no consistent effect on vaccine coverage or knowledge and attitudes of parents after clinic-based education programs (Clayton, 1994; Lieu, 1994). Five other studies did not meet quality criteria for review.

4.1.5 Client Incentives

Some programs attempt to get clients to agree to be vaccinated or have their children vaccinated by offering positive incentives such as money, toys, or discount coupons for retailers.

The Task Force found three studies which met their inclusion criteria. These studies showed an increase in vaccine coverage in response to offers of cash or gift certificates but the changes were small and not statistically significant. Ethical concerns were raised that incentives may constitute coercion. Insufficient evidence was found to determine the effectiveness of incentives in improving coverage.

4.1.6 Client-Held Vaccination Records

Some have suggested that clients would be more aware of their vaccination status if they kept a copy of their vaccination record.

The Task Force found four studies which met the quality criteria and four additional studies which did not. Although three studies which were included in the review found median increases in coverage of 5 to 15%, none were statistically significant. Because of the small number of studies, the variety of programs, and the lack of statistical significance, the Task Force could not establish the effectiveness of client-held vaccination records in improving immunization coverage.

4.1.7 Vaccination Requirements for Child Care, School, and College Attendance

Daycare centres, schools as well as colleges and universities may require proof that incoming students have had certain vaccinations. The Task Force found nine studies which showed that vaccination requirements are effective in increasing coverage. Three studies found that the incidence of measles and mumps was lower in US states that required school-age children to be vaccinated against these diseases. Three additional studies found lower rates of diseases in jurisdictions with vaccination laws and enforcement. Three studies reported improvement in vaccination coverage:

Table 5: Effectiveness of Vaccination Requirements

	Median Increase in Vaccination Coverage	Range
Used alone	15%	5% to 35%

4.2 Provider-Oriented Interventions

4.2.1 Provider Reminder or Recall Systems

Providers can be reminded that clients are due (reminder) or overdue (recall) for specific vaccinations by a variety of means; for example, notes in client charts, mailings, checklists, flowcharts or computer notifications. The content of the reminders varies from a simple notation that a vaccine is due to a reminder combined with additional information.

The Task Force reviewed 30 studies conducted in a wide range of settings with diverse providers (residents, physicians, non-physician providers) and clients of all ages. Whether used alone or in combination with other interventions, provider reminder and recall systems were effective in improving vaccination coverage.

Table 6: Effectiveness of Provider Reminder or Recall Systems

	Median Increase in Vaccination coverage	Range
Used alone	17%	1% to 67%
Used in combination with other interventions	14%	1% to 36%

4.2.2 Assessment Plus Feedback for Providers

Some programs assess vaccination coverage and give feedback to the provider (ACIP, 1996). An example of such a program can be found at: www.cdc.gov/nip/afix/default.htm. Another example is provision of information about frequency of missed opportunities to vaccination providers at a particular site (Sabnis, 2003).

The Task Force reviewed 14 studies which evaluated this intervention and found it to be effective in improving coverage among adults and children in a variety of settings including private practice, public health clinics, and community health centres etc.

Table 7: Effectiveness of Assessment plus Feedback for Providers

	Median Increase in Vaccination coverage	Range
Used alone	16%	9% to 41%
Used in combination with other interventions	17%	1% to 43%

4.2.3 Provider Education

Research has repeatedly shown that health care providers strongly influence clients' immunization decisions. In a study of adults in British Columbia, 87% indicated that they would be willing to receive pertussis immunization if it was recommended by a physician or nurse (Skowronski, 2004). Among African American parents in California, 86% said that they relied on doctors or nurses for advice about immunizations (Lashuay, 2000).

A Cochrane review had specifically examined the effectiveness of printed educational materials on improving the behaviour of health care professionals (e.g., family practitioner, obstetrician, pediatrician) for a range of practice (Freemantle, 2000). Printed educational materials were items like monographs, publications in peer-reviewed journals and clinical guidelines. The review only included randomised controlled trials or well designed quasi-experimental studies, controlled before and after studies (CBAs) and interrupted time series analyses (ITS). An update to this review is planned but has not been published when the present document was written.

Studies of health practitioners' knowledge, attitudes or satisfaction were included if there were objective measures of professional performance (e.g., number of tests ordered, prescriptions for a particular drug) or patient outcome (e.g., number of caesarean sections performed). Eleven studies were included for review but all were found to be of poor quality (e.g., poor reporting of results and inappropriate analysis). The estimates of benefit from printed educational materials ranged from -3% to 243% for provider outcomes (e.g., prescribing behaviour), but none were statistically significant. The authors concluded that the effects of printed educational materials compared with no intervention appear small and of uncertain clinical significance.

The Task Force on Preventive Services reviewed four studies which met the quality criteria for inclusion. They examined the ability of provider education to increase providers' knowledge or change attitudes about vaccinations to deliver more appropriate vaccinations. Education was provided through written materials, videos, lectures or continuing medical education programs.

One study found a small but non-significant improvement in vaccination coverage among adults, another found provider education (i.e., a manual explaining the importance of influenza vaccination in hospitalized patients) alone produced less improvement in coverage than standing orders or provider reminders. Two other studies found small improvements in provider knowledge and attitudes; for example, medical students and family practice residents who received training on case-based curricular materials on immunization had small increases in test scores when examined afterwards. Overall, the Task Force determined that there was insufficient evidence to state whether provider education by itself is effective in increasing vaccination coverage, even though provider education used in combination with other interventions is effective.

A separate Cochrane review was conducted which reviewed systematic reviews of provider (e.g., physicians, nurses, other health care professionals) behaviour change strategies (Grimshaw, 2001). The outcome of interest was not limited to vaccination but to the full range of medical practice. Forty-four reviews were included of which 15 focused on broad strategies (e.g., continuing medical education, dissemination and implementation of guidelines, programs to enhance the quality and economy of primary care), 14 focused on interventions targeted at specific behaviours (e.g., prescribing), and 15 focused on the effectiveness of specific interventions (e.g., printed educational materials, outreach visits, opinion leaders, audit and feedback, mass media and continuing quality improvement). Even though current state of knowledge was found to be imperfect, the Cochrane Collaboration identified some strategies that are effective:

- Passive dissemination (e.g., mailing educational materials to targeted clinicians, passive dissemination of consensus guideline recommendations) is generally ineffective and is unlikely to result in behaviour change when used alone; however, this approach may be useful for raising awareness of the desired behaviour change.
- Active approaches (e.g., educational outreach and ongoing feedback) are more likely to be effective but are also likely to be more costly.
- Interventions of modest effectiveness include audit and feedback, and use of local opinion leaders.
- Generally effective strategies include educational outreach (for prescribing behaviour) and reminders.
- Multifaceted interventions based on assessment of potential barriers to change are more likely to be effective than single interventions. However, it is difficult to disentangle which components are likely to be more effective under different settings.

Overall, the reviewers found many systematic reviews to be of poor quality because methodological weaknesses in the original studies were ignored. Critics have also pointed to the lack of a theoretical base on which to conduct research into physician behaviour change (Grimshaw, 2002).

4.3 System-Oriented Interventions

4.3.1 Standing Orders

Standing orders allow professionals who are not physicians e.g., nurses or pharmacists to give vaccinations without direct physician involvement at the time of vaccination. The purpose of standing orders is to reduce missed opportunities. The Task Force reviewed 11 studies of the use of standing orders in clinics, hospitals and nursing homes. All were conducted with adults.

The Task Force concluded that standing orders were effective for use among adults in hospitals, nursing homes, private practices and other outpatient settings:

Table 8: Effectiveness of Standing Orders

	Median Increase in Vaccination Coverage	Range
Used alone	51%	30% to 81%
Used in combination with other interventions	16%	6% to 26%

The US Advisory Committee on Immunization Practice (2000) states that standing order protocols should only be administered by health care professionals trained to screen clients for vaccination contraindications, administer vaccines, and monitor clients for adverse events. Standing order protocols need to (2000):

- Identify persons eligible for vaccination based on their age, vaccination status, or presence of a medical condition that puts them at high risk.
- Provide adequate information to clients regarding the risks for and benefits of a vaccine and documenting delivery of that information.
- Record client refusals or medical contraindications.
- Record administration of a vaccine(s) and any post-vaccination adverse events.
- Provide documentation of vaccine administration to clients and their primary-care providers.

The policies and protocols for standing orders need to include a quality assurance process to maintain appropriate standards of care.

4.3.2 Reducing Out-of-Pocket Costs

The cost of vaccinations can be a barrier to immunization. Covering the cost of vaccines or their administration can increase the number of clients who get appropriate vaccinations.

The Task Force reviewed 19 studies which used this intervention alone or in combination with other interventions and found it effective in increasing vaccination coverage. Studies were conducted with adults and children of low or mixed socio-economic status and in a broad range of settings.

Table 9: Effectiveness of Reducing Out-of Pocket Costs

	Median Increase in Vaccination Coverage	Range
Used alone	10%	-1% to 29%
Used in combination with other interventions	16%	-8% to 47%

4.3.3 Expanding Access in Health Care Settings

Limited hours during which vaccination services are available or long distances to travel to vaccination locations can be a barrier to clients seeking to obtain immunization. These barriers can be reduced by administering vaccines in additional locations, especially if these locations are closer to where clients live and work. Expanded hours of operation at night or on weekends, drop-in clinics or express lane vaccination services are other methods to improve access to vaccination.

The Task Force reviewed 16 studies that examined expanded access. Studies were conducted among adults and children and in a variety of settings including public health clinics, community clinics and private practices. No statistically significant improvement was found in two studies that examined expanded access by itself; however, expanded access when used in combination with client reminder and recall, provider education, standing orders, clinic-base education, community-wide education etc. was found to be effective.

Table 10: Effectiveness of Expanding Access in Health Care Settings

	Median Increase in Vaccination Coverage	Range
Used in combination with other interventions	13%	-8% to 35%

Multi-component approaches may be more effective because they are more intense or because the combined effects of the various components increase the overall effectiveness of each one.

4.3.4 Home Visits

Home visitation improves the health and well-being of children by providing education and supportive services to families who are at risk. Services can include promotion of positive health-related behaviours and quality infant care-giving as well as measures to reduce family stress by improving social and physician environments (American Academy of Pediatrics, 1998). Research on Home Visitation have shown that successful programs benefit the neediest families by reducing child abuse and neglect, and helps mothers defer subsequent pregnancies so they can move into the workforce (Olds, 1999).

The Task Force reviewed 7 studies that examined this intervention and found it to be an effective way to increase vaccination coverage. One randomized controlled trial assessed the effectiveness of home visits in increasing immunization levels among infants of inner-city Los Angeles. In depth assessments were made by case managers before infants were 6 weeks of age, with home visits 2 weeks before immunizations were scheduled. Of 365 newborns who were followed up to 1 year of age, immunization completion was 13.2% higher in the intervention group than controls (Wood, 1998).

Table 11: Effectiveness of Home Visitation

	Median Increase in Vaccination Coverage	Range
Home Visit	10%	-1% to 49%

When successful home visitation programs were evaluated, they were found to be a cost-effective intervention because foster care placements, child abuse worker time, hospitalizations and emergency visits were reduced (American Academy of Pediatrics, 1998; Olds, 1999). However, when vaccine uptake was the only outcome measured, the cost to vaccinate each additional child was high (e.g., \$12,022 USD in the study by Wood, 1998).

These findings suggest that it would not be cost effective to establish home visitation solely for immunization. However, it would be cost effective if existing home visitation programs included vaccination assessment and delivery as one of its services.

4.3.5 Vaccination Programs in Schools

School-based vaccination programs aim to improve coverage among children who are 5-18 years. Written consent from parents and guardians are usually required. The studies which were reviewed were almost always multi-component and included efforts to educate students, parents and teachers about vaccines, provider reminders and free vaccines. Only one of the studies had a concurrent comparison group from an adolescent clinic in which vaccination was available but not promoted in a special program (Lancman, 2000). All the studies except one (Andrews, 1990) were conducted to assess the acceptance of hepatitis B vaccine at a time when the majority of students were unvaccinated; the single study evaluated rubella vaccine uptake. The Task force found school-based vaccination programs effective in improving coverage among adolescents of any socio-economic status.

Table 12: Effectiveness of Vaccination Programs in Schools

	Median Increase in Vaccination Coverage	Range
School-based Immunization	58%	11% to 92%

See Appendix 3 for a summary of the level of evidence for each intervention.

5.0 STRATEGIES TO IMPROVE TARGETED VACCINE UPTAKE BY AT-RISK ADULTS

Targeted vaccines are those given to specific groups because certain factors (e.g., occupation, lifestyle, chronic disease) make them particularly susceptible to a disease. For example, pneumococcal vaccine and annual influenza vaccination are recommended for people with chronic disease like heart or lung disease, diabetes etc. Hepatitis B and annual influenza vaccine are recommended for health care workers.

Vaccine uptake by targeted groups is generally low. In a study of health care workers at a Canadian cancer centre, only 22% received annual influenza vaccination in the past 5 years; 29% did not receive any influenza vaccine and the rest received it in some years but not others (Mah, 2005).

In 2005, the Task Force on Preventive services published a systematic review of interventions to improve targeted vaccination for influenza, pneumococcal and hepatitis B among at-risk adults. The reviewers differentiated universal recommendation from targeted indications. Universal recommendation was defined as vaccination of all people in a given age group (e.g., annual influenza vaccination of adults ≥ 65 years). Targeted indication was defined as medical, occupational, behavioural or other risk factor that identified people who should receive the vaccine (e.g., annual influenza vaccination of health care workers).

Most of the available evidence on effectiveness came from studies that evaluated interventions implemented in combination (i.e., multi-component interventions). The paucity of evidence on the effectiveness of interventions when implemented alone and the variety of intervention combinations which were studied made the assessment of evidence much more complicated.

See Appendix 5 for a summary of interventions which were found to be effective and ineffective.

5.1 Provider Reminder Systems

The only intervention found to be effective when implemented alone was provider reminder systems. The Task Force found 7 studies which evaluated this intervention in relation to influenza and pneumococcal vaccination:

Table 13: Effectiveness of Provider Reminder Systems

	Median Increase in Vaccination Coverage	Range
When used alone	17.9%	-1% to 72%

The Task Force found 23 quality studies which evaluated multi-component combination interventions to increase vaccination coverage among at-risk populations. Study populations included health care workers (i.e., nurses and physicians), inpatients and outpatients. The settings studied included outpatient clinics, hospitals, long-term care facilities and the workplace.

Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

The Task Force found strong evidence of effectiveness in the following combination of interventions, as shown in Table 14:

Table 14: Effectiveness of Combination of Interventions

	Median Increase in Vaccination Coverage	Range
Enhanced access <i>plus</i> Provider/system intervention	27.8%	-0.5% to 31%
Enhanced access <i>plus</i> Provider/system intervention <i>plus</i> Client intervention	22.8%	-5.9% to 67%

6.0 IMMUNIZATION INFRASTRUCTURE

6.1 Immunization Registries

Immunization registries are defined as confidential, population-based, computerized systems for maintaining information about vaccinations (CDC, 2001). Registries are viewed as an important component of immunization programs by supporting clinical care and public health functions (Hinman, 2004). This is accomplished by (Linkins, 1998):

- Maintaining databases that store information on each immunization encounter;
- Consolidating scattered immunization records to enable an assessment based on complete and accurate information;
- Promoting automated recall of clients who need immunizations;
- Providing practice- and community- based coverage estimates.

Missed immunization opportunities are common because providers do not know their clients' immunization status. Even when it is known, few providers remind their clients when a vaccine is due. On top of that, immunization schedules have become increasingly complex leading to confusion about which vaccines are recommended for different age groups. (Freeman, 2003; Linkins, 1998). Registries are seen as a way to rectify some of these problems. In addition, registries can prevent unnecessary duplicative doses of vaccine, manage vaccine inventory and produce official immunization records (Linkins, 2001).

Development of immunization registries has been endorsed by a number of organizations, including the American Academy of Pediatrics and the American Medical Association (Hinman, 2004). In 1998, the Canadian Consensus Conference on a National Immunization Records system recommended that comprehensive immunization registries be established in all provinces and territories (Health Canada, 1998). The intent of the meeting was to seek agreement about registry goals and best practices from leaders and practitioners in the Canadian public health and clinical practice communities. The following recommendations for an effective national immunization registry were made:

6.1.1 Registry Components

- Universal enrolment, including the entire target population and all immunization providers. Canadian immunization registries should include all children in Canada. As a minimum start-up, they should include all children from birth to age 7 years. They should be expanded in short order to include all school-age children. These registries should have the capacity to include other target populations such as travelers, candidates for influenza and pneumococcal immunization, and residents of long-term care facilities. There should be lifelong retention of information.
- Recording all immunization events, with ability to link to information about adverse vaccine reactions and incidence of vaccine-preventable diseases.

Core Public Health Functions for BC: Evidence Review

Communicable Disease (Immunization)

- Individual provincial and territorial systems, with this level of government providing central support. The operation of the registries should be locally based, where data are entered and the capacity for generating reports exists. These systems need a common set of data elements and standards, including immunization logic.
- Common elements that are nationally consistent; i.e., consistent within and between provincial and territorial registries
- Ability to interact with other health information systems, including those dealing with disease surveillance and adverse vaccine reactions
- Capacity to draw enrolment directly from birth records, provincial and territorial health insurance enrolment records, school and day-nursery enrolment records, and immigration notifications.

6.1.2 Registry Design

- Registries must be flexible in design and, in particular, be able to accommodate data entry from multiple sources.
- There must be a commitment at a senior level to the concept of registries, a legislative foundation for registries, and the exchange of immunization information.
- Compatibility of registries within their province or territory and compatibility with other provinces and territories should be ensured by adhering to national standards. Provincial and territorial governments should make the computerization of local public health departments and health care practices a priority.
- All provincial and territorial governments must provide a legislative foundation for immunization registries within provincial public health and privacy legislation. This legislation should make participation mandatory.
- Public support must be achieved and maintained by ensuring the individual's ability to access their own records, and by providing tangible evidence of benefit through notifications about due and overdue immunizations. Data subjects should only have to give information once. Preserving the confidentiality of information is absolutely essential to maintain public confidence. There should be clear guidelines about how data may be used and acceptable use.
- Privacy interests must be involved at every stage of development and implementation.
- Provider support and participation are critical; providing incentive to providers and partnerships with provincial and territorial medical associations will be required. Providers should be given aggregate reports and should be able to access their own practice data. Operation should be simple, efficient, and user-friendly. There should be relief from client requests for immunization records.
- Immunization registries should be developed as a model audit tool for quality improvement, and used for educating health care providers.

Core Public Health Functions for BC: Evidence Review

Communicable Disease (Immunization)

- Registry operators should support the system by regular reporting to policy makers about progress towards coverage targets and by identifying cost savings.
- Registries must support reporting functions that assist in ensuring an efficient immunization system with maximum population coverage.

The Centers for Disease Control and the National Vaccine Advisory Committee (NVAC) in the US have also produced policy statements highlighting 12 key attributes of an immunization registry (Horne, 2000; Wood, 1999). These were based on minimum functional standards developed by the American Immunization Registry Association in 1997 (Hinman, 2004). These attributes are:

1. Accurately and completely consolidate all immunization records from multiple providers.
2. Electronically store data on all NVAC-approved core data elements.
3. Link electronically with birth data to automatically populate the registry.
4. Permit providers to electronically retrieve information on all immunization records at the time of encounter.
5. Permit providers to electronically submit information on all immunization encounters on the same day as vaccine administration.
6. Ensure accurate and complete immunization records through automated de-duplication and edit checking.
7. Protect confidentiality and security of the registry's medical information.
8. Recover lost data.
9. Exchange immunization records using Health Level 7 standards.
10. Automatically determine the immunizations needed at medical encounters, based on recommendations from the Advisory Committee on Immunization Practices.
11. Identify individuals late for immunization and produce recall notices.
12. Produce authorized immunization records.

Consolidation of immunization records from multiple sectors is crucial for registry success. Several evaluations of immunization registries in the US have shown that this can be accomplished and the resulting immunization data are more accurate and complete. In two rural areas of Colorado, researchers showed a 50% increase in up-to-date rates for 2 year-olds when registry records were compared with provider records at different delivery sites (Kempe, 2004). In one Texas county, coverage rates based on the immunization registry was 23.9% higher when compared with randomly selected clinic charts of children aged 12-35 months (Boyd, 2002). When researchers evaluated registry data in Denver, they found that accuracy improved from 44% at registry initiation to 100% three years later. Accuracy was measured by comparing registry data with chart abstraction data (Davidson, 2003).

The costs to achieve full registry functionality are significant. Several studies have reported on development costs (Slifkin, 1999; Rask, 2000; McKenna, 2002) while others have measured costs borne by providers (Glazner, 2004). In one study based on 16 immunization registries, the annual cost to operate immunization registries was compared with the annual cost to manually retrieve records, to conduct national coverage surveys as well as the cost of duplicate immunization (Horne, 2000). The estimated annual costs per child in a fully operational registry

ranged from \$1.60USD to \$6.23USD with a mean of \$3.91USD. The average cost per encounter for manually retrieving and reviewing a child's immunization record was \$14.50USD. The calculated annual cost to maintain a US-wide network of immunization registries was \$78.2 million USD. This compared with an annual cost of manual record pull of \$74.2 million USD. Other costs which could be offset by registries included coverage surveys and duplicative immunizations. The cost of national immunization surveys which were designed to measure coverage at the state level was \$11.1 million USD. It should be noted that surveys only assess coverage but do not fulfill the other functions of a registry. Duplicative immunization costs of \$26.5 million USD could also be averted through the use of fully functional registries (Horne, 2000).

The NVAC has identified four challenges which need to be addressed when developing immunization registries (CDC, 2001; Linkins, 2001):

1. Protecting each person's privacy and the confidentiality of information collected.
2. Ensuring participation of all providers and recipients – Registries will be most useful if they have active participation from the majority of vaccination providers.
3. Overcoming technical and operational challenges to ensure functionality.
4. Ensuring sustainable funding to develop and maintain immunization registries.

Population-based immunization registries can be an effective means for ensuring that citizens remain current with recommended vaccination schedules. However, the mere presence of a registry does not ensure more complete vaccine coverage. Other strategies discussed above, such as the use of registry generated reminder and recall are needed.

6.2 Vaccine Cold-Chain

Vaccines are biological agents which are used to protect individuals against diseases by inducing prophylactic immunity^{3,4}. In order for vaccines to induce optimal immunity, vaccine potency needs to be maintained. While great strides have been made to improve vaccine thermostability, many vaccines remain sensitive to temperature and environmental conditions. Unfortunately there is no simple and inexpensive method that can be used in the field to assess whether a vaccine has retained minimum required potency (Galazka, 1998). The only surrogate measure is adherence to proper vaccine storage and handling requirements.

Cold-chain refers to all equipment and procedures used to ensure that vaccines are protected from inappropriate temperature and light, from the time of transport from the manufacturer to the time of administration (Canadian Immunization Guide, 2002). In developed countries, studies have shown that the most common deficiencies in cold-chain maintenance are: high temperatures during storage or transport, exposure of adsorbed vaccines to freezing, refrigerators without thermometers, failure to monitor temperature readings regularly, and storage of drugs, drinks and

³ For a comprehensive review of the stability of individual vaccines, the reader is referred to *Thermostability of Vaccines* (Galazka et al., 1998).

⁴ For guidance about individual vaccine storage, transport and handling, readers are referred to *Vaccine Management: Recommendations for Storage and Handling of Selected Biologicals* (Centers for Disease Control and Prevention, 2005).

food with vaccines (Galazka, 1998). Economic (i.e., wastage) and medical harm (i.e., vaccine failure) can arise following lapses in the cold chain and this is of increasing concern as the number and cost of vaccines continue to increase (Kendal, 1997).

Vaccines vary considerably in stability. Adsorbed diphtheria and tetanus toxoids are the most stable vaccines while oral polio vaccine is the least stable. Toxoids can remain stable at elevated temperatures but lose potency when frozen because the aluminum-based adjuvant is destroyed by freezing (Brandau, 2003). The physical change induced by freezing provides the basis of the shake test (Canadian Immunization Guide, 2002).

The stability of viral vaccines is determined by the rate of loss of viral antigen during storage. The following factors can have a negative effect on the stability of virus vaccines: higher temperatures, pH of the suspension medium, excipients used to stabilize vaccine preparations, repeated freezing and thawing, and exposure to light (Peetermans, 1996). Viruses with a stable structure are used inactivated or as live liquid preparation, while viruses with a more labile configuration need lyophilisation to become practically usable. For example, lyophilised MMR vaccine needs to be used immediately after reconstitution or stored in a dark place at 2⁰C to 8⁰C. Once constituted, unused vaccine must be discarded within 8 hours (CDC, 2005).

7.0 VACCINES IN RELATION TO OTHER DISEASE

7.1 Food- and Water-borne Disease

Vaccines are available for diseases such as hepatitis A, cholera and typhoid. Travellers to developing countries are strongly encouraged to be vaccinated against hepatitis A, and typhoid vaccine is recommended for travelers who have prolonged exposure (> 1 month) to potentially contaminated food and water. Some travellers may benefit from cholera vaccination but individual risk assessments should be made. For further information, readers are referred to the *Canadian Immunization Guide 2002* (p. 93-100: hepatitis A; p. 214-221: typhoid; p. 77-81: cholera).

The section of this report that addresses vaccine uptake by at-risk adults is most relevant.

7.2 Emerging Communicable and Zoonotic Disease

Rabies vaccine should be offered to people at risk of contact with rabid animals (e.g., certain laboratory workers, veterinarians, animal control and wildlife workers). Travellers to endemic areas where there is not likely to be access to adequate and safe post-exposure vaccination should also consider pre-travel immunization. Persons exposed to a potentially rabid animal should receive rabies prophylaxis. For schedule and dosage, readers are referred to the *Canadian Immunization Guide 2002* (p. 196-198). The section of this report that addresses vaccine uptake by at-risk adults is most relevant.

7.3 Vector-borne Disease

Travellers to countries where Japanese Encephalitis and Yellow Fever occur should be vaccinated against these diseases. Japanese encephalitis virus is a flavivirus whose principal vectors are *Culex* mosquitos. Yellow fever virus is an arbovirus spread by the *Aedes aegypti* mosquito. For further information, readers are referred to the *Canadian Immunization Guide 2002* (p. 128-133: Japanese Encephalitis; p. 233-240: Yellow Fever).

Lyme disease is a tick-borne zoonosis caused by the spirochete *Borrelia burgdoferi*. Three to five cases of Lyme disease is reported to public health in British Columbia each year (BCCDC website). Lyme disease vaccine does not protect all recipients against infection; therefore its use should only be considered on individual assessments of the risk of exposure to infected ticks and the relative risks and benefits of immunization compared with other protective measures. For further information, readers are referred to the *Canadian Immunization Guide 2002* (p. 128-133). The section of this report that addresses vaccine uptake by at-risk adults is most relevant.

7.4 Blood-borne Diseases

Hepatitis B infection is usually associated with exposure to infected blood or body fluids. Common means of transmission include sexual contact, injection drug use and perinatal transmission. Hepatitis B vaccine induces antibody production which confers immunity to the disease. The vaccine can be used pre-exposure to protect those who are at risk because of:

- Occupational factors (e.g., health care workers with blood exposure).
- Lifestyle factors (e.g., injection drug use).
- Geographic factors (e.g., parts of the world with higher prevalence of hepatitis B).

In British Columbia, hepatitis B vaccine is offered free-of-charge to grade 6 students, infants and those who are at high risk of hepatitis B infection. For further information, readers can refer to the *Canadian Immunization Guide* 2002 (p. 102-116). The section of this report that addresses vaccine programs in schools, vaccine uptake by at-risk adults, and earlier sections applicable to routine infant/childhood vaccination are most relevant.

7.5 Reproductive and Sexual Health

See hepatitis vaccine under blood-borne diseases.

Sexual activities involving oral-fecal/anal contact may predispose to the spread of hepatitis A infection. Persons at risk should be vaccinated against hepatitis A.

Early in the course of illness, persons infected with Human Immunodeficiency Virus (HIV) have no contraindications to the use of any vaccine except for BCG (Bacille Calmette-Guérin). As the condition progresses, the use of live vaccines becomes increasingly dangerous, and the risks and benefits of a particular vaccine need to be carefully considered. For further information, readers can refer to the *Canadian Immunization Guide* 2002 (Table 6, p. 27-28). The section of this report that addresses vaccine uptake by at-risk adults is most relevant.

7.6 Tuberculosis

BCG (Bacille Calmette-Guérin) vaccine has been used in some risk groups to protect them against tuberculosis. However, the protective efficacy of the vaccine is variable. Infants in some Aboriginal communities have routinely received BCG vaccination but this practice is being phased out by First Nations and Inuit Health Branch (Langley, 2004).

7.7 Infection Control

See hepatitis B vaccine under blood-borne diseases. The section of this report that addresses vaccine uptake by at-risk adults is most relevant.

8.0 CONCLUSIONS

1. Client reminder and recall systems as well as provider reminder and recall systems have been found to be effective in improving immunization coverage in children and adults in a range of primary care settings.
2. Multi-component interventions which include client or community or provider education as a component have been found to be effective in improving vaccination coverage. There is inadequate evidence to show the effectiveness of client or provider education when used alone.
3. System-oriented interventions such as standing orders, reducing out-of-pocket costs of immunization, expanding access to health care settings have been found to be effective in improving vaccination coverage.
4. Existing home visitation programs should consider including vaccination assessment and delivery as a component of its service because this would increase vaccine coverage.
5. Multi-component interventions which enhance access combined with provider interventions and/or client interventions have been found to be effective in improving vaccine uptake by at-risk groups (e.g., health care workers).
6. Provincial governments should commit to developing and supporting immunization registries, and be prepared to provide adequate ongoing operating funds.
7. Great strides have been made to improve vaccine thermostability but many vaccines remain sensitive to temperature and environmental conditions. In order for vaccines to induce optimal immunity, vaccine potency needs to be maintained by careful attention to the cold-chain.

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Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

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Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)

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APPENDIX 1: IMMUNIZATION PROCEDURE

A. Immunization Technique

Refer to Canadian Immunization Guide 2002, p. 38.

B. Informed Consent

1. Refer to Canadian Immunization Guide 2002, Guideline 5, p. 61.
2. The following section of the *Infants Act* defines consent (please note that the legal definition of an “infant” is a person under the age of 19 years):

Consent of “Minors”: *Infants Act*

(2) *Subject to subsection (3), an infant may consent to health care whether or not that health care would, in the absence of consent, constitute a trespass to the infant's person, and if an infant provides that consent, the consent is effective and it is not necessary to obtain a consent to the health care from the infant's parent or guardian.*

(3) *A request for or consent, agreement or acquiescence to health care by an infant does not constitute consent to the health care for the purposes of subsection (2) unless the health care provider providing the health care*
has explained to the infant and has been satisfied that the infant understands the
(a) *nature and consequences and the reasonably foreseeable benefits and risks of the health care, and*
(b) *has made reasonable efforts to determine and has concluded that the health care is in the infant's best interests.*

3. Canadian Medical Protective Association 2002 letter regarding vaccination recommendation for new vaccines which are not publicly funded:

When physicians are obliged to recommend vaccines

Whether physicians should notify parents of new vaccines depends on whether administration of the vaccine is considered the standard of care by other physicians in the community. There are a number of factors that determine whether such a standard of care has developed. Courts might look to standards expressed in accepted medical publications, the common practice of other physicians, and recommendations adopted by professional bodies or health organizations. Specific circumstances, such as an outbreak of a particular infection, may also influence the standard of care.

If physicians do recommend these vaccines, the informed consent discussion with parents should disclose:

- *the material risks and benefits of the vaccine;*
- *the possible consequences of refusing the vaccine;*

Core Public Health Functions for BC: Evidence Review

Communicable Disease (Immunization)

- *the fact that the cost of the vaccines is not covered by provincial health plans; and*
- *information about their actual cost.*

Physicians should take the time to answer parents' questions, and provide written material describing the nature of the vaccine, its benefits and risks, and the recommendations for its use. They should also clearly document this discussion.

It is then up to the parent to decide whether to accept or refuse the recommendation for vaccination. A parent's refusal of the vaccination should also be thoroughly documented by the physician. A detailed note should be made in the child's medical record of the consent discussion and the refusal. The physician could also ask the parent to sign a standard form stating that he or she has been informed of the benefits and risks of the vaccine, but has refused the vaccination although fully aware of the risks of doing so.

When parents can't pay

The difficulty is when a parent refuses a vaccination solely for cost reasons. This raises a troubling issue for physicians and is not one that lends itself to an easy solution. It is clearly frustrating and discouraging for physicians to recommend a course of preventive treatment, which the patient accepts as a valid recommendation but cannot be followed because it is unaffordable.

In such a situation, all that physicians could reasonably be expected to do is reiterate the benefits of the vaccines and document the refusal in the medical record. Physicians might also suggest alternate sources of funding that might be available in the community or at the workplace. These suggestions should also be documented in the medical record.

C. Adverse Events Following Immunization

1. Refer to Canadian Immunization Guide 2002, Guideline 10, p. 62.
2. If client experiences an adverse event following immunization, please complete the B.C. Adverse Events Reporting form. This is a multi-part form that is not available online but is available from BCCDC (Tel: 604-660-0584).

APPENDIX 2: METHODODOLOGY OF SYSTEMATIC REVIEWS

I. Task Force on Community Preventive Services

The Task Force on Community Preventive Services makes recommendations for the use of various interventions based on the evidence gathered in the rigorous and systematic scientific reviews of published studies conducted by the review teams of the Community Guide.

The Community Guide is being developed by the non-federal Task Force on Community Preventive Services (the Task Force), whose members are appointed by the Director of the Centers for Disease Control and Prevention (CDC). Although convened by the U.S. Department of Health and Human Services, the Task Force is an independent decision-making body. Task Force members have expertise in:

- Behavioural and social sciences
- Communications sciences
- Decision and cost-effectiveness analysis
- Dentistry
- Epidemiology
- Information systems
- Managed care
- Management and policy
- Primary care medicine
- Quantitative policy analysis
- State and local health departments

The Task Force receives guidance from consultants with experience in creating evidence-based guidelines, liaisons from federal agencies, and representatives of professional organizations involved in public health.

Vaccine-Preventable Diseases Chapter

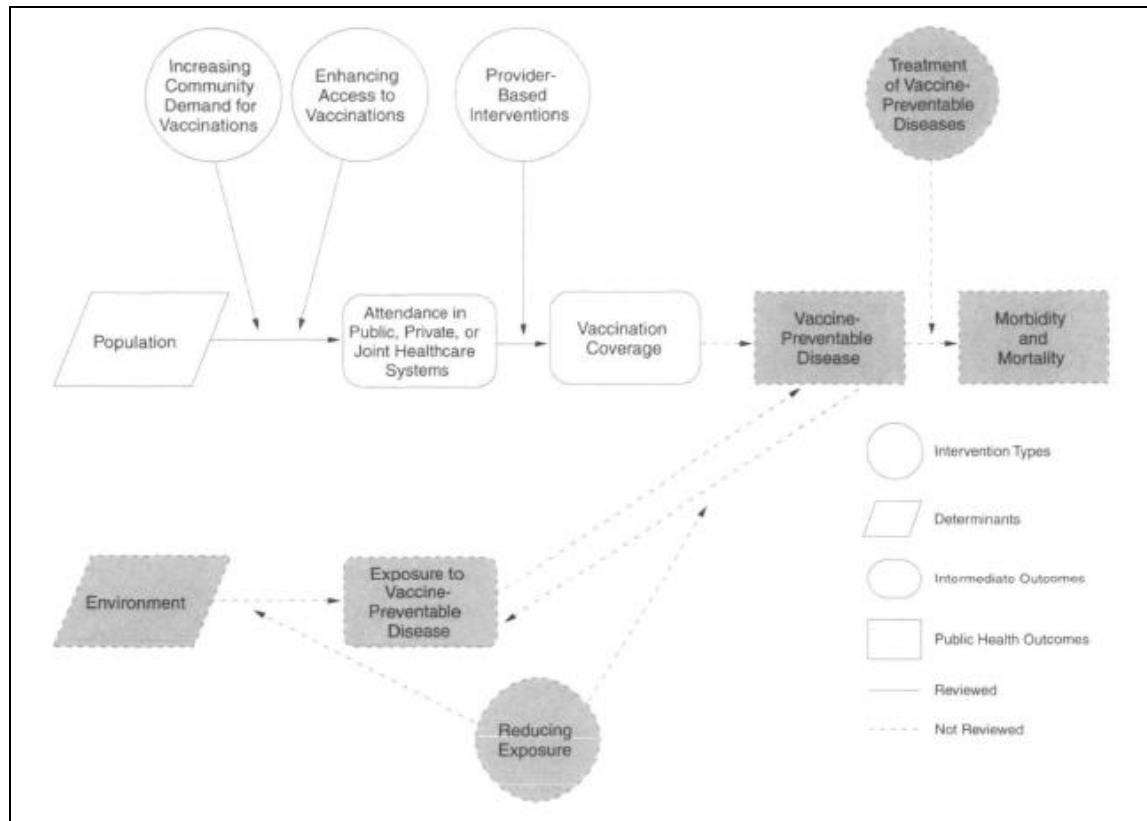
A "logic framework" (Figure 1) was developed which illustrates the conceptual approach to the review on vaccine preventable diseases. It describes hypothesized links between a population, environmental and health system determinants, and various outcomes. The logic framework describes population-based interventions to reduce vaccine preventable disease and characterizes the outcomes that they attempt to influence.

This review focused on four broad categories of interventions to increase vaccination coverage: 1) interventions to increase community demand for immunizations, 2) interventions that enhance

**Core Public Health Functions for BC: Evidence Review
Communicable Disease (Immunization)**

access to immunization services, 3) interventions that mandate immunizations, and 4) provider-based interventions. They conducted an electronic search of Medline, Embase, Psychlit, CAB Health, and Sociological Abstracts, reviewed reference lists, and consulted with experts. They reviewed evidence on the effectiveness of 17 interventions within these categories.

Figure 1: Logic Framework



Studies were included if they 1) were published in books or journals from 1980 through 1997 (In 2001, some published studies from 1995-2000 were added and updated); 2) addressed recommended adult, adolescent, or childhood vaccines; 3) were primary studies rather than, for example, guidelines or reviews; 4) came from industrialized countries; 5) were written in English; 6) were relevant to one or more of the 17 identified interventions 7) provided information on one or more outcomes selected for review; and 8) compared a group of people who had been exposed to the intervention with a group who were not exposed, or were less exposed (i.e., concurrent or pre/post). Where studies existed that did not meet these criteria but that had been recommended by one or more experts as having the potential to change a preliminary assessment of effectiveness, those studies were also reviewed.

Multiple reports on a single study were treated as one study but different intervention arms were treated as separate observations. For both of these reasons, the number of studies shown may not necessarily match the numbers of references cited. After the individual studies making up the body of evidence of effectiveness for an intervention were identified, they were evaluated, their results extracted, the body of evidence summarized, and the strength of the body of evidence assessed.

Each study meeting the explicit inclusion criteria was read by two reviewers who used a standardized abstraction form to record 1) information about the intervention being studied; 2) the context in which the study was done (e.g., population or setting); 3) descriptions of the evaluation and the results; and 4) an assessment of how well the study was executed. Any disagreements between the two reviewers were reconciled by consensus among the chapter development team during the process of summarizing results into evidence tables. For the two interventions where the literature was most extensive (provider reminder/recall; patient reminder/recall), they excluded studies with least suitable designs. Studies that did not make a concurrent or before-after comparison were never included.

They assessed the quality of study execution by systematically considering eight threats to validity: 1) definition and selection of study and comparison population; 2) definition and measurement of exposure/ intervention; 3) assessment of outcomes; 4) followup/ completion rates; 5) other bias; 6) data analysis; 7) confounding; and 8) other (e.g., lack of statistical power). Studies with serious problems in quality of execution were not considered further in the review.

To summarize the findings on the effectiveness of an intervention across multiple studies, they displayed the results of individual studies in tables and reported the median and range of reported effect measures. In addition, the body of evidence is characterized as strong, sufficient, or insufficient based on the numbers of available studies, the strength of their design and execution, and the size and consistency of reported effects.

The primary outcome of interest was always a measure of vaccination (i.e., vaccine coverage or doses delivered). Information on disease outcomes and other outcomes (such as knowledge or attitudes for educational interventions) could also be abstracted if available and relevant. They represented results of each of the studies as point estimates for net change in vaccination coverage attributable to the interventions.

Depending on the study, vaccination coverage could be with a series-complete coverage measure (i.e., the proportion of persons up-to-date with each of several vaccines) or coverage with one or more individual vaccines. When a study presented more than one vaccine result (but not a series-complete measure) they used an equally weighted average of coverage differences. They selected effect measures for inclusion in the following ways. When available, they used measures adjusted for potential confounders in multivariate analyses in preference to crude effect measures. In children, they used outcome measures among children closest to age 2 years. In studies that made comparisons between multiple groups, they compared each intervention group with the group that received no intervention (or the least intensive intervention). They included separate effect measures where possible for children, adolescents, and adults, but did not otherwise typically report different effect measures for different subpopulations.

Finally, to assist users in assessing the likely generalizability of available evidence on effective interventions, they defined important characteristics of the interventions (e.g., the specific vaccinations delivered) and characteristics of the target populations and settings where the intervention had been implemented. We then reported on the availability, or lack of availability, of studies (e.g., studies might have been done in urban but not in rural areas, or to increase the delivery of influenza but not MMR vaccination).

Source

1. Shefer A, Briss P et al. *Epidemiological Reviews* (1999): 21(1): 96-147.
2. <http://www.thecommunityguide.org>

II. Cochrane Collaboration

The Cochrane Collaboration is an international non-profit and independent organization, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide. It produces and disseminates systematic reviews of health care interventions and promotes the search for evidence in the form of clinical trials and other studies of interventions.

The major product of the Collaboration is the Cochrane Database of Systematic Reviews, which is published quarterly as part of The Cochrane Library. Those who prepare the reviews are mostly health care professionals who volunteer to work in one of the many Collaborative Review Groups, with editorial teams overseeing the preparation and maintenance of the reviews, as well as application of the rigorous quality standards for which Cochrane Reviews have become known. The activities of the Collaboration are directed by an elected Steering Group and are supported by staff in Cochrane Entities (Centres, Review Groups, Methods Groups, Fields/Networks) around the world.

A systematic search was performed for the initial review using MEDLINE and four other bibliographic databases: EMBASE, PsychINFO, Sociological Abstracts, and CAB Abstracts. Authors also performed a search of The Effective Practice and Organization of Care (EPOC) registers to update reviews. Two authors reviewed the lists of titles and abstracts and used the inclusion criteria to mark potentially relevant articles for full review. The reference lists of all relevant articles and reviews were back searched for additional studies. Publications of abstracts, proceedings from scientific meetings and files of study collaborators were also searched for references.

Randomized controlled trials (RCT), controlled clinical trials, controlled before and after studies (CBA) and interrupted time series (ITS) studies written in English were selected. Each study was read independently by two reviewers. Disagreements between reviewers were resolved by a formal reconciliation process to achieve consensus. Results are presented for individual studies as relative rates for randomized controlled trials and as absolute changes in percentage points for controlled before and after studies. Pooled results for RCTs were presented using the random effects model.

Source:

<http://www.cochrane.org/docs/descrip.htm>

**APPENDIX 3: INTERVENTIONS TO IMPROVE COVERAGE OF UNIVERSALLY
RECOMMENDED VACCINES**

Interventions with Evidence of Effectiveness

Effective Interventions	Type of Evidence*
Client reminder and recall systems	1+
Multi-component interventions that include client or community or provider education	2++
Vaccination requirements for child care, school, and college attendance	2++
Standing orders for adults	2++
Reducing out-of-pocket costs of vaccination	2++
Expanding access in health care settings as part of a multi-component intervention	2++
Vaccination programs in schools	2++
Home visits	2++
Provider/reminder and recall systems	2++
Assessment plus feedback for vaccination providers	2++

*Based on grading scheme developed by NHS Health Development Agency (2005). *Grading Evidence and Recommendations for Public Health Interventions: Developing and Piloting a Framework* (see Appendix 4).

**Level of evidence was assessed by one member of the Working Group (LY).

Interventions with insufficient evidence for effectiveness were not rated.

APPENDIX 4: GRADING EVIDENCE FOR PUBLIC HEALTH INTERVENTIONS

Evidence of the Efficacy of an Intervention – Did it Work?

Level of Evidence	Type of Evidence
1++	High quality meta-analyses, systematic reviews of RCTs (Including cluster RCTs), or RCTs with a very low risk of bias.
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1-*	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias.
2++	High quality systematic reviews of, or individual high quality non-randomised intervention studies (controlled non-randomised trial, controlled before-and-after, interrupted time series), comparative cohort and correlation studies with a very low risk of confounding, bias or chance.
2+	Well conducted, non-randomised intervention studies (controlled non-randomised trial, controlled before-and-after, interrupted time series). Comparative cohort and correlation studies with a high risk of confounding, bias or chance.
2-*	Non-randomised intervention studies (controlled non-randomised trial, controlled before-and-after, interrupted time series), comparative cohort and correlation studies with a high risk of confounding, bias or chance.
3	Non-analytical studies (e.g., case reports, case series).
4	Expert opinion, formal consensus.

* Studies with a level of evidence (-) should not be used as basis for making recommendations.

Source: NHS Health Development Agency. (2005). *Grading Evidence and Recommendations for Public Health Interventions: Developing and Piloting a Framework*. Adapted from SIGN (2001).

APPENDIX 5: INTERVENTIONS TO IMPROVE COVERAGE OF TARGETED VACCINES

I. Interventions with Evidence of Effectiveness When Used Alone:

Effective Interventions	Type of Evidence*
Provider reminder system	2++

II. Interventions with Evidence of Effectiveness When Implemented in Combination:

Intervention	Type of Evidence
Enhanced access <i>plus</i> Provider/system intervention	2++

Intervention	Type of Evidence
Enhanced access <i>plus</i> Provider/system intervention <i>plus</i> Client intervention	2++

*Based on grading scheme developed by NHS Health Development Agency (2005). *Grading Evidence and Recommendations for Public Health Interventions: Developing and Piloting a Framework* (see Appendix 4).

**Level of evidence was assessed by one member of the Working Group (LY).

Interventions with insufficient evidence for effectiveness were not rated.